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European Pharmaceutical Distribution: Key Players, Challenges and Future Strategies

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EXECUTIVE SUMMARY

Most prescription medicines in most European countries reach the ambulatory patient by the classic distribution chain: manufacturer-prewholesaler-wholesaler-community pharmacy-patient.

In 2005, there were 673 full-line wholesalers with 1,458 operating sites in the EU. Their potential customer base consisted of almost 150,000 final supply outlets or dispensing points (134,800 community pharmacies, 8,000 dispensing doctors and 6,400 hospital pharmacies).

Pharmacies have a monopoly on the supply of all medicines to the public in France, Spain and Sweden, whereas in a growing list of countries, including Denmark, Germany, Hungary, Italy, the Netherlands, Poland, Portugal and the UK, over-the-counter medicines can also be purchased in non-pharmacy outlets. Physicians in rural areas in some countries (mainly Austria, the Netherlands, Switzerland the UK) are allowed to self-dispense for their patients if there is no local pharmacy service.

Most customers receive on average a twice-daily delivery service from each of two full-line wholesalers. In addition to any direct accounts, pharmacies in countries that do not impose a 'public service obligation' on wholesalers may also purchase a limited range of the more popular products from short-line distributors.

The number of wholesalers in a country varies from two in Finland and Sweden to around 200 in Italy. In both the Scandinavian countries a system of single channel distribution operates, i.e. manufacturers make exclusive distribution contracts with a single wholesaler which alone is responsible for meeting the needs of the entire market. In the UK, Pfizer (from March 2007) and AstraZeneca (from February 2008) decided to limit distribution to one and two wholesalers respectively, acting as agents. In all other countries, multichannel distribution is found, where wholesalers purchase from all manufacturers and every pharmacy can choose from any wholesaler serving its territory as all stock the full product range.

Wholesalers are largely independent companies, either privately-owned or owned by their pharmacist customers as co-operatives. 70% of all wholesalers operate only within certain regions of their country.

Community pharmacies make up wholesalers' most important customer group. With the exception of Norway and some Baltic States, the majority of pharmacies in all EU countries are still independents, though company-owned chains increasingly dominate sales in Ireland, the Netherlands and the UK. These self-distribute to their own outlets from central warehouses. Uniquely, all Swedish pharmacies are part of a state-owned chain, Apoteket.

The clear trend towards fewer wholesaling companies and fewer warehouses is continuing. The bigger companies are buying up the smaller ones and extending their national reach. They are also integrating backwards into prewholesaling and forwards through acquisition into ownership of pharmacy chains in all countries that allow companies rather than just individual pharmacists to own retailers. At least one of Europe's 'big three' - Phoenix, Celesio and Alliance UniChem (Alliance Boots) – is ranked by sales within the top three wholesalers in Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland,

Italy, Latvia, Lithuania, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and the UK. In the case of Denmark, Norway and the UK, the 'big three' share all top-three positions. The same wholesalers own a total of 6,000 pharmacies across 11 European countries, including virtually every pharmacy in Norway.

A key requirement is for the wholesaler to take title to the goods it sells, and by this gain the right to dispose of them as it chooses. The base price, set by the authorities, on which distribution margins are added is for most countries the MSP or CIF price. Throughout Scandinavia and also in the Netherlands, however, it is the pharmacy purchase price that acts as the base for the pharmacy selling price, with the wholesale margin subject to free negotiation. The percentage component can be fixed or regressive and is sometimes combined with a flat free. In some countries there is a cap on wholesaler earnings for very high cost drugs.

Pharmacies are paid on a fee-for-service basis and in addition are reimbursed for the acquisition costs of the medicines they dispense less the co-payments they collect from patients. The calculation of the remuneration component for dispensing social health insurance prescriptions differs in every European country. It is usually based on (a) a fixed fee per item; (b) a certain percentage of the cost or delivery price of the item, or (c) some combination of the two. In some countries, the percentage component is fixed, sometimes it is regressive and in others there is a cap on pharmacists' earnings for very high-cost drugs. The gross dispensing margin may be eroded by compulsory rebates to social health insurance or by special taxes.

Though wholesalers perform an excellent distribution service, some manufacturers are concerned about the rising cost of this, the role of wholesalers in encouraging the use of PIs and the failure of the traditional supply channel to prevent access by counterfeit medicines. Other negative views of wholesalers come from their rising power, in particular their diversification strategies, and their failure to offer pan-European solutions.

Direct distribution, in which the wholesaler is bypassed, has always been more common with OTCs, but it is a growing trend with prescription drugs too in some countries. Sometimes this is allied to homecare (in the Netherlands and the UK) or is intended to counter parallel trade strategies (e.g. in Germany). It is not popular with pharmacies.

In comparison to the US, mail order of medicines in Europe is very underdeveloped, being mainly limited to OTCs or to non-reimbursed prescription medicines for 'embarrassing problems'. Dutch-based DocMorris is the main provider, with its customer base primarily in Germany.

Wholesalers are most concerned at being relegated to the role of logistics service provider, in receipt of a flat-rate fee rather than a distribution margin. GSK and Pfizer have both adopted this distribution solution in the UK. Though discussions are ongoing between wholesalers and Pfizer in Germany, the concept has yet to spread outside the UK.

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ABBREVIATIONS

AESGP	Association Européenne des Spécialités Pharmaceutiques Grand Public
AT	Austria
ABDA	Bundesvereinigung Deutscher Apothekerverbande (Germany)
ADF	Associazione Distributori Farmaceutici (Italy)
AFSSAPS	Agence Française de Sécurité Sanitaire des Produits de Santé (France)
AIP	apotekens inkopspris (Sweden)
APB	Association Pharmaceutique Belge (Belgium)
AUD	Australian dollar
BAPW	British Association of Pharmaceutical Wholesalers
BGL	Bulgarian lev
CAGR	compound annual growth rate
C&D	Chemist & Druggist (UK)
CH	Switzerland
CIF	cost, insurance and freight
CIP	cost, insurance and packaging
CSO	contract sales organisation/Community Service Obligation (Australia)
CSRP	Chambre Syndicale de la Répartition Pharmaceutique (France)
CZ	Czech Republic
CZK	Czech koruna
DE	Germany
DK	Denmark
DKK	Danish krone
DoH	Department of Health (UK)
DTP	direct to pharmacy
EAHP	European Association of Hospital Pharmacists
EC	European Community
ECJ	European Court of Justice

EDI	electronic data interchange
EEA	European Economic Area
EEK	Estonian kroon
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFTA	European Free Trade Area
EMEA	European Medicines Agency
EU	European Union
FI	Finland
FIP	Féderation Internationale Pharmaceutique
FR	France
GIRP	Groupement International de la Répartition Pharmaceutique
GMS	General Medical Services (Ireland)
GP	general practitioner
GSK	GlaxoSmithKline
GW	Glaxo Wellcome (former name)
HSE	Health Services Executive (Ireland)
HU	Hungary
HUF	Hungarian forint
IFPW	International Federation of Pharmaceutical Wholesalers
IMS	Intercontinental Medical Statistics
IR	Ireland
IS	Iceland
IT	information technology
KD	Kronans Droghandel
KNMP	Koninklijke Nederlandse Maatschappij ter Bevordering der Pharmacie (NL)
LFN	Läkemedelsfömånsnämnden (Sweden)
LIL	Lithuanian litas
LSP	logistics service provider

LTL	Lithuanian lat
LVL	Latvian lat
M&A	merger and acquisition
MSP	manufacturer selling price
MwST	Mehrwertsteuer (Austria & Germany)
NA	not available
NHS	National Health Service (UK)
NL	Netherlands
NMD	Norsk Medisinaldepot (Norway)
NO	Norway
NOK	Norwegian krone
ŐBIG	Őesterreichisches Bundesinstitut für Gesundheitswesen (Austria)
OECD	Organisation of Economic Co-operation and Development
OFT	Office of Fair Trading (UK)
OTC	over-the-counter (medicine)
PBS	Pharmaceutical Benefits Scheme (Australia)
PFHT	prix fabricant hors taxe (France)
PGD	Patient Group Direction (UK)
PGEU	Pharmaceutical Group of the European Union
PI	parallel import
PLN	Polish zloty
PPA	Prescription Pricing Authority (UK)
PPRS	Pharmaceutical Price Regulation Scheme
PPTTC	prix public toutes taxes comprises (France)
PSNC	Pharmaceutical Services Negotiating Committee (UK)
PT	Portugal
R&D	research and development
RON	Romanian new leu

SAFA	Sociedad Anonima Farmaceutica Aragonesa (Spain)
SEK	Swedish krona
SKK	Slovakian koruna
SKU	stock keeping units
TVA	taxe sur la valeur ajoutée (France, Belgium)
UK	United Kingdom
US	United States
VAT	value-added tax
WHO	World Health Organisation
WSP	wholesaler selling price

CHAPTER 1
FROM FACTORY GATE TO PATIENT

1.1 Distribution Chain

Everywhere in Europe, from the largest to the smallest national market (table 1.1), most medicines are prescribed by office- or clinic-based general practitioners (GPs) and dispensed to patients by community (or retail) pharmacies. Patients expect – and sometimes urgently need – to obtain any medicine prescribed for them with the minimum of delay. An estimated 20 billion packs of medicines are dispensed in the European Union (EU) annually in response to prescriptions being presented at pharmacies.

Table 1.1: Pharmaceutical market values (€ million at manufacturers' selling prices) in European countries, 2005

Germany	24846
France	23838
Italy	15749
UK	15569
Spain	11332
Greece	3821
Netherlands	3795
Belgium	3657
Poland	3546
Portugal	3105
Switzerland	2709
Sweden	2673
Austria	2411
Hungary	1844
Finland	1740
Denmark	1536
Ireland	1514
Czech Republic	1338
Norway	1304
Romania	1083
Slovakia	565
Bulgaria	489
Slovenia	442
Lithuania	322
Latvia	181
Estonia	106

Source: EFPIA

Pharmacies could not possibly find place to stock (or afford to purchase) the tens of thousands of different forms of medicines (known as stock keeping units or SKUs) available on each national market, and therefore depend on a well-functioning distribution system. While a manufacturer may sometimes undertake to ship its products to pharmacies via a logistics service provider (LSP), known as direct distribution, more usually goods pass through one or more middlemen (indirect distribution). The first of these middlemen is often a prewholesaler, with responsibility for getting stock from the production site or place of importation to wholesalers, hospitals, warehouses of pharmacy multiples for self-distribution, or other large customers. Wholesalers then respond to community pharmacies, which order to meet the demands of an individual patient's prescription or

to top up stock. No part of the chain actually markets prescription medicines.

The standard distribution chain for the retail market is therefore:

Manufacturer → prewholesaler → wholesaler → community pharmacy → patient.

1.2 Prewholesaling

Prewholesaling is logistics outsourcing, encompassing activities undertaken after the main manufacturing processes before the company sells the stock. At its most basic it covers the provision of product storage, in place of a manufacturer's own finished goods store, and distribution services to wholesalers' warehouses. But being a customised service it can also provide a wide range of other services, including:

- arranging collection by freight forwarders from production site;
- shipment;
- importation;
- sales order processing and debt recovery; and
- financial and information flow management.

Prewholesalers have long been a feature of the French and Italian markets in particular, but now they are widespread, with major wholesalers entering the business too.

1.3 Wholesaling

Wholesalers have two main functions:

- to maintain an economical and efficient distribution network to supply pharmacies and other dispensing points with medicines and related products sold into the market by manufacturers and importers; and
- to simplify customers' restocking by providing an efficient order and supply service through which they can quickly obtain all the products needed.

Title VII of Directive 2001/83/EC (as amended by Directive 2004/27/EC) defines the activities involved in wholesale distribution of medicinal products as procuring, holding, supplying and exporting medicines within the European Economic Area (EEA), apart from supply to the public. It also makes provision for individual member states to issue wholesale dealing authorisations, set distribution and storage requirements, and enforce these through inspections.

Under Article 80 of the Directive, holders of a wholesale dealing authorisation must:

- obtain their supplies of medicines only from persons who are themselves in the possession of a distribution authorisation, or from a manufacturer;

- supply medicines only to persons who are themselves in possession of a distribution authorisation, or who are authorised or entitled to supply medicines to the public in the member state concerned;
- have in place an emergency plan to ensure effective implementation of any recall;
- keep records, for inspection purposes, giving for any transaction with medicines received or dispatched at least the following information:
- date
- name of the medicine
- quantity received or supplied
- name and address of the supplier
- (NB: Given the widespread use of automatic picking machines in warehouse, it is not currently possible for wholesalers to retain batch records of good supplied to pharmacies.)
- keep records for inspection by the competent authorities for a period of five years; and
- comply with the principles and guidelines of Good Distribution Practice (94/C63/03).

To the frustration of wholesalers, more than ten years after the formation of the European Medicines Agency (EMEA) and 15 years after the creation of the notional single EU market there is still not a single medicinal product which can be distributed throughout the EU without additional authorisations. Wholesalers can, however, store products with the authorisation of another member state, but are not allowed to bring them to market.

In wholesaling and pharmacy terms each national market is therefore considered discrete. A wholesaler in country X orders medicines from a manufacturer or its agent in country X, and a wholesaler in country Y orders similar ones from a manufacturer in country Y. All pharmacies place their orders locally, and these are processed locally and delivered in vans in familiar local liveries from local warehouses.

There is competition between wholesalers in all European countries, ranging from one to more than two hundred firms.. Norway's NMD lost the last monopoly in western Europe one year after the EEA agreement came into force in 1994. A similar fate befell the state-owned wholesalers in the former Soviet Union satellite countries of central and eastern Europe.

Numerically, the majority of wholesalers (about 70% of the European total) only supply customers in distinct regions of the country in which they are based, but unsurprisingly, wholesalers that operate nationwide generally hold the larger market shares (table 1.2).

***Table 1.2: Numbers of pharmaceutical wholesalers in* Europe, 2006**

Country	Nationwide wholesalers		Local/regional wholesalers	
	Companies (wholesaling market share)	Warehouses	Companies (wholesaling market share)	Warehouses
Austria	3 (81%)	15	6 (19%)	9
Belgium	3 (65%	20	8 (21%)	7
Czech Republic	4 (98%)	28		
Denmark	2 (95%)	7		
Finland	2 (99%)	6		
France	3 (94%)	180	2 (6%)	13
Germany	4 (>75%)	78	12 (<25%)	30
Greece	7 (33%)	7		
Hungary	4 (90%)	16	10 (10%)	10
Ireland	3 (90%)	10		
Italy	81 (89%)	214		
Lithuania	7 (92%)	7	8 (8%)	8
Luxembourg	3 (80%)	3		
Netherlands	5 (86%)	15		
Norway	3 (100%)	7		
Portugal	2 (40%)	14	8 (46%)	15
Slovenia	2 (75%)	2	9(25%)	9
Spain	3 (38%)	64	55 (62%)	127
Sweden	2 (96%)	6		
Switzerland	4 (80%)	9	30	
UK	3 (91%)	46	11 (11%)	11

Source: GIRP

Most wholesalers are either private companies or co-operatives owned by their pharmacy customers. The latter type is especially prevalent in Belgium, Greece, Portugal and Spain. Manufacturer ownership of wholesalers, banned in some countries, is rare. Examples include Oriola-KD (owned by Orion, Merck Sharp & Dohme and Organon), operating in both Finland and Sweden, and three Hungarian wholesalers: Hungaropharma (majority-owned by Gedeon Richter and Egis), Medimpex (Gedeon Richter and Egis) and Humantrade (Teva).

1.3.1 Full-line Wholesalers

Full-line wholesalers distribute the full range or nearly the full range of prescription medicines, regardless of whether it is a fast-moving 'blockbuster' or a seldom used but equally vital medicine. They stock not only straightforward, easy to handle lines but also lines that require special storage and handling, such as narcotic analgesics and inflammables, and temperature-sensitive, seasonal products like vaccines.

Due to all the necessary extra security and documentation measures needed, narcotics costs wholesalers six times more than non-narcotics to handle, the British Association of Pharmaceutical Wholesalers (BAPW) estimates. The requirements of storing and transporting medicines in the cold chain are also onerous. With bulky products and long transit times, refrigerated vehicles must be used. With small volume deliveries and short (< 3 hours) shipping times, insulated packaging without cooling elements may provide adequate protection, but temperature stabilising materials such as cool packs within isotherm boxes are used if transit is more prolonged.

Temperature-monitoring devices must be used to demonstrate compliance with regulations. The cost of shipping at an assured 2°C-8°C range is approximately double that for products able to withstand ambient conditions.

In 2005, there were 673 full-line wholesalers with 1,458 operating sites in Europe. On average, one warehouse served 329 pharmacies and 1.11 million people. German full-liners held the largest number of different SKUs, more than 60,000, while Hungarian full-line wholesalers stocked fewer than 7,000.

European full-line wholesalers collectively link 3,500 manufacturers to almost 140,000 dispensing points for ambulatory patients (community pharmacies and self-dispensing doctors), with France and Luxembourg providing the extremes (table 1.3).

***Table 1.3: Numbers of out-of-hospital dispensing points in Europe* for human medicines (latest available year)**

Country	Population (million)	Community pharmacies	Self-dispensing doctors
Austria	8.0	1126	992
Belgium	10.3	5268	-
Bulgaria	7.8	4400	-
Cyprus	0.7	434	-
Czech Republic	10.2	2107	few
Denmark	5.4	284	-
Estonia	1.4	307	-
Finland	5.2	797	-
France	60.0	22561	few
Germany	82.4	21651	-
Greece	11.2	9350	few
Hungary	10.2	2050	few
Ireland	3.9	1268	140
Italy	58.5	17524	-
Latvia	2.4	909	-
Lithuania	3.5	675	-
Luxembourg	0.4	79	-
Malta	0.4	225	-
Netherlands	16.1	1625	480
Norway	4.6	367	-
Poland	38.2	9693	-
Portugal	10.4	2557	-
Romania	22.6	5000.	-
Slovakia	5.4	1070	-
Slovenia	2.0	260	few
Spain	41.8	19766	-
Sweden	8.9	800	-
Switzerland	7.4	1679	3928
UK	59.0	12250	2225
Total Europe	454	134825	c8000

Source: adapted from Federfarma

Community pharmacies are by far European wholesalers' most important customer group (table 1.4), somewhat different from the picture in the US (table 1.5).

Table 1.4: Share (%) of sales of medicines from European wholesalers by customer group, 2006

	Community pharmacies	Hospital pharmacies	Dispensing doctors	Drugstores	Other
Belgium	97	3	-	-	-
Czech Republic	71	29	-	-	-
Denmark	70	30	-	-	-
Estonia	90	10	-	-	-
Finland	76	24	-	-	<2
France	99	1	<1	-	-
Germany	99.5	0.5	-	-	-
Greece	100	-	-	-	-
Hungary	84	16	-	-	-
Ireland	84	16	-	-	-
Italy	98.5	1	-	-	0.5
Lithuania	85	14	1	-	-
Netherlands	79	8	6	-	7
Norway	80	20	-	-	-
Portugal	98	<1	-	2	-
Slovenia	82	18	-	-	-
Spain	99	1	-	-	-
Sweden	87	13	-	-	-
Switzerland	54	19	25	3	-
UK	82	10	8	-	-

Source: GIRP

Table 1.5: Customers of US wholesalers

Customer group	Share of wholesalers' sales (%)
Independent pharmacies	19.3
Hospitals	20.4
Chain drug stores and warehouses	16.4
Physicians' offices, clinics and nursing homes	13.6
Mail/internet pharmacies	5.5
Food stores and mass merchandisers	11.2
Government sites	3.2
Speciality pharmacies	0.01

Source: Healthcare Distribution Management Association

Delivery frequency averages twice each weekday, throughout the year and in all weathers. Pharmacies in Belgium, Germany, Greece, Ireland, Italy, Portugal and Spain are daily supplied more frequently than the average, and those in Denmark, Finland, Lithuania, Netherlands, Norway, Slovenia and Sweden are supplied less frequently. As pharmacies each use an average of two full-line wholesalers (one as a back-up) this means eight deliveries per day in Germany or two in Sweden, for example.

Almost all orders (>90%) are placed via electronic data interchange (EDI) terminals in the pharmacy in the larger countries, and generally are delivered within a few hours, or overnight at worst.

The umbrella body for full-line wholesalers in Europe is the European Association of Pharmaceutical Full-line Wholesalers (*Groupement International de la Répartition Pharmaceutique*; GIRP; www.girp.org). GIRP members employ about 140,000 people and distribute over 100,000 different products with an annual value of around €100 billion (almost the size of Portugal's entire gross domestic product).

Founded in 1960, GIRP represents the national associations of full-line wholesalers serving 31 European countries. The three pan-European wholesalers, Phoenix, Celesio and Alliance UniChem, are individual members as is the Spanish-based co-operative representative body Sociedad Europea de Cooperacion Farmaceutica (www.secof.org). Associate external members may be companies or organisations (not necessarily based in Europe) whose business interests are related to the pharmaceutical industry and its distribution.

1.3.2 Short-line Wholesalers

Short-line wholesalers deal with a more limited range of fast-moving lines (table 1.6). They don't offer an emergency service or handle 'problem' or rarely-used products, on which full-line wholesalers say they make a loss. With lower costs, short-line wholesalers can offer pharmacies preferential terms, but allied to an inferior service (e.g. minimum order size, carriage charge, at best overnight delivery via third-party carrier).

Table 1.6: Typical stockholding (SKUs) of full- and short-line wholesaler in UK

	Full-line	Short-line
Domestic brands		100
Cold chain range	200	60-80
Generics	3,500	600
Parallel imports	500	700
Medicinal foods/borderline substances	200	80
Total product lines	16,000	1,600

Source: BAPW

In countries where short-liners exist, especially the UK (where 1,600 wholesale dealing authorisations have been issued but there are only 11 major wholesalers), there is considerable resentment on the part of full-line wholesalers because the former cream off the most profitable 5-10% of the business. Full-line wholesalers carry a large percentage of slow moving lines, yet their margin structure is based on an average mix of business. In order to subsidise the long, loss-making 'tail', full-line wholesalers need a significant share of the profitable end of the market too, they argue. Payers, in general, have not been sympathetic to this viewpoint, however. It should also be noted that full-line wholesalers sometimes have short-line distributors affiliated within their group: Cordia Healthcare is part of Alliance Boots and Trident is part of AAH (Celesio), both in the UK, for example.

1.3.3 Public Service Obligation

Several countries – Belgium, Finland, France, Greece, Italy, Norway, Portugal & Spain - have national legislation that precludes the existence of short-line wholesalers. Under the so-called 'public service obligation', every wholesaler serving that market is required to deliver virtually any marketed product within a certain time period. Details are provided under the country heading in chapter 3. In practice, even where there is no obligation enshrined in law, competitive pressures on full-line wholesalers and voluntary codes of practice ensure pharmacies receive a comparable service.

Similar supply obligations on pharmacies apply, either in law but more usually as part of their contract with the health insurer, or in professional codes of conduct.

On the European level, Article 76 of Directive 2004/27/EC introduced a new requirement for storage of a product in any member state if it had a single marketing authorisation and Article 81, also new, creates the obligation for continuous supplies of medicines from manufacturers to wholesalers and onwards to pharmacies:

'The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a member state shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the member state in question are covered'.

1.3.4 Multi- and Single Channel Distribution

Most wholesalers, full- or short-line, supply products from a number of different manufacturers in competition with other wholesalers operating in the same market. In Finland and Sweden, an alternative approach to this traditional multichannel system has developed: single channel distribution. In this case, a manufacturer makes an exclusive distribution arrangement for a period of time with one wholesaler, which alone is responsible for meeting all demands in the country for the affected products.

Single channel has advantages for both manufacturers and wholesalers:

- distribution costs are lower;
- communication and co-operation overall is better;
- recalls are quicker and easier to make;
- there is improved product knowledge by the wholesaler;
- parallel import (PI) and counterfeit entry is minimised;
- the wholesaler is assured of a higher volume throughput;
- the credit risk for the manufacturer is less;
- there is no competition over discounts between wholesalers (there are no discounts);

- the manufacturer obtains better inventory control and faster data feedback (i.e. real-time data on realised sales, non-existent in multichannel distribution);
- it leads to larger orders being placed and larger stocks being held; and
- there is also no need to appoint specialist import agencies or prewholesalers.

Foreign manufacturers would otherwise have difficulty in quickly supplying small batches with Finnish or Swedish labelling.

The downsides are that one wholesaler carries the sole responsibility for stocking and delivering each product throughout the country, earned margins are less, and there are antitrust concerns with pharmacies unable to select suppliers. Proponents counter with the argument that customers are no more disadvantaged than if the manufacturer distributed direct. They also point out that because of lower transport costs and volume efficiency gains the pressure to increase public prices is less. Single channel distribution was in fact brought in by the Finnish government in the 1970s as an efficiency measure.

Single channel should in principle change the relationship of wholesalers with their suppliers and its customers. Whereas multichannel wholesalers focus their attention on the pharmacist – competing on trading conditions, service and value-added – with single channel the focus is on the supplier. The loss of a handful of pharmacy accounts to a multichannel wholesaler may be annoying but the loss of one or two contracts with large manufacturers may do much more serious damage to a single channel wholesaler. Nevertheless, the two wholesalers (in fact the same companies in both countries) appear to have operated successfully in Finland and Sweden for a number of years.

1.3.5 Parallel Importers

Parallel trade is the process by which goods protected by an intellectual property (IP) right, such as a patent or trademark, placed in circulation in one market, are imported into a second market without the authorisation of the IP rights holder. With third parties exploiting the price differences for virtually identical prescription medicines across the single market that makes up the 30 nations of the current EEA, the practice continues more than 40 years after it started despite determined efforts by manufacturers to stamp it out.

Every transaction normally involves two authorised wholesalers in different member states, a parallel exporter in the country of origin and a parallel importer in the country of destination. There are more than 100 parallel importers and exporters trading across much of the EEA, with the majority of the former based in the UK. Through national associations many are represented at EU level by the European Association of Euro-Pharmaceutical Companies (www.eaepc.org). Table 1.7 shows some of the leading players.

Table 1.7: Leading parallel importers (alphabetical order)

Germany	CC Pharma (http://pharma-gerke.de) Emra-med/MPA (www.emramed.de) Eurimpharm (www.eurim.de) Kohlpharma/MTK (www.kohl-pharma.de) Pharma Westen (www.orifarm.de)
Netherlands	Polyfarma (www,opggroep.nl) Stephar (www.stephar.nl)
Scandinavia	Orifarm (www.orifarm.dk) Paranova (www.paranova.dk)
UK	Chemilines (www,chemilines.com) Interport (www,interportltd.com) Lexon (www.lexonuk.com) Munro (www.munrowholesale.com) Stephar UK (www.stephar.co.uk) Waymade (www.waymadehealhtcare.plc.uk)
Poland	Delfarma (www.delfarma.pl)

Source: author

Parallel importers need an abbreviated form of marketing authorisation (or an EMEA parallel distribution notice for centrally-approved products) before bringing a parallel import to market. Invariably, the pack labelling and patient package insert have to be changed into the language of the country of destination, and for these procedures a manufacturing authorisation is needed too.

1.4 Pharmacy

Pharmacy can be a place, a profession and sometimes a business. The main purpose of pharmacy practice is to help patients make the best use of their medication.

Community pharmacists are at the heart of healthcare services, practising in conveniently accessible public pharmacies. Sound, objective advice on health issues can be obtained from a health professional in an informal environment, without the need to make an appointment and without charge. It is estimated that every day more than 46 million people somewhere in Europe visit a community pharmacy.

Pharmacists represent the third largest healthcare professional group in Europe., with 63% being female. Overall, 71% of the pharmacist workforce is employed in community practice, with Denmark (17.8%) and Germany (85.5%) forming the extremes (table 1.8).

Table 1.8: Pharmacist distribution (%) across pharmacy practice fields as a percentage of total pharmacist workforce, 2006

Country	Community	Hospital	Academic/ research	Sales/ marketing	Regulatory	Production	Other industry	Not classified
AT	89.4	5.3	0	0	0	0	0	5.3
CZ	82.9	5.4	3.7	0.6	1.4	1.1	5.0	0
DK	17.8	7.2	5.9	0	9.2	44.7	0	15.1
FI	59.0	6.0	2.4	0	2.4	9.0	21.1	0
FR	76.5	6.7	0	0	0	5.0	11.4	0.5
DE	85.5	3.4	0	0	0	0	0	11.2
HU	65.6	6.8	2.5	7.5	0.6	10.2	6.9	0
IS	35.4	6.2	4.3	26.0	3.5	26.0	9.7	11.1
IE	68.0	10.0	5.0	0	1.0	5.0	11.0	0
NO	80.5	18.3	8.4	0	4.8	14.5	0	26.4
PT	58.8	7.9	5.9	0	0	6.9	12.0	8.5
CH	77.9	1.3	0	0	0.4	3.1	0	17.2
UK	44.0	15.0	1.0	0	0	3.3	7.0	29.5
Total	70.8	7.5	0.9	0.6	0.3	4.2	6.3	9.5

Source: FIP

Community pharmacists are represented at European level by the Pharmaceutical Group of the European Union (PGEU; www.pgeu.org). Founded in 1959, its members are the national associations and professional bodies for community pharmacists in 29 European countries, including all EU member states, EU candidate countries and European Free Trade Area (EFTA) members. Through its membership, the PGEU represents about 400,000 community pharmacists contributing to the healthcare of more than 500 million people throughout Europe.

Whether the provision of healthcare services, including pharmaceutical services, should be subject to the rigours of EU free market principles has been subject to some debate. While a new directive on services in the internal market specifically excludes services provided by healthcare professionals, including pharmacists, the European Commission's Directorate-General for Competition has voiced concern at what it sees as unnecessary barriers to pharmacy ownership rules in some countries.

European Directives 85/432/EC and 85/433/EC regulate the mutual recognition of pharmacy degrees, the broad content of undergraduate university education and provide control of access to the profession in other member states. Pharmacists registered anywhere in the EEA can also take temporary and occasional work in any other member state without having to register with that country's professional regulator.

The size of the population on average served by one community pharmacy is highly variable across the EU (table 1.9), but care must be used in interpreting the data.

Table 1.9: Population per pharmacy (latest available year)

Austria	7131
Belgium	1948
Bulgaria	1453
Cyprus	1636
Czech Republic	4836
Denmark	18835
Estonia	4433
Finland	6512
France	2609
Germany	3822
Greece	1198
Hungary	4976
Ireland	3084
Italy	3336
Latvia	2585
Lithuania	5156
Luxembourg	5570
Malta	1778
Netherlands	9810
Norway	8530
Poland	3945
Portugal	4013
Romania	4200
Slovakia	5028
Slovenia	7692
Spain	2044
Sweden	11125
Switzerland	1713
UK	4798
Total Europe	3367

Source: adapted from Federfarma

The table includes main pharmacies only and several countries with a low density of these also have supplementary retail outlets from which OTC medicines may be purchased, as well as prescriptions handed in for dispensing elsewhere and later collected. A few countries also have self-dispensing doctors in rural areas. Austria has almost as many dispensing doctors as community pharmacies, so while there is only one pharmacy per 7,000 inhabitants there is one dispensing point per 3,700 inhabitants.

Four different types of community pharmacy can be found today in Europe, according to van Mil and Schulz[1]:

- Scandinavian model - relatively large pharmacies, each serving 10,000-18,000 people, and focused mainly on medicines;
- Southern European model (also found in Belgium and France) – very small pharmacies that serve approximately 2,000-2,500 clients, and also sell parapharmaceuticals and cosmetics;
- Anglo-Saxon model (found in UK & Ireland and resembling those in the US and Australia) – selling many non-medical items in addition to medicines and each serving approximately 3,500 people; and
- Central European model (found in Germany, Switzerland, Austria and further east) – focusing on all kinds of healthcare provision and serving 3,000-5,000 people.

In most countries pharmacists have monopoly rights on dispensing prescription medicines to the public. Qualified pharmacy assistants can dispense under the supervision of a pharmacist in both the Netherlands and the UK, while pharmacies in Finland, Norway and Sweden have pharmacist support staff with a three-year university level qualification known as 'prescriptionists' who can dispense without pharmacist supervision. Pharmacists in these three Nordic countries undertake a 5-6 year Master in Pharmacy course.

1.5 Hospitals

Drug expenditure in Europe's public hospitals accounts for about one-fifth of the total. However, because hospital prescribing has an important knock-on effect on prescribing in the community it attracts great interest from suppliers.

Although there are examples of distribution direct to hospital wards, the hospital pharmacy (table 1.10) is the usual custodian of all medicines destined for hospitalised inpatients.

Table 1.10: Hospital pharmacy in Europe (various years)

Country	Hospitals	Hospital beds	Hospital pharmacies	Hospital pharmacists
Austria	310	71741	49	237
Belgium	223	73000	344	750
Bulgaria				
Cyprus			40	
Czech Republic	458	113013		200
Denmark	69	18557	18	180
Estonia	21	3500	29	67
Finland	375	40000	24	470
France	3052	520000	2668	4451
Germany	2240	552700	550	1730
Greece	334	53614	70	320
Hungary	157	80429	149	407
Ireland	370	15000	155	250
Italy	1425	268524	800	2500
Latvia	112	18139	44	154
Lithuania	159	27727	92	104
Luxembourg	9	2500	7	23
Malta			3	
Netherlands	129	53000	85	400
Norway	68	14257	31	250
Poland	790	184000	690	2099
Portugal	205	35404		600
Romania				
Slovakia	89	39558	88	198
Slovenia	26	10147	27	56
Spain	767	159614		1112
Sweden	75	27925	100	283
Switzerland	363	48565		159
UK	450	310000	332	4397

Source: EAHP

With distribution to the larger hospital markets across Europe manufacturers have made a pre-emptive strike, establishing a pattern of direct deliveries and less frequent delivery cycles in many countries (e.g.

Austria, Belgium, France, Germany, Greece, Italy, Portugal and Spain). Only in the Baltic States, Denmark, Finland, Ireland, the Netherlands, Norway, Slovakia, Slovenia, Sweden and the UK are wholesalers involved in distribution to hospitals, and then to widely different rates, depending both on the country and company policy.

Sometimes, wholesalers are nominated as distribution centres for contracts which are set by the manufacturers or the manufacturer has an agreement with certain wholesalers which then act at its agent, forwarding the stock on a fee-for-service basis. In most cases, however, the contracts are managed by the manufacturer, who delivers direct via prewholesalers or LSPs, with wholesalers at most used for emergency or top-up deliveries.

Among the findings of a 2005 survey by the European Association of Hospital Pharmacists (www.eahponline.com), covering 825 hospitals in 22 countries, were the following results pertaining to distribution:

- On average each hospital formulary contained 694 new chemical entities, nearly double the number five years earlier. The highest number was recorded in Greece (1,551), the smallest (225) in Norway.
- Hospitals in the Baltic States, Norway, Slovakia, Slovenia, Finland, the Czech Republic, Hungary and Poland were most likely to purchase drugs from wholesalers, whereas direct from industry was primarily the channel chosen in the larger markets of France, Germany, Italy, Spain and Belgium. In the past five years, direct purchasing from manufacturers increased by 4% overall (but by >30% in France).
- The majority (61%) of hospitals did not form groups for purchasing drugs. Those which participate in group purchasing are most frequently grouped regionally (23% of hospitals, especially in the Netherlands, Austria and Switzerland), although this type of purchasing is 14% less than five years before. 12% of hospitals overall participated in national multi-hospital alliances, with the highest percentages found in Norway (88%), Denmark (80%), Slovenia (63%) and Luxembourg (50%).
- 90% of respondent pharmacies provided a centralised medicine distribution service. Complementary ward-based distribution services were mainly found in the Netherlands.
- Only 25% of hospitals overall performed unit dose distribution to individual patients, with this practice most common in the Netherlands, Spain, Belgium and France.
- Manual picking applied in 97% of cases. Only two hospital pharmacies used robots.
- 20% of hospitals scanned bar codes when picking stock for distribution to wards. These were mainly in France, Italy and the Netherlands.
- Pharmacies in Italy, the Czech Republic, France and Ireland were most likely to provide a service to outpatients through the inpatient pharmacy.
- Hospitals in the Czech Republic, Italy and France were especially likely to provided medicines to patients on discharge. Overall, 64% of hospitals did this for routinely prescribed medicines. Less common was supply for home administration with antibiotic infusions (20%),

analgesic infusions (29%), total parenteral nutrition solutions (35%) and cyostatic injections (35%).

1.6 Dispensing Doctors

Pharmacies have an absolute monopoly for prescription medicine supply to ambulatory patients in Denmark, Germany, Greece, Italy, Portugal, Spain and Sweden. In these countries the multi-disciplinary practice of pharmacy and medicine is illegal, even to those qualified in both professions. Legislation everywhere else provides that doctors dispense only in exceptional circumstances and where, for example in rural areas, a service from a pharmacy is unavailable, usually because it is not viable.

The highest proportion of self-dispensing doctors in Europe are found in Switzerland, specifically in the German-speaking cantons of Uri, Nidwalden, St Galen and Schwyz. In contrast, French- and Italian-speaking Swiss cantons limit doctor's ability to dispense. Nevertheless, dispensing doctors account for 24% by value of the total pharmaceutical market, a larger share than hospitals. There are ongoing legal disputes with pharmacists and a 2006 report from OECD/WHO recommended that Swiss doctors cease dispensing activities.

Doctors who self-dispense the drugs they prescribe have remained an important market segment in the UK. There were 5,353 dispensing doctors (in 1,166 practices) dispensing medicines to 3.5 million patients in rural parts of England in 2006, according to the Dispensing Doctors Association. These accounted for 16% of all English prescription drug expenditure in the year to April 2007. Numbers of Dutch dispensing doctors, in contrast, have been steadily falling in parallel with the growth in pharmacy numbers there.

There always have been tensions between dispensing doctors and pharmacists. The former argue they offer a genuine service to otherwise disadvantaged patients, while the latter allege the profit motive. Earnings from dispensing have been variously put at 20-30% of total income for dispensing doctors. Not every pharmacy necessarily suffers from the competition, however, as in some countries, such as Austria or Ireland, dispensing doctors have to draw their stocks from community pharmacies at cost price plus a fixed mark-up.

Comparisons of the costs involved in doctor-versus-pharmacist dispensing are difficult to make given the differing methods of payment, allowable expenses, staff and capital involved. The patient demography each group serves is also fundamentally different. Nevertheless, when the same person is diagnosing, prescribing and dispensing, the suspicion that a potential conflict of interest could emerge remains.

CHAPTER 2
EVOLUTIONARY CHANGES WITHIN WHOLESALING AND PHARMACY

2.1 Wholesalers

Wholesaling is basically a local business and the opportunities for expansion of any wholesaling operation in its own domestic market are often limited.

Wholesalers cannot increase the demand for prescription products and are at the mercy of government-imposed margin and/or price cuts.

The first step taken to restructure the business was to seek productivity improvements. Greater efficiency meant considerable investment in computer technology and automation – investment, wholesalers argue, that is analogous to manufacturers' investment in R&D – which in turn meant fewer and larger units dependent on a high volume throughput.

Diversification into new product areas, such as over-the-counter (OTC) medicines, generics, parallel imports, cosmetics, toiletries and baby products (everything that a community pharmacy sold), helped feed the volume as well as providing sales with higher margins. Wholesalers also sought new markets (such as hospitals, clinics, nursing homes and home healthcare) and new business areas (such as medical and surgical supply, or data processing).

At the same time, pressure on dispensing remuneration resulted in pharmacies making extra demands of their wholesalers. Orders became smaller, more frequent, less regular and there was more shopping around for special offers and 'cherry picking' of higher discounted lines. There are no contracts as such between the parties and in an attempt to win and retain customer loyalty wholesalers often offer pharmacies are number of added-value services. These range from special promotional deals, finance, loan guarantees, merchandising, own brands, training, market information, to computers and pharmacy software.

Expansion by wholesalers into other national markets is a more recent phenomenon. It has taken a variety of forms, including acquisition, merger, joint venture and co-operative agreement. Unlike the situation with new pharmacy openings in most countries, wholesalers can open up an affiliate in any other EU country should they wish, subject to holding a wholesale dealing authorisation there. This option is generally not feasible though as they would find problems in obtaining suppliers (manufacturers view new wholesalers with great suspicion) and in recruiting customers (who are already being adequately supplied by other wholesalers). Furthermore, wholesalers recognise that many national differences will persist.

As a result independent wholesalers from different countries initially entered into alliances rather than attempting to operate in another country themselves. The joint venture approach also avoided the need to use capital on acquisitions before the final shape of the post-1992 European 'single market' was clarified. It also gave companies the benefit of working together and gaining experience in new markets.

Several multicountry alliances were formed in the late 1980s/early 1990s – Organisation des Répartiteurs Pharmaceutiques Européenes, First

Pharmaceutical Wholesale Network, Pharma- Holding AG, Tredimed, and Intenational Pharmaceutical Service Organisation – involving almost 40 wholesalers in every EC member state at the time except Ireland[2]. None seems currently active.

In more recent years, the emphasis of the larger players has clearly switched away from international alliances to overseas acquisition of other wholesalers, often followed by consolidation of regional players, and to vertical integration – especially backwards into prewholesaling and forwards into pharmacy retailing.

Over the past decade, with a few exceptions, the numbers of wholesale companies and wholesale warehouses have continued to fall (table 2.1). Warehouse consolidation is constrained by the need to have a certain minimum number of strategically-sited storage facilities to serve the territory the wholesaler operates in.

***Table 2.1: Numbers of full-line wholesale companies and* warehouses, 1995 vs 2005**

Country	1995		2005	
	Wholesalers	Warehouses	Wholesalers	Warehouses
Belgium	34	50	11	27
Denmark	3	6	2	7
Finland	2	9	2	6
France	16	210	5	193
Germany	19	104	16	108
Ireland	5	14	3	10
Italy	215	312	81	214
Netherlands	5	23	5	15
Norway	4	7	3	7
Portugal	37	42	10	29
Spain	106	202	58	191
Sweden	2	7	2	6
Switzerland	7	12	4	9
UK	21	63	11	57

Source: GIRP

2.1.1 Major Pan-European Wholesalers

Three wholesalers have been at the forefront of acquisitions locally and across national borders in Europe - Phoenix, Celesio and Alliance UniChem (the distribution arm of Alliance Boots) – and now dominate several markets (table 2.2). It was estimated that by 2004 they held a combined 46% market share in EU, with in excess of 55% in Germany, France and the UK. By 2006/07, the combined shares of the 'big three' were even higher in some countries, e.g. Denmark 100%, Norway 100%, UK 92%, France 70% and Germany 63%. Each also has a wholesaling operation in Russia, with Celesio and Phoenix in Croatia too.

Table 2.2: Leading five wholesalers by sales by country, 2006

Country	1st ranked	2nd ranked	3rd ranked	4th ranked	5th ranked
Austria	Herba (Celesio)	Kwizda	Phoenix	Jacoby	Richter
Belgium	Febelco	Aprophar/Alpha	Pharma Belgium (Celesio)	CERP Phardip (CERP Lorraine)	Laboratoria Flandria (OPG)
Czech Republic	Phoenix	Alliance UniChem	Pharmos	Gehe Praha (Celesio)	
Denmark	Nomeco	Max Jenne (Celesio)	KV Tjellesen (Celesio)	-	-
Estonia	Tamro Eesti (Phoenix)	Magnum Medical	Apteekide Koostöö Hulgimüük	Nordic Pharma	AS Oriolo (Oriola-KD)
Finland	Tamro (Phoenix)	Oriola (Oriola-KD)	-	-	-
France	OCP (Celesio)	Alliance Santé (Alliance UniChem)	CERPSs		
Germany	Phoenix	Gehe (Celesio)	Anzag	Sanacorp	Noweda
Greece	Prosyfape	Lavifarm	Syfa Salonica	Stroumas	Marinopoulos
Hungary	Hungaropharm	Phoenix	Humantrade	Medimpex	Euromedic Pharma
Ireland	United Drug	Cahill May Roberts (Celesio)	Uniphar	-	-
Italy	Comiphar (Phoenix)	Alleanza Salute (Alliance UniChem)	Farmintesta (Secof)	Unico	So Farma Morra
Latvia	Tamro (Phoenix)	Limedika	Medikona		
Lithuania	Eurovaistine	Tamro (Phoenix)	Limedika	Armila	Medikona
Luxembourg	CPL	Hanff Frères	Mathis Prost	NA	
Netherlands	OPG	Interpharm (Alliance UniChem)	Brocacef (Phoenix)	Mosadex	Regifarm
Norway	NMD (Celesio)	Tamro (Phoenix)	Holtung (Alliance UniChem)	-	-
Portugal	Alliance UniChem	OCP (Celesio)	Codifar	UFP	Cofanor & Cooprofar
Slovenia	Kemofarmacija (Celesio)	Salus	Farmadent	Pharmakon	Gopharm
Spain	Cofares	Safa (Alliance UniChem)	Hefame	Cecofar	Federció
Sweden	Kronans Droghandel (Oriola-KD)	Tamro (Phoenix)	-	-	-
Switzerland	Galenica (Alliance UniChem has a 20% stake)	Amedis (Phoenix)	Voigt	Unione	-
UK	AAH (Celesio)	UniChem (Alliance UniChem)	Phoenix	Mawdsley-Brooks	

Source: GIRP

Three wholesalers dominating the available market is a feature not restricted to Europe. McKesson, Cardinal Health and AmerisourceBergen collectively share in excess of 90% of the US market. Sigma, Symbion (formerly known as Mayne) and API hold a similar share of the Australian market, while four groups from Japan's 128 wholesalers (Mediceo Paltac, Alfresa, Suzuken and Toho) share 90% of the market. What is unusual about Europe, however, is that while the national markets are largely

separate ones in wholesaling terms, many countries are dominated by one or more of Phoenix, Celesio and/or Alliance UniChem.

2.1.2 Prewholesaling

It was once thought that the main difference between wholesalers and prewholesalers was that the former handled individual drug packs to many customers and the latter dealt in pallet loads to a few, but the situation today is far more complex (table 2.3).

Table 2.3: Differences between wholesaling and prewholesaling

Wholesaler	Prewholesaler
Business model	
Margin on trading	Product sales cash neutral
Wholesaler sets selling price	Principal sets selling price
Fee for services to pharmacy	Fee for services provided
Using buying power for product for own benefit	Using buying power for services for mutual benefit
Own customers	Principal's customers
Sales information sold to IMS	Sales information owned by principal
Services and products	
Owned stock	Consignment stock
Only marketed products handled	Wide range of stock types handled:
	clinical trial products
	compassionate use products
	quarantine products
	unlabelled vials
	printed packaging material
	promotional material
Physical infrastructure	
Multiple small warehouses	Few large warehouses
2-5 x same day delivery	1 x next day delivery
High speed detail picking	Some detail picking, mostly case pick, some pallet pick
Local customers	Local and cross border customers
Small vans for transportation	Larger vans and trucks
Technical infrastructure	
Local based IT infrastructure	European based IT infrastructure
Operational reporting local	European consolidated operational reporting required
Batch tracking limited	Full batch tracking
IT validation limited	IT validation detailed

Source: Alloga-Europe

Prewholesaling provides multinational manufacturers with local warehouses, local people and local market knowledge within a European network structure consolidated into a single contract. Several of the larger wholesalers have created prewholesaling operations. For these wholesalers the supplier now also becomes a customer. This has always been the case with the single channel systems in Finland and Sweden, so there is limited room for third-party distributors in these markets. As well as profit generation opportunities, prewholesaling offers wholesalers economies of scale, especially when existing facilities can be utilised.

It appears necessary for a wholesaler to set up a separate prewholesaling division or to form a subsidiary company. This is to ensure each division remains driven by customer needs: prewholesaling by manufacturers' needs and wholesaling by those of pharmacies, dispensing doctors and hospitals. Prewholesaling does not offer major opportunities to regional wholesalers who cannot offer national distribution to a manufacturer

Celesio and Alliance Boots each have a prewholesaling arm, and can provide services through local affiliates across much of Europe (table 2.4); Phoenix' current prewholesaling services are largely limited to Scandinavia and eastern Europe. All offer a single point of management contact/negotiation, with integrated national, regional or pan-European tailored prewholesaling solutions. Activity-based costing is preferred.

Table 2.4: Prewholesaling affiliates of Celesio and Alliance Boots

	Movianto (Celesio)	**Alloga-Europe (Alliance Boots)**
Austria	Movianto Austria (Sanova Pharma)	Richter**
Bulgaria		Sopharma**
Czech Republic	Movianto Czech Republic (Realpol)	Alliance UniChem Czech Republic
Denmark	Movianto Denmark (KV Tjellesen)	
Finland		Oriola**
France	Movianto France (formerly DGX Pharma)	Alloga France
Germany	Movianto Germany (formerly Sanalog Logistik)	Loxxess Pharma*
Hungary		Cemelog**
Ireland	Movianto Ireland (Cahill May Roberts)	United Drug**
Italy		Alloga Italy (formerly Chipparoli)
Netherlands		Alloga Netherlands
Norway	NMD	Holtung
Poland		Orfe**
Portugal		Alloga Portugal
Spain	Movianto Spain (formerly SEUR Pharma)	Alloga Spain
Sweden		KD**
Switzerland		Alloga Switzerland*
UK	Movianto UK (formerly Healthcare Logistics) Movianto Northern Ireland (formerly Castlereagh Pharma)	UniDrug*

* Alloga associates ** Alloga partners

Source: company websites

Logistically, bulk stock is best held as close to the point of administration to patients as possible (i.e. in country warehouses), but the situation with a new high-priced product whose pattern of usage has not yet been established differs, especially if it has a short shelf life. In this case it is better to initially centralise stockholding in one or two depots or hubs serving all of Europe.

Furthermore, with the so-called 'postponement solution' packs can be non-country specific (alternatively called 'white' or 'nude' boxes) with national labelling according to local requirements added by the prewholesaler (under Good Manufacturing Practice conditions and with a manufacturing authorisation) to meet specific orders. The manufacturer can either provide the labelled packs/package inserts or the distributor can arrange for these to be printed locally. With postponement packaging it is possible to reduce the normal three months' stockholding to one month. As the business grows, finished stock can be split later between two or more warehouses.

Cold chain transportation can be done in a matter of hours on receipt of an order, either by the distributor's own refrigerated road transport (within a single country/the Benelux region) or via a carrier by air in cold packs (across national borders). Insurance cover may be available from the carrier (this is unlikely to be sufficient for high tech drugs as it based on the weight of goods), or is taken out separately by the distributor or its principal.

Though prewholesalers have the most experience of delivering to wholesalers and hospitals, they can just as easily deliver to community pharmacies or GP offices. A limiting factor is that is that access to the drop-off point must be guaranteed at the time the delivery is made.

2.1.2.1 Alloga

In 2000, Alliance UniChem acquired a minority shareholding in Switzerland's Galenica of about 20%. As a result of this investment, two 50:50 joint ventures were set up: prewholesaling across Europe (Alloga) and community pharmacy in Switzerland (Galenicare). Alliance UniChem sold 30% of Alloga to Galenica and two years later it acquired 100% of Alloga outside Switzerland, with Galenica retaining Alloga's prewholesaling business in Switzerland (becoming a partner in Alliance UniChem's Alloga Europe) plus Galenicare.

Alloga today is one of Europe's leading healthcare logistics providers, present in 22 countries, either directly, as associates or in partnership with other specialist providers. Its main European distribution centre is in France. This handles about 5 million order lines each year. Its 30,000 square metre capacity depot includes space for over 200 cold chain pallets. Relabelling is also possible here. The company has also built up its Dutch logistics centre in Veghel as a secondary European distribution hub. All facilities are ISO 9001-certified and linked to a European co-ordinated quality framework. As a pan-European provider, Alloga offers a 'network' benefit to healthcare players of all sizes from the largest pharmaceutical company to the smallest biotech.

2.1.2.2 Movianto

First known as AVS Solutions (where 'AVS' stood for added-value services) and then Celesio Solutions, Movianto offers itself as the initial point of contact for manufacturers with the Celesio group. Its origins go back to when Gehe inherited the Paris-based depository Dépot Généraux from OCP. The prewholesaling business has a turnover of €4 billion, 15 warehouses situated across the continent, a capacity for 200,000 pallets and has 1,200 employees. It handles global distribution for several principals.

Pan-European distribution is possible from a single point, such as one of its two German facilities (Neunkirchen and Kirst) either side of Frankfurt – Europe's largest air freight hub. Any part of Europe can be reached within 24 hours. Like Alloga, Movianto Germany also offers country-specific labelling at the time an order is placed.

Among recently concluded contracts are those with TopoTarget for distribution of the orphan drug Savene (dexrazoxane) to hospitals and oncology centres across Europe, with Celgene for distribution of the anticancer Revlimid (lenalidomide) to pharmacies and hospitals in Germany, and with Actavis for distribution of its generic range to wholesalers and hospitals in Austria.

The UK affiliate incorporates three previously established companies in the field, Farillon, Distriphar UK and Healthcare Logistics. It has considerable experience with cold chain distribution, including a five-year contract with the NHS to deliver vaccines to every GP every week and a next-day service with a chilled renal solution to 9,500 pharmacy accounts. A Lloyds pharmacy at the Milton Keynes depot is used for home deliveries. It partners with Advent to provide nursing services.

2.1.2.3 AS Healthcare

A relatively new entrant offering a full range of prewholesaling solutions to the pharmaceutical and biotech industries – supply chain management, financial management and customer relationship management - is Arvato Services Healthcare (www.arvato-services-healthcare.com).

Part of the €19 billion Bertelsmann family worldwide media, finance and communications group, AS Healthcare emphasises it is the only pan-European player in this market that is not owned by wholesalers or transport carriers. Established first in 2002 on a greenfield site in Germany (Harsewinkel), followed by a second German facility in Düsseldorf, specialised warehouses are now found also in France (Paris & Troyes), Belgium (Zaventem) and the UK (High Wycombe), with further countries coming on board soon.

Clients, several with cold chain requirements, include Alexion, Biogen Idec (direct distribution of Avonex to pharmacies, hospitals and wholesalers in Europe), Chiron, Encysive, Genzyme, Lundbeck (full European distribution except Scandinavia) and Menarini. AS Healthcare does not own vehicles, instead it chooses the best carrier for each market. Homecare services, with nursing support, are a future target.

2.1.2.4 Other

Better known as depositaries, there have long been a number of national prewholesalers in France (e.g. Depolabo www.depolabo.fr; Eurodep www.eurodep.fr) and Italy (e.g. Euroinvest).

One of the earliest prewholesaling services provided by a wholesaler was OPG's Red Swan Pharma Logistics (www.red-swan.nl). Orders placed before noon will be delivered anywhere in the Benelux region the following working day, it says.

UniDrug (www.udg.co.uk) is a 50:50 joint venture between United Drug and Alloga in the UK. It has a 20,000 square metre facility in South Normanton, Derbyshire. United Drug itself (www.united-drug.ie) offers prewholesaling in Ireland.

Euro Pharm Logistics (www.europharma.org) is a consortium of independent prewholesalers in 11 countries. If a pan-European solution was needed discussions would need to be had with each affiliate separately (i.e. Pharma Logistics in Belgium, CSP Translab in France, Logosys in Germany, Lavipharm in Greece, Allphar in Ireland, Faustfarm in Italy, Pharma Logistics in the Netherlands, Europharma Nordic in Norway, Logifarma in Portugal, Farmadis in Spain and Healthcare Logistics in the UK), though assistance would be provided by the Paris-based central office.

France-based Aexxdis (www.aexxdis.com) also offers pan-European prewholesaling services.

Competition to wholesalers for prewholesaling services has been provided by manufacturers themselves. Pharma Logistik GmbH (or PharmLog; www.pharmlog.de) was founded in 1993 by six major manufacturers to distribute across Germany. The current shareholders are Bayer, Boehringer Ingelheim, GSK, Meda, Merck, and Novartis. As well as the shareholders, other companies including AWD Pharma, Novartis Behring, Ferring, Intendis, Jenapharma and Novo Nordisk, use PharmLog for prewholesaling services in Germany. The company has a 40,000 square metre site in Bönen employing 250 persons and has a daily capacity for 4,000 orders, 22,000 items, 1 million packaging units and 20,000 parcels.

2.1.3 Manufacturing

Switzerland's leading wholesaler Galenica has a manufacturing affiliate Vifor, which claims a 33% global market share in anti-anaemia products (57% market share in US). It also owns 15th-ranked UK OTC company Potters.

European wholesalers have identified the growth opportunities presented by generics. Some have got directly involved in their production, while others have preferred to source where prices are keenest. Alliance UniChem launched its Almus range of generics in the UK in 2003, followed by France in 2006. A gradual pan-European roll-out of Almus generics is foreseen and the company has also tied up with Cardinal Health to access the US market. Brocacef of the Netherlands has stepped up its generic interests through Aeramphic, Genfarma and Magnafarma while Slovenia's Farmadent is planning to invest in generics production.

Gehe (Celesio) disposed of its generic interests many year ago and OPG sold its Dutch Pharmachemie generic production unit to Teva. Boots Healthcare International, an OTC manufacturer, had to be sold as a condition of the Alliance UniChem and Boots merger.

2.1.4 Contract Sales

Ashfieldin2Focus, formed through the merger of Ashfield Healthcare (acquired by Ireland's United Drug in May 2000) and In2Focus (added in June 2005), claims to be the leading contract sales organisation (CSO) in both the UK and Ireland, supplying 76 syndicated and dedicated sales teams and 1,200 representatives to pharmaceutical manufacturers. It also has a growing presence in the US. United Drug has invested over £30 million in its UK CSO operation, including infrastructure, technology and acquisitions

Alliance UniChem acquired leading French CSO Cider Santé in 2005 for €12 million and Celesio is also involved in the CSO business in Germany via Pharmexx, in which it has a 30% stake.

2.1.5 Clinical Trial Supplies

Phoenix has established Phoenix Pharma-Einkauf in Germany as a clinical trial procurement and supply management subsidiary.

2.2 Pharmacy

2.2.1 Demographic Changes

In contrast to the situation with wholesalers, the numbers of pharmacies have either increased or remained relatively steady in most European countries over the past 20 years (table 2.5).

***Table 2.5: Change in numbers of community pharmacies since* 1986**

Country	1986	1993	2003	Latest available year
Belgium	4930	5237	5256	5268
Denmark	313	300	327	284
Finland	577	575	800	802
France	21186	22325	22697	22,500
Germany	20376	20296	21305	21651
Ireland	1000	1140	1230	1400
Italy	15268	16000	16808	17524
Netherlands	1400	1496	1707	1810
Norway	400	312	502	559
Portugal	2268	2485	2759	2557
Spain	17500	18217	20098	20741
Sweden	786	750	870	875
UK	12700	11968	10463	12250

Source: various

One key factor behind growth in pharmacy numbers has been the weakening or even total abolition of the rules concerning establishment of new pharmacies (table 2.6) and of pharmacy ownership restrictions.

Table 2.6: Pharmacy establishment rules (status as of March 2007)

Country	Are there specific geo/demographic criteria for opening new pharmacy?	If 'No', is establishment based on population needs?
Austria	Yes	-
Belgium	Yes	-
Bulgaria	No	No
Cyprus	No	No
Czech Republic	No	No
Denmark	No	Yes
Estonia	Yes	-
Finland	No	Yes
France	Yes	-
Germany	No	No
Greece	Yes	-
Hungary	No	No
Italy	Yes	-
Ireland	No	No
Latvia	Yes	-
Lithuania	No	No
Luxembourg	Yes	-
Malta	Yes	-
Netherlands	No	No
Poland	No	No
Portugal	Yes	-
Romania	No	No
Slovakia	No	No
Slovenia	Yes	-
Spain	Yes	-
Sweden	No	Yes*
Switzerland	No	No
UK	No**	Yes

* Apoteket has the right to decide on the establishment of pharmacies

** While there are no restrictions on pharmacy openings in the UK, there are controls on contracts to provide NHS pharmaceutical services. \For the average pharmacy, 80% of turnover is NHS prescriptions, so few pharmacies open without an NHS contract

Source: PGEU

2.2.2 Ownership Changes

Up to the end of the 1990s, pharmacy ownership by non-pharmacists used to be found in only five countries and this was largely because there was no specific legislation on pharmacy ownership in place there. Ownership criteria have now been at least partially liberalised in 16 countries (table 2.7).

Table 2.6: Is it possible for a non-pharmacist to own a pharmacy?
(status as of March 2007)

Austria	No	
Belgium	Yes	
Bulgaria	No	
Cyprus	No	
Czech Republic	Yes	
Denmark	No	
Estonia	Yes	
Finland	No	
France	No	
Germany	No	
Greece	No	
Hungary	Yes	
Italy	No	Except for municipal pharmacies – these can be managed by companies
Ireland	Yes	
Latvia	Yes	Pharmacist-ownership criteria to be implemented by 2010
Lithuania	Yes	
Luxembourg	No	
Malta	Yes	
Netherlands	Yes	
Norway	Yes	
Poland	Yes	
Portugal	Yes	
Romania	Yes	
Slovakia	Yes	
Slovenia	No	
Spain	No	
Sweden	No	Only Apoteket can own pharmacies
Switzerland	Yes	
UK	Yes	

Source: PGEU

Governments in Austria, Italy and Spain are amongst those under pressure from the European Commission's Directorate Generals for Competition and the Internal Market to reverse legislation barring non-pharmacists or corporate bodies from running a pharmacy. Such restrictions are only compatible with the freedom of establishment enshrined in Article 43 EC in cases where it can be shown that this is in the public interest, the Commission believes, It has already rejected claims that blanket restrictions are necessary to protect public health.

Vigorous defence of the current Spanish pharmacy system (also referred to as the 'Mediterranean-continental' model) came in a recent study of the situation across Europe by FEFE, the Spanish pharmacists' association, and the Valencia College of Pharmacists.

The situation where only a fully trained professional can own a pharmacy and establishment of premises is governed by planning regulations that take into account geography and demography is not only the most effective model but is also the most popular among EU member states, the study found. This system prevails in 45% of EU countries, while the deregulated or 'Anglo-Saxon' model is present in only 25% of EU nations, with the remaining countries having a mixed system, though one more akin to Spain's.

In countries following the Spanish system there is greater equality of access in terms of the cost and availability and the quality of the services provided,

according to the study. In states with deregulated systems, pharmacies tend mainly to appear in concentrations in the more profitable areas, with a lack of outlets in rural areas. The report says that deregulation has led to permanent pharmacy closures in the UK, a scarcity of trained professionals in the Netherlands, and inequality of access to pharmacies in Sweden and Denmark. In addition, if deregulation occurs quickly, medicine prices may rise sharply and monopolies may take shape, as has occurred in Argentina and Chile, notes the report.

Limiting the ownership of pharmacies to trained professionals improves the quality of service as such outlets are more likely to prioritise public health, says the study. It also argues that the system provides patients with a greater range of options as they access to healthcare advice from a trained pharmacist, an alternative to a doctor's consultation. Removing the necessity for proprietors to be qualified has proved to be a disincentive for professionals – in deregulated countries there are fewer community pharmacists.

If the Spanish system was implemented across the EU, around 92,000 pharmacies would open, the report concludes.

Italian pharmacists also disagree with the European Commission's viewpoint – on the basis of a 2003 verdict by the country's Constitutional Court ruling that wholesalers be prohibited from owning private pharmacies (in contrast to pharmacies owned by communes) as such businesses should be mutually exclusive. The Commission is known to be unhappy that only pharmacists can own private pharmacies in Italy, pharmacists can act as wholesalers there, yet wholesalers are barred from pharmacy ownership. A case at the ECJ is pending.

It should be noted that in accordance with Directive 2005/36/EC on the recognition of professional qualifications, member states have the right through legislation, regulation or administrative steps to forbid *'companies from pursing certain pharmacists' activities or subjecting the pursuant of such activities to certain conditions'.*

2.2.3 Supervision Changes

While arguments have raged over whether community pharmacies need to be owned by pharmacists or not, it has consistently been the case across Europe that the physical presence of a pharmacist (as owner or employee) was necessary during opening hours for a pharmacy to operate. Now, with technology available to allow remote supervision, even this position is being challenged.

In the UK there are ongoing discussions about allowing pharmacists to supervise more than one pharmacy, thus no longer guaranteeing the constant presence of a pharmacist on the premises. Though enabling legislation has yet to be developed or even consulted on, the Health Act 2006 replaces 'personal control' by a pharmacist with the 'responsible pharmacist' concept. Every pharmacy will have a responsible pharmacist who will have a statutory duty to secure the safe and effective running of it, but will be empowered to be absent for given periods of time to fulfil other professional roles provided certain criteria are met. The Act makes provisions to enable supervision to be delegated to suitably trained support staff, and considers the possibility of a single pharmacist being responsible for more than one pharmacy in exceptional circumstances.

With the preponderance of chains, the majority of community pharmacists in the UK are employees and there are some fears that employers will exploit this potential opportunity to replace pharmacists with technicians and so cut costs. On the other hand it might allow independent pharmacists to open additional premises (remotely supervised) under their existing health service contract.

Though the Netherlands already gives considerable freedom to qualified assistants to act independently of pharmacists and unmanned dispensing kiosks support patient access to medicines out of hours, the Dutch parliament has recently upheld the need to have a pharmacist on the premises during the times the pharmacy is operating, and this will be part of the new pharmacy bill.

2.2.4 New Functions and Responsibilities

Greater competition between pharmacies has meant that distinguishing features and diversification in offerings has had to be sought in order to remain in profit. This has resulted in a sometimes dramatic change in job orientation of community pharmacists, from technical experts who practised in relative isolation to providers of product and general health-related information and services, highly visible and accessible to the public.

Economic pressures on the drugs bill, the increasing complexity and potency of medicines, and a wider acknowledgement of the pharmacist's skills allied to closer liaison between the healthcare professions, have boosted pharmacy's decision-making input into the choice of drugs. Following in the steps of their hospital-based counterparts, community pharmacists now increasingly act as gatekeepers of public-funded pharmaceutical expenditure, influencing what the doctor prescribes and what the patient receives.

Pharmacists advise on the rational use of medicines via input into local formularies, by performing medicine use reviews for individual patients, and by maintaining patient medication records. Uniquely in Europe, UK pharmacists, along with nurses, are allowed to become independent prescribers. Increasingly, pharmacists in many countries offer medication management or pharmaceutical care services. Defined as 'the responsible provision of drug therapy for the purpose of achieving definite outcomes which improve a patient's quality of life', this had to compete with commercial realities. Pharmaceutical care is outside the scope of this report but interested readers are referred to pan-European overviews of the subject[1,3] .

As long as the physician agrees and the patient is informed and does not object, pharmacists are in principle able to substitute a cheaper but bioequivalent generic for the prescribed brand in a growing number of European countries, many where generic usage is already extensive (table 2.8). Therapeutic substitution by the pharmacist – with a different chemical entity from the same therapeutic class – is forbidden everywhere except in *bona fide* emergencies.

Table 2.7: Generic substitution rights and usage levels in European countries, 2005

Country	Generic substitution rights for pharmacists?	Share of generics in retail market by value at MSP (%)
Austria		13.4
Belgium		8.5
Denmark	Yes	12.9
Finland	Yes	22.6
France	Yes	7.9
Germany	Yes	29.1
Greece		10.7
Hungary	Yes	34.2
Ireland		7.7
Italy		13.1
Latvia	Yes	50.2
Netherlands	Yes	17.6
Norway	Yes	13.0
Portugal	Yes	12.7
Slovenia	Yes	35.6
Spain	Yes	5.9
Sweden	Yes	13.2
Switzerland	Yes	7.8
UK		26.3

Source: EFPIA/GIRP

Incoming parallel trade is at double digit penetration levels in some countries (table 2.9).While the decision is influenced by payer incentives or sanctions, whether a parallel import is used or not in individual cases is largely the pharmacist's choice alone, unless the patient objects. Dispensing a PI is not generally regarded as substitution.

Table 2.8: Parallel import penetration, 2005

Country	% of pharmacy market
Denmark	15.7
Germany	5.9
Netherlands	11.5
Norway*	8.2
Sweden	13.9
UK	14.5

* share of total market

Source: EFPIA member associations (cited in 'The Pharmaceutical Industry in Figures')

At the same time as gaining more influence on prescription drug use, pharmacists were losing their monopoly over the sale of a growing number of OTC medicines due to efforts by governments to improve access, increase competition and reduce prices. Loss in counter revenue from sales of simple remedies or nicotine-based smoking cessation aids to non-pharmacy outlets like supermarkets and grocery stores were, however, offset by a growing number of new prescription-to-OTC switches (e.g. ranitidine, topical hydrocortisone, chloramphenicol eye preparations, simvastatin, 'morning after' emergency contraception, sumatriptan in the UK), over which pharmacy retains its sales monopoly.

2.2.5 Rise of Pharmacy Multiples

Following from the question of pharmacist or non-pharmacist ownership is the issue of pharmacy multiples. It has been estimated that 13.5% of pharmacies across Europe's 18 leading countries are already in chains of two or more outlets (table 2.10). Admittedly, this share is inflated by the figure for the UK alone, where more than half of the 16,974 pharmacies belonging to chains among the 126,152 pharmacies in the 18 countries can be found.

In countries where multiple ownership is currently forbidden (and even where it is allowed), so-called 'virtual chains' sometimes exist (or co-exist). These are independently-owned pharmacies gathering together under a common symbol or brand to share the benefits of bulk purchasing and common marketing, often under the direction of a wholesaler. Examples of virtual chains include Alliance Boots' Alphega (in France, Greece, Italy, Spain and the UK), Vantage from AAH (Celesio) in the UK, and Connect from Celesio in Ireland. Phoenix has purchased two of the largest buying groups in the UK (Numark and Nucare) as well as a minority share in France's Plus Pharmacie symbol group.

***Table 2.9: Share of community pharmacies in actual or virtual* chains by country**

Country	Pharmacy chain (%)	Virtual chain (%)
Austria	1.6	2.1
Belgium	22.0	3.8
Czech Republic	9.9	0
Denmark	18.4	0
Finland	19.4	0
France	0	60.0
Germany	5.7	62.4
Hungary	0	0
Italy	8.8	0
Netherlands	19.2	11.2
Norway	98.1	0
Poland	10.0	0
Slovakia	5.6	0
Slovenia	0	0
Spain	0	1.0
Sweden	100.0	0
Switzerland	18.0	44.0
UK	73.0	49.0
18-country total	13.5	27.3

Source: OTC Distribution in Europe 2007, James Dudley Management

Europe's 'big three' alone own and operate their own chains totalling almost 6,000 pharmacies in 11 European countries (tables 2.11 and 2.12).

Table 2.10: Extent of pharmacy ownership in Europe by Alliance Boots, Celesio and Phoenix

Country	Alliance Boots	Celesio	Phoenix
Austria			O
Belgium		O	
Czech Republic		O	
Estonia			O
Ireland	O	O	
Italy	O	O	O
Latvia			O
Lithuania			O
Netherlands	O	O	O
Norway	O	O	O
UK	O	O	O

Source: company websites

***Table 2.11: Examples of share of pharmacy ownership by big three* wholesalers**

Country	Total pharmacies	Approx % owned by Celesio	Approx % owned by Alliance Boots	Approx % owned by Phoenix	Approx % owned by other wholesalers	Source
Ireland	1,412	4	3	0	0	Irish Pharmaceutical Union, 2007
Netherlands	1,730	2	4	4	15*	ÖBIG, 2005
Norway	559	22	23	33	0	Norges Apotekerforening, 2007
UK**	12,500	14	13	3	1	James Dudley, 2007

* mostly OPG with 223 pharmacies currently

** 53% of UK pharmacies in 2005 were in chains of five or more outlets

Wholesalers now own the largest pharmacy chains in the Estonia, Ireland, Netherlands, Norway, Romania, Switzerland and the UK, but they don't dominate everywhere. Vilnius-based Maxima, Lithuania's largest retailing group, has pharmacy chains across the CEE countries: Lithuania's Eurovaistine (210 outlets), Latvia's Euroaptieka (40), Estonia's Euroapteek (18), the Czech Republic's Eurolekarna (15) and Slovakia's Eurolekaren (10). It is currently rebranding them all under a common Euroapotheca name.

Even where pharmacy ownership is disbarred, wholesalers have strong leverage on many pharmacies via their terms of trade. In Germany, for example, Booz, Allen & Hamilton estimates the numbers of independent pharmacies linked with the leading wholesalers in 2006 were 3,500 to Phoenix, 2,500 to Celesio and 2,000 to Sanacorp. Wholesalers also tie pharmacies in through loan guarantee schemes. In return for future business commitment, AAH's Statim Finance subsidiary, in which the major banks are lending partners, has helped more than 3,000 UK pharmacists buy a pharmacy since the scheme was established in 1985.

CHAPTER 3
COUNTRY PROFILES

3.1 Austria

There are nine full-line wholesalers, members of ARGE Pharmazeutika, in Austria: Herba Chemosan (www.herba-chemosan.at), Kwizda (www.kwizda.at), Phoenix (www.myphoenix.at), Jacoby, Richter, L Kögl, G&M, Mayrhofer and Pharmosan. Herba Chemosan (acquired by Celesio) is the market leader. Direct delivery to pharmacies by manufacturers is allowed (as long as a wholesaling authorisation is held) but is uncommon.

Patients receive medicines from main pharmacies (1,160), branch pharmacies (18) and self-dispensing doctors (992). A pharmacy may establish a maximum of one branch within 4 kilometres of the original pharmacy. One quarter of all public pharmacies are found in the capital Vienna. Only pharmacists or partnerships where a pharmacist's share is 51% are allowed to own pharmacies, with wholesalers Herba, Phoenix and Jacoby holding minority interests in some premises.

A number of preconditions must be fulfilled to open a new pharmacy:

- the responsible pharmacist must have a minimum of five years' experience, be an EEA national and have a good command of the German language;
- there must be a physician's surgery in the neighbourhood;
- the nearest alternative pharmacy must be at a minimum distance of 500 metres;
- each of the neighbouring pharmacies must still have the potential to supply 5,500 people; and
- the pharmacist owner can only own one pharmacy.

Dispensing doctors, who can supply both prescription medicines and OTCs, are supposed to procure supplies from pharmacies, though several wholesalers hold pharmacy licences to get round this restriction.

3.2 Belgium

Seventy five percent of the pharmacy market is supplied by five co-operative wholesalers: Febelco (www.febelco.be), Aprophar, Pharma Belgium (Celesio; www.pharmabelgium.be), CERP Phardib (a subsidiary of France's CERP Rouen), and Laboratoria Flandria (OPG). Febelco (formed from the mergers of Asma-Borgers, Inter Nos and Lifak), which enjoys a national market share of 28%, is much stronger in Dutch-speaking Flanders than in French-speaking Wallonia. The second-ranked wholesaler, formed by the 2005 merger between Alfa Répartition (focusing on Wallonia) and Aprophar (Flanders), is a subsidiary of France's CERP Lorraine.

Belgian wholesalers have a public service obligation. In accordance with Article 22bis of *l'arrêté royal* of 6 June 160 (as modified in 1999), they are required to:

- continually hold a stock of at least two-thirds of all marketed medicines with sufficient for one month's supply;
- have sufficient staff, services and transport to be able to supply pharmacies daily;
- be able to supply medicines within 24 hours of order receipt or more promptly in an emergency; and
- arrange for a back-up wholesaler to deliver if necessary.

There are just over 5,200 community pharmacies in the country, owned both privately (75%) and by mutual health insurance companies or co-operatives (25%). Pharmacies in Belgium have a long history of associating with each other: the first grouping of 28 pharmacies was formed in d'Anvers in 1835.

All types of medicines (including OTCs, and herbal and homoeopathic medicines) may only be sold from pharmacies. Quality labels are granted to certain parapharmaceutical products (mainly hygiene, dietary and babyfood items) by the Belgian private pharmacy owners association Association Pharmaceutique Belge (APB) when these are allied to pharmacy, the pharmacist can add-value through advice, and they have been tested and approved by the APB's own laboratory. Control of entry to the APB label scheme has now been transferred to Farmaplus, a joint venture between the APB and the pharmaceutical industry.

There are no specific regulations on pharmacy ownership, but a pharmacist must be present at all times. Vertical integration between pharmacies and wholesaler groups is growing. Numbers of premises are linked to the population size. For example, in large urban areas (communities with over 30,000 inhabitants) the number of pharmacies cannot be higher than the figure obtained by dividing the number of inhabitants by 3,000. In rural areas (<7,500 inhabitants), the population size is divided by 2,000. In practice, because pharmacy density is already high, a freeze on new openings has been in place since 1994.

3.3 Bulgaria

There are still a large number of pharmaceutical wholesalers but the main companies are: Libra (www.libra-org.com 17% market share; Phoenix), Higia/Actavis (www.higia.bg 12.6%), Commercial League (9.6%), Sting (5.6%) and Sopharma Trading (www.sopharmatrading.bg 5%). Iceland's Actavis acquired shares in Balkanpharma in 1999, and rebranded Balkanpharma's distribution division Higia as Actavis.

Bulgaria has 4,300 private pharmacies and about 100 state-owned/municipal pharmacies. Only 2,100 have National Health Insurance Fund dispensing contracts.

There are also 330 drugstores, selling OTCs and other health-related goods.

In relation to its population, the only European country with a higher pharmacy density than Bulgaria (one per 1,810 inhabitants) is Greece (one per 1,320). Despite the large number for the population overall, many rural areas do not have a pharmacy and rely on doctor dispensing. Consolidation is inevitable as the average pharmacy has a turnover of only BGN 6,300 and debt is high.

According to the 1995 Drug Act, pharmacies should only be owned by pharmacists, though there were no establishment criteria for new premises. Ownership demands were not strictly enforced and a number of chains emerged under a franchise model facilitated by wholesalers. A new 2007 law limits pharmacy ownership to a pharmacist, who must be registered under the country's trade law as a sole proprietor or a single member limited liability company. The three partners in the government coalition rejected an amendment that would have allowed corporate entities and non-pharmacists to enter the retail pharmacy business. Existing groups, such as Sofiski Apteki (Sopharma Trading), Pharma Expert (Higia), Obraztsovi Apteki (Commercial League) and Lege Artis (Sting), have been given a one-year transitional period to comply. While chains represent just 10% of pharmacy numbers, they account for more than 30% of the retail market.

3.4 Cyprus

In contrast to other EU member states, 40% of the population of Cyprus is not covered by statutory health insurance for outpatient medicines. As a consequence, there are two distinct market segments that operate independently, public and private. The uninsured must pay the full price for medicines in the private sector, as decided by importers.

There are 60 importers/wholesalers and 50 importing pharmacies. The latter are among the 440 privately-owned community pharmacies, 40% of which are in the Nicosia region alone. There are also another 40 hospital pharmacies that supply ambulatory patients within the public healthcare system. No geographic or demographic criteria limiting pharmacy numbers exist with the Pharmacy Board responsible for awarding pharmacy concessions. The majority ownership stake must be in the hands of a pharmacist, and each pharmacist can only own one pharmacy. In practice, most pharmacists run their own pharmacies, there being only one pharmacy chain on the island.

3.5 Czech Republic

Until 1990, there was just one state-owned pharmaceutical distributor, Zdravotnicka Zasobovani, and when its depots were privatised these were mostly acquired by western wholesalers. A large number of small entrants accompanied liberalisation and at one time there were 400 wholesalers, but a consolidation process since has resulted in the four members of the Association of Pharmaceutical Wholesalers – Phoenix (www.mypin.cz), Alliance Healthcare (www.alliance-healthcare.cz; Alliance Boots), Pharmos, and Gehe Pharma Praha (www.gehe.cz; Celesio) - controlling 98% of the market.

There were 2,617 pharmacies, including 24 branch outlets, as of the end of March 2007, equivalent to one outlet per 3,930 inhabitants. All community pharmacies are privately owned. Anyone can own a pharmacy and there are no preset geographic or demographic criteria for new openings, with concessions awarded by district authorities. Pharmacy chains are allowed and 225 pharmacies, or 9% of the total, are in groups of more than five outlets. Each of Europe's 'big three' wholesalers own pharmacies in the Czech Republic. Druzstvo Lékáren, with 240 members, is one of the biggest buying groups in the independent sector. From 2005 doctors were allowed to dispense. This resulted in the first ever decline in the numbers of

community pharmacies. Pharmacy also lost its monopoly on some OTC medicines in 1998.

3.6 Denmark

Three wholesalers used to operate in a multichannel system in Denmark - Max Jenne (www.maxjenne.dk; Celesio), KV Tjellesen (www.tjellesen.dk; Celesio) and Nomeco (www.nomeco.dk; Phoenix) – but the first two were acquired separately by Celesio and consolidated. Max Jenna's focus had been on western Denmark while KV Tjellesen was stronger in the east. Wholesalers mainly supply community pharmacies, with hospitals in the majority of counties taking deliveries from the central purchasing agency Amgros.

Denmark manages with the lowest density of pharmacies in Europe (just 252 or 1 per 21,400 population) and has even closed down 25 premises since 1985. However, to support the network of main pharmacies there are affiliated branch pharmacies, numbering 55. The branch pharmacy has its own separate premises and professionally qualified staff, one or more of whom must be a pharmacist. It may retail the same products as the pharmacy and may also dispense prescription medicines.

In addition to pharmacies and branch pharmacies there are several different types of retailer (pharmacy outlet, OTC outlet, delivery facility, supermarket) where different types of products may be purchased or - in the case of prescription medicines - picked up.

Pharmacy first lost its medicines supply monopoly in 2001, with the range of non-pharmacy purchases extended in 2003, and over 10% of OTCs are now sold through 1,300 new retail outlets. OTCs may also be sold via the internet (e.g. Dit Apotek). Price competition with OTCs is allowed.

Around 82% of pharmacy turnover comes from dispensing prescriptions, 7% from the sale of OTC medicines, and the balance from the sale of parapharmaceuticals and services. There are considerable differences in the turnover of individual pharmacies, ranging from DKK 11 million to DKK 145 million.

In order to ensure there are sufficient pharmacies in rural districts, an equalisation scheme operates whereby pharmacies with relatively large turnovers pay a sales tax to other pharmacies that do not have such high earnings. Around DKK 50 million is redistributed annually as a consequence and about a half of all pharmacies receive a subsidy.

Only pharmacists may own pharmacies, and the standard situation is that the proprietor pharmacist works only in the pharmacy he or she owns. However, a change in the law in recent years has seen the emergence of a 15 pharmacies with a supplementary licence issued by the Danish Medicines Agency. This came about after it was decided that the financial equalisation arrangement benefiting small pharmacies would be phased out over five years from 2005 for premises in urban areas. If a pharmacy is about to close down the Agency assesses whether one is needed and if so it will offer a supplementary licence to operate this pharmacy to another pharmacy owner in the area.

While there are no pharmacy multiples, there is one virtual chain, Apotekeren. A complaint was filed by the manufacturers' body LIF in 2007

alleging Apotekeren members were given special discounts by KV Tjellesen, though the Danish Medicines Agency found no evidence of this.

On average there are 15,000 inhabitants per dispensing unit (pharmacy or branch pharmacy), but coverage varies greatly across the country from 11,000 inhabitants per pharmacy in Viborg county to 23,000 per pharmacy in Roskilde county. In 2005, the Danmarks Apotekerforening found that the average Dane had to travel 3.8 kilometres to the nearest dispensing point. Six out of 10 Danes lived less than 3 kilometres from a pharmacy. In even small towns there was a pharmacy outlet, an OTC outlet or a delivery facility where medicine ordered at the local pharmacy could be picked up. If these units are included, the average distance is 1.6 kilometres, and three out of four Danes could pick up their medicine at a delivery facility less than 2 kilometres from their homes.

Pharmacies supply on average 167,000 pack items a year, or approximately 630 every working day. This high throughput is possible because their premises are large, automated and employ in comparison with other countries a high number of staff (an average 14.2 full-time equivalents in 2005, inclusive of the proprietor).

3.7 Estonia

Although more than 30 companies hold wholesale dealing authorisations, two – Tamro Eesti (www.tamro.ee; Phoenix) and Magnum Medical (www.magnum.ee) – have a combined 50% market share. A new entrant in 2004, Apteekide Koostöö Hulgimüük, has 15%. Other players include Armila Eesti (Nordic Pharma), AS TopMed, AS Oriola (Oriola-KD) and Pharmac MS.

One third of the country's 328 main pharmacies (figure at end of 2005) can be found in the two main cities of Tallinn and Tartu. During the year, 14 premises closed and 58 new ones opened. Non-pharmacists may own pharmacies and up to 80% are organised or affiliated in some way in vertically-integrated chains with wholesalers. Apteek1 (www.apteek1.ee), the leading pharmacy multiple with 190 outlets and a 35% retail market share, is controlled by Tamro Eesti (Phoenix). There are also 196 pharmacy branches plus pharmacy counters for retailing OTCs. Medicines account for more than 80% of the turnover of the average pharmacy, and three quarters of this share represents prescription medicines.

Establishment criteria for new pharmacy openings came into effect from the beginning of 2006. A new licence will not be granted in urban areas by the Ministry of Social Affairs when each existing pharmacy serves fewer than 3,000 inhabitants. The minimum distance between a new and an existing pharmacy in rural areas is 1 kilometre. Licences may not be transferred to a new location further than 500 metres from the old one.

3.8 Finland

Apart from Sweden, Finland is the only EU country to practice single channel distribution, where each manufacturer has an exclusive nationwide distribution contract with one of the two wholesalers, Tamro (www.tamrosuomi.fi; Phoenix) and Oriola (www.oriola-kd.com; Oriola-KD). The latter is owned by three manufacturers: Orion (85.6%), Merck Sharp & Dohme (12.5%) and Organon (1.9%). Tamro and Oriola looked like they would face competition (and the breakdown of single channel distribution)

when Sweden's KD entered the market in 1999, but the following year KD was acquired by Oriola.

Wholesalers are obliged by Finnish law to hold 'sufficient' stock.

The number of pharmacies in Finland has not changed much over time, and no pharmacy has closed during the last 15 years. Finland currently has 802 pharmacies of which 603 are main pharmacies, 197 are branch pharmacies, and two are situated in university premises. On average a Finnish pharmacy serves 6,509 inhabitants.

There are also about 160 medicine chests, usually located in post offices or grocery stores, selling a limited selection of OTC medicines under the supervision of the main pharmacy. If customers need information in addition to that found in the product's patient information leaflet they must make a telephone call to a pharmacy. The number of medicine chests has steadily declined over time due to an increase in the number of branch pharmacies and the migration of people from rural areas to the cities. Doctors are not allowed to dispense medicines.

On average, there are per pharmacy 1.7 pharmacists, 4.6 prescriptionists and 3.2 pharmacy technicians/assistants. The number of pharmacists has grown steadily since the beginning of the 1990s. Their required university education takes 5-6 years, and results in a Master of Science degree. The university education of prescriptionists takes only 3 years and results in a Batchelor of Science degree. Prescriptionists may dispense prescription medicines without direct supervision of a pharmacist, though the pharmacist remains responsible for defining working procedures and in case of malpractice.

With permission from the National Agency of Medicines the owner of a pharmacy – who must be a pharmacist - may run up to three branch pharmacies in areas that are too sparsely populated to support main pharmacies of their own. Branch pharmacies are allowed to be staffed by prescriptionists under the supervision of the pharmacy to which they belong.

Nearly 99% of Finns live in a municipality with at least one pharmacy. Only 42 municipalities out of a nationwide total of 444 did not have a pharmacy in 2004, whereas 200 municipalities did not have a health centre. Of the 42 municipalities without a pharmacy, 16 were on the archipelago or in the very north of Finland. Here, access to medicines is ensured through local agreements like home delivery.

A 2007 survey by market researchers Taloustukimus found that most of the 1,000 respondents were happy with their pharmacy services. They especially appreciated advice on correct usage, drug interaction checks, in-use monitoring and the possibility of receiving a cheaper substitute. However, more than half preferred to receive drug information from a doctor. Interestingly, although internet usage overall in Finland is very high, only 2% of respondents sought to purchase medicines online. Purchasing OTCs from pharmacies was preferred to use of supermarkets or other outlets. Most people appreciated the fact that prices were the same in all pharmacies across the country.

3.9 France

Wholesalers take 75% of manufacturing output - part via prewholesalers (better known in France as *dépositaires*) - hospitals 16%, and direct sales to pharmacies the remaining 9%. Virtually all sales from wholesalers (99.5%) go to community pharmacies, with direct distribution (via prewholesalers) supplying hospitals. Wholesaler sales (by value) can be broken down as 89% prescription medicines, 5% OTCs and 6% other products.

M&A activity and rationalisation has resulted in a marked fall in the number of wholesalers to just seven major companies in four groups today (table 3.1): Office Commercial Pharmaceutique or OCP (www.ocp.fr; Celesio), Alliance Healthcare (www.alliance-healthcare.fr; formerly Alliance Santé; part of Alliance Boots), Coopérative d'Exploitation et de Répartition Pharmaceutiques (better known as the CERPs - a regional network of pharmacist-owned, financially-independent co-operatives), and Phoenix (www.phoenixpharma.fr). A family-owned firm, RBP Pharma, and another co-operative, Giphar Sogiphar, are two small remaining players.

Table 3.1: Wholesalers in France, 2007

Group	Head office	Number of warehouses	Market share (%)
Groupe OCP (Celesio)		51	38
- OCP Répartition	Paris		
- Droguerie médicinale Martin	Clermont-Ferrand		
- Bourely Répartition	Marseille		
- Comptoir Pharmaceutique Méditerranéen	Monaco		
Alliance Santé (Alliance UniChem)	Asnieres	62	28
Reseau CERP			28
- CERP Rouen	Rouen	31	14
- CERP Rhin Rhône Méditerranée	Belfort	17	8
- CERP Lorraine	Nancy	13	4
- CERP Bretagne Nord	Saint-Brieuc	8	2
Phoenix Pharma (Phoenix)	Créteil	7	4.
Giphar Sogiphar		1	0.5
RBP Pharma		1	0.3
Total		189	98.8%

Source : CSRP

The combined market share of France's top four wholesalers has been almost constant at 98-99% for the past several years, with relatively little shift among them.

Recently, the largest of the CERPs, CERP Rouen, merged with the German co-operative wholesaler, Sanacorp, producing Europe's largest pharmacist-owned wholesaler with a staff of 5,000, 12,000 customers and a turnover of about €5.3 billion. Operations in France, Belgium and Germany will be centrally co-ordinated from a common limited liability company in a fourth European country (Italy) in which both co-operatives will hold 50% each.

All wholesalers in France are full-line, holding 25,000 SKUs (of which 8,700 are medicines). A public service obligation (Article R 5115-13 of the *Code de la Santé Publique*) ensures this. It requires every wholesaler to:

- Communicate to the French Healthcare Products Agency (AFSSAPS) details of the territory it covers (every district containing one or more pharmacies where sales are normally made must be included).
- Hold in stock at least 90% of all medicines used in France, whether reimbursed or not.
- Have a two-week supply capacity for their usual customers.
- Be able to deliver within 24 hours at a maximum.
- Inform the public authorities as soon as there is a reduction in stockholding.

When no other source of supply is available, the Director General of AFSSAPS can as an exception require a wholesaler to deliver to a pharmacy outside its normal territory.

In practice, deliveries are made at least twice a day, both in rural and urban areas. Almost all orders by pharmacies are electronically transmitted and are usually prepared and delivered within four-six hours of being placed, although two hours is sometimes possible if this is necessary. On average, one warehouse supplies 140 pharmacies, although there are great regional differences, for example Ile-de-France has one warehouse per 260 pharmacies and Champagne-Ardennes has one per 56 pharmacies.

Promotion of generics has been a key cost containment policy of the government and OCP has introduced its own generic purchasing programme for pharmacies, Evolutio.

At more than 22,500 outlets, pharmacy numbers appear to have stabilised. An estimated four million French people visit a pharmacy each week. The sector is highly traditional, with any item classified as a medicine not on open display, no product self-selection, and most customers seeking product recommendations rather than demanding a specific brand.

Despite long and constant pressure from supermarkets, the profession has successfully maintained its monopoly over the supply of all medicines (including herbal and homoeopathic products) granted it under an 1803 law. The monopoly also extends to the likes of medical devices, dressings, lens cleaning solutions, insecticides, and even food supplements, cosmetics and dietetic products when they meet the definition of a medical product laid down in Article L.5111-1 of the Public Health Code. In recent years pharmacists have gained even greater powers, in substituting prescribed brands with generics and dispensing formerly hospital-only products on the *retrocession* list, for example.

Pharmacy owners are obliged to employ an assistant pharmacist when annual turnover exceeds a certain amount. The use of qualified dispensing assistants (*preparateurs*) is widespread, but they can only work under the supervision of a pharmacist.

A licence from the *préfet* (the government's regional representative) of the local *département* is necessary to operate, with demographic criteria regulate new openings. There is a maximum of one pharmacy per 2,500 inhabitants in rural areas and one per 3,000 in urban areas. Only pharmacists or partnerships of pharmacists may own a pharmacy and the main owner must always be on the premises during opening hours. Sole proprietors account for two thirds of pharmacy owners. There are also a number of member-only pharmacies owned by mutual insurance funds (68) or miners' welfare societies (68).

While there are no private chains, aggregation around wholesaler-affiliated buying groups (*groupements*) is common.

There are just a handful of self-dispensing doctors (*propharmaciens*), and should a pharmacy open in their area then the physicians have to cease dispensing. Mail order or supply of medicines via the internet are not allowed. Some parapharmacies have opened either independently or within supermarkets, often grouped under one umbrella name. Although not having the legal status of a pharmacy, these shops are managed by a pharmacist and sell a range of parapharmaceuticals.

The distribution chain, working in reverse, plays an important role in the disposal of unwanted medicines in France. The system started in 1994 and is co-ordinated by an association called Cyclamed. It selects products returned to pharmacies by patients that could be reused for humanitarian purposes and to incinerate, with energy recovery, the rest. The boxed returns are picked up from pharmacies by wholesalers, which also supply material to publicise the scheme and arrange for a waste contractor to collect the 'destroy' containers for incineration when full. Charities bound by the Cyclamed convention collect the supplies initially considered reusable from pharmacies direct or via a wholesaler. Through a levy on sales through pharmacies the previous year, manufacturers finance all external costs. Awards are given to stimulate competition between the regions.

3.10 Germany

Among 16 wholesalers in Germany, four have nationwide coverage: Phoenix (www.phoenix-ag.de), 28% market share; Gehe (www.gehe.de; Celesio), 18%; Andreae-Noris Zahn – better known as Anzag (www.anzag.de), 17%; and Sanacorp (www.sanoacorp.de), 13%.. The remainder are regional players, the largest of which is Noweda (www.noweda.de) with a national market share of 10%. Altogether these companies have 106 warehouses and 13,000 employees and all are represented at national level by the *Bundesverband des pharmazeutischen Grosshandel* (PHAGRO; www.phagro.de).

Financial holdings are complex. Sanacorp owns a 25% stake in its rival Anzag. Noweda sold 19% of its 25% stake in Anzag to Alliance UniChem. Sanacorp has now merged with fellow co-operative, France's CERP Rouen.

At 60,000-80,000, German wholesalers hold the highest number of different SKUs in the EU, although only 30,000 are medicines. Wholesalers deal almost exclusively with community pharmacies, with their sales breakdown as follows: 78% prescription medicines, 12% OTCs and 10% other products. Manufacturers supply the 550 hospital pharmacies directly, with an estimated 150 community pharmacies having agreements to supply smaller hospitals without their own in-house pharmacy. The European

Commission has found fault with the way German hospitals procure medicines, alleging it is tantamount to a regional supply requirement.

At around 21,500, community pharmacy numbers have remained steady for several years. Bavaria is home to 3,400 or 16% and Baden-Württemberg has 2,780 or 13%, while at the other extreme Bremen just has 175 pharmacies or 0.8% of the national total. There are no dispensing doctors in Germany.

In principle, all medicines should be sold in pharmacies. While this still holds true for prescription-only medicines, certain OTCs are widely available from around 3,800 drugstores, 2,500 health shops and 7,000 other outlets (food stores, supermarkets, etc). PHAGRO members do not deliver to these outlets.

Pharmacies must hold sufficient stock to cover the average demand over two weeks (Section 15, Ordinance on the Operation of Pharmacies or *Apothekenbetriebsordnung*). In an appendix certain drugs are listed that must be stocked or be obtained in a short period of time. Section 17 of the Ordinance requires pharmacies to deliver medicines without any delay. Concerning mail-order pharmacies, the requested items must be dispatched within two days. While the Federal Civil Court (*Bundesgerichtshof*) has said public pharmacies depend on full-line wholesalers to fulfil their supply obligations, general public service obligations for wholesalers are not yet implemented. There are no demographic or geographic criteria for the establishment of pharmacies.

Three quarters of pharmacies deal with two wholesalers each, an equal proportion (12%) are supplied by either one wholesaler or by three, and the remaining few pharmacies are supplied by four or five different wholesalers. Almost all orders are placed electronically.

In terms of total numbers of wholesaler deliveries per day, the breakdown by share of pharmacies is as follows:

1/day <1%

2/day 15%

3/day 23%

4/day 38%

5/day 12%

6/day 6%

>6/day 5% (declining)

For many years, only pharmacists were able to own pharmacies, and then just one pharmacy (the so-called *Mehrbesitzverbot* rule). The 2004 Health Reform Act changed the situation so that a single pharmacist or partnership of pharmacists was allowed to own one main pharmacy and up to three branch pharmacies all located within one *Landkreis* (administrative district) or in adjacent ones. Germany has 313 *Landkreise* and therefore large-scale, nationwide pharmacy chains are effectively prohibited. Just as in other countries, a large number of independent German pharmacies (possibly half

the total) participate in co-ordinated marketing and buying activities, some managed by wholesalers.

The operation of the mail-order pharmacy DocMorris in Germany has been highly controversial, in particular when the Dutch company opened a pharmacy in Saarbrücken in the region of Saarland. This is the only non-pharmacist owned pharmacy in the country and the matter has been referred to the ECJ (joined cases C-171/07 & C-172/07). In another gesture which ABDA found highly provocative, a form of DocMorris pharmacy franchise is on offer. Although remaining owned by their pharmacists individually, around 40 German pharmacies have signed up. These outlets carry the DocMorris logo, have a standardised appearance and sell OTCs at discount prices. Unlike DocMorris' mail operation in the Netherlands, however, these, like other German pharmacies, are not allowed to waive 50% of the patient co-payment for prescription drugs under statutory health insurance.

The leading parallel importer in Germany, Kohlpharma, has also developed the AVIE pharmacy franchise concept, currently with about 40 members.

3.11 Greece

As well as the mainland, Greece consists of about 2,000 islands (of which around 200 are inhabited), a fact which likely contributes to a country of just 12 million people supporting 120 private and 27 co-operative pharmaceutical wholesalers. Each group has about half the market. The leading co-operatives are Prosyfape and Syfa Salonica. The leading private wholesalers are Lavifarm, Alliance Santé (Alliance Boots), Stroumsas and Marinopoulos.

Given the 'lowest in Europe' pricing policy practised since 1997 (now modified as the average of three lowest European prices – two from the former EU-15 plus Switzerland and one from the 10 countries that joined the EU in 2004), Greece is a major parallel exporter. Parallel exports in 2004 were about 21% of total Greek pharmaceutical sales at public prices, IMS estimates.

The high export volume has provoked loud and repeated concerns over product shortages affecting Greek patients. The regulatory authority, the National Drug Organisation, responded by issuing a circular in 1998 to remind wholesalers they must meet the demands of the domestic market first. In 2001, another circular obliged the distribution chain to keep sufficient stock to meet anticipated needs plus 25%. A third circular, also in 2001, required wholesalers to submit details to the Organisation of all exports (including to other EU member states) on a quarterly basis.

The country's topography also gives it Europe's highest density of pharmacies on a population basis, equivalent to just one pharmacy per 1,162 inhabitants nationwide. Of the approximate 10,000 pharmacies, 3,000 are found in the Attica area and 1,200 in Thessaloniki. In municipalities with populations of up to 1,500 only one pharmacy licence may be granted, and in municipalities with higher populations the number of pharmacies is capped at one per 1,500 inhabitants. Only pharmacists and partnerships of pharmacists may own pharmacies.

Pharmacies have a virtual monopoly for supply of all medicines (prescription-only and OTC) with just a few local doctors or health centres

in isolated areas licensed to hand out medicines. Food supplements too are only available from pharmacies.

3.12 Hungary

Up to 1992, Hungaropharma was the sole national distributor of medicines, receiving local products direct from manufacturers and imports via Medimpex, and supplying state-owned central warehouses in each of the 19 counties and the capital Budapest. Hungaropharma is now owned jointly by the state and three domestic pharmaceutical manufacturers (Gedeon Richter, Egis [Servier] and Béres). Medimpex evolved into a wholesaler, initially with Gedeon Richter and Egis holding equal stakes, but since 2007 it has been 100% owned by Hungaropharma. Germany's Phoenix, the only foreign entrant, first entered the market with the acquisition of Parma Medical Supplies in 1995 and of Calix the following year.

By 2006, five wholesalers – Hungaropharma (www.hungaropharma.hu), Phoenix (www.mypin.hu), Humantrade (www.teva.hu; Teva), Medimpex (www.mpx.hu) and Pannomedicine (www.pannomed.hu) – shared about 85% of the market, with Hungaropharma alone on 35%. There are in addition about 6-8 smaller wholesalers, including Pharmafontana (part of the Hungarian OTC manufacturer Naturland group).

Hungary is apparently unique among EU countries in that, in accordance with national law, all manufacturers have to distribute to pharmacies via wholesalers.

The country has 2,050 community pharmacies, 350 of which are in Budapest. Despite pharmacy owners claiming the market was already saturated and profitability low, ownership and establishment rules were completely abolished from the beginning of 2007, and more outlets are expected to appear.

Multiple pharmacies were already a feature as up to 49% of a pharmacy could be in non-pharmacist hands. Around 250 pharmacies are effectively organised in multiple groups, with Pharmafontana's 186-strong chain in and around Budapest the biggest. The requirement for a pharmacist to own at least a 51% share has now been dropped, though one of the owners will still have to be a pharmacist. New openings previously required the go-ahead from the Chamber of Pharmacists; now the Chief Pharmacist just has to be notified.

It has been reported that up to 500 pharmacies have signed agreements with Hungaropharm, assuring the wholesaler of 80% of their business in return for more favourable terms.

As well as pharmacy liberalisation, the 2006 Safe and Economical Supply and Distribution of Medicines and Medical Devices Act also allowed the sale of more than 300 OTC products – mainly analgesics - outside pharmacies for the first time, and the creation of e-pharmacies and mail-order pharmacies (but only for OTCs). Both the Post Office and the government have plans to bring mobile pharmacies to the most isolated regions.

There are a few dispensing doctors in rural areas, who are supplied by pharmacies. Out of 149 hospital pharmacies, employing 439 pharmacists and 804 technicians, 62 supply outpatients as well as inpatients.

3.13 Iceland

Prior to 1996, all Icelandic pharmacies were privately owned, with their number and geographic location decided by the Department of Health. As part of the revised Pharmaceutical Act, effective March that year, all restrictions on pharmacy ownership and new openings were swept away. Within a year pharmacy numbers rose by almost 30% (admittedly only from 44 to 57), with almost all the new outlets in the Reykjavik area. The population served on average by one pharmacy fell from 6,100 to 4,800.

Discounting on the patient's share of part-reimbursed products was also allowed, and resulted in savings of 10-15% on the co-payment, according to a survey by the Competition Surveillance Agency. The fact that pharmacies - in the Reykjavik area anyway - 'seemed to have no difficulty offering their customers large discounts', a spokesman from the Department of Health noted, was one factor behind a revision of the rules on both maximum wholesale and maximum pharmacy prices, and a reduction in the standard reimbursement rate from 68% to 65%. The government was pleased with the early results.

In more recent years the expansion of overall pharmacy numbers has more or less stopped, with new openings in the Reykjavik area balanced out by rural closures. If a rural pharmacy is threatened with closure, the Department has the option of granting dispensing rights to a local health centre but not to give financial support to the affected pharmacy.

Pharmacy concentration has also taken place. By 2001, three groups – two private chains (Lyfja and Lyf & Heilsa) and a purchasing group of independents (Plus-apoteken) - controlled about 85% of the market. By 2004, concentration increased further so that the two private chains alone controlled 85%, with only one truly independent pharmacy remaining in the country (table 3.2) Separately branded low-price pharmacies owned by the two main groups were only found in Reykjavik and in Akureyri, Iceland's second city.

Table 3.2: Pharmacy ownership in Iceland, May 2004

Pharmacy chain/group	Total number of pharmacies	Parmacies in Reykjavik area	Pharmacies outside Reykjavik area
Lyfja	20	11	9
Lyf & Helilas	29	21	8
Plus-apoteken	9	5	4
independent pharmacy	1	1	0

Source: Anell[4]

Another disappointment for the government was that contrary to the main aim of liberalisation, it realised no savings to the Social Security Institute – procurement discounts given by manufacturers were retained by the chain and the only savings passed on were to patients in the form of lower co-payment, and then only in urban areas[4]. Indeed, reimbursement costs steadily increased between 1993 and 1999.

The leading pharmacy chain today is Lyfja (also trading under the Apótekiò name); it is also the largest shareholder in Litis, which runs the 45-strong 'Farma' chain in Lithuania.

In response to pharmacy consolidation, the Icelandic wholesale market also consolidated to the point where Actavis became the only major supplier of generics. Local media interest was shown in 2006 into reports that Actavis-owned companies in Denmark were selling the same generic products between five and 10 times cheaper than in Iceland. The Icelandic government asked the Medicines Pricing Committee to investigate, made reimbursement changes designed to force down the prices of generics by 14% over two years, and even considered setting up a state-owned company to guarantee a supply of cheap generics.

3.14 Ireland

Three wholesalers control over 90% of distribution to 1,412 community pharmacies: United Drug (www.united-drug.ie; 44% market share), Uniphar (30%) and Cahill May Roberts (Celesio, 20%). Uniphar is a co-operative in which about 40% of Irish community pharmacists have a stake. Most multinational manufacturers use these wholesalers as prewholesalers also, with only GSK and Abbott (along with several domestic generic companies) distributing direct.

The pharmacy sector by tradition has been a liberal one, with the only proviso that all premises had to be managed by pharmacists. Multiple ownership is allowed and pharmacist-owned chains began appearing in the early 1990s. In 1996, needs-based criteria for opening of new premises were introduced for the first time, only to be revoked in 2002. There are no current plans to regulate the setting up or ownership of pharmacies. The only requirement with a new pharmacy is to notify the Pharmaceutical Society of Ireland of its location and the name(s) of the pharmacist(s) operating it. Self-dispensing doctors also practice in rural areas more than five kilometres from the nearest pharmacy. A limited range of OTCs for common conditions can also be supplied by non-pharmacy outlets, although 90% of products for self-selection are bought in pharmacies.

Pharmacy numbers grew by 17% in the decade to 2005, while the number of dispensing doctors declined by 37%. The current pharmacy total is about 1,400. New openings have tended to cluster in city centres. Chain pharmacies in particular have become more common, involving 470 pharmacies (of which 160 are non-pharmacist owned) compared with 168 in 1995, although 758 pharmacies are still sole proprietorships.

While United Drug has declared an intention not to compete with its community pharmacy customer base, the other two Irish wholesalers, as well as Alliance Boots, now have pharmacy ownership interests. Cahill May Roberts (Celesio) bought a number of small chains, including the Unicare group, in 2001, and announced an aim – prior to the abolition of restrictions on new pharmacy contracts – to secure control of over 20% of the market in two years. Uniphar has a joint venture scheme that allows pharmacists to buy into a pharmacy over 12 years. McSweeney, the third-largest group (table 3.3), is Dutch-owned.

Table 3.3: Leading pharmacy multiples in Ireland, 2007

Chain	Number of outlets
Unicare (Allphar)	58
Boots (Alliance Boots)	41*
McSweeney	28
Hickeys	26
Sam McCauley	22
McCabes	17
Bradleys	16

* only 36 currently have General Medical Services dispensing contracts

Source: Irish Pharmaceutical Union

The 2006 Pharmacy Act introduced 'Fitness to Practice' provisions and also removed the 'three-year rule' under which pharmacists not trained in Ireland (many are trained in the UK) were unable to run a pharmacy less than three years old.

3.15 Italy

Concentration among Italian wholesalers has for many years lagged well behind the process in northern Europe. There are still around 200 players, but a small group of wholesalers dominate: Comifar (www.comifar.it; Phoenix), Alliance Healthcare (formerly Alleanza Salute; www.alliance-healthcare.it); Alliance UniChem), Unico, So.Farma Morra, Farvima and AFM (www.afmspa.it; Celesio). Three others – Cotifar , Unifarma and Farcopa – formed the Farmintensa consortium (www.farcopa.it/presenta/farmintena), headquartered in Verona, partly to improve competitiveness but also as a defensive measure against further predatory action by the likes of Celesio and Phoenix. Farmintesa has reorganised its warehousing system so that pharmaceutical companies do not have to make as many deliveries. Before the change, Farmintesa's warehouses would receive up to 1,200 deliveries/year from a single manufacturer; this figure is now down to 24.

Under a public service obligation (Law Decree No 538 of 30 December 1992), wholesalers must hold sufficient stock to ensure usual and emergency supply of 90% of branded medicines on the reimbursement list plus at least one pre-packed product for each of the formulations in the National Formulary. Delivery must be made within 12 hours, even in the case of an industrial dispute, according to an agreement between the wholesalers' association, ADF, and the trade unions.

The majority of pharmacies, some 17,500 outlets, are privately owned but there are still 1,400 pharmacies managed by the local authorities. Private pharmacies are represented nationally by Federfarma, and public pharmacies by Assofarm. Nationally, there are about 3,300 inhabitants per pharmacy, but regional variations are quite large (table 3.4).

Table 3.4: Pharmacy numbers in Italy by region, 2007

Region	Private pharmacies	Public pharmacies	Total	Inhabitants per pharmacy
Valle D'Aosta	42	7	49	2508
Piemonte	1428	101	1529	2832
Liguria	570	22	592	2690
Lombardia	2328	392	2720	3453
Veneto	1193	87	1280	3672
Bolzano	106	0	106	4501
Trento	137	27	164	3034
Friuli-V.Giulia	345	20	365	3301
Emilia-Romagna	1011	190	1201	3457
Marche	430	69	499	3044
Toscana	886	201	1087	3310
Lazio	1311	137	1448	3639
Abruzzo	469	26	495	2625
Umbria	216	50	266	3229
Molise	162	6	168	1916
Campania	1528	38	1566	3697
Puglia	1055	19	1074	3788
Basilicata	201	2	203	2939
Calabria	758	1	759	2647
Sicilia	1405	9	1414	3545
Sardegna	531	8	539	3061
Total Italy	16112	1412	17524	3336

Source: Federfarma

Private pharmacies can only be owned by pharmacists, individually, in partnership or as co-operatives. Municipal pharmacies can be managed by companies, including wholesalers, and the 'big three' have seized the opportunity, already controlling 244 of the total of 1,412 (17%). Alliance Healthcare (www.alliancefarmacie.it; Alliance Boots) runs pharmacies in Rimini (totalling 8), Lucca (6), Cesena (4), Pontedera (3) and Sandicicci (8). Admenta (Celesio) has pharmacies in Bologna (36), Cremona (14), Milano (84), Lissone (3), Prato (14), Parma (3) and San Giovanni Valderno (2). Comifar (Phoenix) has 21 pharmacies in Firenze.

Provision of pharmacies across the country is regulated by the *Pianta organica delle farmacie*, with licensing by the regional authorities. For towns with populations up to 12,500, one pharmacy is allowed per 5,000 inhabitants, and for towns with populations in excess of 12,500, one pharmacy can serve 4,000 people. In addition, new openings must be at least 200 metres away from existing premises.

Pharmacies used to have a medicines supply monopoly, but in 2006 the government agreed that OTCs could be sold from other retail outlets as long as a pharmacist was present. A number of types of new OTC outlets have emerged including *Autofarmas* on motorways and *Corner della Salute* in supermarkets.

Most medicines reach ambulatory patients by the usual prewholesaler-wholesaler-pharmacy route, but as a cost containment measure under Law 405/2001, regions have started to purchase some medicines directly from manufacturers and to dispense these to patients discharged from hospital or attending out-patient clinics through local health authorities and hospital pharmacies. In practice, such products follow a twin distribution route as some wholesalers and community pharmacies have agreed to handle

regional purchases at much lower margins than normal in order to limit their volume losses.

Date-expired, damaged or recalled stock is cleared from wholesalers and pharmacies shelves every six months by an independent company, AssInde, for incineration. As part of an inter-sector agreement, AssInde refunds the distribution chain in full or in part on behalf of pharmaceutical manufacturers. The arms-length nature of the refunding system helps avoids disputes that might jeopardise business relationships.

Hospital distribution is almost exclusively direct from manufacturer via depositaries. Wholesalers are not involved.

3.16 Latvia

Under former Communist rule all distribution was centralised through Farmacija. Established in the country since 1993, Tamro SIA (www.tamro.lv; Phoenix) now dominates with a 29% wholesale market share. Other major players are Farmserviss, Recipe Plus (www.recipe.lv), Magnum Medical (formerly Pharma-Services Riga), Oriola (Orion-KD) and Briz.

The current situation is that non-pharmacists can own pharmacies and no establishment criteria apply. With almost 140 outlets, the Senior Farm chain is one of the largest in the Baltic States and claims a 20% retail market share. Tamro (Phoenix) owns the Gimenes Aptieka pharmacy chain (www.gimenesaptieka.lv) and Europatheca (formerly Europtieka), part of the Lithuanian Maxima group, also has a chain. There are four other multiples with around 20 pharmacies each. Combining Gimenes Aptieka with other pharmacies with which Tamro has a co-operation agreement gives it around a 20% retail market share.

A 2003 law (due to come into effect in 2010) will limit future pharmacy ownership to either pharmacists or local governments only, as well as setting criteria for new openings. Existing chains are likely to be unaffected.

3.17 Lithuania

The four leading wholesalers among more than 70 companies holding wholesaling authorisations are UAB Tamro (www.tamro.lt; Phoenix), Limedika, Armilia and Medikona. The top two each have about 20% market share. Tamro owes its presence to the acquisition of the former state-owned monopoly distributor, Lietuvas Farmacija.

As of March 2005 there were 1,488 community pharmacies in Lithuania, representing one per 2,302 inhabitants. Geographic and demographic criteria for new pharmacy establishment have been abandoned, and now the municipalities grant pharmacy licences according to flexible criteria set by the State Medicines Agency. Pharmacies may be owned by companies, as long as pharmacists represent three-quarters of all board members. As a result, pharmacy chains exist. Some are vertically integrated with wholesaler operations, such as Tamro's Seimos Vaistine chain (83 outlets; www.tamro.lt/sv), formed from the acquisition of two existing groups, Farmacijos Projekta and Vogne. Others are pure retailing operations (e.g. Euroapotheca, a 210-outlet chain, formerly known as Eurovaistine, which alone has one-third of the market).

Leading Polish wholesaler PGF has announced two acquisitions in Lithuania, wholesaler Limedika and pharmacy chain Gintarine Vaistine (112 outlets). Only 20% or so of the country's pharmacies remain as independents and most of these are located outside urban areas. Rural areas also have a few self-dispensing doctors.

3.18 Luxembourg

The Grand Duchy has 87 community pharmacies and four pharmaceutical wholesalers: Comptoir Pharmaceutique Luxembourgeois, Hanff Frêres, Mathis Prost and Prophac. Any pharmacist wishing to establish a new pharmacy must obtain a concession from the state, and the ratio of one pharmacy per 5,000 inhabitants must not be exceeded.

3.19 Malta

Though there is local production of generics, multinational pharmaceutical companies are all represented in Malta through about 90 agents, which act as importers and distributors.

There are two types of pharmacies: those in the private system (totalling 210) and National Health Service pharmacies (totalling 52, in hospitals and out-patient clinics). The Ministry of Health is responsible for awarding pharmacy concessions, but prior consultation with the Malta Chamber of Pharmacists is required.

There are only two private chains (of seven and four outlets each), with the majority of pharmacies run by pharmacist proprietors, though in principle non-pharmacist ownership is allowed.

3.20 Netherlands

There are four nationwide full-line wholesalers supplying pharmacies OPG (www.opggroep.nl; market share 26%), Alliance Healthcare (formerly known as Interpharm; Alliance Boots; 23%), Brocacef (www.brocacef.nl; Phoenix; 18%) and Mosadex (www.mosadex.nl; 13%).

Mosadex is owned by pharmacists and only supplies community pharmacies; the others are private companies and supply both pharmacies and hospitals. The balance is made up of smaller pharmacist-owned self-distributing groups (13%), including Regifarm and Plurifarm, and direct distribution (7%). Much of the last-named is for specialist homecare products. Very approximately, 80% of wholesale turnover goes to community pharmacies, 10% to dispensing doctors and 10% to hospital pharmacies.

OPG, a former co-operative, supplies all sectors of the market through separate divisions: OPG Groothandel for community pharmacies, OPG Medico for dispensing doctors, and OPG Distrimed for hospitals. The group also includes Red Swan, which has two parts, Pharma Logistics for prewholesaling and Pharma Services for homecare, and the leading Dutch parallel importer, Polyfarma. Mosadex has recently acquired another parallel importer, Dr Fisher Farma.

As well as wholesaling, Brocacef has three generics businesses, Aeramphic, Genfarma and Magnafarma, the last-named having dropped parallel imports to focus on generics. Alliance Healthcare's interests include Dutch parallel

importer Stephar (now unrelated to the UK importer of the same name) and a pharmacy software development company, Pharmapartners.

There are no regulatory obligations on holding stock or delivery time imposed on wholesalers or pharmacies in the Netherlands. Wholesalers deliver once daily to pharmacies and hospitals. Orders placed by 6pm are delivered into special lockers in the pharmacy overnight. Almost all pharmacy requirements are purchased from wholesalers.

The Dutch medicines supply chain to ambulatory patients is one of the most liberal in Europe. As well as 1,810 community pharmacies for 92% of the population, there are 480 self-dispensing doctors serving the remaining 8%, almost 4,000 drugstores/drugstore departments within supermarkets, 15 *politheken* or polyclinic pharmacies (sited in hospitals to provide a pharmacy service to non-patients), several homecare companies delivering to patients' homes, mail order/internet pharmacies, and 760 other OTC outlets.

The sale of OTC products by non-pharmacies has been allowed for more than a century and today drugstore chains like Kruidvat, Etos and DA account for 80% of this business, though this share is likely to fall as in 2007 the government decided to reinstate a 'pharmacy-only' (*uitsluitend apotheek*) category of non-prescription medicines . Other outlets can also obtain a licence to sell a limited range of OTCs if the distance to the nearest pharmacy, dispensing doctor or drugstore is at least three kilometres.

Until 1998, specific demands on pharmacies were set by the government which generally led them to be owned by pharmacists. With reform, chain pharmacies began appearing from 1999. Establishment rules for new premises, non-statutory but enforced by pharmacy's own professional body in the Netherlands, *Koninklijke Nederlandse Maatschappij ter Bevordering der Pharmacie* (KNMP), were also abolished that year.

Officially there are 470 (25%) of pharmacies in chains, but this seems an underestimate (table 3.5). Ownership structure varies. Some, like Mediveen (now being branded as Mediq Health Centres) and Lloyds, are 100% owned by wholesalers, while in others non-pharmacists have minority shares. Even drugstore groups Etos and DA and a health insurance fund created their own pharmacy chains, although the drugstore pharmacies have since been disposed of. There are also two pharmacy-owned co-operative chains (Prickartz and Thio Pharm).

Table 3.5: Leading multiple pharmacies in the Netherlands

Pharmacy chain	Owner	Owner type	Number of outlets
MediveenMediq	OPG	wholesaler	223
Farmassure/Escura	Brocacef (Phoenix)	wholesaler	90
De Vier Vijzels	Alliance Boots	wholesaler	75
Lloyds Apotheken	Celesio	wholesaler	56
Apotheken in Overdracht	Regifarm	wholesaler	37
VNA	VNA	foundation	80
DSW	DSW	health insurance fund	5
Prickartz	pharmacists	co-operative	21
Thio Pharm	pharmacists	co-operative	16
Total			603

Source: updated from Vogler et al[6]

There are also several large wholesaler-affiliated symbol groups including the following:

- Kring Apotheken (www.kring-apotheek.nl; 302 pharmacies; Alliance Boots is 51% owner of Kring).
- Mediveen/Mediq (220 pharmacies linked to OPG).
- Service Apotheek (185 pharmacies linked to Mosadex).
- Escura (115 pharmacies linked to Brocacef/Phoenix).
- Medsen (68 pharmacies linked to Regifarm).
- Lloyds (60 pharmacies linked to Celesio).

Mediveen, Farmassure, De Vier Vijzels and Lloyds Apotheken formed the Association of Chain Pharmacies (*de Associatie van Ketenapotheken*) in early 2005, and later the same year two more groups joined, boosting pharmacy membership to 440. Determined to prove the independent pharmacy wasn't a dying breed, 230 independents set up the Dutch Pharmacy Co-operation (*de Nederlandse Apotheek Cooperatie*).

Drugstore chains Etos and DA are experimenting with prescription drop-off/collection schemes, where dispensing is done at a remote pharmacy. In the case of Etos it is using special counters at Albert Heijn supermarkets for this purpose.

A growing number of community pharmacies offer a weekend and late night service. Among the newly-opened pharmacies in 2005, two were 'out-of-hours pharmacies'. In total there are now 28 'out-of-hours' pharmacies.

Pharmaceutical care is highly advanced. With several pharmacists per pharmacy and 95% of patients always visiting the same pharmacy, pharmacy-based medication surveillance schemes developed as far back as the 1980s. Ninety-five percent of pharmacists and GPs meet six to eight times every year in one of 800 local pharmacotherapeutic forum groups.

The Netherlands hosted Europe's first mail-order pharmacy in the early 1990s, sponsored by health insurers Geové and Zilveren Kruis, followed by Merck-Medco's Eurocare Mailorder. Both ventures soon folded, but what is now the continent's largest internet pharmacy, DocMorris, was founded in the Netherlands in 2000 (though Germans have always made up the majority of its customer base).

Doctors dispense for about 8% of the population. This is allowed if the distance to the nearest pharmacy is more than 4.5 kilometres. Numbers of self dispensing doctors have fallen by 11% over the past decade, whilst pharmacy numbers have grown by 14%.

Since 2000, 30-50 new pharmacies have opened each year and there have only been 6-10 annual closures. 2000 was an exceptional year for closures, as all 12 Boots pharmacies, which only opened in 1999, quit the Dutch market. It was reported that the Boots concept of drugstore-pharmacies was not well accepted by consumers and the company also experienced difficulty in hiring qualified staff.

Pharmacy manpower differs from elsewhere in Europe in that pharmacies are large and there are many pharmacy technicians. Qualified assistants

perform many of the tasks (e.g. dispensing, counselling patients) that in other countries are the principal responsibility of pharmacists.

3.21 Norway

By law, medicines have to be sold to pharmacies through a wholesaler. Wholesalers are required to deliver any marketed product to any pharmacy within 24 hours. Pharmacies are obliged to always keep a stock of all commonly prescribed and demanded medicines.

For 400 years, all Norwegian community pharmacies were pharmacist-owned independents. There was also one state-owned pharmaceutical wholesaler, Norsk Medisinaldepot (NMD; www.nmd.no). A decision was taken to abolish NMD's monopoly after Norway joined the EEA, and two other wholesalers entered the market: Holtung, which is 51% owned by Sweden's Kronans Droghandel (itself owned by a group of pharmaceutical manufacturers) and 49% by a number of Norwegian pharmacy owners, and ADA, part of the Finnish/Swedish Tamro group.

NMD, which originally retained three quarters of the wholesaling market, was also slated for privatisation. By then, a majority of pharmacies had decided to collaborate in purchasing from competing wholesalers and created Apokjeden ('the pharmacy chain') and, in 2001, Apokjeden completed a cross-shareholding deal with Tamro, one of NMD's two competitors. Under this arrangement, Tamro would have exclusive rights to deliver to Apokjeden pharmacies. The competition authority stepped in and requested Apokjeden to reduce the number of its affiliated pharmacies. It also decided that no single group could control more than 40% of Norwegian pharmacies

The structure of the pharmacy and wholesale system then changed substantially after the new Pharmacy Act came into force in March 2001, liberalising pharmacy openings. The stated goals were to increase accessibility and service, make pharmacy more efficient and bring prices of medicines down. It was part of a larger political trend towards deregulation in the country, following liberalisation in energy supply and telecommunications.

Under the Act there would be no limits on the number or location of pharmacies, and no real limitations concerning ownership (except that pharmaceutical manufacturers and prescribers were excluded from ownership). The only cap on corporate ownership was that no pharmacy chain would be allowed to own more than 40% of all pharmacies in the country. All pharmacies must be run by a pharmacist.

Together with the deregulation of the establishment of pharmacies, the liberalisation of ownership led to large increase in pharmacy openings: 128 (+32%) in the three years to March 2004. In addition, many pharmacy owners decided to cash in and sell their business to one of the wholesalers, each of which had already been acquired by Europe's 'big three'.

From being a market with one dominant wholesaler and entirely independent pharmacies (both types of businesses exclusively in Norwegian hands), distribution in Norway today is now effectively run by three foreign-capitalised players that own both wholesalers and pharmacies, In theory the wholesale system is multichannel, but in practice pharmacies get nearly all their supplies from the wholesaler that owns them.

By the end of 2006, 92% of all 559 pharmacies, including hospital pharmacies, in Norway were wholly owned by one of three vertically-integrated pharmacy chains, Vitusapotek (part of Celesio), Apotek 1 (Phoenix) and Alliance Apotekens (Alliance UniChem) (table 3.6).

***Table 3.6: Norwegian pharmacy chains wholly owned by* wholesalers, 2006**

Pharmacy chain	Wholesaler (wholesaling market share)	Owner	Share of pharmacies (%)	Pharmacy market share (%) by value
Apotek 1	Apokjeden Distribusjon AS www.apotek1.no (35%)	Tamro (Phoenix)	38	35
Vitusapotek	NMD Grossisthandel www.nmd.no (45%)	Celesio	31	25
Alliance Apotekens	Holtung AS www.holtung.no (20%)	Alliance UniChem	23	18
		Total	92%	78%

Source: adapted from Norges Apotekerforening/Farmastat

Of the remaining pharmacies, some had part-ownership contracts with chains and were also loosely connected with the independent chain 'Ditt Apotek', while others had an agreement with a chain, mostly Apokjeden, but were not owned by it. This left just 15 pharmacies (2.7% of all pharmacies) that were totally independent. Alliance UniChem also took over Farmaka, a central dispensing unit for monitored dosage systems.

Ökokrim, the Norwegian counter-fraud authority, is currently investigating the three wholesalers in relation to illegal price fixing allegations that reportedly have cost the state the equivalent of €12.3 million in inflated invoices for medicines.

While medicines are mainly distributed by community pharmacies, there are four alternatives:

- Pharmacies can open branch pharmacies (*filial apotek*) if a pharmacy is considered necessary in a region but no pharmacist can be found to open it. Branch pharmacies are run by prescriptionists (*reseptar),* but the pharmacist manager in the main pharmacy to which the branch pharmacy belongs has the legal responsibility for it.
- Hospital pharmacies, which are allowed to dispense for out patients.
- The Norwegian Medicines Agency might decide to establish a pharmacy outlet in an area not served by a pharmacy. It can sell and supply non prescription medicines. It has no independent right to dispense prescriptions, but is affiliated to a pharmacy that exercises this right. Most pharmacy outlets are located in grocery stores. In 2005 there were approximately 1,249 pharmacy outlets, affiliated to about half the pharmacies in the country. Self-selection is not allowed.

- LUA ('medicines outside pharmacies') outlets are allowed to sell about 50 kinds of OTC medicines defined by the Medicines Agency. In 2005, there were about 5,700 LUA outlets.

On 1 March 2006 there were 559 dispensing points in Norway, whereas in February 2001 there had been 399, a 40% increase. 65 new pharmacies were opened in 2001 alone. In 2004, 16 new pharmacies opened. In comparison, between 1990 and 2000 the number of pharmacies increased by 72.

Reform has also led to longer pharmacy opening hours but Norwegian pharmacies are not competing by offering lower co-payments to patients. Some restrictions still remain. For example, non-pharmaceutical products cannot contribute more than 15% of the total sales of any community pharmacy, and no own-label OTCs are allowed.

Liberalisation led to a decline in the number of pharmacists per pharmacy, from an average of 2.2 in 2000 to an average of 1.8 in 2005. The total number of pharmacy staff has also fallen, from 15.5/pharmacy in 2000 to 11.5 in 2005. Some administrative tasks have been taken over by chain head offices and ordering is now more co-ordinated.

Between one and nine pharmacies per year closed since 2001. These were mostly pharmacies had had been opened after the new Act came into force. In rural, scarcely populated areas, no pharmacy has closed since the reform. One reason for this is that the Ministry of Health agreed with the pharmacy chains that if a pharmacy in a rural area (which was opened before 2001) was about to close, one of the pharmacy chains would take over this pharmacy or establish a new one in the same area. This agreement has applied three times – three rural pharmacies were closed and reopened.

The number of inhabitants per pharmacy has fallen sharply from 11,370 in 2001 to 8,533 in 2005. Nevertheless, Norway still has a relatively low pharmacy coverage compared with most European countries. As of 1 January 2005, 199 of the 434 municipalities in Norway did not have a pharmacy, which is just nine fewer than before the reform.

Norway has a centralised body, LIS, that negotiates agreements on the purchasing and delivery of medicines to public hospitals. All 31 hospital pharmacies and about 40 community pharmacies deliver medicines to hospitals, with NMD currently holding the contract to act as sole distributor to hospital pharmacies.

3.22 Poland

While there are still almost 200 wholesalers, concentration is ongoing and most are now private firms. The leading five wholesalers – Polska Grupa Farmaceutyczna (PGF; www.pgf.com.pl) , Farmacol (www.farmacol.com.pl) , ACP Pharma (www.acppharma.pl; formerly known as Orfe, owned by the Dutch OPG group), Prosper (www.prosper.pl) and Torfarm (www.torfarm.com.pl) – had a combined 60% market share in 2006. The fact that the top five's share has remained largely unchanged since 2000 suggests that the concentration process has peaked. In 1995, the leading five wholesalers shared just 18% of the market.

Torfarm expects to move into second position, with an 18% market share in 2007, following actual and planned acquisitions of Galenika Silfarm and Optima Radix respectively. Prospects for lower-ranked players are considered poor, suffering chronic problems with late payment from pharmacies and hospitals. Cefarm Bialystok, one of the last state-owned wholesalers, has created an online pharmacy offshoot www.cefarm24.pl.

There were 13,000 community pharmacies in Poland at the beginning of 2006, including about 200 still in state ownership. By the end of the same year, the total had grown to a estimated 15,000. As in several other countries, urban areas in particular became over-supplied with outlets. The combined effects of competition from other pharmacies, loss of OTC sales to non-pharmacy retailers, falling prices and delayed reimbursement is reportedly forcing up to one third towards bankruptcy. The average number of pharmacists per pharmacy is now just 1.2, whereas ten years previously it had been five or six.

In accordance with an October 2002 amendment to the Pharmaceutical Law, pharmacies do not have to be owned by pharmacists. There are no controls on pharmacy numbers based on demographic or geographic criteria at present either. However, a May 2004 amendment to the same Law limited a single owner to 1% of the pharmacies in each of the country's 16 regions (prior to 2004 the limit was 10%). As sister companies have been created with the single aim of getting around this 1% limitation, some tightening up of the legislation is expected. However, as the amended law is not retrospective, existing chains, like the largest, PGF's Aptek Polskie, will not have to divest pharmacies.

Suggesting perhaps that its policy of deregulation has not been a success, and in an attempt to bring some stability to the pharmacy sector, the government is planning to reintroduce establishment criteria (one pharmacy per 4,000 inhabitants, minimum distance apart in urban areas 500 metres, minimum pharmacy size 120 square metres).

In an interesting development, PGF plans to open its own Apteki pharmacies in the UK via an affiliate DOZ, and if successful will expand into Ireland also. PGF is likely to be looking to capture the expatriate market. Since Poland joined the EU in 2004 there has been a large influx of Poles into both Ireland and the UK. Pharmacists will be Polish-speaking, PGF says.

3.23 Portugal

Of more than 300 holders of wholesale authorisations, three companies dominate - Alliance Healthcare (www.alliance-healthcare.pt; Alliance Boots; 23% national market share), OCP (Celesio; 17%) and Codifar (11%) – though there are marked regional variations and only Alliance UniChem and OCP operate nationwide (table 3.7). In 2005, Alliance UniChem sold 49% of its Portuguese business to the pharmacists' body, Associação Nacional das Farmácias, and 2% to an independent investment company.

***Table 3.7: Market share (%) of leading wholesalers in Portugal by* region, 2006**

Region	Alliance UniChem	OCP	Codifar	Cooprofer	CFN
Aveiro	34.0	12.9	0.0	22.8	21.4
Baja	28.9	14.9	36.6	0.0	0.0
Braga	13.1	21.5	0,0	14.5	18.9
Bragança	22.7	38.5	0.0	23.6	11.0
Castello Branco	21.8	9.7	2.3	0.0	0.0
Coimbra	11.8	6.3	0.1	6.6	0.8
Evora	24.4	4.6	26.8	0.0	0.0
Faro	46.9	5.9	32.0	0.0	0.0
Guarda	24.6	29.8	0.0	1.1	2.1
Leiria	10.2	16.6	14.8	0.0	0.0
Lisboa	25.6	14.1	23.7	0.0	0.0
Portalegre	39.9	6.4	28.3	0.0	0.0
Porto	27.4	21.2	0.0	24.6	24.6
Santarém	15.1	43.0	7.0	0.0	0.0
Setúbal	26.9	18.8	22.6	0.0	0.0
Viana do Castelo	15.7	22.1	0.0	26.2	19.4
Vila Real	26.0	31.6	0.0	19.1	21.6
Viseu	28.4	30.1	0.0	8.5	8.7
total Portugal	23.1	17,2	10.9	8.0	7.7

Source: Mercafar Distribução Farmacéutico SA, personal communication

Wholesalers must have 'permanent availability of drugs which may be deemed sufficient in quantity and variety to promptly address the needs of a certain geographic area' (Article 12 of Decree Law 135/95).

Following intervention by the national competition authority in 2006, the previous establishment and ownership criteria for opening new pharmacies have been greatly modified.

Now anyone, except doctors, wholesalers and manufacturers, can own pharmacies, with the proviso that each proprietor cannot have an interest – directly or indirectly – in more than four pharmacies. There has to be a minimum distance of 350 metres between premises (previously 500 metres), with each outlet serving a population of not less than 3,500 (previously 4,000), though demographic criteria will not apply in rural areas where there is no existing pharmacy within a 2 kilometre radius. Opening hours were also extended.

The changes are expected to result in up to 300 new pharmacy openings. Pharmacies can run branches, known as *postos farmacêuticos moveis,* to ensure adequate pharmaceutical provision in rural areas.

Since new legislation in 2005, OTCs can also be sold from non–pharmacy sales outlets under the supervision of a pharmacist or pharmacy technician (he or she is allowed to supervise up to five sales outlets within an area of 50 kilometres). Two reports published a year after the change provide differing views on the impact on prices. The Portuguese Observatory of Healthcare claims that OTC prices have risen overall, and they are higher in non-pharmacy outlets than in pharmacies. By contrast, the medicines regulator Infarmed contends that prices have fallen by 5%, and for 60% of OTCs sold outside pharmacies, prices were lower than when pharmacies had a monopoly.

3.24 Romania

The leading wholesalers, from a total of almost 400 mostly family-owned players, are Heliofarm, Oifarm, Farmexpert (60% owned by Germany's Anzag), A&D Pharma-Mediplus Exim (www.adpharma.ro) and Pharmafarm (www.pharmafarm.ro; acquired from Celesio by Hungary's Gedeon Richter in 2007).

Pharmacies were among the first healthcare facilities to be privatised in the post-Communism era and today, along with wholesalers, are entirely in private hands. While most pharmacies, totalling more than 6,600, are owned by a single pharmacist, there are also pharmacy chains, including 90-outlet Help Net (owned by local wholesaler Farexim), Europharm (owned by ADM Pharma), Pharma Net (Pharmafarm), and Omnia and Remedio (both part of Montero) as ownership criteria are not clearly defined by law. There has been some debate about scaling down the size of chains to a maximum of four outlets each.

In the national capital, Bucharest, there cannot be more than one pharmacy per 3,000 inhabitants, in county capitals the limit is one per 3,500 inhabitants, and in other towns it is one per 4,000 inhabitants.

OTCs can also be sold by drugstores, of which there are around 1,000.

3.25 Slovakia

Eleven wholesalers control 95% of the market, with Fides (www.phoenix.zz.sk; Phoenix), Unipharma (www.unipharma.sk) and Med-Art (www.med-art.sk) alone having more than 50%.

In 2006, there were 1,098 community pharmacies and 88 hospital pharmacies. Medicines of any kind can only be supplied to the public through pharmacies. Companies as well as pharmacists may own pharmacies, but so far few chains exist.

Each wholesaler is obliged by law to report all sales to pharmacies to the State Institute for Drug Control on a floppy disk. The data obtained are processed by the Institute for statistical purposes, to monitor prescribing trends and market development, as well as for checking product movement and adherence to legal provisions. As part of their reimbursement claim, pharmacies are also obliged to provide a floppy disk each month containing the following information on each dispensed item:

- pharmacy code;
- drug code;
- number of packs issued;
- amount to be charged to insurance company;
- patient co-payment;
- date of supply;
- code of prescribing doctor;
- code of recommending doctor; and

- diagnosis the drug was prescribed for.

3.26 Slovenia

The two leading wholesalers, out of a total of 11, have a combined 75% market share: Kemofarmacija (www.kemfarm.si; Celesio) and Salus (www.salus.si).

There are 82 private, pharmacist-owned pharmacies and others owned by local authorities. In order to obtain approval to open a new pharmacy two restrictions have to be respected: the minimum distance between pharmacies should be 400 metres and the minimum population served by one pharmacy should be 5,000. Self-dispensing doctors are allowed and some OTCs may be sold in 'specialised stores' as well as pharmacies.

Hospitals must purchase medicines from wholesalers.

3.27 Spain

Wholesaling is largely organised on a regional level through 35 pharmacist-owned co-operatives that control almost 75% of the market.

Cooperativa Farmacéutica Española, better known as Cofares (www.cofares.es), whose capital is held by 8,600 Spanish pharmacists, had an 18.7% national market share in 2005; the top five wholesalers from a total of about 100 companies (50 headquarters) together had a 55% market share (table 3.8). Cofares strengthened its leading position at the end of 2006 with a merger with Hermandad Farmacéutica del Mediterráneo (Hefame).

Table 3.8: Wholesaling groups in Spain

Head office	Affiliated company
Grupo Cofares	Cofares Alcofarsa Cefargal Cefatesa Cefex SA Cofalsa Cofaresa Difarcasa Difcalsa Difnarsa Disfasur Farmics SA Hefame Unicefar SA
Grupo SAFA	SAFA Galénica Farmacen Medicamenta Alfanor AlfaMadrid Drogfesa Farmalianza Mayfar Molina Serrano Safándalus Seresa
Federació Farmacéutica	
Cecofar	
Centro Fco.SA	
Coop. Fca. Canaria	
Coop.Fca. del Noroeste	
Coop.Fca.Asturiana	
Coop. Fca. Andaluza	
Grupo D'Apotecaris	Coop.D'Apotecaris Bamesa
Hefagra	
Coop.Fca.Tenerife	
Coop.Fca.Gallega	
Hdad.Fca.Aragonesa	
Centro Europeo dfe Reparto	
Coop.Fca.Xerezana	
Grupo Sanal	Sanjurjo Alonso Farmanosa Farmacéutica Yebra
Euroserv	
Coop.Fca.Real	
Ddad.Fca.Almeriense	
Coop.Fca.Vascongada	
Coop.Fca. de Jaén	
Coop. Fca. Navarra	
Centro Fco.Nacional	
Centro Fc. Del Norte	
Coop.de Talvera	
Unión Fca. Guipuzcoana	
Coop. Fca. Gibraltar	
Coop.Fca. de León	
Coop.Fca. de Zamora y Valladolid	
Coop. Fca. Extremeña	
Centro Fco. Asturiano	

Head office	Affiliated company
Sum. Fco. Egara	
Comer. Fca. Madrileña	
Coop. Fca. Guipuzcoana	
Coop. Fca. Salamantina	
Coop. Fca. Riojana	
Asoc. Fca. Malagueña	
Coop. Fca. Leridana	
Coop. Fca. Ávila	
Trust Fco.	
Coop. Fca. Menorquina	
Coop.Fca. Melilla	
Central Fca. Burgalesa	
Desfa	

Source: Fedifar

The newly formed company, Cofares Hefame, is expected to achieve sales of €3.3 billion, giving it a 28% market share. It has 42 warehouses serving 12,500 pharmacies in all regions including the Canary Islands, making it the only wholesaler with true nationwide coverage.

Just one wholesaler is in foreign hands, second-ranked Sociedad Anonima Farmacéutica Aragonesa (SAFA; 14% market share). Part of Alliance UniChem since 1998, its original focus was on northern and central Spain, but in 2006 it expanded the geographical scope of its operations through the acquisition of the largest independent wholesaler not under co-operative ownership, Farmacen. SAFA has now been renamed Alliance Healthcare (www.alliance-healthcare.es) Other leading wholesalers are Federació (6.9% market share, the top co-operative in Catalonia) and Cecofar (6.8%).

A number of the wholesaler co-operatives have joined together to form purchasing groups (table 3.9) to obtain improved terms and conditions from manufacturers, but they also collect products for parallel export and share logistics. Ofsa also operates as a prewholesaler.

Table 3.9: Wholesaling purchasing groups in Spain

Group	No. of co-operatives	Market share (%), 2005	Leader
Unycop	10	26.4	Hefame
Satel/Ofsa	7	26.4	Cofares
Edifa	14	8.8	Aragofar
Novafar	3	4.2	Hefagra

Source: SAFA

Wholesalers have an obligation to hold sufficient quantity and variety of stock to ensure usual and emergency supplies (Royal Decree 2259/1994), and pharmacies are also obliged to hold a stock minimum.

Pharmacies have a legal monopoly on the sale of all medicines. For the country's population the number of premises (20,741 or one per 2,120 inhabitants on average) is high by European standards, but there a large

regional differences, from 1 pharmacy per 1,085 people in Navarra to 1 per 3,273 in Ceuta. Andalusia plays host to 17% of the country's pharmacies, Catalonia to 14%, and 13% are in Madrid. The average pharmacy size is only 100 square metres, the average turnover €740,000 (75% from National Health Service dispensing and just 5% from OTC sales), and a typical staff complement would consist of a single female pharmacist and three assistants.

Around 25 buying groups exist, each of less than 50 pharmacies, but there are no chains. Pharmacists or partnerships of pharmacists must own at least 75% of each pharmacy. New openings are controlled by demographic (from 600 to 4,000 inhabitants per pharmacy) and geographic (250 metres from another pharmacy) criteria which vary somewhat between the different autonomous communities.

Annual growth in pharmacy numbers has averaged 0.9% in recent years. Entry regulations were considered unnecessarily strict by the European Commission which, in mid-2006, sent the Spanish government a 'reasoned opinion' (the second stage of infringement proceedings). Spain responded, supporting the current pharmacy model, and the final opinion from the Commission is awaited.

Spain is the main source country for parallel trade and the high level of exporting has sometimes created supply shortages locally. To help address the problem and to complement the public service obligation, Royal Decree 725/2003 was introduced. This requires manufacturers, wholesalers and pharmacies to track product movement:

- Manufacturers have to provide the Ministry of Health with information on the number of units sold to wholesalers.
- Wholesalers have to report to both the Ministry and the health authority in their autonomous community the number of units supplied to either pharmacies or other wholesalers in Spain.
- When requested by manufacturers, the Ministry will compare the number of units bought by wholesalers with the number of units supplied to pharmacies and other wholesalers within Spain, and inform manufacturers of the transaction dates, quantities, batch numbers and final destination of their stock.
- Wholesalers are obliged to retain invoices and documentation relating to all medicines entering and leaving their warehouses.

Royal Decree 725/2003 is due to be replaced by another, detailing an improved traceability scheme involving manufacturers, wholesalers and pharmacists, and electronic codes on packs.

Wholesalers are not involved in supplying hospitals in Spain. This is done by manufacturers direct via regional hospital stores.

3.28 Sweden

Wholesaling is managed on a single channel basis, with just two companies – Tamro (www.tamro.se) and Kronans Droghandel (www.kd.se; KD). Tamro is owned by Phoenix and KD is part of Oriola-KD (www.oriola-kd.com), itself owned by a group of manufacturers. Each wholesaler has year-long exclusive distribution contracts with manufacturers for the entire country for

different products. Prior to 1995, the contracts covered each manufacturer's full product range, but following the 1991 Competition Act and review of the single channel system by the competition authority, the contracts have been on a product-by-product basis - although splitting a company portfolio between the two wholesalers remains rare.

Swedish wholesalers describe themselves as service providers, a hybrid between traditional wholesalers and LSPs. Unlike LSPs they take ownership of the stock and also invoice pharmacies. They also bear responsibility for loss or damage of goods on their premises and for bad debt (although with a single state-owned customer for now debt is not an issue), but they do not set their selling prices, this being the responsibility of the Pharmaceutical Benefits Board. Wholesalers supply community pharmacies, hospital pharmacies, healthcare centres and veterinarians, all on a daily basis.

Tamro's market share is currently 54%, with KD on 42%; direct delivery – primarily with large volume intravenous infusions – makes up the balance with 4%. Despite the limited competition, market shares have shifted noticeably over time. M&A activity among manufacturers is one factor. If two companies using different logistics partners merge, one distributor will miss out post-merger. Fifteen years ago, Tamro had a 70% market share. This fell to 48% by 2004, but – the recent loss of Pfizer business notwithstanding – it has slowly re-established its leading position.

Since 1970 Apoteket AB, a company under state control, has been given exclusive rights to supply all types of medicines to the public. It operates a chain of 875 community pharmacies, 76 hospital pharmacies, and 30 Apoteket shops for OTC and other healthcare purchases. Community pharmacy numbers have fluctuated between 810 and 850 in recent years, although there has been a recent surge.

Pharmacies are often located within shopping centres or close to primary healthcare centres or hospitals. In rural areas, Apoteket has arrangements with owners of 875 grocery and convenience stores to act as Apoteket representatives. As well as obtaining small packs of about 20 common OTC preparations from a cupboard owned by Apoteket, patients can drop off their prescription and collect the medicine later after it has been dispensed at an Apoteket branch.

The company has 11,000 employees. In 2006, its sales amounted to SEK 37 billion, of which 70% represented prescription medicines. An estimated 90 million customer visits were made to Apoteket branches and 64 million prescriptions dispensed. Customers can book appointments to see 'pharmaceutical specialists' at 600 stores, there are 'health coaches' at 130 outlets, and 200 shops offer patient medication profiles. Apoteket has four production facilities for products that are commercially unavailable in Sweden. Apoliva is an own-label range of health products.

ApoDos multipacked drugs are supplied as a compliance aid to 164,000 patients (primarily the elderly in nursing homes). Since 2006, Apoteket has offered a mail delivery service to patients' homes for orders placed by phone or on its website (www.apoteket.se). Sweden has reportedly the highest share (62%) of electronic prescriptions in the world. Apoteket runs the Poisons Information Service on behalf of the state and includes the Swedish Institute of Health Economics as a non profit-making subsidiary.

Like any monopoly, Apoteket has had its critics, though surveys conducted by the company itself show a growing level of customer satisfaction. It has opened more stores and customer service points in response to complaints about long waiting times and poor, even rude, service. Opening hours have been lengthened too. Outlets were generally open from 10am to 6pm during the week; a few opened on Saturday, but only until 2pm, and all pharmacies were closed on Sundays (an estimated 10% even closed throughout the summer holiday season).

Apoteket's monopoly has been discussed for the past decade but it first came under serious threat when in 2005 the ECJ in case C-538/02 held that 'the Swedish state monopoly on retail sales of medicinal preparations is contrary to European law'. The following year a new centre-right government gained power and reform was set in motion. As the first result, nicotine-based smoking cessation aids will shortly be available from non-pharmacy outlets subject to their holding a permit from the Medical Products Agency. Of greater significance, deregulation of the pharmacy sector (or 're-regulation' as Apoteket describes it) has been promised as early as 2009. The objectives are to guarantee a safe and secure supply of medicines, increase accessibility and improve the level of service, and to increase price pressure.

Lars Reje, a 'special investigator', was appointed to propose how competition to Apoteket (which is expected to remain in state ownership) could be brought about with both prescription and non-prescription medicines. His report is due by the end of 2007. As a second step, Mr Reje is due to propose by April 2008 a limited range of OTCs to be available from non-pharmacy outlets.

Liberalisation of the retail environment might be accompanied by a change from single channel wholesale distribution to multichannel, as the former was effectively maintained through Apoteket's monopoly. However, if wholesalers are disallowed from pharmacy ownership (as is the case in Finland), then single channel may continue.

While new players are expected to enter and Apoteket may have to divest some outlets, current players – the two existing wholesalers and Apoteket - are reportedly keen to compete vigorously in all sectors, i.e. prewholesaling, wholesaling and retailing. Kronans Droghandel and Tamro fear that if Apoteket entered the domestic wholesaling market aggressively it would soon dominate. The pharmacy chain makes the equivalent of €50 million profit per year, pays almost no dividends and can borrow at less than commercial rates because it is a government-backed organisation, they point out. Apoteket's strategy documents also reveal proposals to buy pharmacies in other major EU countries and to develop a European supply chain. Under its former name, Apoteksbolaget (National Corporation of Swedish Pharmacies), Apoteket had previously owned the Swedish wholesaler Apotekarnes Droghandelsaktiebolag (ADA), which achieved a market share in excess of 60%. ADA was sold by Apoteksbolaget to Tamro in 1995.

3.29 Switzerland

Switzerland manages with just three wholesalers – Galexis (www.galexis.ch; 59% market share); Amedis (www.amedis.ch; 31%) and Voigt (www.voigt.ch; 10%) – supplying a variety of clients: 3,928 dispensing doctors, 1,679 pharmacies, 693 drugstores and 570 hospitals. Galexis (part

of the Galenica in which Alliance Boots has a near 20% stake) and Amedis (Phoenix) cover the whole country, while Voigt focuses on the German-speaking cantons. A fourth player, Unione Farmaceutica Distribuzione (which had the market leading position in the Italian-speaking canton of Ticino), was majority acquired by Galenica in 2006.

Galenica is a highly diversified group including – unusually for a wholesaler – a significant research-based manufacturing division (Vifor), focussing on products for anaemia that are marketed in over 70 countries. Provision of databases, including the Swiss drug Compendium, and medical practice software are other business areas.

Galenica has had a strategic partnership with Alliance UniChem since 1999. Galenicare (www.galenicare.com), the retailing division involving both wholesalers, runs the 100-strong Amavita pharmacy chain in Switzerland which is complemented by a further 21 Coop Vitality pharmacies through a joint venture with Coop Swizerland. As another part of the deal Galenica operates Alloga, its market-leading prewholesaling division, in Switzerland, while Alliance UniChem provides similar services in other European countries through Alloga-Europe. Most recently, Galenica added homecare to its portfolio of offerings, via the acquisition of Mediservice.

Of total manufacturer output in Switzerland, 59% goes to wholesalers, 26% is direct delivery (mainly to hospitals) and 15% goes to dispensing doctors. The total market by value in the first half of 2007 can be broken a down as pharmacy 53%, dispensing doctor 24%, hospital 19%, mail order 2% and drugstores 2%.

There are no regulations on pharmacy ownership or establishment and numbers of premises have doubled since 1970 to 1,699. One fifth are in chains, with Galenica alone having 115 pharmacies either as part of its Armavita group or franchised. The canton of Waadt plays host to 14.5% of all Swiss pharmacies, 13% are in Zurich, 11% in Bern and 11% in Ticino.

Accounting for 24% of all pharmaceutical sales (and one third of sales of prescription medicines), dispensing doctors are an important market segment. They are more commonly found in German-speaking cantons.

Helsana, an insurance company, supported the launch of the first mail-order pharmacy in the country in 1997, and today there are several.

3.30 UK

Distribution in the UK has evolved to fit the varied nature of the market. Over 1,600 wholesale authorisations have been issued by the regulatory body, and these are split between full-line wholesalers, short-line distributors and independent pharmacy traders (table 3.10). Self-distributing pharmacy chains, a feature for many decades, do not require wholesale authorisations as they are considered to be part of the pharmacy.

Table 3.10: UK retail distribution market shares (%), 2005

Full-line wholesalers	71
Short-line wholesalers	13
Self distributors	13
Direct to pharmacy	3

Source: BAPW

Of the 11 full-line wholesalers, three with a combined wholesale market share of about 87% have near national coverage – AAH Pharmaceuticals (www.aah.com; Celesio; 42%), UniChem (www.unichem.co.uk; Alliance Boots; 30%) and Phoenix Healthcare Distribution (www.myp-i-n.co.uk; Phoenix; 15%) – and eight operate regionally - Maltby & Sons, Mawdsleys (www.mawdsleys.co.uk) Munro Wholesale Medical Supplies (www.munrowholesale.com), Norchem, PIF Medical Supplies (www.pif-medical.co.uk), Sangers (Maidstone), Sangers (Northern Ireland) and Sants Pharmaceutical Distributors (part of United Co-op's healthcare division). All but one is a member of the British Association of Pharmaceutical Wholesalers (BAPW): UniChem resigned in 2007 following its single agency agreement with Pfizer.

Ninety two percent of wholesaler sales of prescription medicines in the retail market go to community pharmacies and 8% to dispensing doctors. By product type the breakdown by value is 73% domestic brands, 19% generics and 8% parallel imports from full-line wholesalers, but 46% parallel imports, 45% generics and only 10% domestic brands from short-line distributors.

Multiple pharmacy ownership is highly developed. Over the past decade the proportion of pharmacies in groups of five or more outlets has risen from a third to a half. Over 450 in-store supermarket pharmacies alone have opened since 1990. Those pharmacies that dispense a relatively high number of prescriptions are more likely to be part of multiple groups. Multiple pharmacies also tend to enjoy higher sales of OTCs.

The leading chains are shown in table 3.11.

Table 3.11: Leading pharmacy chains in UK, 2007

Company	Number of pharmacies
Lloyds Pharmacy (Celesio)	1625
Boots Community Pharmacies (formerly Alliance/Moss; Alliance Boots)	1500
Boots Health and Beauty	800
Co-operative Group Pharmacy	429
Rowland (Phoenix)	384
Superdrug (AS Watson)	226
Tesco	197
Sainsbury	143
Co-op Healthcare	139
Day Lewis	100
Morrison	95
PCT Healthcare	90
Asda (Wal-Mart)	85
Paydens	75
William Chemists	50
H Weldricks	46

Source: James Dudley, personal communication

There are no restrictions on new pharmacy openings but to obtain a contract to dispense National Health Service prescriptions (which account for 80% of the average pharmacy's turnover) the owner has to apply to the local NHS administrative body, the primary care trust. This will decide if a new pharmacy is 'necessary or desirable' for the proper provision of NHS pharmaceutical services. The Office of Fair Trading in 2004 completed an investigation into these arrangements and recommended complete deregulation. Supermarkets in particular welcomed this view, as installing a new pharmacy for them effectively meant buying an existing outlet in the neighbourhood and transferring its NHS contract. However, the government did not go along fully with the OFT's ideas, but granted four exceptions to contract limitation on new pharmacy openings:

- pharmacies in large shopping developments;
- pharmacies intending to open more than 100 hours per week;
- applications from members of a consortium to establish a one-stop primary care centre; and
- internet or mail-order pharmacies

Anyone can own a UK pharmacy, including non-pharmacists and companies. In each pharmacy there must be a pharmacist in personal control at all times the pharmacy is open, and in addition company-owned pharmacies must appoint a superintendent pharmacist who is responsible for ensuring all legal and ethical requirements of pharmacy practice are met.

Medicines on the General Sale List can be sold by any retailer with lockable premises. Nevertheless, sales through pharmacies account for 63% of all OTC purchases.

UK pharmacists may opt to be trained as independent prescribers. In all other EEA countries, only doctors or dentists may prescribe human medicines.

Wholesalers, acting in the normal way or as agents with GSK and Pfizer products, are virtually the only supply channel for prescription brands to community pharmacies, but there are several supply routes into NHS hospitals, including direct from manufacturer, via a wholesaler, or via a regional short-line store. As a whole, the hospital market is 50% serviced by wholesalers, with the two leading players, AAH and UniChem, accounting for 27% and 13% of that figure respectively. Homecare providers like Healthcare at Home and Clinovia are supplied direct. Vaccines are supplied under contract direct to clinics and GPs on a weekly basis by Movianto (Celesio).

CHAPTER 4
THE ECONOMICS OF DISTRIBUTION

4.1 Prewholesale Margin

Unlike other parts of the chain, prewholesalers don't own their own stock. Goods remain the manufacturers' property. They are held on consignment until a sale is executed and this passes through the prewholesaler's books. The prewholesaler will levy a fee, which unlike the wholesaler margin in most countries is not government-regulated, for the service provided under contract. The commission, expressed as a percentage of sales, can range from 1-2% for straightforward distribution of expensive and non-bulky products to 20-25% if the products are bulky at varying prices (e.g. dietetics, infusion solutions) or require controlled conditions, or if supplementary administrative or promotional services are included.

Prewholesalers give manufacturers full visibility as to where stock is at batch level at any time, as well as its final destination, and in real time. This negates the need to repurchase expensive data from information intermediaries in order to monitor sales trends and to ensure production best satisfies demand.

4.2 Wholesale Margin

A key requirement is for the wholesaler to take title to the goods it sells, and by this gain the right to dispose of them as it chooses.

In the normal course of events, a wholesaler purchases products from a manufacturer and resells them to community pharmacies. The wholesaler is responsible for ordering and holding stock to enable predicted levels of demand to be met, as well as for the collection of debt resulting from these transactions. The manufacturer pays for his goods to be transported to the wholesaler; the wholesaler pays for their onward delivery to each pharmacy account. Very occasionally, with a manufacturer start-up for example, goods will be stocked by wholesalers on a consignment basis until product demand is proven.

The base price, set by the authorities, to which distribution margins are added is for most countries the manufacturer's selling price (MSP) or import (cost for insurance and freight; CIF) price. Throughout Scandinavia and also in the Netherlands, however, it is the pharmacy purchase price that acts as the base for the pharmacy's selling price, with the wholesale margin subject to free negotiation between each manufacturer and each wholesaler.

Superficially simple methodologies applied in setting wholesaler margins often preclude effective international comparison. Terms such as a percentage mark-up on the MSP, a percentage margin of the wholesale selling price (WSP) to pharmacies, or margin of the final public price – with or without value-added tax (VAT) – are not synonymous but are sometimes translated or interpreted that way.

The percentage component can be fixed or regressive (i.e. varying inversely with the cost of the drug), and is sometimes combined with a flat fee. In some countries there is a ceiling or cap on wholesaler earnings for very high-cost drugs.

Some of the blame for the confusion can probably be laid at the door of wholesalers themselves. They feel that transparency on the matter is not in their interests. They fear downward pressure by manufacturers and/or governments to some European 'norm'. If any figures are quoted, these are invariably gross, not net, margins and, depending on the country, can be the average for the mix of all goods handled, and can apply just to medicines (prescription and OTC), or just to reimbursed products.

Nevertheless, there is little doubt that average gross margins (a) vary considerably across Europe and (b) have been squeezed over the past decade (table 4.1).

Table 4.1: Average gross wholesale margins (%), 1995 vs 2005

Country	1995	2005
Denmark	7.3	6.25-6.75
France	8.5	6.5
Germany	13.7	6.2
Greece	NA	4.5
Hungary	NA	6.2
Poland	NA	8.9
Portugal	10.0	7.5
Spain	12.0	<4
Sweden	3.4	NA
UK	12.5	12.5

NA = data not available

Source: GIRP

Margin/mark-up differences can sometimes be explained by differences between the markets. Whether or not discounts are routinely offered to customers is the most important factor. The density of population or pharmacies is another. For reasons of geography, climate and terrain, wholesalers in some countries have higher operating costs than others elsewhere. In addition, there are often very large differences between the types and numbers of products handled and, to a lesser extent, in the delivery frequency. This heterogeneity has long been recognised by the European Commission, which has no plans to harmonise or approximate distribution conditions or margins.

Parallels with the costs of distribution in other industrial sectors are misleading and unhelpful to the pharmaceutical wholesaler's case. The need for constant assurance of medicines' availability, careful storage and handling, security, punctuality and speed of delivery require training and know-how unknown in most other fields of distribution.

4.3 Pharmacy Margin

A community pharmacy is a business owned or managed by a pharmacist. Pharmacists have always wanted to be paid for what they know, but the payers throughout Europe have traditionally based pharmacy remuneration on what pharmacists do for the statutory healthcare system. While this is changing, and more rapidly in some countries than others, the basic function is to dispense national health or social health insurance prescriptions.

Pharmacists are paid on a fee-for-service basis and are also reimbursed for the acquisition costs of the medicines they dispense, less the co-payments they collect from patients. The calculation of the remuneration component for dispensing social health insurance prescriptions differs in every European country, and is often highly complex.

It is usually based on:

- a fixed fee per item;
- a certain percentage of the cost or the delivery price of the item; or
- some combination of the two.

In some countries, the percentage component is fixed, sometimes it is regressive, and in others there is a cap on the pharmacist's earnings for very high-cost drugs. The dispensing margin may be eroded by compulsory rebates to social health insurance or by special taxes. Pharmacists point out that in collecting the patient co-payment charge, and in sorting, coding and dispatching the prescription forms for reimbursement claims they save the social insurance agencies considerable sums of money - even that they act as unpaid tax collectors.

4.4 Situation in National Markets

4.4.1 Austria

All medicines, whether prescription or OTC, are subject to official regressive maximum mark-up scales at both the wholesale (tables 4.2 & 4.3) and retail level (tables 4.4.& 4.5). For each group, there are two scales, depending on the product's status. Medicines newly introduced in Austria are assigned to the 'red box' category, where they can remain for up to two years. Medicines offering significant therapeutic innovation can be reclassified into the 'yellow box' category, where pricing is free up to the EU reference price. Other medicines are either listed in the 'green box' category, where prices for reimbursement have to be negotiated, or placed in the 'no box' category without reimbursement. Pharmacists can grant patients a discount on the public price arrived at through these scales only for OTCs or with private prescriptions.

***Table 4.2: Wholesale mark-up scale in Austria for 'yellow box' and* 'green box' medicines**

MSP (€)	Maximum mark-up (%) on MSP	WSP (€)
<6.06	15.5	-
6.07-6.22	-	7.00
6.23-12.11	12.5	-
12.12-12.32	-	13.62
12.33-53.78	10.5	-
53.79-54.77	-	59.43
54.78-181.68	8.5	-
181.69-184.22	-	197.12
184.23-339.14	7.0	-
>339.15	Fixed amount €23.74	

Source: ARGE Pharmazeutika

Table 4.3: Wholesale mark-up scale in Austria for all other products

MSP (€)	Maximum mark-up (%) on MSP	WSP (€)
<6.06	17.5	-
6.07-6.22	-	7.12
6.23-12.11	14.5	-
12.12-12.32	-	13.87
12.33-53.78	12.5	-
53.79-54.77	-	60.50
54.78-181.68	10.5	-
181.69-184.22	-	200.76
184.23-339.14	9.0	-
>339.15	Fixed amount €30.52	

Source: ARGE Pharmazeutika

Table 4.4: Pharmacy mark-up scale in Austria for 'privileged' customers (e.g. sickfunds, non-profit hospitals)

WSP (€)	Mark-up (%) on WSP	Public price (€) exc. MwST	Pharmacy margin as % of public price
<10.00	37.0	-	27.0
10.01-10.15	-	13.70	-
10.16-20.00	35.0	-	25.9
20.01-20.45	-	27.00	-
20.46-30.00	32.0	-	24.2
30.01-30.94	-	39.60	-
30.95-60.00	28.0	-	21.9
60.01-62.44	-	76.80	-
62.45-100.00	23.0	-	18.7
100.01-104.24	-	123.00	-
104.25-120.00	18.0	-	15.3
120.01-124.21	-	141.60	-
124.22-150.00	14.0	-	12.3
150.01-155.45	-	171.00	-
155.46-200.00	10.0	-	9.1
200.01-207.55	-	220.00	-
207.56-350.00	6.0	-	5.7
350.01-357.07	-	371.00	-
>357.08	3.9	-	3.8

Source: ÖBIG[6]

Table *4.5* : *Pharmacy mark-up scale in Austria for private customers

WSP (€)	Mark-up (%) on WSP	Public price (€) exc. MwST	Pharmacy margin as % of public price
<7.29	55.0	-	35.5
7.30-7.58	-	11.30	-
7.59-15.70	49.0	-	32.9
15.71-16.25	-	23.40	-
16.26-26.25	44.0	-	30.6
26.26-27.19	-	37.80	-
27.20-63.09	39.0	-	28.1
63.10-65.44	-	87.70	-
65.45-90.74	34.0	-	25.4
90.75-94.26	-	121.60	-
94.27-108.99	29.0	-	22.5
109.00-113.38	-	140.60	-
113.39-130.80	24.0	-	19.4
130.81-135.73	-	162.20	-
135.74-203.43	19.5	-	16.3
203.44-211.39	-	243.10	-
211.40-363.30	15.0	-	13.0
363.31-371.37	-	417.80	-
>371.38	12.5	-	11.1

**** In addition to these mark-ups, a fixed 15% can be added as a private sales mark-up (Privatverkaufszuschlag)***

Source: ÖBIG6

The Chamber of Pharmacists has also agreed with the Federation of Social Health Insurance Institutions for its members to pay a rebate to the sickfunds each year of 2.5% of any dispensing turnover that exceeds the average dispensing turnover across the country. Products with a WSP greater than €200 are exempt from the rebate calculations.

VAT (Mehrwertsteuer; MwST) for medicines is 20%, the same as the standard rate. However, the Ministry of Finance refunds part of the VAT paid on reimbursed medicines to the sickfunds.

4.4.2 Belgium

For all branded medicines, the wholesale and retail margins are fixed (table 4.6) With generic medicines, margins can equal in value terms those of the corresponding originator brand.

Table 4.6: Wholesale and pharmacy margins in Belgium

Public price (€) exc. VAT	Wholesale margin	Pharmacy margin
<24.00	13.1% of WSP (15.08% of MSP)	31% of public price* (51.7% of MSP
24.01-38.97	€2.18	€7.44
38.98-66.75	€2.18 + 0.68% of public price* above €24**	€7.44 +2.32% of public price* above €24**
>66.76	€2.18 + 0.77% of public price* above €24**	€7.44 +2.61% of public price* above €24**

* excluding VAT

** addition applies to reimbursed drugs only

Source: ŐBIG[6]

Remarkably, the pharmacy margin structure has been unchanged since 1987 but a new one is under discussion. Under the proposed system there would be a service fee (HON) plus an economic mark-up (MEC). The HON fee would have three levels – initially €1.60, €3.25 or €5.35 – dependent on the product's ATC (anatomical-therapeutic-chemical) class, subsequently adjusted for inflation. The MEC mark-up would be 7.5% on products with an MSP of up to €160 and 4.3% on products with a higher MSP.

VAT (*taxe sur la valeur ajoutée*; TVA) for medicines (prescription and OTC) is 6%. The standard rate is 21%.

Pharmacies traditionally offered rebates to patients on their statutory co-payments made during the year but this practice was abolished when a pharmacy tax corresponding to 7.7% of patient co-payment was introduced in 2002. The level of the tax is adjusted periodically to ensure that pharmacy margins collectively do not exceed a negotiated maximum budget. For 2006, this budget was fixed at €467 million.

4.4.3 Bulgaria

The distribution mark-ups on the MSP (domestic products) or CIP price (imports) depend on which of three price groups the product falls into (table 4.7). Both wholesaler and pharmacy mark-ups are capped in cash terms for the most expensive products regardless of their actual price.

Table 4.7: Distribution marks-up on MSP in Bulgaria, September 2007

MSP (BGL)	Wholesale mark-up (%)	Pharmacy mark-up	Total mark-up (%)
<7.00	10	28	38
7.01-30.00	9	25	34
>30.00	7	20	27
	(maximum BGL 15)	(maximum BGL 30)	(maximum BGL 45)

Source: Ministry of Health

Margins were last revised in 2004, when a fourth band for the cheapest products was eliminated, and following from the 2007 Medicines Law a new Ordinance on price regulation is currently under review by the Council of Ministers. This is expected to introduce two new sets of regressive mark-up scales, depending on whether the medicine is included in the positive list or not. For positive list products wholesalers will earn a 4%, 3.5% or 2.5% mark-up, and pharmacies an 11%, 10% or 8% mark-up. For prescription medicines outside the positive list, the wholesaler mark-ups will be 8%, 7% or 5%, and the pharmacy mark-ups will be 22%, 20% and 16%.

First introduced in 2002, VAT on medicines and all other goods and services is 20%.

4.4.4 Cyprus

Margins only apply in the private sector. In the public sector, medicines are dispensed from hospital pharmacies with no mark-up.

Importers/wholesalers receive up to 6% of the import price for shipping and handling, plus a 25% margin to arrive at the wholesale price. The maximum mark-up for pharmacies is 33% of the WSP (corresponding to a maximum margin of 25% of the public price). Medicines are zero-rated for VAT. The standard rate is 15%.

4.4.5 Czech Republic

The maximum combined wholesale and pharmacy mark-up on the MSP was set by the Ministry of Finance in 1996 at 35%. This was decreased to 32% in 1999 and further decreased to 29% from the beginning of 2006. From August the same year, the linear mark-up became a regressive one. There is now a maximum total mark-up of 33% for products with an MSP of less than CZK 150 and a maximum 10% mark-up for those above CZK 5,000 (table 4.8).

Table 4.8: Combined wholesaler/pharmacy mark-up scale in the Czech Republic

MSP (CZK)	Constant part of mark-up (CZK)	% of MSP above the lower limit
0-150	0	33
151-300	49.5	32
301-500	97.5	28
501-1000	153.5	25
1001-2500	278.5	22
2501-5000	608.5	18
>5000	1058.5	10

Source: AESGP[7]

The scale applies to all types of medicines sold by pharmacies. The sharing of the combined mark-up is theoretically negotiated freely between wholesalers and pharmacies, though when the total mark-up was fixed at 29% the average split was 8% to the wholesaler and 21% to the pharmacy. For competitive reasons pharmacies do not always take their full allocation, especially with OTCs, and a wide range of public prices can be found among different pharmacies

VAT applies at the lower rate of 5% to all medicines. It was levied at the level of the wholesaler until 2004, but like other EU member states it is now added to the pharmacy selling price. The standard VAT rate is 19%.

Long-term debt, especially in the public hospital sector, has been a recurring issue. In a well publicised case, AVEL members stopped supplies to three of the most indebted hospitals in 2006, claiming non payments totalling CZK 400 million, with some debt dating to 2004.

4.4.6 Denmark

Since 2001 the wholesaler margin has not been regulated by law, and can be negotiated individually between manufacturers and wholesalers. It is thought to average about 4% of the public price. Wholesalers are allowed to grant cost-related discounts to pharmacies (discounts in kind - like free stock - remain forbidden), though at least one half of this discount has to be passed on by the pharmacy to its customers.

Every second year, the *Danmarks Apotekerforening* and the Ministry of Interior and Health negotiate the gross profit of the pharmacy sector as a whole, based on current figures and forecast developments. In 2003, the agreed profit – which must cover the cost of operating the pharmacies and the proprietor pharmacists' own salaries – was about DKK 2.1 billion.

Including non-dispensing and even non-medicinal turnover in the formula used to calculate the dispensing fee is a unique feature of the Danish market. Its rationale is to discourage pharmacies from diversifying their business too far away from a focus on medicines.

Since the most recent revision, effective April 2007, pharmacies receive a flat rate mark-up of 8.5% on the pharmacy purchase price, to which DKK 13.35 is added. The pre-existing prescription fee of DKK 10/item has been retained, and is included in the public price. A desired 'side effect' of the new system is that it favours the dispensing of cheaper products required

under the mandatory substitution system. Pharmacists may not sell below the price listed in the reimbursement list, *Medicinpriser.*

VAT on medicines is at the standard rate of 25%.

4.4.7 Estonia

Maximum mark-ups for wholesalers (table 4.9) and retail pharmacies (table 4.10) apply, using regressive scales. They apply to all types of medicines.

Table 4.9: Maximum wholesaler mark-up in Estonia

CIF price of pack (EEK)	Maximum mark-up on CIF price (%)
<25.00	20
25.01-45.00	15
45.01-100.00	10
100.01-200.00	5
>200.00	3 (to maximum of EEK 100/pack)

Source: ŐBIG[6]

In cases where the importer and wholesaler are different entities, they have to share the same margin, with the total cost-plus percentage added not exceeding the maximum allowed. Dealings between local wholesalers follow the same rule.

Table 4.10: Maximum pharmacy mark-up in Estonia

WSP (EEK)	Proportional mark-up (% of WSP)	Fixed mark-up (EEK)
<10.00	0	6
10.01-20.00	40	6
20.01-30.00	35	0
30.01-40.00	30	0
40.01-50.00	25	0
50.01-100.00	20	0
100.01-700.00	15	0
>700.00	0	80

Source: ŐBIG[6]

Maximum mark-ups are often not fully realised, so patients may benefit from shopping around different pharmacies.

VAT applies to prescription and OTC medicines at the lower rate 5%. The standard rate is 18%.

4.4.8 Finland

The wholesale margin may be freely set, and results from confidential negotiations between manufacturers and wholesalers, but is believed to average about 3.5%. With single channel distribution, no discounts are offered to pharmacies by wholesalers.

The pharmacy mark-up on the pharmacy purchase price (AIP) is regulated and regressive (table 4.11). It is valid for all types of medicines, whether reimbursable, non reimbursable, branded, generic or OTC.

Table 4.11: Finnish pharmacy mark-up scale for all medicines

WSP (€)	Public price (€), exc.VAT and pharmacy tax
<9.25	AIP x 1.5 + €0.50
9.26-46.25	AIP x 1.4 +€1.43
46.26-100.91	AIP x 1.3 + €6.05
100.92-420.47	AIP x 1.2 + €16.15
>420.47	AIP x 1.125 + €47.68

Source: ŐBIG[6]

In addition, pharmacies receive a fixed dispensing ('expedition') fee per prescribed product of €0.42 including VAT.

The price to the public is the same throughout the country – even for non reimbursed medicines where the AIP is not approved by the Pharmaceuticals Pricing Board (*Lääkkeiden hintalautakunta*) – because the AIP to be applied for the calculation of the pharmacy mark-up has to be the same for all pharmacies.

Pharmacies have to pay the state a turnover-dependent pharmacy fee ranging from zero to 11% (table 4.12). It works out at 7% or €205,000 on an average basis. The idea is that larger pharmacies will earn a little less than smaller pharmacies for dispensing a product of the same cost, so evening out the performance of different-sized pharmacies and hopefully securing the country-wide provision of pharmacy services. The fee system also generates around €120 million annually for the government.

Table 4.12: Pharmacy fee payable to the state in Finland

Pharmacy annual turnover (€)	Pharmacy fee at lower limit (€)	Fee (%) exceeding lower limit
672662-784398	-	6
784398-1998620	6704	7
1008620-1232591	22400	8
1232591-1569792	40317	9
1569792-2017238	70665	9.5
2017238-2465929	113173	10
2465929-2914371	158042	10.25
2914371-3699516	204007	10.5
3699516-4819672	286447	10.75
>4819672	406886	11

Source: Association of Finnish Pharmacies

VAT (*arvonlisävero*) is 8% for all medicines. The standard rate is 22%.

4.4.9 France

Components of the public price:

Public price (*prix public toutes taxes comprises*; PPTTC) = MSP (*prix fabricant hors taxe*; PFHT) + wholesale mark-up + pharmacy mark-up + VAT (TVA)

For reimbursed products, wholesaler mark-ups are fixed according to a regressive scale (*marge dégressive lissée*) last revised early in 2004 (table 4.13). When the MSP is at or below €22.90, the mark-up on the MSP is 10.3%. It is 6% for the part of the MSP between €22.91 and €150.0, and 2% for that part above €150.

Table 4.13: Wholesale mark-up scale for reimbursed medicines in France

MSP (€)	Mark-up (%)
that part <22.90	10.3
that part 22.91-150.0	6.0
that part >150	2.0

Source: Comité Economique des Produits de Santé

Wholesalers' discounts to pharmacies are limited by law to 2.5% of the wholesale selling price (and average about 1.8% for reimbursed products), apart from generics where they can reach 10.74%.

An exceptional new tax on wholesalers, at 0.21% of pretax turnover, was introduced in 2006. This had been expected to continue into 2008, and generate up to €50 million/year for the government, but in amendment to the 2008 budget it was announced that this saving would be realised instead by cutting the wholesaler margin via a ministerial order.

The pharmacy mark-up for reimbursed products is applied in a similar manner to wholesalers (table 4.14), i.e. different rates are applied and added according to the MSP. There is in addition a flat fee of €0.53 per item dispensed paid.

Table 4.14: Pharmacy mark-up scale for reimbursed medicines in France

MSP (€)	Mark-up (%)
that part <22.90	26.1
that part 22.91-150.0	10.0
that part >150	6.0

Source : Comité Economique des Produits de Santé

There are therefore three cases:

- when the PFHT is <€22.90: PPTTC = PFHT x 1.3926 +0.5411;
- when the PFHT is >€22.90 but <€150.0: PPTTC = PFHT x 1.18436 + 5.31083; and
- when the PFHT is >€150.0: PPTTC = PFHT x 1.10268 + 17.56283

For generic products not included in the reference price system, the mark-up is adjusted so that pharmacies receive the same cash amount as if the

originator brand (whose price is usually 30-40% higher) had been dispensed.

Pharmacies are not required to pay any rebate to social security, though they can offer discounts to their customers as long as these do not exceed 2.5% of the MSP for originator products and 10.74% of the MSP with generics.

Both wholesaler and pharmacy margins are free for products outside the reimbursement system.

TVA is 2.1% on reimbursed medicines and those used in hospitals, whereas for non-reimbursed prescription medicines and OTCs it is 5.5%. The standard rate is 19.6%.

4.4.10 Germany

Components of the public price:

Public price (*Apothekenverkaufpreis*) = MSP (*Fabrikabgabepreis)* + wholesale mark-up + pharmacy mark-up – statutory rebate + VAT (*Mehrwertsteuer*; MwST)

Different mark-up scales for wholesalers apply depending on whether the medicine is a prescription-only product (table 4.15) or a non-prescription bound product (table 4.16) that is reimbursed as an exception (e.g. for children). The current scale for the former group runs from +6% to +15%, with a minimum mark-up of €0.45 and a maximum of €72.0 (prior to 2004, the scale went from +12% to +21%, with mark-ups for products costing more than €684 capped at 3% plus €61). Between each band there is a narrow price range for which a fixed cash mark-up is given. This is to ensure smooth progression across bands.

Mark-ups for non-reimbursed OTC medicines were freed at the beginning of 2004.

Table 4.15: Wholesale mark-up scale for reimbursed prescription medicines in Germany

MSP (€)	Wholesale mark-up as % of MSP	Maximum wholesale mark-up (€)
<3.00	15.0	-
3.01-3.74	-	0.45
3.75-5.00	12.0	-
5.01-6.66	-	0.60
6.67-9.00	9.0	-
9.01-11.56	-	0.81
11.57-23.00	7.0	-
23.01-26.82	-	1.61
26.83-1,200	6.0	-
>1,200	-	72.00

Source: Arzneimittelpreisverordung, 2004

***Table 4.16: Wholesaler mark-up scale for reimbursable OTC medicines* in Germany**

MSP (€)	Wholesale mark-up as % of MSP	Maximum wholesale mark-up (€)
<0.84	21.0	-
0.85-0.88	-	0.18
0.89-1.70	20.0	-
1.71-1.74	-	0.34
1.75-2.56	19.5	-
2.57-2.63	-	0.5
2.64-3.65	19.0	-
3.66-3.75	-	0.7
3.76-6.03	18.5	-
6.04-6.20	-	1.12
6.21-9.10	18.0	-
9.11-10.92	-	1.64
10.93-44.46	15.0	-
44.47-55.58	-	6.67
55.59-684.76	12.0	-
>684.77	3.0	61.63

Source: ABDA

Pharmacies receive for each prescription-only medicine dispensed a fixed €8.10 plus a 3% mark-up on the wholesale selling price. This is quite a change from the pre-2004 situation when the mark-up scale went from +30% to +68%, with products costing more than €543 limited to an 8% mark-up plus €118. The old scale has been retained for reimbursed non-prescription medicines.

Though the MSP can be freely set, every prescription medicine has to have a fixed, common public price in all pharmacies across the country in accordance with the revised *Arzneimittelpreisverordnung* (Medicine Price Regulation). The wholesaler and pharmacy mark-ups on the MSP are calculated by the *Informationsstelle für Arzneispezialitäten*, an institution founded by the associations of manufacturers, wholesalers and pharmacies, which also assigns each SKU a unique *Pharma-zentral-nummer* in bar code form. The public price, listed in the *Lauertaxe*, is used for reimbursement.

Pharmacies have to pay statutory rebates to the sickfunds of €2.30 per prescription medicine and 5% of the value at public prices of reimbursable OTC medicine dispensed. The prescription medicine rebate was previously set at €2, but to offset the loss of savings to the sickfunds of dropping the clause in the draft version of the 2007 health reform bill (*Gesetz zur Stärkung des Wettbewerbes in der Gesetzlichen Krankenversicherung*; GSK-WSG) that would have seen prices set at a maximum rather than fixed, the rebate became €2.30 from 1 April 2007. The GSK-WSG also allowed pharmacies to dispense single tablets for the first time; reimbursement and remuneration for this service are determined through negotiation between the pharmacy and the patient's sickfund.

A regressive pharmacy mark-up scale applies with reimbursable non-prescription bound products (table 4.17). Pharmacy mark-ups on non-reimbursed OTCs are free, with price competition most evident with online pharmacies. The German monopolies commission has criticised the fact that consumers shopping in community pharmacies are not allowed to peruse

and compare different OTCs themselves. The commission says this is not conducive to consumer choice as it makes price comparison difficult.

Table 4.17: Pharmacy mark-up scale for reimbursable non-prescription bound medicines in Germany

WSP (€)	Pharmacy mark-up as % of WSP	Maximum pharmacy mark-up (€)
<1.22	68.0	-
1.23-1.34	-	0.83
1.35-3.88	62.0	-
3.80-4.22	-	2.41
4.23-7.30	57.0	-
7.31-8.67	-	4.16
8.68-12.14	48.0	-
12.15-13.55	-	5.83
13.56-19.42	43.0	-
19.43-22.57	-	8.35
22.58-29.14	37.0	-
29.15-35.94	-	10.78
35.95-543.91	30.0	-
>543.92	8.263	118.24

Source: ABDA

In May 2003, ABDA forecast that 20,000 pharmacy staff would be made redundant during the year as a result of government cost-cutting measures. In the first quarter of the year, around 2,600 staff lost their jobs, with 8.8% of remaining workers facing a cut in hours.

Under the Drug Savings Law (*Arzneimittelversorgungs-Wirtschaftlichkeitsgesetz*; AVWG), effective May 2006, pharmacies lost the right to obtain 'natural rebates' from manufacturers. This practice usually involved the provision of free stock or other non-monetary rebates for bulk orders from predominately generic companies, which pharmacies could subsequently claim full reimbursement for. Towards the end of the year, the BVDA and ABDA associations were threatening rolling one-day pharmacy closures across the country in protest. Loss of natural rebate income to pharmacies was put at €500 million per year.

Wholesaler rebates to pharmacies are now limited by law to a maximum that is equal to the wholesaler's statutory mark-up. These rebates are made either in return for ordering efficiency (electronic placement of orders, placement of many orders at once, or ordering large volumes), or to reward or obtain customer loyalty. Cash discounts are also provided to reward early payment of bills.

VAT on all types of medicines (and other goods and services) is 19%. Prior to 1 January 2007 it stood at 16%.

The net result for a reimbursed product with a public price of €100 splits as follows:

- manufacturer €63.7
- wholesaler €3.8

- pharmacy €18.7
- VAT €13.8

4.4.11 Greece

The wholesale mark-up is 8.43% on the MSP and the pharmacy mark-up is 35% on the WSP. Both apply to all types of medicines. The wholesale mark-up was last reduced (from 12%) in 1997, and there have been no changes to the pharmacy mark-up in recent years.

As in practice the starting price is the WSP, wholesalers are allowed a discount of 7.78% on this price as their margin, but this 7.78% is added back to calculate the pharmacy mark-up.

Take as an example a product with a WSP of €100:

- the manufacturer sells this to a wholesaler at €92.22 (€100 less 7.78%);
- the wholesaler sells the product to a pharmacy at €100 (wholesaler purchase price of €92.22 plus a 8.43% mark-up);
- the pharmacy selling price is €135 (pharmacy purchase price plus 35% mark-up), which with the addition of 9% VAT results in a public price of €147.15.

To support the pharmacy infrastructure in sparsely populated areas (communities with fewer than 5,000 inhabitants), manufacturers and importers are required to offer wholesalers an additional 0.4% discount, from which sum wholesalers are required to provide 4% discounts to rural pharmacies.

Manufacturers can offer wholesalers an optional extra 5% discount (providing this is shown clearly on the invoice) in addition to the 0.4% statutory one, which wholesalers can pass on to pharmacies, but for most brands of multinational companies – and certainly for those products that are at the highest risk of being parallel-exported - this extra 5% is not given. Discounts given to pharmacies cannot be passed on to patients in the form of lower co-payments.

If the product is sold to hospitals, then the price is capped at the WSP to public pharmacies less 13% (or €87 in the example above).

The standard rate of VAT on other goods and services is 19%.

4.4.12 Hungary

Regressive mark-up scales have applied to both wholesalers and pharmacies since 1993. These are common to all product types, regardless of legal or reimbursement status.

The current scale for wholesalers is shown in table 4.18; it was last reduced in 1999. The average mark-up on the MSP in 2006 was 6.06%. Discounts to pharmacies by wholesalers are in the range of 1-3%.

Table 4.18: Wholesaler mark-ups in Hungary

MSP/CIP (HUF)	Wholesale mark-up (%)	Maximum mark-up (HUF)
<150.00	12.0	-
150.01-180.00	-	18.0
180.01-300.00	10.0	-
300.01-333.00	-	30.0
333.01-500.00	9.0	-
500.01-600.00	-	45.0
600.01-1000.00	7.5	-
1000.01-1154.00	-	75.0
1154.01-2000.00	6.5	-
2000.01-2600.00	-	130.0
>2600.01	5.0	-

Source: pharmaFELAX

The current scale for pharmacies is shown in table 4.19; it was last reduced in 2004. The pharmacy mark-up averaged 15.05% in 2006. The mark-up has shown a near steady decline: 20.47% in 2000, 19.3% in 2001, 17.23% in 2002, 15.42% in 2003, 16.64% in 2004 and 17.01% in 2005.

Table 4.19: Pharmacy mark-ups in Hungary

WSP (HUF)	Pharmacy mark-up (%)	Maximum mark-up (HUF)
<500	26.0	-
501-590	-	130
591-1500	22.0	-
1501-1737	-	330
1738-3500	19.0	-
3501-3911	-	665
3912-5000	17.0	-
>5001	-	850

Source: pharmaFELAX

While any wholesaler discounts on reimbursable products cannot be passed on to patients by pharmacies as lower co-pays, for non-reimbursable products pharmacies are required to use the discounted WSP in calculating the mark-up due.

Since 2007, a tax has been levied on manufacturers, wholesalers and pharmacies on sales to the National Health Insurance Fund. For wholesalers this is equivalent to 1% of their annual mark-up on reimbursed products, and for pharmacies it is 0.5-2% (table 4.20), with an additional flat fee levied in cases where the annual pharmacy mark-up exceeds HUF 50 million.

Table 4.20: Pharmacy tax in Hungary

Annual pharmacy mark-up (HUF million)	Monthly tax (%)	Additional fee (HUF)
30-49	0.5	-
50.75	1.0	250000
>75	2.0	500000

Source: author

VAT was introduced in 2004. It is levied at 5% on prescription and OTC medicines, at 15% on parapharmaceuticals, and at 20% on other goods and services.

4.4.13 Ireland

The WSP is supposed to be regulated under a multiyear industry/government agreement, the latest of which – the eighth in a series beginning in 1972 – only came into effect in September 2006. However, in mid-2007, the Health Services Executive (HSE) took a unilateral decision to reduce the wholesale mark-up from 17.66% on the MSP (equivalent to a 15% margin on the WSP) to 8%, effective 1 January 2008, and to 7% from 1 January 2009. For supply through community pharmacies of innovative, high-cost products included in the High Tech Pharmaceuticals Scheme, the wholesale margin remains at 10%.

Much (7-9%) of the current gross margin is given away by wholesalers as discounts to pharmacies, but pharmacies fear this will not be the case when the wholesale mark-up is halved. The numbers of deliveries to pharmacies are also expected to fall. Industrial action by pharmacists in protest at the planned reforms took the form of refusal to supply methadone to drug addicts.

Public prices, and hence the pharmacy margin, varies with the different reimbursement schemes run by the HSE.

With the General Medical Services (GMS) Scheme, covering 30% of the population (but 75% of total prescriptions), the pharmacy receives the WSP plus a fixed dispensing fee of €3.26 per item. For prescriptions filled under either the Drugs Payment Scheme (for people ineligible to join the GMS, 35% of population and 20% of total prescriptions) or Long Term Illness Scheme (for people suffering one of 15 defined chronic illnesses; 2.5% of population and 5% of prescriptions) payment consists of the WSP, a 50% mark-up and a fixed dispensing fee of €2.59. Under the High Tech Scheme pharmacies receive the WSP plus a patient care fee of €49.64/month.

Any medicine (prescription and OTC) that is ingested by mouth is zero-rated for VAT. The standard rate of 21% is levied on all other medicines, as well as on other goods and services.

According to the Irish Pharmaceutical Union, the average pharmacy turnover in 2003 was €1.43 million, a 50% increase over 2000. Sixty percent of revenue came from dispensing, 20% on sales of OTC medicines and 20% on sales of non-pharmaceutical products. The high mark-up in the case of dispensing under the DP or LTI schemes has been a subject of controversy. There is no government clawback of pharmacy procurement discounts either.

Pharmacy margins on sales of OTCs are unregulated but are in the range of 25-33%.

Distribution arrangements to state hospitals have to be discussed in advance with the HSE, according to the 2006 pricing agreement. Where a manufacturer chooses to supply direct, delivery has to be at the same price as to the wholesaler. The HSE reserves the right to appoint one or more wholesalers on a regional or national basis.

4.4.14 Italy

Components of the public price:

Public price = MSP + wholesale margin + pharmacy margin + VAT

The wholesale margin for reimbursed medicines (*Prontuario* category A) is a fixed 6.65% of the pre-tax public price. The margin for non-reimbursed (category C) products is free, but averages 8%.

Purchases by the regions, for direct supply to patients, are entitled to a 50% discount on the public price.

The pharmacy margin for reimbursed medicines is a fixed 26.7% of the pre-tax public price. The margin for non-reimbursed products is free, but by convention is a minimum of 25%. Pharmacies can offer discounts of up to 20% on the public price of non reimbursed medicines to their customers.

Since 2004, pharmacies have been required to pay a rebate to the National Health Service, the level of which depends on pharmacy turnover and on whether the pharmacy is situated in an urban (communities with more than 5,000 inhabitants) or rural area (table 4.21). This brings the effective average margin down considerably, especially for higher-priced products (table 4.22).

Table 4.21: Structure of rebates (%) paid by Italian pharmacists to the National Health Service

	Urban and non-subsidised rural pharmacies		**Subsidised rural pharmacies**	
Product price (€)	**Turnover < €258228**	**Turnover > €258228**	**Turnover <387343**	**Turnover >387343**
<25.82	1.5	3.75	1.5	3.75
25.83-51.65	2.4	6.0	1.5	6.0
51.66-103.28	3.6	9.0	1.5	9.0
103.29-154.94	5.0	12.5	1.5	12.5
>154.95	7.6	19.0	1.5	19.0

Source: Federfarma

Table 4.22: Net margin for average Italian pharmacy after statutory rebate

Product price (€)	Theoretical margin (%)	Rebate to NHS (%)	Effective margin (%)
<25.82	26.7	3.75	22.95
25.83-51.65	26.7	6.0	20.7
51.66-103.28	26.7	9.0	17.7
103.29-154.94	26.7	12.5	14.2
>154.95	26.7	19.0	7.7

Source: Federfarma

Margins for wholesalers and pharmacies on reimbursed medicines were temporarily lowered for the period March 2007 to March 2008 to 6.52% and 26.19% respectively. This is to cover the distributors' share of the 2007 savings when manufacturers opted to rebate the health service rather than reduce prices by 5%.

VAT is 10% on all medicines. The standard rate is 20%.

4.4.15 Latvia

The wholesale price of reimbursable medicines is calculated from the MSP plus a maximum mark-up ranging from 4% to 10% inversely proportional to MSP (table 4.23). For non-reimbursable products, the mark-up is fixed at 15% of MSP.

Table 4.23: Wholesale mark-ups for reimbursable medicines in Latvia

MSP/CIP (LVL)	Wholesale mark-up as % of MSP
<1.99	10
2.00-3.99	9
4.00-7.99	7
8.00-14.99	6
15.00-19.99	5
>20.00	4

Source: ŐBIG[6]

The maximum pharmacy mark-up on the WSP is also on two regressive scales, one for reimbursable products (table 4.24) and another for non-reimbursable products (table 4.25), with the public price = WSP x appropriate coefficient + correction sum + VAT.

Table 4.24: Pharmacy mark-up for reimbursable medicines in Latvia

WSP (LVL)	Coefficient	Correction sum (LVL)
<0.99	1.30	-
1.00-1.99	1.25	0.05
2.00-2.99	1.20	0.15
3.00-4.99	1.17	0.30
5.00-9.99	1.15	0.40
10.00-14.99	1.10	0.90
15.00-19.99	1.07	1.35
20.00-49.99	1.05	1.75
>50.00	1.00	4.25

Source: ŐBIG[6]

Table 4.25: Pharmacy mark-up for non-reimbursable medicines in Latvia

WSP (LVL)	Coefficient	Correction sum (LVL)
<0.99	1.40	0.01
1.00-1.99	1.35	0.06
2.00-2.99	1.30	0.16
3.00-4.99	1.25	0.31
5.00-9.99	1.20	0.56
10.00-19.99	1.15	1.06
>20.00	1.10	2.06

Source: ŐBIG[6]

While both wholesalers and pharmacies tend to apply the maximum mark-ups in full for reimbursable medicines, this is generally not the case with non-reimbursable medicines, which therefore vary in price from pharmacy to pharmacy.

VAT on all medicines is 5%, with 18% on other goods and services.

4.4.16 Lithuania

Maximum mark-ups for wholesalers (table 4.26) and community pharmacies (table 4.27), on regressive scales, apply with all reimbursed drugs, otherwise margins are free. The average wholesaler mark-up, net of discounts, is about 8-9%

Table 4.26: Wholesale mark-ups for reimbursable medicines in Lithuania

MSP/CIP Lithuania (LTL)	Maximum mark-up
<6.43	14.0%
6.44-10.00	LTL 0.9
10.01-19.44	9.0%
19.45-25.00	LTL 1.75
25.01-53.56	7.0%
53.57-68.18	LTL 3.75
68.19-909.09	5.5%
>909.09	LTL 50.00

Source: AESGP[7]

Table 4.27: Pharmacy mark-ups for reimbursable drugs in Lithuania

WSP (LTL)	Maximum mark-up
<8.19	22.0%
8.20—10.00	LTL 1.80
10.01-15.28	18.0%
15.29-25.00	LTL 2.75
25.01-27.28	11.0%
27.29-75.00	LTL 3.00
75.01-500.00	4.0%
>500.00	LTL 20.00

Source: ŐBIG[6]

VAT is 5% on all medicines and foods with medicinal properties, and 18% on other goods and services.

4.4.17 Luxembourg

The wholesale mark-up is 15.21% of the MSP, which equates to a 13.20% margin on the public price excluding VAT (TVA). For medicines imported from Belgium (i.e. the majority), the pharmacy mark-up is 46.70% of the WSP (or 31.83% of the public price less TVA). With imports from other countries, the pharmacy mark-up is 50.20% of the WSP (equivalent to a 33.42% margin on the TVA-exclusive public price). However, the difference is effectively ruled out by a requirement, in force since 1983, that pharmacies pay a rebate to social security for any non-Belgian product dispensed.

TVA on all types of medicines is 3%. The standard rate is 15%.

4.4.18 Malta

In the private system, importers/wholesalers receive a fixed 15% mark-up on the CIF price for all types of medicines. Pharmacies receive a 20% mark-up on the WSP. Medicines are currently zero-rated for VAT, though from 2010 a reduced rate of 5% is expected to apply. The standard rate is 18%.

4.4.19 Netherlands

Price regulation in the Netherlands is at the level of the WSP, i.e. the wholesale margin is unregulated, even for reimbursed medicines, and is based on individual agreements that vary between the mix of different products handled (i.e. domestic brands, generics and PIs). Agreements are normally for a one-year term. Discounting to pharmacies is extensive, especially with generics and PIs.

The turnover of the average pharmacy amounted to €2.3 million in 2005 (+2% on 2004). This is broken down as 86% from dispensing prescription medicines, 9% from OTC sales and 5% on sales of medical devices. The total number of reimbursed items dispensed that year per pharmacy averaged 75,700 (+2.5% on 2004).

Pharmacies are reimbursed at the maximum pharmacy purchase prices listed in the tariff (*taxe*) of the KNMP, and are remunerated with a dispensing fee (€6.10 per item, a level unchanged since 2003 when it increased from €6.00). This fee applies irrespective of the product cost or the quantity supplied (though, depending on the product, supply is limited to 15, 30 or 90 days, or one year for oral contraceptives only). The basis of the fee is set out in the Healthcare Charges Act and its level is established through periodic negotiations between insurers and the KNMP. It results from dividing income and costs by the number of prescriptions handled.

Dispensing doctors do not receive a per item dispensing fee but instead are given a basic annual fee of €8.60 per insured patient, which is increased by €0.60 for every patient younger than 65 years and by €20.80 for every patient older than 65 years.

Though the average pharmacy realised €427,000 in dispensing fees in 2005, procurement discounts from manufacturers and wholesalers are an important income supplement. A 2006 survey showed discounts averaged 16.5% of the purchase price, unchanged over 2004. Generics, in particular, offer the highest profit potential (table 4.28).

Table 4.28: Specimen discounts available to Dutch pharmacies on product X, 50mg, 30 tablets

	Domestic brand	Parallel import	Generic
Pharmacy purchase price	€31	€18	€14
Clawback	€1.86	€1.08	€0.84
Dispensing fee	€6.10	€6.10	€6.10
Discount	7%/€2.17	14%/€1.96	35%/€4.90
Profit	€6.41	€6.98	€10.16

Source: IMS Health

Discounts have been a recurring topic of discussion, negotiation and even legal challenge over the years. Originally, they could be retained in full but a form of clawback was introduced by the Ministry of Health, Sport and Culture in 1999 to recover part.

Towards the end of 2002, an outgoing minister announced the clawback would be increased from 6.82% (to a maximum of €6.80/dispensed item) for all products to 8% (maximum €9.00) for single source products and

40% (maximum €20) for off-patent multisource products – including the originator brand. This differentiated clawback was widely criticised and successfully challenged by the KNMP in the courts. The original 6.82% clawback (maximum €6.80) was re-introduced and additionally it was agreed that generic list prices would be cut by an average of 40% from January 2004 and that new generics should be priced at 40% of the brand level. Prices of branded originals with marketed generics were also cut by 40% a year later. The latest round of clawback negotiations is ongoing.

VAT (*belasting toegevoegde waarde*) is 6% on all medicines. The standard rate is 19%.

4.4.20 Norway

All discounts on sales to wholesalers need to be included on the invoice.

The Norwegian Medicines Agency controls the maximum prices of all prescription medicines, whether reimbursed (blue prescriptions) or not (white prescriptions), by setting their maximum pharmacy purchase prices and the maximum pharmacy mark-ups. The mark-ups are 8% for the first NOK 200 and 5% for any amount above NOK 200. There is also a fixed per pack amount paid to pharmacies of NOK 21.50. With narcotics an additional NOK 10 handling fee may be charged.

Margins on OTCs are free. In 2003, the industry association estimated the following price build-up for non-prescription medicines: manufacturer 36.3%, wholesaler and pharmacy combined 44.3%, and government (VAT) 19.4%.

The standard rate of VAT (*merverdiavgift*) of 25% applies to all medicines.

4.4.21 Poland

The wholesale margin for reimbursed medicines is a maximum 8.91% of WSP (9.81% of MSP). Wholesalers routinely offer discounts to their customers, averaging 3-5% of WSP. Margins for non-reimbursed products are unregulated but are thought to average about 14%.

For pharmacies, maximum mark-ups with reimbursed products are on a regressive scale (table 4.29) which has not been modified since 2001. The average mark-up is about 20%. Because the maximum mark-up is not always applied, the actual cost to patients of receiving the same medication will vary between different pharmacies.

Table 4.29: Maximum pharmacy mark-ups for reimbursed drugs in Poland

WSP (PLN)	Pharmacy mark-up
<3.60	40%
3.61-4.80	PLN 1.44
4.81-6.50	30%
6.51-9.75	PLN 1.95
9.76-14.00	20%
14.01-15.55	PLN 2.80
15.56-30.00	18%
30.01-33.75	PLN 5.40
33.76-50.00	16%
50.01-66.67	PLN 8.00
66.68-100.00	12%
>100.00	PLN 12.00

Source: ŐBIG[6]

Pharmacy margins on non-reimbursed drugs are also free, but are believed to average 23% of the VAT-exclusive public price.

There are proposals from the government to replace maximum distribution margins with fixed lower ones, and combine these with a maximum MSP. Discounting along the chain would then be banned, with price competition only at the manufacturer level. The planned change is in response to pharmacies using their wholesaler discounts to compete for repeat business from patients by entirely or largely waiving the fixed co-payment charge of PLN 5 that would otherwise be due with reimbursed drugs.

VAT on medicines is 7%, but 22% on most other goods and services.

4.4.22 Portugal

As a share of the public price (excluding VAT), wholesale and pharmacy margins for all types of medicines were unchanged at 8% and 20% respectively for decades. In 2005, margins for reimbursable medicines were reduced to 7.45% for wholesalers and to 19.15% for pharmacies, and in 2007 these were further reduced to 6.87% for wholesalers and to 18.25% for pharmacies. Margins for non-reimbursed products are free.

VAT (*imposto sobre valor acrescentado*) is 5% on medicines (prescription and OTC), with the standard rate at 21%.

4.4.23 Romania

Maximum wholesaler and pharmacy mark-ups are set by the Ministry of Health. Wholesalers can add 7.5% to the MSP, whereas pharmacies use a regressive scale (table 4.30).

Table 4.30: Maximum pharmacy mark-ups in Romania

WSP (RON)	Maximum mark-up (%)
<2.00	24
2.01-5.00	20
5.01-7.50	15
>7.50	12

Source: AESGP[7]

VAT on all types of medicines is 9%. It was reduced to this level from the standard rate of 19% in 2004 to lessen the financial burden on patients.

4.4.24 Slovakia

The mark-up on the MSP with both prescription and OTC medicines for wholesalers is 13% and for pharmacies it is 21%.

With effect from the beginning of 2007, VAT on prescription medicines was reduced to 10%. The standard VAT rate of 19% applies also to OTCs.

4.4.25 Slovenia

Prices for all medicines are controlled by the Medicines Agency at the level of the WSP. The wholesale margin therefore is not regulated and results from negotiation between distributors and manufacturers, but is believed to average 6-9%.

Pharmacies contracted with the Health Insurance Institute are paid on a points based fee-for- service principle for dispensing and do not receive a margin as such. Fees are independent of the product dispensed and its price. However, the average margin as a share of the public price works out at about 12%.

VAT is 8.5% on all types of medicines, while the standard rate is 20%.

4.4.26 Spain

If the product's MSP is less than €89.62, the wholesale margin in accordance with Royal Decree 2402/2004 is a fixed 7.6% of the WSP. If the MSP is greater than €89.62, the wholesale mark-up is a flat rate €7.37 regardless of the product cost. The margin has been cut five-times since 1997 (table 4.31), and all wholesalers claim they need to parallel export (with free margins), either individually or as purchasing groups, to remain viable businesses.

Table 4.31: Decline in the Spanish wholesaler margin

Year	Wholesale margin
1945	12%
1997	11%
2000	9.6% if MSP <€78.34, fixed €8.32/pack if MSP >€78.34
2005	8.6% if MSP <€89.62, fixed €8.43/pack if MSP >€89.62
2006	7.6% if MSP <89.62, fixed €7.37/pack if MSP >€89.62

Source: author

The pharmacy margin is a fixed 27.9% of the public price (before VAT) if the MSP is less than €89.62. If the MSP is higher than this amount, then the mark-up is a flat rate €37.53 regardless of the product cost.

The margin structures are common to all medicines, i.e. reimbursable, non-reimbursable, brands, generics and OTCs.

Pharmacies also pay a rebate to the health system based on monthly reimbursed sales (table 4.32).

Table 4.32: Pharmacy clawback in Spain

Monthly sales of reimbursed medicines at MSP (€)	Rebate (%)
<31,627.66	0.0
31,627.67-42,628.59	8.0
42,628.60-57,067.29	9.4
57,067.30-117,572.39	10.9
117,572.40-203,517.12	13.5
203,517.13-288,774.29	14.5
>299,774.30	15.0

Source: Ministry of Health & Consumer Affairs

Other than when justified by high volume orders or early payment terms, all discounts or their equivalent given by manufacturers to wholesalers or pharmacies were banned by the 2006 Medicines Law, which also reaffirmed that distribution can be carried out by marketing authorisation holders as well as by wholesalers.

VAT on all medicines is at the lower rate of 4%. The standard rate is 16%. There is no longer any requirement for the public price to appear on the pack labelling (with and without VAT). This suggests the authorities are looking to revise prices more frequently.

4.4.27 Sweden

Components of the public price:

Public price (*apotekens utförsäljningpris*; AUP) = pharmacy purchase price (*apotekens inköpspris*; AIP) + pharmacy mark-up

The wholesale mark-up is not regulated but based on free agreements between suppliers and wholesalers, and is not made public. On average, it

is estimated to be 2.7% of the MSP. No discounts are given to pharmacies with single channel distribution.

Pharmacies have two statutory mark-up scales – one for prescription medicines (table 4.33) and the other for OTCs (table 4.34) - set and revised by the price-setting body, *Läkemedelsförmånsnämnden* (LFN) in discussion with Apoteket, so AUPs are common throughout the country. Revisions to the scales are normally made annually, with the last change made in January 2006. The breakdown of turnover by Apoteket in 2004 approximated to 80% from out-patient prescriptions, 12% from inpatient prescriptions and 8% from OTCs.

Table 4.33: Pharmacy mark-up scale for prescription-only medicines in Sweden

AIP (SEK)	AUP
<75.00	AIP x 1.20 + SEK 31.25
74.00-300.00	AIP x 1.03 + SEK 44.00
300.00-6000.00	AIP x 1.02 + SEK 47.00
>6000.00	AIP + SEK 167.00

Source: LFN

Table 4.34: Pharmacy mark-up scale for OTCs in Sweden

AIP (SEK)	AUP (exc.VAT)
<20.00	AIP x 1.42 + SEK 4.10
20.01-50.00	AIP x 1.40 + SEK 4.50
50.01-100.00	AIP x 1.12 + SEK 18.50
100.01 – 1000.00	AIP x 1.11 + SEK 19.50
>1000.01	AIP x 1.10 + SEK 29.50

Source: LFN

On average, the pharmacy margin works out at about 16%, low by European standards, but Swedish pharmacies, unlike those elsewhere, are not commercial operations.

Prescription medicines are zero-rated for VAT, while OTC medicines and other goods and services attract the standard rate of 25%.

4.4.28 Switzerland

Distribution margins for all product types are shared between wholesalers and pharmacies/dispensing doctors. No wholesale margin is defined in law. Instead wholesalers levy fees on customers and on manufacturers, the latter averaging 5% of MSP.

For both prescription medicines and OTCs the margin for pharmacies averages 32% of the public price. It is made up of their share of the distribution margin plus a points-based fee structure, billed to patients, for dispensing reimbursed products. Pharmacies are also required to rebate the health insurers for 2.5% of the value of prescription-only medicines supplied.

VAT is 2.4% on all medicines. The standard rate is 7.6%.

4.4.29 UK

Components of the public price:

Public price = MSP + wholesale margin

Pharmacy remuneration for dispending under the National Health Service (NHS) is not part of the public price. As professional fees and allowances, it is paid separately.

Wholesale Margin

The wholesale margin for branded prescription products (whether reimbursed or not) is conventionally 12.5% of the public price. Wholesalers give an average of 10% of this away as purchase discounts to their pharmacy customers (table 4.35), who in turn lose much via the government's discount recovery scale (see below).

Table 4.35: Typical wholesaler discount structure to UK pharmacy customers

Qualifying monthly purchases (£)	Discount to pharmacies (%)
<1000	0
1001-15000	9.75
15001-25000	10.50
>25000	10.75

Source: trade

It is often stated that the 12.5% gross margin is laid down in the Pharmaceutical Price Regulation Scheme (PPRS). In fact, the only mention in the current (2005) Scheme and its two predecessors is the following: 'After appropriate consultation, the Department of Health (DoH) will from time to time indicate the level of margin normally allowable in published NHS prices of supplies distributed through wholesalers.' The 12.5% figure was apparently arrived at in 1983, when it was reduced to its present level from 15%. However, documentary evidence does not appear to exist, so 12.5% has, by default, become the recognised custom and practice.

A joint government/industry review of 'the appropriateness of the provisions relating to the distribution margin' was announced as part of the 2005 PPRS, before Pfizer announced changes to its method of distribution that triggered the Office of Fair Trading investigation into all aspects of UK distribution of NHS medicines. The DoH was already the recipient of annual cycles of financial data from brand companies under the PPRS, and quarterly sales and price data on generics from manufacturers and wholesalers. Since Pfizer's move, it has requested PPRS-member manufacturers to 'voluntarily' supply quarterly gross and net sales data on brands by customer group (i.e. community pharmacies, hospitals and dispensing doctors). A similar request has been made to wholesalers.

Unbranded generics are outside the scope of the PPRS and their wholesale margins are free. Trade sources suggest wholesale margins of 15-25% for generics. Generics and PIs are 'net price' items, i.e. they are not discounted by wholesalers. Also not discounted by wholesalers are narcotics, cytotoxics, cold chain or rarely used products. If the pharmacist is unable to obtain a

discount from a supplier for such items then no discount deduction is made, providing the product is included in Drug Tariff Part II on the list of 'Drugs for which discount is not deducted' (formerly known as the ZD or zero discount list).

As a consequence of their agency distribution schemes, GSK and Pfizer pay their distributors a flat rate fee per item handed rather than a percentage margin. This fee is thought to be in the region of £0.35-0.45, around the cost of domestic first class letter postage.

Pharmacy remuneration and reimbursement

Community pharmacies and self-dispensing doctors are paid via professional fees for the services they provide to the NHS and, in addition, are reimbursed for the costs of medicines they dispense less the statutory, fixed per item prescription charges they collect from patients.

For England and Wales, remuneration results from an annual cycle of negotiations between the DoH and the national representative bodies for pharmacy contractors (the Pharmaceutical Services Negotiating Committee; PSNC) and for dispensing doctors (Dispensing Doctors Association). Similar, but separate, negotiations take place between different bodies in Scotland and in Northern Ireland.

For the purposes of pricing a prescription and reimbursing the pharmacy or dispensing doctor for the expenditure entailed, the principle of paying the product's net acquisition price applies. However, the Prescription Pricing Authority (PPA) does not generally ask for invoice copies for each and every transaction. Instead, it initially bases reimbursement for branded products on published trade (or basic NHS) prices. For (unbranded) generics, the rates published in Part VIII of the Drug Tariff for England and Wales are used.

Because every NHS dispensing contractor can purchase at better than basic NHS prices, the DoH applies an adjustment procedure to all contractors to claw back on average the amounts in excess of net acquisition prices. This is done by offsetting reimbursement made to each dispensing contractor the following year. This adjustment procedure is known as the discount recovery scheme (though it is commonly referred to as 'the clawback'). It is based on periodic discount inquiries among a sample of contractors.

Discounts are provided by wholesalers or other intermediaries out of their distribution allowance from manufacturers, who are therefore the prime source.

The amounts initially reimbursed to dispensing contractors are based on one of the following:

- the list price of a brand according to the Chemist & Druggist (C&D) Price List;
- the price of a generic if it is listed in Part VIII of the Drug Tariff; or
- the price the pharmacist paid for a specifically ordered 'special' or unusual item as recorded on the invoice from the supplier.

Each branded product line – whether the regular version supplied by the domestic marketing company or a cheaper parallel-imported version – is priced according to the full C&D price of the domestic brand. In all other EU countries, PIs have different (lower) list prices than domestic equivalents, but in the UK part of the savings from PI use are instead recovered via the clawback.

Payment is usually calculated on the basis that the exact quantity prescribed has been supplied. Calculations for split packs are based pro rata on the pack size that the pharmacist has endorsed on the prescription. 'Special containers' that cannot be subdivided (e.g. collapsible ointment tubes, aerosol cans) and calendar packs are paid for in full even if a smaller quantity than their contents is prescribed, as is residual stock of unusual items (known as 'broken bulk').

Discount Clawback

The DoH in conjunction with the PSNC used to arrange annual discount inquiries among a sample of 350 pharmacies (out of the 10,500 total in England and Wales) to be able to calculate the level of discounts available on the average 'basket' price of drugs bought by the average contractor. (The Boots chain has always exempted its branches from the inquiry process, though the sample otherwise had the same pattern of ownership and range of outlet sizes as the national picture.)

Separate clawback calculations were made for discounts available for NHS dispensing with brands, generics and PIs, i.e:

- the actual discounts (from the C&D price) for all domestic brands purchased;
- the discounts obtained on a sample of 100 generics compared to fixed Drug Tariff rates;
- with PIs, a sample of 20 brands subject to competition from parallel trade was selected for survey and the 'discount' (i.e. the difference between the price of the domestic version in the C&D Price List and the average of five prices for the same product being offered by five different parallel trade suppliers) calculated.

These discounts are weighted according to their usage by value of each type in the contractors' returns and added together. GSK brands have been treated separately from non-GSK brands as a consequence of the UK company's changeover to dealing directly with pharmacies/dispensing doctors as part of its agency distribution scheme.

Discount is recovered using a percentage of the net ingredient cost (the sum of basic NHS prices of products dispensed in a month) and is identified on a contractor's monthly statement.

Before the clawback scale is finalised, the PSNC negotiates offsets with the DoH relating to additional costs faced by pharmacies and for pricing errors detected at the PPA.

An annual balance sheet is prepared that measures the actual discount recovered each month against the target percentage. At the end of each year any under- or over-recovery of discount is collected or paid back in the next year by a minor adjustment to the clawback scale.

Occasionally, there are shortages of Drug Tariff Part VIII generics, and pharmacies can claim reimbursement of the more expensive version supplied for products temporarily on the 'no cheaper stock obtainable' list.

The clawback is on a graduated scale in proportion to the value of items dispensed. The DoH assumes that the bigger the dispensing operation the greater its buying power and hence its ability to negotiate better discounts from suppliers (regardless of whether or not it actually uses that buying power).

Although the overall clawback figure is published, its breakdown is not, ostensibly on the grounds of confidentiality. The latest year for which information has been obtained from the PSNC (with GSK/non-GSK brand differentiation excluded) is 1994-1995 (table 4.36).

Table 4.36: Breakdown on pharmacy clawback in England and Wales, 1994-95

	Purchase weighting	Discount (%)	Gross discount weight
Domestic brands	83.47	7.18	7.00
Generics	8.83	18.79	1.86
PIs	4.15	13.47	0.56
Zero discount	3.55	-	-
Total/average	100.0	8.22	
Less offsets	(0.32)		
Average clawback target	7.90%		

Source: PSNC

This means that for reimbursement in the year from April 1994 the DoH assumed an average pharmacy (then dispensing 3,000 NHS items/month) could obtain the following:

- an average 7.18% discount on domestic branded prescription drugs, accounting for 83.47% of usage by value;
- an average 18.79% discount (relative to the Drug Tariff price) for generics, which were credited for 8.83% of value usage; and
- an average 13.47% discount (relative to the C&D price for the equivalent domestic brand), accounting for 4.15% of total usage.

Although often criticised, the discount/clawback approach does have some merits:

- discounts act as a competitive lever for wholesalers and ensure they get paid promptly;
- pharmacies like to think they can beat the system and profit; and
- for manufacturers, discounts give some small measure of control over the market.

The clawback theoretically acts as a price deflator, because it forces pharmacies to negotiate higher discounts/better prices with their suppliers to keep them on the right side of the discount average (i.e. retaining more than they have to pay back later). Again in theory, by pushing for higher discounts, pharmacies merely increase the clawback in subsequent years. Pharmacies might be temporarily in pocket, but the only winner at the end of the day is the DoH.

The clawback is also the only direct means for the DoH to realise savings from the use of PIs. In fact it is the main driver for PI use. Those pharmacies that don't dispense PIs and cannot obtain equivalent discounts on domestic brands will be out of pocket. After the 1989 discount inquiry, the proportion of the clawback attributed to PIs increased three-fold and was the main trigger for a decision by Boots to first stock PIs.

Though discounts obtainable on PIs have fallen and generic market prices are now much closer to those in the Drug Tariff, the discount environment for brands tended to be fairly stable. With a clawback purchase weighting in excess of 80%, the greatest potential losses to dispensing contractors would follow if they failed to hit the discount target on brands. Hence the huge outcry when the Glaxo agency scheme was announced in 1991. With Glaxo brands then accounting for more than 15% of the UK prescription market, pharmacies were worried that they would have difficulty in achieving the threshold level of purchases from wholesalers to qualify for the same level of volume discounts as before (once Glaxo lines had been taken out of the system).

The alternative to the clawback – reimbursing pharmacies for the actual purchase price of each and every item dispensed – is seen as a bureaucratic nightmare, and from the DoH's perspective it would also remove the incentive to purchase as economically as possible. The UK market is different from all others in Europe in that 80% of prescribing is for unbranded products (whether these are off-patent or not).

The clawback continues today. In England and Wales for pharmacies it averages 9.5.%. Annual savings to the NHS from the clawback exceeded £900 million in 2005. However, the current discount recovery scale remains based on the most recent discount inquiry that was conducted in 2001. The DoH has accepted a PSNC request that further inquiries are unnecessary, though these continue in Scotland.

The change has come about because of two main factors:

- The majority of pharmacies are now in chains, with chain ownership often in the hands of the big wholesalers. Vertical integration has changed the discounting relationship between wholesalers and the pharmacies they own.
- A new pharmacy contract came into effect from April 2005. As part of the deal, the DoH has assured pharmacies they can retain £500 million of their purchase profit each year. As a check on this, the PSNC collects and analyses actual discounts offered on a DoH-selected sample of products to a sample of pharmacies. The £500 million is being refunded to pharmacies by quarterly adjustments to the Drug Tariff reimbursement prices of the commonest (Category M) generics. An additional £300 million in wholesaler discounts per annum is being

recovered and used to fund the new clinical services that pharmacies are being encouraged to offer.

With the clawback continuing it can only mean that total purchase profits from discounts amount to a minimum of £800 million (the clawback) + £500 million + £300 million, a total of £1.6 billion, though the PSNC will not confirm this.

Dispensing Doctors

As part of the latest dispensing doctor NHS contract from April 2006, the on-cost – the link between remuneration and drug costs - has been dropped. Payment now follows the same principles as for community pharmacies. However, instead of a flat rate dispensing fee there is a sliding scale based on prescribing volume (per prescriber, not per practice) (table 4.37).

Table 4.37 : Dispensing fees for UK dispensing doctors

Prescription items per month	Dispensing fee per item (£)
<400	2.309
401-500	2.276
501-600	2.246
601-700	2.218
701-800	2.192
801-900	2.168
901-1250	2.145
1251-1750	2.125
1751-2000	2.107
2001-2500	2.090
2501-3000	2.076.
3001-3500	2.064
3501-4000	2.053
>4000	2.045

Source: Dispensing Doctors Association

The average fee paid between April-November 2006 was £2.139.

Dispensing doctors also benefit from procurement discounts and hence are subject to the clawback. As with pharmacies, the clawback percentage increases in bands. These bands currently run from 3.17% (for practices - not individual prescribers - with monthly drug costs up to £2000) to 11.18% (for practices whose monthly drug costs exceed £24,000). Most practices fall into one of the two top price bands and are therefore subject to discount deductions of 11.03% or 11.18%. Unlike pharmacies, zero-discounted items are not exempted from the dispensing doctor clawback.

There is also a voluntary dispensary services quality scheme, which if satisfactorily completed pays £2.58 per dispensing patient.

All costs of running a dispensary are met from the dispensing fee and procurement profits that are not clawed back. However, income is not inconsiderable. It has been estimated by the Dispensing Doctors Association that, comparing a dispensing with a prescribing practice having similar numbers and types of patients, dispensing income subsidises medical services to the tune of about £30,000 per general practitioner per annum.

OTCs

Wholesale and retail margins are negotiated on a free market basis, but the manufacturer will typically receive half of the public price (excluding VAT).

VAT

General practitioner prescribed items under the NHS are exempt from VAT, while VAT at the standard rate of 17.5% applies to OTCs, private prescriptions and hospital drugs.

4.5 Private Prescriptions

In most EU countries where the wholesaler margin under the statutory scheme is set by law, manufacturers in practice offer the same margin to non-reimbursed prescription brands. Wholesalers are therefore indifferent as to whether the product is going to be dispensed against a social health insurance prescription or against a private prescription - not that they can do anything about it. This is the situation in Belgium, Spain and the UK, for example, but not in Italy, where the wholesale margin for non-reimbursed category C lines is freely set.

Pharmacists like private prescriptions for two main reasons. Firstly, they provide cash in hand – full payment is received at the time of dispensing rather than several weeks or months later as happens with social health insurance reimbursement. Secondly, private prescription margins in some countries are free from government interference. Margins for private prescriptions may be freely set in France, Italy, Poland and the UK, for example,

Non-reimbursed category C prescriptions can be especially profitable for Italian pharmacists as manufacturers often use promotional offers.

While pharmacy mark-ups in Germany have been liberalised for OTC medicines, they remain fixed for prescription drugs (at 3% of the pharmacy purchase price plus a consultation fee of €8.10), whether reimbursed by the statutory sickfunds or not. Similarly, in Denmark, pharmacies earn a flat rate DKK 20 profit per prescription plus 8.5% which is largely paid back into an equalisation fund. In the Netherlands all prescription drugs attract a fixed dispensing fee of €6.10. In Belgium, Spain and Sweden too the margin scales are common for reimbursed and non-reimbursed prescription products alike.

CHAPTER 5
PROFILES OF LEADING DISTRIBUTORS

5.1 Alliance Boots

With more than 100,000 employees, Alliance Boots (www.alliance-boots.com) was formed from the £7 billion merger in July 2006 of Alliance UniChem and Boots. Together with associates, its 380 wholesale warehouses serve 125,000 pharmacies, hospitals and health centres in 14 countries in Europe, Asia and Africa. The company has 3,000 retail stores (2,700 of which are pharmacies) in five European countries as well as in Thailand, which dispense a total of 160 million prescriptions a year.

Just seven months after the merger, the board backed a £11.1 billion takeover offer from Stefano Pessina, its executive deputy chairman, to take the company private, backed by Kohlberg Kravis Roberts, an American private equity firm.

Alliance UniChem itself was created in 1997 by the merger of UniChem and Alliance Santé.

Established as a pharmacy buying group in the UK in 1938 with just 100 customers in its first trading term, UniChem first developed as a co-operative then converted to a public limited company and was listed on the London Stock Exchange in 1991. The following year it acquired a 92-strong pharmacy chain, Moss (including 29 pharmacies situated within supermarkets). Before this time UniChem had not owned a single pharmacy, as its rules as a co-operative precluded this. During the period up to the merger with Alliance Santé, Moss expanded to more than 500 outlets and the company also merged its Portuguese wholesale business with the Portuguese business of Alliance Santé.

Alliance Santé was formed in 1989 as a loose affiliation between an existing Franco-Portuguese group, Européenne de Répartition Pharmaceutiques et d'Investissements, France's Ile de France Pharmaceutique and Alleanza Farmaceutica of Italy. The new group signed an alliance with Spain's SAFA (somewhat paradoxically, given subsequent developments, this move was designed to fend off foreign entry into the latter's market). It then acquired a stake in a start-up Greek venture, LAS, together with local manufacturer/distributor Lavipharm.

Boots was created from a single Nottingham pharmacy 130 years ago. Early development was through organic growth but was followed by an acquisition strategy. Until recently, when it was overtaken by Lloyds, Boots was Europe's largest pharmacy chain for more than a century. Most of its early non-UK retail operations were unsuccessful, however. Openings in Canada, Japan, the Netherlands and New Zealand were soon closed down, though Boots has since returned to the Netherlands.

Beginning in January 2007, Alliance Boots has been rebranding its wholesaling businesses as 'Alliance Healthcare'. These are present in the Czech Republic (www.alliance-healthcare.cz), France (www.alliance-healthcare.fr), Norway (www.holtung.no), Russia (www.alliance-healthcare.ru), Spain (www.alliance-healthcare.es)and the UK (www.unichem.co.uk), as well as associates in Egypt (UCP), Germany (www.anzag.de), Portugal (www.alliance-healthcare.pt), and Turkey

(www.hedealliance.com.tr). It also entered into an agreement to form a joint venture with Guangzhou Pharmaceuticals of China.

Its retail pharmacies are found in Ireland (Boots), Italy (Alliance Farmacie Comunali), the Netherlands (Alliance Apotheek and the Kring Apotheek franchise), Norway (Alliance Apotek), Russia, Switzerland (Amavita) and the UK (Boots). Its own UK outlets are again having to be being renamed. After the merger with Alliance Santé, Moss Pharmacies were changed to Alliance Pharmacies (www.alliancepharmacy.co.uk) and now, along with Boots Pharmacies (www.boots.com), they will become Alliance Boots Pharmacies.

Boots has always been at the forefront of delivering innovations in pharmaceutical care in the UK. It was the first pharmacy group to start home delivery of medicines and the first to offer monitored dosage systems as a compliance aid with multiple medication for residential care homes. Because it has acquired the appropriate registration, Boots is presently the only pharmacy chain to operate private Patient Group Directions (PGDs). These allow certain of its pharmacists to agree treatment protocols for defined patient groups with local doctors, and take responsibility for prescribing and treatment delivery. Under a PGD, Boots is piloting an erectile dysfunction programme in three stores in Manchester. When it is clinically appropriate, this allows men to be prescribed sildenafil by pharmacists after an initial consultation.

Other pharmaceutical care initiatives available at selected UK Boots branches include hair retention programmes, weight loss programmes, healthy heart checks, Chlamydia screening, emergency hormonal contraception, osteoporosis screening, anticoagulation clinics, substance misuse and needle exchange services, and the NHS minor ailments scheme. In 2006, Boots pharmacists delivered over 100,000 medicines use reviews and 16,000 people received influenza vaccination by nurses employed for this purpose in 130 Boots pharmacies.

Bringing together community pharmacists from eight countries (UK, France, Italy, Spain, Portugal, Czech Republic, the Netherlands and Switzerland), the European Pharmacists Forum (www.europeanpharmacistsforum.com) is sponsored by Alliance Boots.

Most recently, in a move that was said to be partly designed to help both companies become truly global players, a sourcing and marketing agreement was signed between Alliance Boots and major US distributor and healthcare services company Cardinal Health. The first result is expected to be the US introduction of Alliance Boots' Almus range of generics. Cardinal, one of the 'big three' wholesalers in the US with a turnover approaching $90 billion, only has manufacturing interests in Europe, having already sold to Alliance UniChem the UK shortline distributor companies it earlier acquired from Intercare for £38 million. Alliance Boots has now consolidated and rebranded these as Cordia Healthcare. Some believe that should the group ever wish to divest its full-line wholesaling interests, Cardinal could be a likely bidder.

5.2 Celesio

Founded as a wholesaler in Dresden by Franz Ludwig Gehe in 1835, Gehe changed its corporate name to Celesio in 2003, its 100th year as a public limited company (though it still trades as Gehe in Germany). Celesio (www.celesio.com) is headquartered in Stuttgart and listed on the Frankfurt

Stock Exchange. Turnover in 2006 amounted to €21.6 billion, with net profits rising 10% to €425 million. Its EU wholesaling share was 20%.

International expansion took off with the purchase of France's leading wholesaler OCP for FFr 2.6 billion in 1993 followed by AAH of the UK for £400 million two years later. Later acquisitions have included a share in Germany's Anzag (2003), and SEUR (Spain), Realpol (Czech Republic), Sanalog (Germany) and Soquifa-Medicamentos (Portugal), all in 2004.

Prohibited from expansion into pharmacy retailing in Germany, Celesio has built up through acquisition a number of chains elsewhere, totalling 2,100 pharmacies in seven countries. The key development occurred in 1997, when Gehe acquired for £684.6 million the UK pharmacy chain Lloyds which had grown from a single pharmacy in 1974 to 902 outlets. Second-ranked wholesaler UniChem, which also had its own 460-strong Moss pharmacy group, tried unsuccessfully to outbid AAH/Gehe for Lloyds. Gehe's UK wholesaling company AAH had already built up a 400-strong chain of its own, trading under the Hills banner. Simply adding Hills to the Lloyds total resulted in a chain of 1,300 outlets, larger numerically than Boots, even after a number of overlapping premises were sold back to the independent sector, though smaller in turnover.

Lloyds branches dispensed 122 million NHS prescriptions in 2006, performed 160,000 medicines use reviews and, under its 'champion the health' initiative, offered free diabetes testing (750,000 people tested to date) and free blood pressure testing (1.4 million people tested to date), and distributed one million nit combs free of charge. Lloyds was the first UK pharmacy chain to become accredited to process electronic prescriptions.

A number of non core business have been divested including the group's German generic production interest, Gehe Medica (consisting of Azupharma, Jenapharm, Aliud Pharma, Allphamed and GNR-Pharma), and Lloyd's UK healthfood store chain Holland & Barrett.

Table 5.1: Celesio's wholesaling and retailing interests in Europe, 2006

Country	Wholesaling branches (employees)	Wholesaling revenue (€ million)	Pharmacies (employees)	Pharmacy revenue (€ million)
Austria	7 (787)	906.5	-	-
Belgium	5 (301)	384.9	91 (431)	97.6
Czech Republic	3 (217)	186.1	43 (351)	36.3
Denmark	4 (263)	198,1	-	-
France	52 (4664)	7039.9	-	-
Germany	19 (2502)	3632.5	-	-
Ireland	3 (244)	299.2	60 (987)	121.6
Italy	1 (150)	127.6	162 (758)	205.5
Netherlands	-	-	56 (878)	151.9
Norway	4 (445)	442.3	132 (1387)	391.4
Portugal	9 (297)	476.9	-	-
Slovenia	9 (543)*	315.6*	-	-
UK	19 (3912)	3455.0	1556 (15543)	2266.0
Total	135 (14325)	17464.6	2100 (20335)	3270.3

* including subsidiaries in Croatia and Romania

Source: Company website

Celesio's April 2006 decision to takeover Doc Morris (see below) led predictably to a backlash by German pharmacists, who had been battling through the courts for several years against the controversial internet pharmacy. Several pharmacy customers are said to have switched away from Celesio to other wholesaler accounts. The company admitted that its first-half 2007 revenue growth was depressed by a combination of this factor in Germany and the loss of Pfizer business in the UK. Relations with German pharmacists worsened when, apparently acting on a tip-off from two Celesio branches, competition authorities raided the offices of pharmacy organisations looking for evidence of a collective boycott against the wholesaler.

5.3 DocMorris

DocMorris (www.docmorris.com) started as an internet pharmacy in 2000 in Luxembourg financed by external investors. Because of the complexities of doing business in the Grand Duchy, the pharmacy moved after a few months to Heerlen in the Netherlands, close to the German border. It enjoyed 91% CAGR between 2002 and 2005, and has shown profitable operating results since 2004. 2006 turnover was €175 million, almost entirely based on sales to German patients, especially with prescription medication.

Over half of patients are more than 50 years old, most suffer from chronic illnesses, and the majority live in urban areas. DocMorris is now by far the largest pharmacy serving Germany, with over 800,000 customers since it began, a market share in excess of 1%, and holding an estimated 80% of German mail-order business. Because of all the court actions and publicity given to ABDA complaints and its *Initiative Pro Apotheke* (Campaign for Pharmacies) aimed at stopping DocMorris, it is now one of the most recognisable brand names in Germany. It has 330 full-time employees.

The Netherlands has maximum, not fixed prices, and DocMorris has been able to attract business by offering a combination of 50% savings on statutory co-payments to German patients and lower prices/rebates to German sickfunds. In return, many sickfunds direct their members to the DocMorris website, and make provision to be invoiced directly by it.

Because of the need for the pharmacy to receive the patient's prescription before dispensing, almost 90% of orders come by mail, with 9% online and 1.5% by telephone.

DocMorris delivers free of charge to the patient (average delivery time 2-3 days). Around 80% of prescriptions are repeat ones, and the company claims to save each chronic patient €60-100 per year on average. It also dispenses private prescriptions, when a €2-3 rebate from DocMorris to the patient is provided. German pharmacists are not allowed to discount the *Lauertaxe* price. However, a court ruling decided that in offering lower prices, DocMorris did not infringe the price regulation because this regulation did not cover cross-border transactions. The court also did not see a problem with DocMorris' practice of reimbursing patients for half their statutory co-payment for sickfund prescriptions. Medication profiles are provided to every patient on a quarterly basis (covering only medicines obtained from DocMorris) and warning letters are sent to the patient's physician if a potential drug interaction is detected.

A retail branch of DocMorris opened in the German city of Saarbrücken in July 2006, making it the first non-pharmacist owned pharmacy in the country. The regional Ministry of Justice, Health and Social Affairs in Saarland ruled the pharmacy was legal, leading to several complaints by local community pharmacists and by ABDA. These were soon dismissed by a regional court, which decided that the Dutch firm was not breaching any competition law, but an administrative court ordered DocMorris to suspend operations from Saarbrücken while compliance with German pharmacy establishment rules was assessed. The higher administrative court of Saarland then lifted the operational ban (arguing that employment of qualified staff was sufficient to meet safety concerns) and referred the matter to the ECJ for final resolution (joined cases C-171/07 & C-172/07). The German government has said current pharmacy regulations guarantee 'the independence of the pharmacy profession and serve to safeguard public health and protect consumers'.

In another controversial development, DocMorris is trying to attract independent German pharmacies to join its brand partnership. This is apparently a form of franchising (franchising itself is illegal in Germany) that goes beyond the 'co-operation' that many German pharmacies currently have with forms of buying groups. The aim is to have 100 pharmacies signed up by the end of 2007, and 500 contracted by 2011. (As of September 2007 the number had reached about 40.) DocMorris pharmacies attempt to cash in on the name of the online pharmacy that most Germans associate with discount drugs, though the emphasis is on OTCs. Private label OTCs and generics are planned.

In a move that infuriated its pharmacy customers at home, German full-line wholesaler Celesio recently acquired a 90% stake in DocMorris for €200 million. Doc Morris will remain a separate legal entity from Celesio but it will add total revenues of €172 million and the branded pharmacies from which DocMorris draws monthly fees.

5.4 OPG

OPG (www.opggroep.nl) is the clear leader in all sectors in the Netherlands it has entered: wholesaling, prewholesaling, community pharmacy, medical supplies, homecare and parallel trade. It was also one of the first wholesalers to diversify into different business areas and into other countries.

Founded in Utrecht by a group of local pharmacists in 1899 as Onderlinge Pharmaceutische Groothandel (Mutual Pharmaceutical Wholesalers), the company was listed on the Amsterdam stock exchange in 1991, although its co-operative status was initially retained. However, soon a wider shareholding base (principally insurance companies) was considered necessary to fund expansion, especially abroad.

International developments were first through collaboration with UniChem and Sanacorp in the Pharma-Holding AG alliance, which then developed into the larger International Pharmaceutical Service Organisation alliance that rented an office on OPG's Utrecht site. In 1995, OPG purchased a Belgian co-operative wholesaler, Flandria, against strong competition from another co-operative in the Flanders region, Inter Nos. After the bankruptcy of fellow Dutch wholesaler Medicopharma, OPG acquired several depots for servicing dispensing doctor accounts plus Pharbita to add its own generic manufacturing interests, Pharmachemie.

Within the Netherlands, OPG Groothandel offers wholesaling services to pharmacies, OPG Medico supplies dispensing doctors, and OPG Distrimid supplies hospitals. The company operates in the medical supplies and associated services market under a variety of names – Combicare (stoma/incontinence care, wound care), Hermedico, DiabetesDirect (both diabetes care), Zorg Service Nederland (service to homes for the elderly) and Tefa-Portanje (feeding and intravenous technology, respiratory care). OPG's Polyfarma is the country's leading parallel importer.

Under the Red Swan name (www.red-swan.nl), OPG provides both prewholesaling services in the Benelux countries (Pharma Logistics division) and specialist distribution of biopharmaceutical products to Dutch patients living at home with associated nursing services (Pharma Services division). Established in 1990, Pharma Logistics has 50 principals, 80 employees and a 14,000 square metre warehouse facility. Just as with prewholesaling, OPG pioneered homecare in the Netherlands, setting up Pharma Services in 2004. It currently has 60 employees and 11 principals, and supplies high-tech drugs and services to 15,000 patients.

The company today has a market capitalisation of €1.5 billion and is active in seven countries apart from the Netherlands: Belgium (wholesaling), Denmark (medical supplies), Germany (medical supplies), Hungary (medical supplies), Norway (medical supplies), Poland (prewholesaling, wholesaling & retailing) and Switzerland (medical supplies). OPG has a particularly strong hold on the diabetic supply market in Germany, having acquired DiabetConcept to add to its existing Dia Real operation there. Leading Danish homecare medical supplies company Kirudan was also acquired in 2007.

In 1995, OPG first entered the retail market by acquiring all eight Dutch pharmacies in the Mediveen chain from the department store group, Koninklijke Ahold. It now owns 223 pharmacies, giving it a 14% retail

market share, with another 250 Dutch pharmacies as customers of OPG wholesaling. OPG's Mediveen pharmacies are being rebranded as Mediq Apotheek healthcare centres ('patient becomes customer'), including independent local doctors on the premises. The Mediq concept is also open to independent pharmacies to join as a franchise. Each centre offers longer opening hours, a greater choice of self-care products, on-line health information, 24-hour patient access to personal medication lockers with PIN codes, and home delivery. 'You have to be different to DHL or UPS otherwise you do not have a business model', OPG's Marc van Gelder argues.

Separate divisions offer pharmaceutical packaging (www.pharmapack.nl) and contract analytical services (www.reilabs.nl). OPG's generic production arm in Haarlem, Pharmachemie, was sold to Teva.

5.5 Phoenix

Phoenix (www.phoenix-ag.de) is part of the Merckle family group, which also includes the German generic manufacturer, ratiopharm. It originally consisted of the five German regional wholesalers acquired in 1994: Ferd Schulze (Mannheim) and Otto Stumpf GmbH (Berlin), and listed firms F Reichelt (Hamburg), Otto Stumpf AG (Nuremburg) and Hageda (Cologne). Turnover in 2006 amounted to €19.89 billion. Supplying 43,000 pharmacies with 100,000 deliveries per day, Phoenix' EU wholesaling share in 2006 was 18%.

Presence outside Germany has been built up through acquisitions that included Comifar (Italy), Hestag (Austria), Commercio Ingrosso Medicinali (Italy), Brocacef (Netherlands), SAM (Italy), Parma (Hungary), Ardeapharma (Czech Republic), Calix (Hungary), Fides (Slovenia), Libra (Bulgaria), and most notably the leading player in the Nordic area, with a current 54% regional market share, Tamro. In 1995, its hundredth year of operation, Finland's Tamro acquired Sweden's leading wholesaler ADA and, in 2000, concluded a strategic alliance with Phoenix. This was followed by Phoenix taking a majority stake in the Scandinavian wholesaler in 2003, which it converted into a 100% holding the following year.

Through Tamro, Phoenix has come to dominate Scandinavia and the Baltic States. Tamro and ADA had a pre-existing joint venture in the Baltics, Oy Tamda, with depots in all three countries (Tallinn and Tartu in Estonia, Riga in Latvia, and Kaunas in Lithuania), as well as in the St Petersburg area of Russia. Although pharmaceutical consumption was only 10% of that in Sweden or Finland, the combined population of the Baltics (23 million) and the growth potential were considered major attractions.

Phoenix' nationwide presence in the UK was assembled by the acquisition and integration of a number of regional wholesalers, including East Anglian Pharmaceuticals and Numark, a pharmacy buying group for own-brand OTCs.

Phoenix today has a wholesaling presence in Austria, Bulgaria (Libra), Croatia, the Czech Republic, Denmark (Nomeco), Estonia (Tamro), Finland (Tamro), France, Germany, Hungary, Italy (Comifar), Latvia, Lithuania, the Netherlands (Brocacef), Norway (Apokjeden), Poland, Slovakia, Sweden (Tamro), Switzerland (Amedis) and the UK. Through Libra, Phoenix now also reaches into Macedonia and Serbia. It claims leading positions in 12 of these 20 countries: Bulgaria, Czech Republic, Denmark, Estonia, Finland,

Germany, Hungary, Italy, Latvia, Lithuania, Slovakia and Sweden. Pharmacies are owned in Austria, Estonia, Italy, Latvia, Lithuania, the Netherlands, Norway, and the UK.

CHAPTER 6
PROS AND CONS OF THE TRADITIONAL WHOLESALE MODEL

6.1 Wholesalers' Case

Wholesalers argue their core services are speedy, efficient, reliable, comprehensive and cost-effective for all parties. Because incoming orders are pooled, complexity is minimised and there is a reduction in transaction costs between parties at either end of the chain.

In a paper commissioned by GIRP[8], researchers at the Institute of Pharmacoeconomic Research in Vienna estimated that the current impressive total of 28 billion pharmaceutical distribution transactions a year in EU countries would increase to an improbable 528 billion without the involvement of wholesalers. On average every working day in 2004, a European full-line wholesaler received 13,181 orders (in Germany the daily average was 64,700).

Costs for the manufacturer associated with direct distribution – warehousing and transportation, order processing and credit control, bad debts, negotiation of price and discount structures, and marketing activities by a sales force – are especially difficult to justify if the majority of accounts order relatively small amounts on a frequent basis. From a nationwide perspective, a wholesaler's network makes 100% market coverage easier to attain.

To generate loyalty to a particular wholesaler, added value services are routinely offered, both to suppliers and to pharmacy customers. These services can be expensive to provide, so they sometimes attract a separate fee. Alternatively, they may be built into modifications of the margin and discount structures.

Full-liners stock virtually every medicine marketed in the country in which they operate. Because in their levels of service they do not distinguish between products (and hence between manufacturers) market access is assured for all. Equal treatment is especially important for small and medium-sized manufacturers.

For manufacturers, the advantages of using wholesalers include the following:

- provide efficient and cost-effective logistics;
- rapid distribution of new products at launch;
- reduce transactions via aggregate ordering and shipments;
- handle difficult SKUs including narcotics, refrigerated products and biologics;
- manage accounts receivables and assume customer credit risk;
- handle customer service;
- provide inventory and sales data to optimise delivery schedules and production planning;

- design interfaces for coded transmission of orders and invoices;
- allow focus on core competencies;
- data and information tracking and reporting;
- manage contracts;
- prompt and efficient system for handling recalls and withdrawals (credit, logistics and destruction);
- reduce waste and related costs in the supply chain through just-in-time inventory management;
- collecting, destroying or exchanging out-of-date stock;
- reduce medication change requests due to product unavailability or high minimum order requirements on pharmacies;
- support medication compliance by patients as repeat medication available when needed; and
- supply of product samples and promotional material to pharmacies and dispensing doctors.

For pharmacies, advantages include the following:

- fewer orders, deliveries and associated administration functions;
- scheduled twice daily same or next day delivery;
- order fill rates consistently >95%;
- product delivery in small, manageable quantities;
- no minimum order or delivery charge;
- sales-related discounts;
- credit;
- inventory management systems (bar coding, stickers, shelf labelling, price labels, electronic order entry);
- point-of-sale equipment;
- emergency supplies;
- remote pharmacies not penalised by additional transport costs, delivery delays or minimum order requirements;
- lower inventory, better inventory control and improved cash flow due to no minimum order requirements;
- single source for all inventory needs;
- special handling for narcotics, cold chain/frozen products and biologics;
- own brands;
- sourcing programmes for generics;
- collection of out-of-date products;

- collection of packaging waste;
- creates greater availability of pharmacist for patient access and care;
- returns and recall processes;
- ensures a safe and efficient supply chain;
- marketing and logo identity programmes;
- advice on taking over existing businesses, opening new businesses or modernising old premises;
- advice on pharmacy layout and merchandising of stock;
- continuing education and in-store staff training programmes; and
- financial and accounting services.

Although the big wholesalers are able to supplement their wholesaling operations with income from retailing and other activities, income from the wholesale margin is crucial. Unlike in the US, there is no stock price inflation in Europe for wholesalers to benefit from. If manufacturers' prices change the direction is invariably downwards.

The margin structure and therefore the entire economics of wholesaling is based on handling a mix of goods – high-volume, high-priced blockbusters and slow-moving, low-cost lines alike. The former subsidise the latter. Margin erosion is just one of the threats facing wholesalers today (table 6.1).

Table 6.1: Threats to full-line wholesaling

Problem	Impact
Higher fuel, transport and staff costs	Higher costs
Product price cuts	Stock deflation, lower base on which margins are earned
Erosion of margins	Fall in income
Liberalisation of retail markets	Market entry by non-pharmacy retailers not serviced by pharmaceutical wholesalers
New distribution channels to patients and wholesalers mail order pharmacies online pharmacies homecare	Wholesalers cut out from business
Direct distribution	Wholesalers cut out from business
Increasing generic use	Reducing line values with costs unchanged
Counterfeit medicines	Impair reputation of secure supply chain
Manufacturer supply quotas	Unable to increase market share or meet increased demand from existing accounts
Using wholesalers as LSPs	Fee-for-service not margin

Source: author

While direct distribution is a more recent threat, supply quotas have been a growing problem for wholesalers since 2001. Most multinational manufacturers now fulfil only those orders necessary to supply the domestic market plus a safety margin, at least for some products and in some European markets.

For legal reasons (i.e. so as not to breach Article 81 EC), quotas are imposed unilaterally by manufacturers without any negotiation over the amounts allocated to each wholesaler for each time period, with little or no explanation, and often with no flexibility to allow for unforeseen events. In many instances, wholesalers say, there is no possible way for them to receive more than the predetermined amount, even when there are *bona fide* higher demands from their usual pharmacy customers and the manufacturer has the stock available to meet this demand.

Wholesalers point out that they are unable to supply customers with substitutes, even near identical PI forms. There are legal issues and also technical ones (e.g. the ordering system does not provide for the possibility to supply alternates). Consequently, from the wholesaler's perspective, each specific product as prescribed and ordered constitutes a separate market. In the light of the dependence described above, manufacturers have to be considered dominant within the meaning of Article 82 EC and supply restrictions are an abuse of that dominant market position, they say.

Quota systems result in wholesalers experiencing shortages of supply, lost sales and increased costs. They make it impossible for new wholesalers to enter the market and prevent existing players from increasing their market share, wholesalers say. Quotas also prevent them from meeting their public service obligations laid down in law. Though wholesalers strongly dislike supply quotas, unlike parallel traders it is rare for them to file formal complaints against such schemes with the competition authorities. GIRP has lodged at least one Article 82 EC complaint with the European Commission – against quotas applied by GSK. The outcome is believed to be pending.

6.2 Areas of Tension

Europe's manufacturers and wholesalers have generally got on with their primary tasks of drug development/commercialisation and distribution well. The wholesaler was seen as the most effective way to contain logistics costs as well as ensuring pharmacies speedily got the right medicines they needed for their patients, but cracks have long been showing in the relationship[9]. As the wholesaling sector has assumed a higher profile than before, it has come under closer scrutiny, and some companies have not liked what they saw.

Manufacturers have seen the move by some wholesalers into generic and OTC production, and especially into retailing, as a direct threat. They were distinctly uneasy when wholesalers legitimised and then boosted parallel trade or encroached on the hospital market, and reacted with trepidation to the implications of the emergence of powerful pan-European groups.

For their part, wholesalers' greatest fears are of direct distribution or being bypassed by other initiatives like online pharmacies or homecare. The involvement of manufacturers, however much at arm's length or localised, in their core business of distribution was unsettling. In a few instances – more than 10 years ago with Glaxo's agency scheme in the UK and Bayer alone with OTCs or the PharmaLog consortia of manufacturers (both Germany), or now with Pfizer's direct distribution initiative – the tension rose to the surface. In most cases, it simmered below, unseen by outsiders.

Part of the problem is the way each party sees the other. Rarely is it a meeting of equals and both sides fear the other has a hidden agenda. Their views on 'who is the customer' also differ. Prescription drug manufacturers

have always recognised the need to be close to the prescriber and, more recently, the patient; sometimes the pharmacist has entered the picture as well. Despite the fact that some 90% of their stock is bought by wholesalers, this group is rarely spoken of by manufacturers as 'the customer'. Wholesalers, however, have always kept in closest contact with their main market, community pharmacies, although in deference to the research-based manufacturer's monopsony in the supply of patented brands, they have tried at least to maintain dialogue with this side too. It has always been a fine balancing act.

Neither group really believed there was a commonality of objectives; those of each side were fundamentally different. Wholesalers want to dominate distribution in the markets in which they operate and expand their role and function elsewhere; manufacturers want to limit wholesalers' power and stay in control. Wholesalers seek larger margins and access to more products, whereas manufacturers want to curb their distribution costs while limiting competition from generics and PIs. For a manufacturer, investment in R&D is aimed at new drug discovery and development, whereas for a wholesaler it means new systems and automation.

6.3 Specific Manufacturer Concerns

6.3.1 Fear and Distrust of Wholesalers' Growing Strength and Diversification Strategies

The larger wholesalers have been expanding continuously through mergers and acquisitions, spreading internationally and vertically integrating into retailing wherever possible. With annual turnovers in excess of €20 billion, they are larger than many manufacturers.

Many companies query the rationale of giving wholesalers a generous distribution margin, if wholesalers give much of this away as discounts to pharmacies in order to boost their overall business and not that of the manufacturer.

With wholesalers' most recent move to rebrand their own pharmacies as healthcare centres, offering a wide range of health-related services and information and not just healthcare products, the manufacturer is pushed further away from the market.

6.3.2 Wholesalers and Parallel Imports

Though they are sometimes reluctant to admit it, wholesalers act as the main source for parallel trade in the countries of supply and the main customers for it in the countries of destination. All co-operative wholesalers in France and Spain have traditionally exported (as indeed have virtually all wholesalers in both countries), whereas Greek co-operatives supply only the domestic market. The leading specialist exporter in France, Pharm-Lab, is a subsidiary of CERP Lorraine, and most of the other 'domestic' wholesalers there have shown significant export activity in the past.

On the incoming side, wholesalers are also closely involved. All parallel trade in Scandinavian countries is supplied to pharmacies by wholesalers, and in both Germany and the UK this channel accounts for about 70% of parallel imports.

Several wholesalers have gone further and created their own shortline supply divisions or even acquired specialist parallel trading companies. For example, Alliance Boots has the following parallel importing/exporting subsidiaries:

- Cordia – consolidating the former PI interests of Cardinal Health (Eurochem/Europharm) acquired from Intercare, plus OTC Direct and Beachcourse (UK);
- Stephar (Netherlands);
- Centro Farmaceuticos de Asturias (Spain)

In 2004, Boots' 1,500 community pharmacies in the UK filled 160 million prescription ítems and did so in part with the 600,000 PI packs per month the pharmacy chain purchased from a range of parallel importers.

6.3.3 Margin Structure Unsuitable for Speciality and High-priced Products

Margins for wholesaling (as well as for community pharmacy) in the top five European countries are set by law for all reimbursed prescription medicines. These margins are capped in some countries (e.g. Italy and Spain) for very expensive products, whilst in others a percentage mark-up scale applies. The average gross wholesale margins (expressed as a percentage of the public price) are in France 9.7%, Germany 17.4%, Italy 9.1%, Spain 9.6% and the UK 12.5%. Though suitable for high volume/low priced products, these margins are thought to give a disproportionate reward to wholesalers for handling low volume/high priced products – the very type of product that now increasingly fills development pipelines:

- of 31 new molecular entities first launched in 2006, 18 were speciality products;
- no fewer than 18 (27%) of the 78 marketing authorisation applications for new molecular entities received by the EMEA in 2006 were for EU-designated orphan drugs; and
- 27% of the industry's development pipeline is represented by products of biotechnology.

6.3.4 Wholesalers Not Main Channel for Distribution to Hospitals

Depending on the country, the hospital market represents 15-30% of total pharmaceutical sales, yet distribution to hospitals Europe-wide accounts for only 8.5% of an average wholesaler's business.

This situation is due to a number of factors:

- More predictable product usage, making forecasting easier and reducing the need for frequent deliveries.
- The common use of tenders or contracts by hospitals to purchase supplies in bulk.
- The availability of larger storage areas within hospitals.
- Special conditions or packaging needs of hospitals.

- Slow payment/debt problems with hospitals, especially in southern and eastern Europe.
- Manufacturers' fears that details of generous discount deals/free stock will leak to other hospitals or to national payers.
- Manufacturers' fears of discounted stock diversion to community pharmacies.

Instead of using wholesalers, manufacturers have established a pattern of direct deliveries and less frequent delivery cycles ho hospitals in many countries (e.g. Austria, Belgium, France, Germany, Greece, Italy, Portugal and Spain). Only in Denmark, Finland, Ireland, the Netherlands, Norway, Sweden and the UK are wholesalers involved in distribution to hospitals, and then at widely different rates, depending both on the country and company policy.

Hospital drugs are purchased centrally for the whole of the country in both Denmark and Norway, while Finland and Sweden operate single channel distribution (i.e. manufacturers contract with one of only two wholesalers in each country for exclusive distribution to both retail and hospital pharmacies there).

6.3.5 Demand for More Detailed and Timely Information

Compared with prewholesalers, wholesalers can only provide manufacturers with very limited and delayed information feedback on the sale and destination of their products. Furthermore, these data have to be purchased from data providers at high cost, with wholesalers profiting from the sale of the data to the intermediary.

6.3.6 Wholesalers Not Offering Pan-European Solutions

Though a true single pharmaceutical market across the EU-27 remains as elusive as ever, the continent is increasingly seen as a single, defined region by pharmaceutical manufacturers. Wholesaling is exclusively a national operation, so it is being bypassed as more manufacturers seek pan-European logistical solutions.

6.3.7 Traditional Supply Channel Fails to Block Entry of Counterfeits

The EU supply chain is supposed to be watertight. Only authorised suppliers can buy or sell authorised products to other parties who are themselves authorised. Although the point (or points) at which this closed loop is broken allowing fakes to enter often remains unknown, there have been a growing number of counterfeit products detected in Europe, thankfully most before they reached patients. Wholesalers and parallel traders are not being blamed directly, it is just the often convoluted route to market that genuine medicines take that increases the risk that fakes may somehow penetrate.

According to the EU Commission, 2.7 million dosage units of counterfeit medicines were seized in 2006, greatly up on the 500,000 seized the previous year. However, determining the extent of counterfeiting and identifying trends cannot be sensibly achieved by reference only to 'seizure statistics'. As anti-counterfeiting expert Graham Satchwell of Proco Solutions explains, there are other important matters that need to be weighed:

- Customs officials, regulators, those within the pharmaceutical industry, consumers - none of these groups are likely to look for, suspect or report concerns about the authenticity of any particular medicine unless they perceive the presence of fakes is at least a possibility. It follows that the more these parties become aware of the true nature of the risk, the more cases will come to light. Awareness is only now growing.

- As public awareness increases so, one might reasonably assume, will the public resources allocated to deal with the problem. Thus the increase in resources allotted to the UK's Medicines and Healthcare products Regulatory Agency should result in an increase in seizures (of products now escaping detection).

- The application of supply quotas by pharmaceutical companies squeezes parallel traders. It is foreseeable that the most desperate of them are likely to turn to "unusual sources" to acquire products at prices which afford the opportunity for profit. Thus, from time to time, one might reasonably expect to see a variation in the extent of the presence of counterfeit medicines as a result of apparently unconnected initiatives and actions.

- World trade in pharmaceuticals continues to grow at about 8%. The use of the Internet in developing countries as a means of reaching out to western markets continues to expand. Mirroring that growth are the numbers of businesses and consumers in Europe prepared to buy direct from distant (and cheap) markets abroad. This market has been growing for several years without showing signs of abating. It has permitted every consumer and business in Europe to access the counterfeit medicines manufacturing heartlands without restriction.

So what is the extent of counterfeit medicines in Europe? *'No one knows, though all available evidence is that it is greater than most people once thought, and the figures are set to continue to grow'*, Mr Satchwell believes.

India, the United Arab Emirates and China are reportedly the main initial sources of counterfeit medicines seized by customs authorities in the EU.

6.4 Pharmacists' Concerns

Wholesalers have traditionally provided community pharmacies with a one-stop supply source. Simplicity in ordering is even more valued when the profession is being urged to take on a broader clinical role than just medicines supply. Wholesaler discounts are a vital component of dispensing remuneration, especially in the UK and the Netherlands. Without these discounts the social insurance system would have to pay higher dispensing fees. The added-value services that wholesalers offer are also highly prized.

Especially in the UK, community pharmacists complain they are now being caught in the middle of a struggle between manufacturers and wholesalers. While this turf war is fought out they suffer inconvenience and extra work, with their patients sometimes experiencing delays in receiving their medicine. UK pharmacists did not ask manufacturers like GSK, Pfizer and AstraZeneca to make changes in product distribution, and see the changes imposed on them almost entirely in a negative light despite manufacturer protestations that it is all done in their and their patients' interests. At best there is confusion as pharmacists struggle to remember which supplier is needed for a particular product and what is the latest cut-off time for

ordering from that supplier. It is all extra hassle which, especially initially, takes time away from the business.

While pharmacists are supportive of the wholesaler network, cracks in the wholesaler-community pharmacist relationship are also beginning to appear. This is especially the case when through the steady and sometimes spectacular acquisition of pharmacies wholesalers change from being the independent pharmacy's friend to being its competitor. There will also always be suspicion that the wholesaler gives favourable attention to its own retail outlets, despite regular denials on this.

Wholesaler-owned pharmacies are certainly not all bad news for the profession, however. They give many more young pharmacists the opportunity to run (if not to control) a pharmacy than would otherwise be the case. While the erosion on the independent sector may have affected the pharmacist's personal standing in the community, wholesaler-owned chains have in many cases contributed to better looking premises, better merchandising, a wider range of goods and services carried, and, most importantly, better training, including continuous professional development, of pharmacists and their staff.

CHAPTER 7
ALTERNATIVE CHANNELS

7.1 Direct-to-Pharmacy Distribution

Direct distribution, cutting out the wholesaler as intermediary, has always occurred to a varying extent across Europe. It is most prevalent in the hospital market, especially in countries like Belgium, France, Germany, Greece, Italy and Spain.

In the retail sector, most direct distribution has traditionally occurred with OTCs. The main advantage for the OTC manufacturer is the ability to control more closely the price of its brands, while remaining the flexiblility to respond quickly to market needs. It can also ensure that brand messages are communicated effectively, provide more influence over consumer perceptions and boost sales through promotional selling. From the pharmacy point of view, demand for OTCs is more predictable and often seasonal, and so purchases can be made in larger volumes at specific times of the year to attract the best terms. Unlike prescription medicines, there is no particular need for urgent delivery. Some generic companies also deliver direct, as do some parallel importers. Again these products are generally bought in greater volume than domestic originator brands, as well as being effective duplicates of brands already on the pharmacy shelves, so urgency of delivery is not paramount.

To the dismay of wholesalers, direct-to-pharmacy (DTP) distribution has grown in importance in some European countries (table 7.1), although this is neither a generalised nor a constant phenomenon. Bayer's 1993 decision to distribute direct its leading OTC brand Aspirin in Germany was a groundbreaking move at the time. Now, if a pharmacy is unable to obtain a particular product from its regular wholesalers and makes an enquiry of the manufacturer concerned, it often will offer to supply direct. The direct share in some countries seems to have stabilised or even fallen. There also seems little or no DTP in the likes of Finland, Hungary and Norway, for example.

Table 7.1: Evolution of direct-to-pharmacy sales in Europe as a percentage of total sales of medicines to community pharmacies, 2003-2006

Country	2003	2004	2005	2006 first half
Germany	12.7	13.0	14.2	15.7
France	13.4	12.5	17.7	NA
Italy	10.1	8.2	9.0	9.8
UK	2.2	2.3	3.1	3.0
Spain	2.4	2.3	2.9	3.3
Belgium	5.6	5.4	5.5	6.0
Switzerland	6.9	7.3	8.9	8.1
Austria	5.8	6.3	6.0	5.4
Ireland	3.6	3.5	4.8	5.6

Source: IMS Health

The rise of homecare in both the UK (8% market share) and the Netherlands (7%) is believed to be a contributor to DTP in both countries. Supply to ambulatory patients by the regions via hospital pharmacies and health authorities since 2002 is a factor in Italy, as is the desire of

manufacturers in both Germany and the UK to limit parallel trade (both incoming and outgoing). Each is discussed further under the country headings in Chapter 3, but an example of a specific case with Boehringer Ingelheim's Spiriva (tiotropium) in Germany was given by the company's Stefan Rinn, speaking at a SMi conference in London in February 2007. Spiriva is Boehringer's leading brand with 2005 sales of €951 million.

Rather than loss of profit from parallel exports of the brand, the main concern was shortages in Germany, leading to a loss of patients treated, Mr Rinn explained. A volume of 18% above domestic demand was supplied to the market in 2006. This was allocated as broadly and fairly as possible to wholesaler warehouses using a stock management system .Internally, there was no incentive to generate exports, as 'he who generates the prescription gets credit for the sale'. If any pharmacy complains of an out-of-stock situation, then deliveries direct from the manufacturer are offered. It might cost Boehringer more and be inefficient for pharmacies, he said, 'but it was still preferred to losing patients'. On average 600 direct orders for Spiriva are handled per day, with two thirds of all German pharmacies already having been supplied in this way. Wholesalers had 'abandoned' up to 30% of their Spiriva business in Germany as a result, he estimated.

For manufacturers, DTP brings both pros and cons (table 7.2).

Table 7.2: Pros and cons of direct distribution from manufacturer's perspective

Opportunities	Limitations
Improved visibility and control over downstream supply chain	Increase distribution costs short term
Improved product penetration	Customer resistance to change even possible sales backlash short term
Increased patient safety by limiting opportunity for counterfeit products to enter the supply chain	Additional restructuring costs
Reduction in unmanaged product flow (limiting parallel trade if quantities as well as channel managed)	Additional customer relations costs
Better distribution terms (circumventing wholesalers' market power and ability to attract concessions)	Unlikely to curb buying power of pharmacy chains
Gain better pharmacist support in the longer term (and moving closer to patient)	
Reduce distribution costs long term	

Source: author

Pharmaceuticals represent the fourth-largest distribution business in Europe, so DTP has attracted the attention of general logistical service providers (LSPs).

International carriers such as Federal Express (www.fedex.com), TNT (www.tnt.com) and DHL/Exel (www.dhl.com) now compete with the healthcare distribution specialists. DHL can be contacted on a multi-country basis through its International Division. Located within its UK-based Hospital Logistics Centre, DHL's 'Healthcare Vision Suite' is claimed to allow potential customers to user-test logistics solutions 'hands on'. In general, carriers do not have refrigerated transport of their own, so the client has to provide the goods in validated packaging material to ensure continuation of the cold chain with LSPs.

7.2 Using Wholesalers as LSPs

7.2.1 GSK's Agency Initiative in UK

Accompanied by the slogan 'Moving closer to our customers', and with considerable controversy, Glaxo (now GlaxoSmithKline; GSK), which was prescription market leader with a 15% national market share at the time, introduced an agency distribution scheme in the UK in 1991-92[10]. Hospital products were added in 1997. Somewhat revised, the scheme continues today, covering all GSK products.

All the 29 full-line wholesalers at the time signed up as Glaxo agents. Instead of the maximum gross wholesale margin of 12.5%, these agents received a management fee for logistical services and sales data supply. This fee was originally set at 5% of the value of Glaxo goods at reimbursement prices handled under the terms of the contract. Terms were later individualised by agent, then changed as first Wellcome and then SmithKline Beecham products came on board after the respective company mergers, and from the beginning of 2007 the fee structure went from being a percentage to a fixed fee per pack.

Glaxo retained ownership of the stock while it was on agents' premises and decided terms for its pharmacy and dispensing doctor customers. At the outset, the manufacturer announced a value-based discount scale, which it periodically modified. This scale was discarded in 2005 and GSK now gives discounts only on brands subject to generic or parallel import competition. PSNC successfully negotiated with the Department of Health to separate GSK products from non-GSK brands in the discount inquiries so as not to disadvantage pharmacies unable to secure discounts with the clawback.

There are unconfirmed reports that in the early 1990s Glaxo tried but failed to launch a similar agency scheme in the Netherlands.

7.2.2 Pfizer's DTP Model

7.2.2.1 Spain

From May 2001, Pfizer became the second manufacturer in Spain after Glaxo Wellcome (GW; now GSK) to introduce a form of dual pricing there. That it announced a scheme apparently similar to GW's just 13 days after the European Commission's unequivocal decision against the latter was seen by wholesalers as especially provocative. (The commission's decision was later largely revoked by the European Court of First Instance and is currently pending before the full European Court of Justice.) Pfizer was the leading pharmaceutical company on the Spanish market, with a 9.7% market share at the time.

Unlike GW, no attempt was made to seek wholesalers' agreement to Pfizer's new terms. Instead, Pfizer initially said it would seek confirmation after a sale was made to a wholesaler that goods automatically supplied at a 'provisional discount' to Pfizer's 'freely fixed' prices were dispensed in Spain. If this confirmation – in the form of pharmacy invoices – was not forthcoming within six months of supply, another invoice to recover from the wholesaler the difference between the 'freely fixed' prices in annex 1 of its sales terms and the 'regulated price' in annex 2 would be raised by Pfizer.

Pfizer cited compliance with Article 100 (2) of the Spanish Medicines Law as justification for the change. This Article – which was only enacted at the end of 1999 and therefore was not available to GW to use in its initial defence – had its origins in the Spanish Constitution, which gives enterprises a right to commercial freedom. Furthermore, while the EU price transparency Directive (89/105 EC) does allow member states to set pharmaceutical prices, this is only justified under Spanish national law if:

- there is a need to protect public health (e.g. to ensure patients have adequate access to medicines); and
- there is a need to control public healthcare expenditure

Neither is applicable to medicines outside the Spanish healthcare system, and Article 100(2) confirms that companies are free to determine prices, except when the conditions for government interference are met:

- the product is sold in the national territory; and
- it is financed by the social security budgets or by public funds belonging to the national Health Service.

Article 100(2) became Article 90(2) of the new Medicines Law 29/2006.

A number of changes to Pfizer policy in Spain have taken place since 2004 and a mixed system now operates.

Direct sales to pharmacies are made through prewholesalers using LSPs. The principal logistics provider is Logista (part of a tobacco group). Direct distribution was apparently Pfizer's preferred approach but, in response to protests from wholesalers and 'serious doubts' expressed by the Ministry of Health that service levels to all 20,000 pharmacies could be maintained with direct distribution alone, Pfizer also signed supply contracts with 18 of the larger wholesalers, cutting out several of the smaller players in the process. Some of the contracted wholesalers acted as purchasing centres for other wholesalers so in reality Pfizer could route its products through about 40 wholesalers and achieve nationwide coverage. Aitena, an LSP, is used as prewholesaler to supply the selected wholesalers.

The manufacturer requires proof each month that sales from contracted wholesalers are made within Spain in order to refund the difference between the price initially charged and the price for the National Health Service. Differences between the two are reportedly often large: several in 2005 were over 100% and some (e.g. with Zarator [atorvastatin] 80mg) were more than 200%. On the other hand, annex 1/annex 2 price differences with 40% of Pfizer's Spanish portfolio were zero.

Pfizer's changes to its scheme followed publication of Spanish Royal Decree 725/2003. Enforcement of Article 100 (now Article 90) only became possible because the Royal Decree introduced requirements for manufacturers, wholesalers and pharmacies to track product movement.

By simple subtraction of domestic resale figures from total sales in Spain, it is possible for manufacturers to know which wholesalers export, as well as how much and when. In fact, the batch tracking method described in the Royal Decree was initially unworkable for technical reasons but Pfizer devised and implemented its own traceability scheme in conjunction with the Spanish Council of Pharmacists. The Ministry of Health has also signed

an agreement with the Council to allow pharmacists to provide the data required by Pfizer, and to certify the sales inside and outside Spain. The apparent success of Pfizer has spurred other manufacturers (e.g. Lilly, MSD, Janssen-Cilag) to follow with dual pricing schemes of their own. GW's original scheme was suspended in 1998.

7.2.2.2 Germany

Pfizer was reported to have sent leading German wholesalers Phoenix, Gehe, Anzag, Sanacorp and Noweda a 40-page prospectus entitled *Modell zur Apothekendirectbelieferung* (Model for Pharmacy Direct Distribution) in 2005. This document invited each wholesaler to become a partner with Pfizer in the manufacturer's proposed new DTP system in Germany. The distributor eventually selected by Pfizer would handle approximately 30 million packs of Pfizer's 750 prescription products. Pfizer would retain stock ownership until delivery to pharmacies, and would determine any discounts or rebates offered to pharmacies. The partner's role was to be limited to supplying and invoicing pharmacies.

In an effort to generate support for its plan, Pfizer telephoned German pharmacists and placed advertisements in newspapers. However, staunch resistance from both PHAGRO and ABDA (and their members) led to Pfizer's DTP plans being abandoned in November 2005. German wholesalers report that Pfizer has re-established contact with them in 2007 and seems keen to press ahead with some form of DTP.

7.2.2.3 UK

From 5 March 2007, community and hospital pharmacy customers of Pfizer's UK subsidiary, as well as self-dispensing doctors, were required to deal with Pfizer direct via its a single appointed distributor, UniChem (Alliance Boots), rather than order from a choice of wholesalers[11]. Despite the critics, who forecast that without multiple supply points product shortages would harm patient care, the changeover seems to have been relatively trouble free. Six months into the new arrangements, 95.72% of dispensing points in the UK had placed orders for Pfizer medicines and received deliveries from Pfizer via UniChem, with 98.89% of all order lines delivered accurately, on time and in full. In total, over 16.7 million packs of Pfizer medicines were shipped DTP.

The introduction of the scheme was strongly opposed by both wholesalers and pharmacy owners. The September 2006 announcement of the new scheme precipitated a flood of complaints to the UK's antitrust body, the Office of Fair Trading (OFT). Because the OFT refused to be rushed into deciding if Pfizer had a case to answer under the Competition Act, and with the March start-up date drawing near, eight wholesalers instead sought an interlocutory injunction at the UK High Court to try to stop the scheme going ahead. They failed and it started on schedule.

Eventually, after receiving a total of around 500 complaints about Pfizer and hearing about the plans of other big manufacturers, the OFT announced it was launching a 'short market study' into pharmaceutical distribution in the UK. This study would consider the likely impact of such changes on competition, the NHS and patients, and was due to report by end-2007.

Pfizer said its DTP scheme would allow the company to take full responsibility for its products from the point at which they left its

manufacturing plants until they are sold to the pharmacists and doctors who dispense them. Ownership and visibility of Pfizer products would remain with Pfizer until sale to the customer took place.

The company emphasised:

- it did not sell Pfizer products to UniChem or to any other wholesaler;
- UniChem did not act as a wholesaler in relation to UK-sourced Pfizer products; and
- pricing and discounting on Pfizer products were the responsibility of Pfizer.

Pfizer was confident that through the changes it would:

- be better able to manage supply and be more responsive to stock shortage situations so that its customers were able to obtain Pfizer medicines;
- reduce the risk of counterfeit medicines by securing the supply chain so that customers would be confident they would receive genuine Pfizer medicines from Pfizer; and
- have improved visibility over the supply chain, and be better able to trace and recall Pfizer medicines with complete confidence if and when required.

Discussions began with the three UK wholesalers with near nationwide delivery capability (AAH, UniChem and Phoenix) in 2005. AAH, the sternest critic of Pfizer's scheme since this was announced, chose to withdraw from talks at the beginning of 2006 'after initial AAH agreement to heads of terms', according to Pfizer's trade director David Watson. Perhaps significantly, notification of withdrawal was received from Celesio headquarters in Germany, not the UK affiliate AAH, he added. Phoenix' bid was 'deliberately half-hearted…I suppose you could say we were fishing', deputy chairman David Cole later admitted.

After a detailed due diligence exercise and a call for tender, Pfizer agreed to partner with UniChem on fee-for-service terms basis to act as its LSP on 'an initially exclusive basis'. The initial contract term is 18 months, but Pfizer said it did not rule out the possibility of having more than one distributor in future, and was prepared to make changes on a local basis if UniChem failed to reach the required levels of service in any part of the country.

Previous twice-daily service levels by wholesalers to customers would be maintained under the new scheme, Pfizer said. UniChem, which had 11 distribution centres in England, Scotland and Wales but no coverage in Northern Ireland, subcontracted Sangers, the Northern Irish affiliate of the Republic of Ireland's United Drug wholesaler, to handle distribution of Pfizer products in the province.

UniChem had reportedly to recruit an extra 400 staff and scale up its business from having accounts with 35% of pharmacies/dispensing doctors to servicing almost 100%.

While there has been talk of modifying gross margins or discount scales for the rest of the business in response, or even changing credit terms or delivery frequencies to customers to cut costs, no wholesaler has yet taken

such drastic steps. The smaller, regional wholesalers are in an especially difficult position as not only are hey be cut off from receiving the 12% of the market that Pfizer lines reprsent, their customer base is likely to drift away to the 'big three'. As a counter measure they started advertising they would transfer orders they could not fill with 'grey market' or PI Pfizer stock to UniChem, and then three regionals – Mawdsleys, Norchem and Maltbys – announced the creation of a trading alliance. UniChem claimed it signed the deal with Pfizer 'to protect pharmacy' from the threat of an LSP from taking on the service.

Impact on Pharmacies

Pharmacies were satisfied with the previous arrangements, which provided competition and choice, and were almost entirely hostile to Pfizer's new scheme. Apart from the burden of opening a UniChem account for those two thirds of customers previously without one, and the additional costs of ordering, reconciling invoices and the extra paperwork (at a time when - with government encouragement - community pharmacists were supposed to taking on a more clinical role), pharmacists had several other concerns:

- Without multiple supply points, Pfizer products might sometimes be unobtainable (after responsibility for supplying oxygen cylinders was taken away from community pharmacies and centralised, delivery problems resulted in the deaths of two patients).
- Early cut-off times for ordering and deliveries late in the day sometimes negated the convenience of the twice-daily service.
- Delivery schedules could not be predicted as in the past. Pfizer believed the problem was largely limited to customers that just ordered Pfizer products from UniChem. While van runs for pharmacies that use UniChem as their first-choice wholesaler, and who order regularly twice a day, can be timed to the nearest 10 minutes, Pfizer-only UniChem accounts may order only three or four times a week, on different days each week, making planning difficult.
- Pfizer's initial discount structure (table 7.3) disadvantaged small independents. Only a small/medium-sized chain would order more than £1 million worth of Pfizer prescription medicines in a year and so obtain a 10.5% discount, but procurement discounts averaging 10% were previously available from a pharmacy's first choice full-line wholesalers on any quantity of Pfizer products.
- Pharmacies would have difficulty achieving the necessary volume with wholesalers other than UniChem to stay in the same discount band once Pfizer products were taken out.
- Pfizer appeared to operate a quota system at pharmacy level (it had been applying quotas at wholesaler level since 2004), with large or unusual orders refused or cut back; this created availability problems for Pfizer medicines.

Table 7.3: Discount bands for community pharmacy customers from Pfizer UK, 2007

Qualifying Pfizer purchases per year	Discount (%)
<£250,000	8.5
£250,000-£1 million	9.5
over £1 million, less than £5 million	10.5
>£5 million	11.5

Source: Pfizer

Impact on Wholesaler Solidarity

The Pfizer UK initiative has certainly shaken wholesaler organisations. Alliance Boots accused GIRP of taking sides in the dispute after GIRP wrote to the UK government complaining about Pfizer's scheme. A October 2006 internal meeting to discuss this was abandoned in acrimony – GIRP said there were 'insurmountable obstacles', while Alliance Boots countered that it was merely raising objections to 'procedural irregularities'. Its executive deputy chairman Stefano Pessina and the architect of the private equity buyout resigned from the GIRP Steering Committee and his company has since threatened legal action against GIRP's president and its executive officer.

UniChem then quit GIRP's UK member organisation, the BAPW, which subsequently suggested that 'respected and significant' short-line wholesalers might join it for the first time. This potential U-turn is known to infuriate GIRP (in 2004 it changed its English name to incorporate the words 'full-line') but BAPW realistically had little choice if it was to remain a going concern, as the UK's only remaining full-line wholesaler is no longer a member. Finally, on 11 June 2007 Alliance Boots' wholesaling division, Alliance UniChem, resigned from GIRP citing 'irreconcilable differences of vision, outlook and approach to pharmaceutical wholesaling'.

Other Manufacturers Follow Pfizer

Despite adverse publicity in the trade press and a dip in the company's UK market share to about 9%, Pfizer's initiative was soon followed by announcements of similar changes by other manufacturers in the UK. In April 2007, AstraZeneca said it planned to appoint two distributors – UniChem and AAH (Celesio) – as opposed to Pfizer's one. Its original start-up date of Q3 2007 was delayed until February 2008. AAH defended its agreement with AstraZeneca after being so critical of the Pfizer-UniChem deal: 'Pharmacists will be relieved that this is not another single channel scheme like that implemented by Pfizer.' The choice of more than one agency partner, it said, 'will ensure that flexibility and choice is maintained for the customer and result in minimal disruption'.

Astellas announced that following complaints that UK pharmacists were having difficulty obtaining supplies of Prograf (tacrolimus) that distribution of all the company's transplant medicines would be made direct from November 2007, using UniChem as sole LSP.

Earlier that year Napp and Sanofi-Aventis both said they would be cutting regional wholesalers out, limiting distribution to just AAH, UniChem and Phoenix, from October 2007 and November 2007 respectively. The 'big

three' already supplied 92% of the wholesale market and most pharmacies would have an account already with at least one, the manufacturers pointed out. Moreover, these wholesalers would be employed as wholesalers (taking ownership of the stock and deciding their own terms to pharmacies), and not as distribution agents, as in the case of both Pfizer and AstraZeneca.

Novartis has also reportedly invited tenders for UK distribution (including from non-wholesalers), and there are press reports that Lilly UK is contemplating making changes. So far only Roche has publicly declared itself satisfied for now with current UK wholesaling arrangements.

7.3 Distance Selling

A pharmacy's location was traditionally the most important determinant of its commercial success. However, many consumers are no longer prepared to wait in line, let alone discuss their health problems in public. Add in the prospect of significant cost savings and the opportunities for distance-selling pharmacy are clear.

Distance selling refers to all transactions with prescription medicines that are not conducted face-to-face. They therefore encompass mail-order pharmacies or the more modern equivalent, online or e-pharmacies. Both types advertise their services via a website and accept prescriptions by post, fax or e-mail (refills can be ordered over the phone but an actual prescription is needed initially). Medicines are then dispatched by regular mail or courier directly to the consumer or pick-up point. The first e-pharmacies, such as drugstore.com, planetRx.com and yourpharmacy.com, appeared in the US from the end of the 1990s. These were followed by conventional pharmacies establishing 'clicks and mortar' businesses to complement their walk-in stores.

Developments in Europe have been much slower. The relatively few online pharmacies that exist are limited to the countries that specifically permit this trade – Denmark, Germany, the Netherlands, Sweden, Switzerland and the UK. However, the Internet is no respecter of national boundaries, a situation that has created tensions with countries opposed to distance selling, such as Belgium, Finland, France, Greece and Ireland.

Longstanding case law permits consumers to obtain small quantities of OTC medicines from other countries and to arrange their importation for their own personal use. In 1989, the ECJ ruled in *Schumacher vs Hauptzollamt Frankfurt-am-Main-Ost* (case C-215/87) that purchase of an OTC medicine from a pharmacy in another member state provided an equivalent guarantee of proper information and quality to that provided when purchasing a comparable product from a pharmacy in the importing member state.

Further clarification, if not the complete breakthrough that online pharmacies were hoping for, came with the outcome of the *DocMorris* judgment at the ECJ in December 2003 (case C-322/01). Doc Morris is a Dutch-based e-pharmacy targeting the German market, and its activities were strongly challenged by German community pharmacists although they were supported by the German sickfunds. The Court was asked to determine whether Germany's then ban on the distance purchase of drugs from another EU member state violated the EU principle of the free movement of goods. The ECJ decided that member states may ban the practice on their territory when it involves prescription-only medicines but

not when exclusively OTCs are sold. The distance selling Directive (97/7/EC) also allows the distance selling of medicines, but national prohibitions are tolerated.

At the time of *DocMorris*, most countries either did not have specific national legislation in place or banned e-commerce with medicines altogether. In light of the decision, some changes have already been made, while other countries have yet to make them. Table 7.4 shows the current legal position across the European Economic Area.

Table 7.4: Is e-commerce permitted with medicines? (status as of March 2007)

Austria	No	
Bulgaria	No	
Belgium	No	
Cyprus	No	
Czech Republic	Yes	Only with OTC medicines and from registered pharmacy
Denmark	Yes	Only through websites run by registered pharmacies
Estonia	No	
Finland	No	
France	No	
Germany	Yes	Only through websites run by registered pharmacies
Greece	No	
Hungary	No	
Ireland	No	
Italy	No	
Latvia	No	
Lithuania	No	
Luxembourg	No	
Malta	Yes	
Netherlands	Yes	Only through websites run by registered pharmacies
Norway	No	
Poland	Yes	
Portugal	Yes	Implementing legislation pending
Romania	No	No legislation either permitting or forbidding e-commerce
Slovakia	No	No legislation either permitting or forbidding e-commerce
Slovenia	Yes	Implementing legislation pending
Spain	Yes	Article 1(5) of new Medicines Law 29/2006 – not yet implemented- allows internet sale only of non-prescription medicines
Sweden	Yes	Only by Apoteket
Switzerland	Yes	
UK	Yes	Only through websites run by registered pharmacies

Source: PGEU

While conventional wisdom is that face-to-face consultation between patient and pharmacist is best, some patients may positively welcome not discussing their condition in this way, especially within earshot of other pharmacy customers. Patients with so-called embarrassing problems - acne, baldness, constipation, erectile dysfunction, incontinence, vaginal thrush, nits and intestinal worms, for example - often seek privacy and anonymity, and for this the online pharmacy is ideal. Treatments for these conditions often require private prescriptions and as a result online pharmacies dispense a far higher proportion of their prescription total as private prescriptions than do community-based, walk-in pharmacies.

Other advantages and disadvantages of online pharmacies for consumers are shown in table 7.5.

Table 7.5: Benefits and disadvantages of online pharmacies for consumers

Benefits	Disadvantages
Service is available 24 hours a day, 7 days a week	Need to use a computer to access the service
Convenience of home delivery	Long cycle time from order to delivery
Easy access to pharmacy services for patients with limited mobility	Service best suited to repeat prescriptions for chronic medications
Wide choice of products	Uncertain credibility, qualifications and location of online pharmacy
Ability to compare prices	Unknown quality or origin of product
Cross-border supply at lower prices	Risk of physical damage, deterioration, loss or confiscation during transit
Product information available online	Risk of unapproved, illegal, stolen, counterfeit, date-expired or otherwise substandard products and theft
Greater customer privacy	No face-to-face contact with pharmacist
	Uncertain cost reductions
	Uncertain reimbursement coverage
	Uncertain transmission of order
	Risk that online records may be hacked and personal data misused
	Difficulty and expense of correcting dispensing errors
	Potential language barriers in foreign websites

Source: Macarthur[12]

The Council of Europe has adopted a resolution setting out standards for mail-order pharmacies that it said all signatory countries should adopt as a minimum. Individual states can set more restrictive standards if they so wish.

There are several highly reputable online pharmacies dispensing prescription medicines to the highest standards. But what damages the sector overall is its lack of regulation. This is exploited by rogue sites using slogans such as 'No prescription? No doctor? No problem'. Customers for prescription-only medicines need only complete online a self-declaration form, allegedly for medical review. An investigation by the *Sunday Times* found three UK-based online pharmacies selling Viagra, Xenical, Reductil and Propecia in this way. A report by Envision, a web analysis company, estimated there were nearly 2,300 sites selling prescription-only drugs direct to the consumer, the majority based outside the EU.

For manufacturers there are several drawbacks:

- the risk of damage to the brand or company reputation from the supply by rogue websites of substandard, date-expired or even counterfeit medicines, inappropriate/incorrect use, or exaggerated claims;
- recalling a drug or a particular batch would be more difficult for online pharmacies that dispatch products to patients in multiple countries;
- international transactions also increase the risk of trademark and copyright infringement; and

- if manufacturers actively support online pharmacies they could jeopardise their relationships with wholesalers and conventional pharmacies.

7.3.1 National Situation

7.3.1.1 Denmark

Danish pharmacists collectively, through the Danish Pharmaceutical Association's website (www.apoteket.dk), offer a mail delivery service within Denmark. Personal importation of medicines by mail is allowed under Order No. 171 of the Danish Medicines Agency, but only from EU/EEA countries. There is no public reimbursement available on drugs purchased abroad, but they can be offered at discounted prices (retail prices within Denmark have to be common throughout the country).

Established in 2004, Euromedicin (www.euromedicin.dk) acts as an 'information intermediary' to allow Danes to purchase prescription medicines at a cost saving from abroad., At present it only uses one foreign pharmacy in the Netherlands for fulfilment. Only non-reimbursed products (mainly oral contraceptives) are offered, although Euromedicin has done a deal with the leading private insurance company *Sygeforsikringen Danmark* (just under one third of the population is enrolled) to meet 50% of the cost. This is refunded direct to the patient, i.e. the same service the insurer offers enrollees with domestic products.

Prescriptions are transferred electronically from the Danish doctor to the Rotterdam pharmacy via Euromedicin. The Dutch pharmacy labels the Dutch domestic items in Danish and issues an invoice in Danish kronor (including VAT at the Danish rate of 25%). As well as prices on offer from Euromedicin, links are made to the Medicines Agency price list for comparable domestic and parallel-imported products. A DKK 18 delivery charge is levied per shipment (Danish pharmacies charge a standard DKK 15 delivery charge for mail supply) with delivery expected within five days. If patients have any medical query they are directed to Euromedicin's 'after sales pharmacy' – a conventional pharmacy in Denmark.

7.3.1.2 Germany

Until January 2004, mail order or any other form of distance selling of medicines (both prescription and OTC) was banned in Germany under Section 43(1) of the Drug Law. This ban was overturned as part of the 2004 health reform law, the GMG.

Guidelines were issued the following March. These relate to the type of information that can be included on websites promoting e-commerce with medicines, the exclusion of certain product types (e.g. some anticancers and radiopharmaceuticals), and requirements for storage and transport.

- the supplying pharmacy, which must be licensed in accordance with the relevant national law, must be situated either in Germany or in another EU/EEA country;
- counselling by the pharmacy staff must be provided in the German language;
- mailing must be within two working days of receiving the order, unless the customer is informed of a delay;

- a free second delivery must be provided if the first is not received;
- a system for tracking deliveries must be used; and
- transport insurance must be taken out.

If a product is prescription-bound in Germany, even if it is not in the country of supply, it requires a prescription from a German doctor before it can be mailed. Packs used for shipping should, for security reasons, not indicate that they contain medicines. The pharmacy is responsible for the medicine reaching the customer in good condition.

Most importantly, Germans may only purchase medicines via mail order if these products are approved in Germany, either by the EMEA or by the German regulatory agency. The only way foreign-based mail-order firms can get round this requirement is by purchasing German-approved products from sources in Germany, either from manufacturers direct or from pharmacies with wholesaling authorisations. German wholesalers have largely refused to supply.

Proponents of change were mainly the sickfunds (due to lower expenses), consumer groups (not only were pharmacy prices seen as high; the very term *Apothekenpreise* had become a generic term to describe any kind of expensive goods) and some pharmaceutical companies (who saw mail order as an opportunity to streamline distribution and get closer to patients with disease management). Opposition came from ABDA (community pharmacists) and PHAGRO (wholesalers).

Cross-border mail order into Germany briefly started in 1995 with oral contraceptives (these are not reimbursed to women over 20 years). Consumers were invited to send their prescriptions to an agent in Hamburg who would forward them to Express Medical Services in the UK. A physician there would check the details before countersigning the scripts and a local community pharmacy would privately dispense and post the product to the woman in Germany. The entire process was supposed to take no more than five days. Prices to be charged, which included shipping, were said to be up to 58% less than the same product from a German pharmacy, and were also less than the cost to patients of PI forms. Schering AG managed to get an injunction to stop the scheme on the basis that importation services cannot be advertised to patients by a third party.

Long before the law change, the sickfunds had been lobbying for a mail order option. Several joined forces as the Campaign for Mail Order Pharmacy in 2001, shortly after the launch of DocMorris.

While community pharmacies were publicly hostile to mail delivery by a third party, they practised it themselves. A 2001 survey revealed that one-third of German pharmacies with webpages – around 800 pharmacies – offered an e-commerce service. There was also a so-called 'courier exemption' in the mail order ban that was reportedly overused to justify delivery other than in the actual pharmacy.

Doc Morris' main competitor in Germany is another Dutch-based company, Europa Apotheek (www.europa-apotheek.com) of Venlo. DM, a non-pharmacy retailer in Germany, has won a court case that enabled it to partner with Europa Apotheek. Patients can leave prescriptions at DM stores and collect their medicine later after it is dispensed by the Dutch online pharmacy. A third Dutch-based firm www.pharmakontos.com specialises in

prescription lifestyle medicines. Additionally, sites in other countries, including www.apotheke-schweiz.ch (Switzerland) and www.euro-drugstore.net (Netherlands), clearly target Germans. One of the first examples of a German-based mail-order pharmacy supplying prescription medicines is www.pharm24.de, and more recently a group of 34 independent pharmacies from southwest Germany formed a mail-order consortium, Mediacamo.

There are also a large number of German sites that only supply OTC medicines (e.g. www.shopapotheke.com; www.zurrose.de; www.mycare.de; www.sanicare.de; www.apo-rot.de and www.versandaop.de). Several belong to the Federal Association of Mail-Order Pharmacists (www.bvdva.de).

For consumers, OTCs have become a much bigger cost issue since 2004 when almost all OTC products were taken out of reimbursement. At the same time, OTCs were removed from price regulation, so public prices can now be freely set, leading to the introduction of discounting and special offers

IMS estimated mail order achieved a 1.2-1.5% share of the total €23 billion German medicines market in 2005. Almost 80% of the products ordered were OTCs.

7.3.1.3 Netherlands

Under the Law on Supply of Medicines, distance selling pharmacies based in the Netherlands must meet standards equivalent to those required of conventional pharmacies.

As well as hosting e-pharmacies that target Germany, the Netherlands has domestically-orientated pharmacy websites too, like www.nationale.apotheek.nl. Owned by TNT, it co-operates with the largest Dutch health insurer CZ which allows it to offer a €2 saving per prescription. Most of the other websites focus just on OTCs.

7.3.1.4 Poland

The sale of medicines over the internet was first prohibited by the lower house of parliament in February 2007, a decision revoked by the upper house a few months later on the basis that the initial ruling contravened EU norms, only for the Health Ministry then to impose conditions that would essentially make the channel unviable. These conditions were:

- a 24-hour telephone helpline must be provided;
- medicines must be transported 'in conditions ensuring temperature control' (assumed to apply even to medicines stable under ambient conditions); and
- the delivered product must contain the name of the medicine on the outside of the packaging.

Opponents to the rules, including the Polish internet pharmacy pioneers, www.domzdrowie.pl and www.cefarm24.pl, say the measures are unnecessary and restrictive. They argue that safety information is available

both online and from package inserts, maintaining a cold chain would be prohibitively expensive and is needed for the vast majority of OTC purchases, and placing the product name on the external mailed package would dissuade patients from purchasing medication for embarrassing conditions.

7.3.1.5 Sweden

Apoteket is currently the only enterprise allowed to sell medicines to the public in Sweden, so there are no mail-order pharmacies independent of this state-owned enterprise. With its monopoly soon to be taken away, Apoteket has launched a number of new initiatives, one of which was a home delivery service for OTC and prescription medicines introduced in August 2006. Orders can be placed by phone or on the internet.(www.apoteket.se) with delivery by letter post. The first time a patient uses this service he or she is offered medication counselling either by phone or at a local pharmacy. Follow-up counselling is scheduled by phone once a year. As well as ordering medicines, patients can obtain online information on healthcare, and can choose to register and subsequently retrieve their prescription data and medication history. 200,000 customers have already registered.

By end-2006, 10,000 packages had been shipped. Apoteket's target is for 10% of all prescriptions to be handled over the internet or phone by 2010.

7.3.1.6 Switzerland

Although the first mail order pharmacy business in Switzerland was established in 1997 – Mediservice (www.mediservice.ch), by health insurer Helsana - the federal government did not formally legalise the practice until 1999, when it amended Article 27 pf the Law on Medicines and Medical Devices (*Heilmittelgesetz*). Mail order is only allowed with prescription medicines on condition that the supplier meets safety requirements, whereas supply by mail of OTC medicines to the public remains disallowed. However, the separate cantons of the Swiss Federation also permit mail order in the following circumstances:

- the medicine has been prescribed by a doctor;
- there are no safety implications;
- appropriate patient counselling is available; and
- adequate medical supervision of the effect of the product is assured.

In addition, medicines may be mailed by any pharmacy to its regular customers. A pre-existing face-to-face relationship between the pharmacist and the patient is required, and the service is only allowed if the patient is unable to pick up the medicine personally in the pharmacy.

Several other companies followed MediService's lead: Medica Line (www.medicaline.ch) and Apotheke zur Rose (www.aporose.ch) also concentrated on the domestic market, the latter through partnership with about 300 dispensing doctors. Apotheke Schweiz (www.apotheke-schweiz.ch) and Victoria Apotheke (www.access.ch/victoria_pharmacy) focussed instead on international sales. Patients using Apotheke Zur Rose's mail service do not pay the pharmacy fee and are also offered rebates of 10% on the cost. Together with supermarket chain Migros, Zur Rose ran a

pilot service in the town of Lenzbourg whereby patients handed in prescriptions at a Migros counter and collected their medicine two days later.

Most Swiss community pharmacies either have websites or are affiliated with an internet pharmacy partner, such as Wellshop (www.wellshop.ch). The latter does not itself ship products to patients' homes but provides the necessary infrastructure (e.g. health and drug related information, 24-hour call centre). The patient either orders the desired product to be picked up at the local pharmacy or authorises its shipment to their home.

7.3.1.7 UK

The government's 2000 strategic plan, Pharmacy in the Future, stated that if proper safeguards and professional standards were in place, the sale or supply of medicines electronically would be allowed. According to a 2007 analysis of 3,160 websites offering medicines from sale by US internet market research company MarkMonitor, no fewer than 570 (18%) were UK-based, yet the presence of registered UK pharmacies with an online presence is so far limited to just one major player, www.pharmacy2u.co.uk.

Launched in 1999, Pharmacy2u's website had over 3,000 visits in its first weekend of operation. Registered customers in the UK may submit both private and NHS prescriptions. Pharmacy2u signed its first contract to supply a hospital trust in 2000, and the following year was invited to conduct one of three pilot programmes for the government's electronic transmission of prescriptions system.

Most recently, Asda (Wal-Mart), the UK's second-largest supermarket chain, has teamed up with Pharmacy2U to offer online customers more than 1,000 OTC lines through www.asda-pharmacy.co.uk. Products and technical support are provided by Pharmacy2U, whose pharmacists validate the orders. Asda plans to offer an online prescription service from 2008. In another recent development, the Rowlands pharmacy chain (Phoenix) has set up an internet pharmacy service (www.rowlandspharmacy.co.uk).

The Royal Pharmaceutical Society has issued guidance on internet pharmacy services covering all types of medicines (http://www.rpsgb.org.uk/pdfs/internetpharmservguid.pdf). This specifically addresses the issues raised in the *DocMorris* case regarding security of the supply chain and availability of advice to customers. The Society is also piloting an internet pharmacy verification scheme under which legitimate online pharmacies based in the UK will show a logo on their websites that links to the Society's database of registered pharmacy premises. At any one time, the UK regulatory authority will be investigating around 100 cases where it believes there have been breaches of the Medicines Act relating to the illegal sale or supply of medicines via the internet.

7.4 Homecare

Homecare involves delivery of product and associated support to the patient's home where treatment is undertaken. A pharmacy licence is required to supply any prescription medicine to patients in Europe, self-dispensing doctors excepted. Therefore, a homecare company has to have its own in-house pharmacy.

Homecare is most developed in the UK and the Netherlands, where IMS estimates it accounts for 8% and 6% of the pharmaceutical market respectively. Some believe that homecare with medicines is illegal in other European countries, though the basis for this viewpoint is unclear.

Commercial homecare providers normally purchase the drug from the pharmaceutical company they contract with and negotiate additional fees for the requested package of support services. The burden of ensuring funding is in place for treatment of a particular patient and obtaining reimbursement lies with the homecare provider. Obtaining funding agreement from NHS primary care trusts for high-cost drugs is vital to their uptake in the UK. This in turn depends on a positive usage recommendation from the National Institute for Health and Clinical Excellence. With very high cost products (e.g. blood factors), homecare providers will normally only handle these on a consignment basis.

Advantages of homecare include:

- saves patients the inconvenience of attending a hospital or clinic on a regular basis while ensuring they continue to receive high quality clinical care;
- provides patients with on-going education, support, compliance monitoring and advice;
- improves patient comfort, allowing them greater independence, privacy and quality of life;
- helps hospitals meet their patient care targets and reduce waiting lists;
- reduces administrative tasks of specialists;
- offers pharmaceutical companies an insight into the structure, processes and varying requirements of the health service;
- allows communication with the patient;
- provides information feedback, including outcomes, compliance monitoring, financial reporting, nursing notes, patient diary and survey results;
- differentiates products in a competitive marketplace (though in UK at least homecare is now the market expectation for some types of drugs);
- gives positive product perception when linked with high-quality services;
- eliminates constraints on prescribing, reimbursement assistance;
- improves sales; and
- produces satisfied patients.

Services from providers are tailored to the needs of the client, be this the health or social services, or a pharmaceutical company. These include aseptic drug compounding and manufacturing, nationwide home delivery from own fleet of unmarked refrigerated vans, drug administration, clinical waste collection and disposal, specialist nursing care and ongoing clinical support. Homecare nurses operate within defined clinical guidelines.

7.4.1 UK

The trigger for homecare's emergence in the UK was the fact that hospitals cannot reclaim the VAT on drugs they supply, while drugs supplied against a prescription to named patients at home are VAT free. With a VAT rate of 17.5%, it means that a drug costing the health service £1,000 to supply in the community would cost £1,175 from a hospital.

According to the Department of Health (Hospital Prescribing 2005 England), the following drugs are supplied in the UK by homecare companies:

- adalimumab (Humira)
- blood/haemophilia factors
- cefotaxime (Claforan)
- ceftazidime (Fortum)
- clozapine (Clozaril)
- colistin (Colomycin)
- darbepoetin (Aranesp)
- desferrioxamine (Desferal)
- erythropoietin (Epoetin)
- etanercept (Enbrel)
- flucloxacillin
- glatiramer (Copaxone)
- growth hormones
- heparin sodium
- imiglucerase (Cerezyme)
- immunoglobulin (Flebogamma)
- interferon beta
- meropenem (Meronem)
- methotrexate
- rituximab (MabThera)
- sodium chloride
- teriparatide (Forsteo)
- tobramycin
- topotecan (Hycamtin)
- total parenteral nutrition

7.4.2 Netherlands

Homecare services are firmly established, with Mosadex' affiliate ApotheekZorg (www.apotheekzorg.nl) having exclusive Dutch distribution rights for Abbott's Humira (adalinumab). ApotheekZorg also supplies Somafer (pegvisomant) and Forsteo (teriparatide). Other homecare companies and the high-value/low-volume speciality biotech products they handle, which, according to IMS, together with the three brands above have a combined market share in the Netherlands of about 6%, include the following:

- OPG's Red Swan (www.red-swan.nl), for Enbrel (etanercept) and Eprex (epoetin alfa);
- Medizorg (http://farma.medizorg.nl), for Aranesp (darbepoetin alfa), Nelasta (pegfilgrastim) and Tracleer (bosentan);
- Klinerva (www.klinerva.nl) for Avonex (interferon beta) and Pegasys (peginterferon alfa); and
- Prevent Care (www.prevent-care.nl) for Zoladex (goserelin).

7.4.3 Belgium

Co-operative wholesaler CERP Phardib (part of CERP Rouen) has launched a homecare service for pharmacies in Belgium.

7.4.4 Profiles of Homecare Providers

7.4.4.1 Clinovia

Founded in 1975, Clinovia (www.clinovia.com) was the first home healthcare provider in the UK and has an annual turnover in excess of £100 million. The company has undergone several changes of ownership and is now part of the BUPA private health insurance group. It is a regular supplier to 8,000 home-based patients (5,500 of these have multiple sclerosis) with eight dispensing points nationwide, a fleet of refrigerated vans and 150 field-based nurses.

With a head office in Harlow, north of London, Clinovia's expertise spans a range of acute, complex and chronic medical treatments, as well as care packages, covering total parenteral nutrition, home chemotherapy, intravenous antibiotics, multiple sclerosis, rheumatoid arthritis, fertility, immunologlobulin therapy, coagulation factors, post-transplant medication, growth hormone, etc. The company is quality accredited under ISO 9001.

7.4.4.2 Healthcare at Home

An independent UK company, established in 1992, Healthcare at Home (www.healthcare-at-home.co.uk) is the market leader in providing acute care at home, with turnover in excess of £250 million. Its head office is in Burton-on-Trent, in the East Midlands. ISO 9001 quality accredited, the company holds authorisations for wholesaling and aseptic compounding. It has 450 employees (over 50% are clinical staff) and its own nurses in 17 regional teams. Its two pharmacies are in Burton and in Leeds, with additional regional distribution points. It receives 23,000 orders per month and is supporting over 12,000 patients on active treatment. It distributes to homes, hospitals, GPs, pharmacies and wholesalers nationwide with its own

62 cold chain vehicle fleet. Separate divisions manage clinical trials and nurse recruitment.

Healthcare at Home holds exclusive UK distribution rights for Enbrel (etanercept). It has heavily invested in IT to provide real time tracking of storage and shipment temperatures, van and nurse movements, and product batches. Distribution to hospital centres in a number of European countries is undertaken with Biomarin's orphan drug, Naglazyme (galsulfase).

7.4.4.3 Mondial Assistance

Clinical support to patients self administering injections at home or whilst travelling can be provided by the Mondial Assistance Group (www.mondial-assistance-group.com) through its local offices in France, Germany, UK, Italy and Spain. Though Mondial does not offer logistical solutions itself it can organise these through third-party LSPs. The company, which is owned by Allianz, has a total of 37 operations and 7,600 employees in 28 countries.

Mondial Assistance entered into its first 'patient relationship management programme' (akin to disease management programmes) with a pharmaceutical company in 2001. Though the service offering is customised to a client's specific needs, the main aim is to improve patient education/compliance and follow-up, also maximising (if applicable) self administration of the drug. It claims a self administration rate of 93.4% (with 3.2% administered by relatives and 3.4% administered by nurses). Each programme generally involves home visits by Mondial nurses or telephone counselling:

- providing product information (anytime the patient wants);
- informing patients about the necessity of correct administration;
- explaining correct storage/handling; and
- coaching and motivating the patient to control their disease and to change lifestyle/behaviour.

Mondial France is currently partnering Lilly on Forsteo (teriparatide) for osteoporosis, offering nursing support for daily injections at home and a 24-hour call centre. The product is delivered on a case-by-case basis to Mondial Assistance, a community pharmacy or the local nurse by a LSP under contract to Mondial. Mondial has also supported Lilly on Xigris (drotrecogin alfa), arranging the express supply of this high-cost anti-sepsis product at six hours' notice to 6,000 hospitals from depots across 10 European countries. Other industry clients include Genzyme.

7.5 Competition Law Issues

Restrictive distribution agreements risk conflict with the EU's antitrust laws: Article 81 EC (anticompetitive agreement between undertakings) and Article 82 EC (abuse of a dominant market position). Though legal advice should always be sought in advance of a change in distribution arrangements, there is in general no requirement on a manufacturer to supply a product to any customer legally entitled to purchase it, provided that the manufacturer has researched all the available distribution options and decided on one or more options as a result of this research.

Under EU law, an exclusive distribution agreement is not itself anticompetitive, unless another potential customer serving that market has suffered 'obvious, immediate and substantial competitive disadvantage' as a result of exclusion, or has been put at risk of being forced out of business by it.

With decision CA98/3/03, the UK's Office of Fair Trading (www.oft.gov.uk) fined Genzyme £6.8 million (reduced on appeal to £3 million) in 2003 for abusing a dominant market position by:

- charging the NHS a price for Cerezyme that includes the price of home delivery and provision of homecare services, thereby ensuring that no one else could provide such services; and
- precluding viable competition from other homecare providers by charging them a price that allowed no possible margin.

CHAPTER 8
FUTURE SCENARIO

8.1 Greater Manufacturer Influence on Distribution?

European manufacturers have had to cope with what they see as growing negative trends and challenges with product distribution:

- Parallel trade.
- Out-of-stock situations.
- Consolidation of wholesalers into major pan-European groups.
- Vertical integration into pharmacy retailing by pan-European wholesalers.
- Pharmacies tied to wholesalers even in countries where chains are disallowed.
- Rebranding of wholesalers as healthcare companies offering services further along the value chain.
- Pharmacists as gatekeepers to physicians' prescribing decisions.
- Generic substitution rights for pharmacists.
- Emergence of counterfeit products in the legal supply channel.
- Pharmacy increasingly the key point of sale.
- Potential product diversion from Europe to the US.

The response has been attempts to secure the integrity of the supply chain, minimise stock diversion and make distribution more cost-effective from a manufacturer's perspective. Methods include stock management systems, direct distribution, price control at the point of dispensing, improved product traceability (visibility of the entire process from the end of the production line to the patient), and anticounterfeiting measures. The issues that led to these measures will not go away, so an even tighter grip on distribution will be maintained in future.

8.2 Is the Future Direct to Pharmacy?

While it has been possible to use LSPs to go direct to pharmacy in some countries with OTCs and generics, and to use prewholesalers or homecare companies to reach the patient with some high-cost/high-touch/low-volume speciality injectables, the bulk of medicines distributed still follow the traditional supply route. It is likely to remain this way.

Given a choice, community pharmacies prefer to deal with wholesalers. This is exemplified by the dual channel distribution situation in Spain with Pfizer's products since 2004. Only 5% of distribution is currently direct, with 95% routed through those 40 wholesalers that Pfizer has contracted with, Cofares estimates.

DTP with an entire product portfolio mix of fast and slow moving brands has so far been limited to the UK. Why the UK? A number of contributory factors are likely:

- incoming parallel trade is the highest in Europe and outgoing parallel trade is growing;
- most of the recorded cases of counterfeits reaching patients have occurred in the UK;
- there is a high level of 'grey market' trade in the UK;
- the 'big three' pan-European wholesalers dominate and control not only wholesaling but a high percentage of community pharmacies too;
- unlike the situation in most other EU countries, UK wholesalers earn a margin on the manufacturer-set public price, so this margin reduces the manufacturer's share; and
- the UK is a more liberal market environment.

To get a distributor to accept a lower fee to provide logistics services than the normal wholesale margin for wholesaling services, the trade-off must be that a significantly greater volume of business is offered. An exclusive deal would allow negotiation of the keenest terms. However, in choosing a single UK distributor, regardless of competition issues and the findings of the OFT's market study, Pfizer may be a one-off. The company said it had been in advance negotiations with all three large wholesalers, with the aim of using all three, although all but UniChem subsequently dropped out. The scope for future single-agency deals in the UK is constrained as geographical coverage by even the largest wholesalers is limited. The two top wholesalers combined can only cover 85-95% of any manufacturer's sales, with the top three needed to cover in excess of 97%, according to research by Taylor Nelson Sofres/AT Kearney. The situation is mirrored elsewhere in Europe, except in the single-channel markets of Finland and Sweden. Wholesalers that operate only in distinct regions are especially a feature of the Belgian, Greek, Portuguese and Spanish markets.

In announcing changes to their UK distribution arrangements, Napp and Sanofi-Aventis have taken a different approach from Pfizer and AstraZeneca. Rather than appoint one or more wholesalers as LSPs, they have both opted to retain the traditional wholesaler model, but with a limit on the number of wholesalers used. If curtailing the growing power of the 'big three' is one of the motivations for these changes by manufacturers, then giving all the business to these same three wholesalers seems a paradox.

For community pharmacists, Pfizer's move has made them confront their future role. Earnings from performing added-value services for the healthcare system will increasingly take funds away from their old core function of medicines supply paid for through dispensing fees and procurement discounts.

8.3 How Will Wholesalers Fight Back?

Wholesalers have been cutting costs for years, but with pressure exerted by both governments and manufacturers further economies will need to be sought. Reducing the number of deliveries from twice to once a day would certainly help, but no one wants to be the first to do this as it would be certain to immediately lose them market share. Pharmacies have adapted their buying practices to multiple daily deliveries and pharmacy representatives have factored these into remuneration negotiations with national payers.

Better information technology, linked to electronic transfer of prescriptions and improved repeat prescribing schemes might allow pharmacies and wholesalers to move to a 'dispense one, supply one' basis with a lower frequency of deliveries, but obstacles remain. If pharmacy customers were split into morning or afternoon deliveries, most would want to be in the morning group. This problem could be partly offset if pharmacies in more countries had secure delivery boxes or lock-ups in which wholesalers could leave deliveries at night when the pharmacy was closed, but issues like deliveries of bulky products or narcotics (requiring signature on receipt) remain.

8.4 More Competition for Pharmaceutical Wholesalers from LSPs?

It is notable that Glaxo, Pfizer and AstraZeneca have each chosen to award their UK DTP distribution contracts to pharmaceutical wholesalers rather than to general carriers, even though in at least one of these instances LSPs were invited to tender for the business. Wholesalers argue they are the pharmaceutical specialists. They have invested greatly in automation, IT, time and effort to understand and deliver the specific needs of both supplier and customer in this area. To compete, LSPs would need qualified staff, wholesale dealing authorisations, training to Good Distribution Practice standards, and specialised facilities and procedures to deal with cold chain products and narcotics. Consistent accuracy in order picking is not a skill that comes easily. There is also the feeling that LSPs work best in getting parcels from A to B, while wholesalers cope better with assembly of highly variable orders and the unexpected. But could this change?

DHL Logistics, in partnership with the US procurement firm Novation, has already replaced a non-profit public agency, NHS Logistics Authority, for non-drug medical supplies to UK hospitals, through a new division, NHS Supply Chain. Could LSPs, primarily operating now as prewholesalers, take over from traditional wholesalers and make regular, scheduled deliveries of medicines to pharmacies?

AS Healthcares, which exemplifies a new breed of general logistic service providers that are diversifying into pharmaceutical distribution in Europe, has already done so. And there are others. From unlikely beginnings as a distributor of fuel/building supplies and as a road haulage contractor, Allied Anthracite Holdings became AAH, the UK's leading pharmaceutical wholesaler and an integral part of Celesio today. Though AAH made several other UK wholesaler acquisitions – Hills Pharmaceuticals, Herbert Ferryman, Mawson & Proctor, Northern Pharmaceuticals, Ayrton Saunders, Raimes Clark, Rudge Roberts and Barclay & Sons - the clear turning point was its 1985 purchase of Vestric from Glaxo for £15 million.

Precedent also exists for breakthrough by LSPs outside Europe. In order to challenge Australia's own 'big three' pharmaceutical wholesalers – Sigma, Symbion and API – a fourth full-line player with nationwide delivery capability has entered the market, a joint venture between DHL and generics company Alphapharm. Alphapharm, like other Australian generics companies, used to distribute direct (as do GSK and Sanofi-Aventis). The joint venture has already won a 17% distribution market share. Future tie-ups between LSPs and pharmaceutical wholesalers are likely.

8.5 Further Restructuring of the Wholesale Margin?

The structure of the wholesale margin goes back many years. It has usually been percentage-based and probably approximated to the real cost of distribution at the time, but medicines were much cheaper then. While distribution costs in other industries have fallen, sometimes by as much as half, pharmaceutical distribution costs have risen. Both governments and manufacturers will continue to address this, the former through more reductions in the gross wholesale margin and the latter by trying to shift the basis to fee-for-service.

Some argue the case for tiered distribution terms, e.g:

- direct distribution for high-priced products;
- fee-for-service for mid-priced products; and
- the traditional wholesale margin for low-priced products.

Aside from the complexities of implementation, it would be difficult to get wholesalers to agree to such cherry picking. Their economic structure is based on handling a mix of goods.

The creation by the Australian government of a new Community Service Obligation (CSO) pool for wholesalers as part of the fourth community pharmacy agreement in 2006 is an interesting development. It shows that even in a cost-cutting environment extra funds can be found for a well-run and comprehensive wholesale network. The pool will provide payments in addition to the 7.5% wholesale mark-up (which was reduced at the same time from 11.1%) for distributors that agree to supply the full range of reimbursed medicines under the Pharmaceutical Benefits Scheme (PBS) to pharmacies across the country.

The CSO fund has been set initially at AUD 150 million/year, but will increase to AUD 173 million/year from August 2008. Wholesalers will be eligible to draw from it if they can show:

- infrastructure capacity to meet required service standards;
- purchase of 100% of the PBS range of products supplied through pharmacies (around 4,600 items), directly from the manufacturer; and
- at least 12 months of distribution sales records showing that at least 30% of sales are to rural and remote pharmacies, and that at least 30% of sales are for low-volume PBS medicines.

New entrants, without 12 months of sales records, need only to show they have the capacity to meet the service standards, which are to:

- supply all medicines listed on the PBS and supplied through community pharmacies that are available from PBS manufacturers and suppliers;
- supply at least one product for each PBS item that does not attract a brand price premium;
- deliver the full range to any pharmacy in Australia (national wholesalers) or to any pharmacy in the state or territory (state or territory wholesalers) within 24 hours of a pharmacy's regular order cut-off time;

- deliver low-volume medicines and single dosage units where requested by a pharmacy; and
- supply to pharmacy at or below the published approved price to pharmacy.

8.6 More Widespread Loss of Pharmacy's Medicines Monopoly?

Pharmacy's so-called monopoly to sell or supply medicines has been under attack in several countries for more than a decade. It is interesting that the term 'monopoly' is never used in connection with the restriction of industrial production of medicines to holders of a manufacturing authorisation or to limiting wholesale dealing to holders of a wholesale authorisation.

Pressure for liberalisation of drug distribution channels, especially with OTC medicines, has come from a number of directions, including supermarket chains, manufacturers, competition authorities and insurance funds. The pharmacy profession has argued against this, emphasising that medicines are unlike other classes of goods, and that only pharmacists can provide objective, neutral and expert advice on treatment options.

With today's more informed consumer, pharmacy's argument increasingly falls on deaf ears and the Czech Republic, Denmark, Finland, Germany, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Romania, Switzerland, and the UK all allow non-pharmacy sales of certain OTC medicines. Sweden is about to join its Nordic neighbours in allowing certain OTCs to be retailed by other non-pharmacy outlets, and other countries – even eventually France and Spain – will follow.

Liberalisation has not seemingly produced the risks to public health that pharmacists had warned of, but greater availability has done little for sales if the Danish experience is anything to go by. Since October 2001, 175 OTC products (mainly small packs of simple analgesics) have been available in Denmark through outlets other than pharmacies, such as convenience stores, supermarkets and petrol stations. The list was extended in 2003. By 2005, non-pharmacy outlets only accounted for 18% of sales of deregulated products, according to the Danish Medicines Agency, and the overall level of usage was largely unaffected, with the exception of one product class - smoking cessation aids – where sales grew by 46% and non-pharmacy outlets accounted for half. Prices, however, fell with greater competition and OTCs were in general 5-10% cheaper in non-pharmacy outlets.

In a report for PGEU[5], consultants ŐBIG compared price development of four freely-priced OTC preparations – paracetamol tablets, ibuprofen tablets, diclofenac cream/ointment and aciclovir cream/ointment – from 1995 to 2005 in six EU countries (Austria, Finland, Ireland, the Netherlands, Norway and Spain). Ireland, the Netherlands and Norway were examples of liberalised markets where price competition might have been expected to take place. However, in none of the six countries were clear price reductions evident for at least two of the products, with regulated Austria and Finland having the most stable price development, and unregulated Ireland and Norway showing the highest price fluctuations and growth rates. The three regulated countries (particularly Finland) and the Netherlands had over the decade lower rates of increase in pharmaceutical expenditure than Ireland and Norway.

8.7 Declining Role of the Pharmacist in Dispensing?

The basic task conferred upon the community pharmacist by the legislator is to ensure the correct supply of medicines against prescription to the public. This role is likely to remain at the heart of the pharmacist's working day for the immediate future, but changes will begin to occur in the more liberal environments, such as the UK and the Netherlands.

The principle of 'hub and spoke' pharmacy, where actual dispensing takes place in a centralised dispensary (hub) and the 'spoke' pharmacies hand the medicine out to the patient with appropriate counselling, is already established within multiple pharmacy groups. The automated filling of monitored dosage systems is a good example of this. Though legislative change would be needed, it is possible to envisage a future in which individual patient supplies could even be prepared by the wholesaler.

If the mechanics of dispensing declines in importance, there are still many opportunities left for community pharmacists (although the main problem they will face is getting paid for them):

In partnership with the prescriber

- advisors on formulary/prescribing
- individual patient input
- providing medicines information to other health professionals
- contribution to budgetary planning
- facilitating the prescribing (and especially the repeat prescribing) process
- acting as safeguard against unsuitable dosing or drug interactions.

Supporting the patient

- advice
- counselling
- medication use reviews
- enhancing compliance
- home delivery
- prescription renewal
- preparation for use of high-tech products

Supporting the payer

- generic/parallel import substitution
- advice to prescribers on lower-cost therapeutic equivalents
- stimulating adherence to treatment guidelines

- advising patients on non-reimbursable OTC alternatives
- routine diagnostic testing
- Pharmacist prescribing in specialist clinics

8.8 Will Multiple Pharmacy Ownership Spread?

By tradition, only pharmacists owned pharmacies in Europe, and this was limited to the one in which they worked full time. This situation was vigorously defended by the profession on the grounds that the public had a right to personal accountability which derived from proprietor ownership. This, it was argued, kept pharmacy out of the hands of those who would be investing for profit, not for service.

A pharmacist owner is still a legal requirement in a number of EU member states, namely Austria, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, Slovakia, Slovenia and Spain. Even newly implemented or pending legislation in Bulgaria and Latvia makes provision for this requirement, although it will not be retroactive.

As a pro-competitive policy, designed to benefit both consumers and governments, partial deregulation of pharmacy ownership – often alongside deregulation in other sectors like telecommunications and energy - has taken place recently in a number of countries including Germany, Hungary, Poland and Portugal, though some restraints were kept in place. Sweden, with its state-owned pharmacy monopoly, is a special case, but some form of deregulation has been promised soon, andh consultations on this are ongoing.

Nordic case studies

Advocates of the *status quo* in markets with regulated pharmacy systems point to the two non-EU Nordic countries as examples of the unexpected, even perverse consequences that complete deregulation can bring.

In principle, free ownership and establishment of pharmacies became possible in Iceland and Norway from March 1996 and March 2001 respectively. The only exceptions were that pharmaceutical companies and prescribers were excluded from ownership. As in all EU countries, a pharmacist was still required to be personally responsible for the services provided at each pharmacy, but the result of takeovers by pharmacy chains means there are just 15 independent pharmacies remaining in Norway today and just one in Iceland.

The expectations of deregulation benefiting competition and cost-containment have not been achieved, ŐBIG believes[5]. On the contrary, '*unfavourable side-effects could be observed, such as extreme market power by other players dominating the pharmacy sector and therefore causing concern in relation to competition, or the uneven spread of new openings of pharmacies with disregard for rural areas'*. If deregulation is on the agenda for political reasons, modifications in legislation should be well prepared and include mechanisms, incentives and rules to prevent adverse effects for all citizens, the consultancy argues.

After reviewing the situation in Norway three years after pharmacy liberalisation, Anell[4] concluded that *'the Norwegian government has irreversibly created a more limited scope for future management of the pharmacy market'*. Rather than promoting competition, he believed, liberalisation had the opposite effect. In particular, vertical integration between pharmacies and wholesalers (which the government was originally advised against):

- '*makes it more difficult to set up an independent pharmacy, since it is difficult to enjoy the same discounts and benefits from wholesalers as existing pharmacy groups';* and
- *'it is even more difficult to set up a new wholesaler, as existing pharmacies are most likely to benefit wholesalers to which they belong'.*

Wholesalers which own a large number of pharmacies in countries where the pharmacist has brand selection or substitution rights can use their purchasing muscle to lever large discounts or rebates on multisource products from manufacturers and other suppliers. The allegation is that rather than passing these savings on to the payer in the form of lower reimbursement prices, they are retained within the chain and apportioned in a non-transparent way between pharmacies and their wholesaler parent. IMS has shown with generics that more than two thirds of the profit is retained by the distribution chain in the UK, the Netherlands and almost certainly in Norway too, the three countries where vertical integration is most complete.

The Norwegian government has been forced to introduce complicated mechanisms, like the 'step price system' for off-patent molecules, in an attempt to rectify market failure. The Icelandic government has even considered setting up its own generic supply company to assure competitively-priced generics**.** In both countries the number of generic and parallel import suppliers is low, and the prices they offer are high. Governments in other countries where vertically integrated chains exist, such as the Netherlands and the UK, have also tried but largely failed to claw back unearned discounts from pharmacies.

Whether wholesalers are allowed to compete for pharmacy ownership or not, recent or pending legislative changes in a number of countries, challenges to the status quo by the European Commission in others and the *DocMorris* case before the ECJ, would certainly seem to suggest that the share of independent pharmacies will continue to decline.

8.9 Conclusions

In many areas of commerce, middlemen are on shaky ground, standing as they do between a manufacturer and the end user. That once useful bridge runs counter to the growing customer-centric movement that successful companies aspire to. Computer company Dell is held as a good example because it eliminated conventional retailers and wholesalers, which added unnecessary time and cost and diminished its understanding of customer expectations.

But medicines are different from personal computers, and Dell's customer base is very different from the patients who take these medicines. Dell offers a comprehensive but numerically limited range of options, while most

pharmaceutical companies each have hundreds of different offerings, and national markets have tens of thousands. Even the most ardent admirer of new IT is unlikely to upgrade to a new computer more than once every few years, while patients might need almost constant changes to their medication profile.

A German customer of Dell has to wait 10 working days as a minimum to receive an order – based on the time it takes to clear the customer's payment, the time taken to assemble the order components, and the time in transit. Deliveries are made only on weekdays between 9am and 5pm (the exact time is unspecified) and no emergency service applies. Each of the 21,500 community pharmacies spread across 356,840 square kilometres of Germany, however, expects an order placed in the morning for any one of the 30,000-plus different pharmaceutical forms marketed by 400 different companies to be received in perfect condition in the pharmacy early the same afternoon.

This premium service from pharmaceutical wholesalers comes at a premium price. In a era of cost-cutting, however, the question is whether pharmacies really need such a 'Rolls Royce' service, particularly when 70% of prescriptions are repeat ones and when the growth of electronic transfer of prescriptions means that it should be possible to better predict patient demands in advance.

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