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ORIGINAL REPORT

Pharmacists' role in reporting adverse drug reactions in an international perspective†

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SUMMARY

Introduction The participation of the pharmacist in national spontaneous reporting systems for adverse drug reactions (ADRs) has not always been a matter of course. Even today, there are a number of countries, in particular the Scandinavian countries, where pharmacists are not authorised to report ADRs. In those countries in which they are allowed to report, they do not always use this opportunity.

Methods We have conducted a review of the literature to investigate the involvement of pharmacists in ADR reporting. In addition, we evaluated the pharmacists' actual contributions in 2001 by means of an international questionnaire-based survey among the countries participating in the WHO Drug Monitoring Programme in September 2002. Apart from the numbers of pharmacists' reports, respondents were asked to indicate their assessment of both the quality and the significance of the contribution. Of the 68 participating countries, 41 responded by returning the questionnaire.

Results and conclusions The appreciation of pharmacists' ADR reports is high in those countries that have more experience with greater numbers of pharmacists' reports. The countries that received fewer reports from pharmacists gave lower scores to their contribution. If the specific contribution pharmacists can make to the quantity and quality of ADR reports were to be exploited to a greater extent, this could lead to a substantial improvement of the international adverse drug reactions reporting system. Copyright © 2003 John Wiley & Sons, Ltd.

KEY WORDS — pharmacists; adverse drug reactions; reporting; international; WHO

INTRODUCTION

Pharmacists play an important role in the field of medicinal drugs including in the scientific field dealing with the safety of drugs—pharmacovigilance. This seems a matter of course. Whereas for doctors pharmacotherapy and the knowledge of drugs form only a minor component of their training, the study of pharmacy focuses almost exclusively on drugs. With respect to pharmacovigilance, both sound clinical judgement of the adverse drug reaction (ADR) and insight into the effects of the drug are required to allow a conclusion to be drawn as to the relationship between the adverse event and the drug involved.

Currently, the role of the pharmacist in the reporting of ADRs is not appreciated everywhere. In the Scandinavian countries, for instance, pharmacists are not authorised to report ADRs,[1,2] and in the United Kingdom they have only recently been allowed to report independently.[3] By contrast, in the Netherlands 40% of the reports on ADRs are submitted by pharmacists and, moreover, their role in the maintenance of pharmacovigilance is substantial.[4]

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A retrospective analysis of the pharmacist's role in ADR reporting

The initiative of an international reporting system for ADRs came in the wake of the thalidomide tragedy in the early 1960s. Although the Food and Drug Administration in the United States had been established some years previously, this disaster was the catalyst for the initiation of systematic collection of data on ADRs primarily through the *Hospital Reporting Programme*. In 1968, ten countries operating a national reporting system decided to collaborate under the auspices of the World Health Organization (WHO) and initiated the *WHO Pilot Research Project for International Drug Monitoring*.[5] In 1971, a resolution of the Twentieth World Health Assembly laid the foundation for the WHO Programme for International Drug Monitoring.[6] In 1972, a report was published that gave rise to the current international monitoring system of national centres collaborating in the WHO Programme.[7,8] In 1973, a resolution by the World Health Assembly supporting the report underlined the importance of exchange of information on ADRs.[9] In the report, whose content is mainly still relevant today, no mention is made of the pharmacist as a reporter of ADRs, although an Annex. does refer to a study from 1965 that made use of data originating from pharmacies.[10,11] In a recent WHO publication entitled *The Importance of Pharmacovigilance*, there is a passage that reads 'inviting reports from all professionals', but the pharmacist as an independent reporter is not mentioned.[12] The *Guidelines for Setting Up and Running a Pharmacovigilance Centre*, issued in 2000 by the WHO, does refer to the pharmacist.[13] Here, pharmacists are mentioned on a par with family practitioners and medical specialists. Pharmacists, nurses and dentists are also specifically mentioned in the WHO-publication *Safety of Medicines: A Guide to Detecting and Reporting Adverse Drug Reactions.*[14]

The different roles of the pharmacist

The role of the pharmacist differs between countries but common factors in all countries are that the knowledge of drugs defines the profession and that quality control and dispensing are the key tasks since the preparation of drugs now constitutes only a minor part of the pharmacist's responsibility. Increasingly, care aspects and clinical knowledge are becoming essential to the study of pharmacy. However, the contribution pharmacists can make using the model of 'pharmaceutical care' is not always exploited to its full extent and judgements of their contributions in this respect are not always favourable.[15]

The various roles of the pharmacist can be categorised as follows:

The pharmacist as a dispenser of drugs. This is the pharmacist's traditional role and characteristically defines the image of the profession. Many practitioners view this as the role befitting the pharmacist. The pharmacist delivers the medication as prescribed by the physician and monitors its quality. In general and if requested, the pharmacist is expected to provide information about the drug he or she dispenses although this is often not seen as an integral part of his or her duties.[16] In addition to the pharmacist's growing (clinical) expertise, the advanced computerisation of pharmacies in many countries has led to the awareness that the above is too limited a role.[17]

The pharmacist as a drug consultant. This is the function the hospital pharmacist fulfils in most countries, albeit that his or her contribution in the pharmacotherapeutic care of patients may vary across countries. The pharmacist is recognised as an expert on drugs and has a consultative role in pharmacotherapy. They may help to draft a formulary or assist in the treatment of individual patients undergoing complicated drug therapies. Much of the literature on pharmacists relates to this function of hospital pharmacists. In the USA, the hospital pharmacist has an explicit coordinating role when hospitals wish to report adverse events.[18] In the Netherlands, legislation is being drafted that will give the pharmacist the status of co-consultant. Pharmacotherapeutic discussion groups (FTOs), in which general practitioners and community pharmacists participate, have helped change the way general practitioners view the pharmacist.[19] In these FTOs, the pharmacotherapy is discussed systematically and, as a rule, decisions concerning the pharmacotherapeutic policy to be adopted are made by mutual agreement. Few other countries have awarded the status of consultant to the community pharmacist although in several countries there have been developments in this direction.

The pharmacist as a 'substitute doctor'. In many parts of the world, there is a shortage of doctors and pharmacists may be the only providers of medical care available to people. The high costs associated with health care may be the reason for this deficiency, but also the large distances to be travelled may play a role. This implies that patients will consult the nearest

pharmacy and ask for therapy they can afford, without prior medical consultation. It needs to be noted that usually pharmacists or pharmacy assistants who are acting as 'substitute doctors' are inadequately trained. In some African countries, for instance, a registered nurse is qualified to set up and run a pharmacy. Although this practice mainly occurs in low-income countries, the increasing use of over-the-counter (OTC) medication may also be relevant in this model.

It is clear that the involvement of the pharmacist in the practice of reporting ADRs is closely related to the function in society the profession is given.

What is known?

There is relatively little quantitative and qualitative information available about the contribution of pharmacists in ADR reporting. In an international review, Griffin notes that in 1986 many countries have accepted pharmacists' reporting ADRs as standard practice.[20] In 1989, Fincham comments: 'Exclusion of pharmacists simply does not make sense'.[21] In their 1993 article on the differences between European countries, Lindquist and Edwards remark: 'Pharmacists who advise patients directly... are the most likely to detect adverse reactions'.[22] Roberts *et al.* conclude in 1994: 'It is hoped that pharmacists in other countries will also be encouraged to participate in ADR reporting, a procedure that could only lead to better patient care'. The Uppsala Monitoring Centre (UMC) regularly publishes an overview of the ways the national reporting systems in the various countries are operated, in which the volume of pharmacist reports are also listed.[1] The literature on the actual contribution of pharmacists in ADR reporting often relates to the hospital pharmacist in the USA, Canada and the UK.[22–25]

The majority of publications concern the ongoing debate in the UK where, for the past 10 years, the desirability of direct reporting by pharmacists has been discussed.[26,27]

In the various textbooks on pharmacoepidemiology and pharmacovigilance, the pharmacist receives little attention, with the exception of Inman who, as early as 1986, devoted a chapter to the role of the pharmacist.[28] The authors examine their contribution in relation to non-prescription drugs. They also point to the value of the medication history that pharmacies keep and the advantage pharmacists have through the use of computer technology. They conclude by stating: 'It is to be hoped that protection of professional territories will not prejudice such a contribution'.

AN INTERNATIONAL SURVEY

To gain insight into the current contribution of pharmacists in ADR reporting, we have conducted an exploratory survey among countries participating in the WHO Drug Monitoring Programme. The aim of our study was to:

1. investigate in which countries pharmacists are authorised to report;
2. determine the proportion of ADR reports submitted by pharmacists; and
3. evaluate per country how the pharmacists' contributions are valued.

METHOD

The survey included countries participating in the WHO Drug Monitoring Programme. The WHO Programme for International Drug Monitoring is coordinated from Geneva by the Quality Assurance and Safety of Medicines Team, which is part of the Department of Essential Drugs and Medicines Policy. The Uppsala Monitoring Centre (UMC) has the operational responsibility for the WHO Programme and maintains the international database of the ADRs it receives from the national centres.

In September 2002, we sent all invited countries a questionnaire by e-mail in which they were requested to list their data on the reports that had been submitted by pharmacists in the year 2001. After 3 months, the countries that had not responded received a reminder. The questionnaire made a distinction between the total number of reports each country had received and the direct reports the national centres had received via the spontaneous reporting system during that period, which is after subtraction of the reports submitted by the pharmaceutical industry sector (marketing authorisation holders). A further distinction was made between reports originating from hospital pharmacists and those stemming from community pharmacists.

In addition, the respondents were asked to indicate their assessment of the quality of the reports. If pharmacists did not participate in the national reporting system, the countries were requested to state the reason why they were not included and to provide any future plans in this respect.

RESULTS

At the time of the survey, 68 countries participated in the WHO Programme and 41 completed forms were returned, two of which (i.e. from Brunei and Surinam)

stemmed from countries that did not participate in the programme, but have a status as observer. Eight countries were associate members meaning that they do not yet meet the criteria for full membership mainly because their pharmacovigilance systems have only recently become operational, which may prevent them from being able to submit their reports on a regular basis.

Eight of the 41 questionnaires were returned in response to our reminder, making the total response of member states of the WHO Programme 57.4% (39/68). Most of the countries that had participated in the programme for more than 10 years returned the questionnaire. Only in 3 of the 41 responding countries, the pharmacist was not authorised to report, i.e. Finland, Norway and Sweden.

Of the 68 countries participating in the WHO Programme for International Drug Monitoring in October 2002, a few had only recently joined the programme, as can be seen in Table 1.

Table 1 lists the total number of ADR reports per country for the year 2001, the number of reports per profession and the number of reports submitted by pharmacists divided into the categories hospital pharmacists and community pharmacists. Four countries, Australia, Canada, the Netherlands and Spain, have a considerable contribution from pharmacists, both in percentage (>20%) and number of reports (>100 reports). This is also the case in Chile and the USA, but a percentage could not be calculated.

In Table 2, the assessments of the clinical information are presented, as well as the ratings of the quality of content and medication history, both per report. In addition, the subjective general judgment of the quality of the contributions of the pharmacists to the national reporting systems is provided. The countries that had the highest score of this subjective general judgment were Australia, Canada, Ireland, Japan, Tanzania and the USA.

DISCUSSION

Although in most countries pharmacists are allowed to report ADRs to their national reporting systems, only a limited number of countries indicate that these contributions are of major significance to the system and quality ratings vary.

Differences per member state

What stands out is the fact that in the Nordic countries mentioned (i.e. Finland, Norway and Sweden), pharmacists do not participate in the national pharmacovigilance system. This is also the case in countries such as Denmark, Iceland and Estonia. Indonesia, Vietnam, Oman, the Czech Republic, Rumania and Slovakia stated that they do not receive any reports from pharmacists according to a WHO survey of 1999.[1] Italy, the United Kingdom and Oman do accept pharmacist reports. In several countries, such as France, Italy and Spain, the reporting of ADRs is mandatory, including that of pharmacists. It is notable that in Sweden, nursing staff are authorised to report, whereas pharmacists are not. In general, only those authorised to prescribe medication are allowed to report ADRs. We did not find a clear relationship between the level of training and the interpretation of the profession of pharmacist and the fact whether or not pharmacists are allowed to report. In Sweden, an extensive study on the contribution pharmacists can make with respect to the detection of drug-related problems was published recently.[29] In Finland, pharmacists are highly trained and there is an extensive network of pharmacies. Not authorising pharmacists to report here is justified as follows: 'It is thought that limited resources would be used more cost effectively when the reporting is focused on medically confirmed serious ADRs from physicians'.[2] In Norway, plans have been developed to involve the pharmacist more closely in the process of ADR reporting, with an emphasis on OTC medication. It must be noted that pharmacist's reports are accepted when submitted in this country, although this occurs only sporadically. Other countries, such as Cuba, Ireland, the Netherlands and Singapore, have launched programmes to promote the participation of pharmacists.[30,31]

The quantitative contribution of the pharmacist

The total number of pharmacist reports per country for the year 2001 is presented in Table 1. In Australia, Canada, France, Japan, the Netherlands, Spain, the UK and the USA, pharmacists submitted more than 1000 ADR reports. All of these countries have at least a 20-year tradition in the systematic collection of ADRs. Chile also received a relatively high volume of pharmacists' reports.

The proportional contribution of the pharmacist needs to be taken into account when analysing the number of reports each country has indicated since the reports are either received directly from health professionals or have been submitted by the pharmaceutical industry. In the latter case, the background of those responsible for the report is not always known, so the number of pharmacists' reports could be underestimated. Some countries could not make this

Table 1. Countries included in our study, year of participation in WHO Drug Monitoring Programme, pharmacists permitted to report, total number of all reports in 2001 and percentage from pharmacists, number of reports direct from health professionals and percentage from pharmacists, total number of reports from hospital pharmacists and community pharmacists

	Country	Since	Permitted	Total no.	% Pharmacists*	Direct	% Pharmacists*	Hospital	Community
1.	Australia	1968	Yes	11.118	30.0	8.289	40.3	2.768	572
2.	Belgium	1977	Yes	2.161	3.7	548	14.4	?	Most
3.	Brazil	2001	Yes	175		53		4	8
4.	Bulgaria	1975	Yes	80		84		—	9
5.	Canada	1968	Yes	7.389	28.4	2.375	88.3	2.097*	—
6.	Chile	1996	Yes	771		528		215	40
7.	China	1998	Yes	7.718		7.718		>50%	Few
8.	Croatia	1992	Yes	±1.200		±50		—	12
9.	Czech Republic	1992	Yes	721		—		2	—
10.	Egypt	2001	Yes	210		—		?	14
11.	Finland	1974	No	713***		?		—	—
12.	France	1986	Yes	33.406	4.0	18.690	7.3	683	673
13.	Germany	1968	Yes	11.124	6.0	3.257	20.6	670**	—
14.	Ghana	2001	Yes	8		—		4	—
15.	Greece	1990	Yes	497		297		—	20
16.	Hungary	1990	Yes	97		61		2	—
17.	Ireland	1968	Yes	2.282	3.4	738	10.6	29	49
18.	Italy	1975	Yes	7.043	1.1	1.008	7.7	—	78
19.	Japan	1972	Yes	26.545	6.0	4.094	39.0	?	±1600
20.	Latvia	2002	Yes	29		16		—	1
21.	Malaysia	1990	Yes	813		746		>50%	<20
22.	Morocco	1992	Yes	1.100	4.3	1.036	4.5	—	47
23.	The Netherlands	1968	Yes	4.139	29.3	3.018	40.2	16	1.198
24.	New Zealand	1968	Yes	2.871	10.0	2.492	11.5	60	226
25.	Norway	1971	No	1.248		1.061		—	2
26.	Oman	1995	Yes	401		—		15	—
27.	Portugal	1993	Yes	1.342	14.6	837	23.4	33	163
28.	Singapore	1992	Yes	561		528		104	6
29.	South Africa	1992	Yes	1.094	2.8	591	5.3	31**	—
30.	Spain	1984	Yes	8.071	24.5	7.494	25.9	556	1366
31.	Sweden	1968	No	3.319 ‡		3.319‡		—	—
32.	Switzerland	1991	Yes	2.361		1.277		?	<30
33.	Tanzania	1993	Yes	38		38		±15	—
34.	Thailand	1984	Yes	±180		±180		±70**	—
35.	Tunisia	1993	Yes	780		776		2	2
36.	United Kingdom	1968	Yes	19.505	11.9	?		1.779	535
37.	Uruguay	2001	Yes	174		166		10	4
38.	USA	1968	Yes	281.761	?	19.332‡	18	±18% §	—
39.	Zimbabwe	1998	Yes	72	5.6	71	5.6	1	3

*Percentages of reports from pharmacists are only calculated if there were more than 1000 reports in total and more than 100 pharmacist's reports in a country.
**Total number of pharmacist's reports; no distinction could be made between hospital pharmacists and community pharmacists.
***Number for the year 2000 according to Saarinen.[2]
†Including about 500 reports from nurses.
‡Including reports direct from patients.
§For the USA, the percentage of pharmacist report of those who could be identified of the total number of reports. Kennedy *et al.* give higher figures for the number of direct reports.[44]

distinction for their direct, spontaneous reports. For these countries, the highest percentages of pharmacists' reports received via the spontaneous reporting systems were recorded by Canada (88.3%), Australia (40.3%), the Netherlands (40.2%), Japan (39%), Spain (25.9) and Portugal (23.4%). The actual numbers are represented in Table 1. Percentages of reports from pharmacists are only calculated if there were more than 1000 reports in total and more than 100 pharmacists' reports in a country.

The qualitative contribution of the pharmacist

Table 2 presents the quality assessments of pharmacists' reports as indicated in response to the relevant question of the questionnaire. All the countries that

Table 2. Subjective judgment of specificity of clinical information, completeness of case details, completeness of medication history and appreciation of the contribution of pharmacists' reports to the National Centre*

	Clinical	Completeness	Drug history	Appreciation
Australia	+	++	++	++
Belgium	±	±	±	±
Brazil	−	±	+	+
Bulgaria	±	+	+	±
Canada	++	++	++	+
Chile	±	+	+	+
China	+	+	+	+
Croatia	±	+	±	
Egypt	++	+	++	
France	±	+	+	++
Germany	±	−	−	±
Ghana	+	+	+	++
Greece	±	±	±	±
Hungary	±	+	±	±
Ireland	+	+	+	+
Italy	±	+	±	−
Japan	+	+	+	+
Latvia	+	+	±	−
Malaysia	±	+	+	+
Morocco	±	±	±	±
Nederland	±	+	+	+
New Zealand	+	±	+	+
Oman	++	±	+	+
Portugal				±
Singapore	+	++	±	+
South Africa				+
Spain	±	±	+	+
Switzerland	±	+	+	±
Tanzania	+	+	+	+
Thailand	±	+	±	+
Tunisia	+	±	±	±
United Kingdom	±	+	+	±
Uruguay	−	±	±	
USA	+	+	+	+
Zimbabwe	+	±	+	±

*Only those countries are included in this figure that accept pharmacist's ADR reports and answered the involved questions.

had received large quantities of pharmacist reports also awarded high ratings to the contributions and regarded them as valuable. This also applies to those countries in which the proportion of the reports by pharmacists in the total volume received is high. It is important to take into consideration that both the quality and significance ratings were subjective.

It was also of interest to determine whether, in those countries in which the pharmacists' contribution was substantial, the reports had predominantly been sent by hospital pharmacists or mainly by community pharmacists. In Japan, the Netherlands and Portugal community pharmacists submit the bulk of reports; in all other countries most reports stem from hospital pharmacists. In an earlier publication, the contribution of the Dutch pharmacists—community pharmacists in particular—has been described in more detail.[4] In the Netherlands, pharmacists have played a significant role in the formation of the national reporting system.[31,32]

The contribution of the hospital pharmacist varies per country. In the USA and Canada, this group is instrumental in the ADR reporting by hospitals.[18,33–35]

THE PHARMACIST AS AN ADR REPORTER

As has been mentioned above, the pharmacist is appreciated in his or her role of reporter in countries in which pharmacists have long been closely involved in the national reporting systems. A review of the literature showed that the quality of the reports of both the hospital pharmacist and the community pharmacist is sufficient to contribute to the systems' success.[4,25,36] Yet, direct reporting by the pharmacist has not been accepted in all countries. Notable in this respect is that in several of the Nordic countries, the pharmacist is mainly restricted to the role of *dispensing pharmacist* and is not considered sufficiently qualified to report on ADRs. Furthermore, in many of the countries in which pharmacists are authorised to report, their contribution to the system is negligible or non-existent. Although there are differences both with respect to the attitude of the various national spontaneous reporting systems towards the pharmacist and to the perception of the function of the profession in society, it is clear that the role of the pharmacist is changing. Fundamental to the pharmacist's role is to ensure that medicines are used safely.[37] The standard practice of preparing and dispensing drugs is increasingly shifting towards pharmaceutical care. The pharmacist's original field of expertise, primarily in the domains of chemistry and formulae, is evolving into more pharmacotherapy-related clinical knowledge. Several countries are considering the possibility of authorising the pharmacist to write certain prescriptions such as repeat prescriptions. In the Netherlands, steps have been taken to award the pharmacist the official status of co-consultant. This will allow the pharmacist access to patient files, which will afford him or her the opportunity to become more actively involved in patient treatment and pharmacovigilance.

There is ample evidence that shows that the pharmacist is both willing and capable to adequately fulfil the role of a reporter of ADRs.[25–27,38–41] In addition to this direct role, the pharmacist can also play a coordinating role, both in general practice and in a hospital setting. The fact that in many countries most

pharmacies are highly computerised is important in this context.

The argument against direct reporting by pharmacists is that their clinical knowledge is limited. On the other hand, one could also argue that the knowledge doctors have about drugs is often limited since this aspect is not given sufficient attention during their training.[42] The contribution a pharmacist can make will vary per country and will depend on the expertise and the status the profession is given within the different health care systems. Cooperation between doctors and pharmacists appears to be of vital importance, with each of the two professional groups contributing their respective expertise and experience to promote the rational and safe use of medicinal drugs.

CONCLUSION

In several countries, the pharmacist plays a prominent role in ADR reporting. Particularly in those countries that have participated in the WHO Drug Monitoring Programme longer and accept pharmacists' reports, the number of pharmacist reports is substantial and the reports are generally highly valued. In a large number of countries, the pharmacist's contribution is small; and in some countries, specifically the Nordic countries, the pharmacist is not authorised to report ADRs independently to the national reporting system.

The aim of a comparison of the various practices and experiences of different countries is to learn from the differences.[5,43] With respect to the potential contribution pharmacists can make to the national reporting systems, the practical experience of countries such as Australia, Canada, the Netherlands and the USA may significantly improve both the quantity and the quality of the reports on ADRs worldwide.

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