



Direct Patient Reporting of Adverse Drug Reactions

A Twelve-Country Survey & Literature review

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List of acronyms

ADR	Adverse drug reaction
AFSSAP	Agence Française de Sécurité Sanitaire des Produits de Santé (FR)
AIFA	Agenzia Italiana del Farmaco (IT)
BfArM	Bundesinstitut für Arzneimittel & Medizinprodukte (D) (Federal Institute for Drugs and Medical Devices)
CBG	College voor Beoordeling van Geneesmiddelen (NL)
CIOMS	Council for International Organizations of Medical Sciences
DMA	Danish Medicines Agency (DK)
DSPS	Danish Society for Patient Safety
IVM	Dutch Institute for Rational Use of Medicines (NL)
EMA	European Medicines Agency
EUDRA	European Drug Regulatory Agencies
FAMHP	Federal Agency for Medicines and Health Products (B)
FDA	Food and Drug Administration (USA)
IMB	Irish Medicines Board (EIR)
INFARMED	National Authority of Medicines and Health Products (PT)
Lareb	Netherlands Pharmacovigilance Foundation (NL)
MEDDRA	Medical Dictionary for Regulatory Activities
MEB	Medicines Evaluation Board (translation of CBG, NL)
MHRA	Medicines and Health related products Regulatory Agency (UK)
MPA (LV)	Medical Products Agency (Läkemedelverket) S
NIHR	National Institute of Health Research (UK)
NSAID	Non Steroidal Anti-inflammatory Drug
PO	Patient Organisations
PSUR	Periodic Safety Update Report
SOC	System/Organ/Class (in taxonomy of ADRs)
SSRI	Selective serotonin reuptake inhibitor
WHO-UMC	WHO-Uppsala Monitoring Centre

Introduction

The European Parliament is now discussing changes to the legislation on pharmacovigilance systems, which Member States will then adopt to harmonize national adverse events systems. An important change to the current law foresees the inclusion of direct patient reporting (DPR) of adverse events.

We here provide background information for policy development on pharmacovigilance in the European Union, particularly for the proposal to allow citizens themselves to report adverse drug reactions (ADRs). The project was commissioned from HAI Europe.

Direct and spontaneous patient reporting offers added value for pharmacovigilance in that it can speed up the acquisition of knowledge about adverse effects. Patient reports are more direct and often more detailed and explicit than indirect reports through health professionals. Unlike reports from clinicians, they often describe how the adverse effects affect people's lives.

Spontaneous direct reporting also has important benefits beyond pharmacovigilance: the patient becomes an active participant instead of a largely passive recipient of treatment, and in the process learns how to manage her or his medicines and to communicate more effectively with health professionals. Lastly, public health estimates of disease burden in populations do not consider the effects on people's everyday lives, and they should.

For these reasons direct patient reporting should be encouraged and routinely incorporated in pharmacovigilance activities.

We investigated the current state of direct reporting of ADRs by:

- a. interviewing people concerned with ADR reporting (working in regulatory agencies or other organisations in 12 countries) about their experiences and attitudes.
- b. reviewing published work on direct reporting of ADRs by patients/ consumers and related matters.

Methods

Interviews

Interviews were conducted by the main researcher, Andrew Herxheimer, between mid-August and mid-November 2009. Key experts in regulatory agencies and in relevant non-governmental organisations were asked about national practice and experience of direct patient reporting. Ten people were interviewed by telephone, nine by exchanging e-mails, and two face to face. The oral interviews lasted between 30 and 45 minutes.

The countries were chosen largely on the basis of their known interest in, and experience with, direct patient reporting of adverse drug reactions. People who took part were from Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands, Portugal, Sweden, United Kingdom, and USA. The European Medicines Agency was also included because it coordinates the work of the national regulatory agencies of Member States.

Literature Review

PubMed, EMBASE and the Cochrane Library were searched for clinical trial reports and reviews on direct patient reporting of suspected adverse drug effects. The search terms were *direct patient reporting*, *side effect*, *adverse drug effect*, *adverse drug reaction*. We also searched the official websites of 14 European regulatory agencies, the European Commission, the EMA and the US FDA for data on pharmacovigilance systems and their legal background.

Further, we obtained data from 5 European patient/ consumer organisations which had run pilot programmes on direct patient reporting. We focused on studies of **spontaneous** reporting of ADRs by patients or consumers in the community, and excluded studies of intensive monitoring, or monitoring in hospital, in drug research or in clinical trials. In such studies a researcher approaches the patient looking for possible adverse effects; no initiative is required from the patient. The articles were obtained and a narrative review prepared.

Results

Interviews

We first briefly note the current state of patient reporting in each country, beginning with those where experience has been greatest. We then summarise what came out of the interviews, but refer to publications where they are relevant.

Countries where patient reports are collected

Netherlands

Patients began to report possible ADRs to Lareb in April 2003. Lareb is unusual in that it is a foundation ['Stichting'] independent of the Dutch national drug regulatory authority [College voor Beoordeling van Geneesmiddelen, MEB]; it collects and analyses all reports of suspected ADRs for the MEB, and regularly forwards them to the MEB. Within two weeks the MEB copies the reports to the companies whose products are concerned.

Since April 2004 Lareb accepts reports from patients/consumers and from health professionals as having equal value, but reports from patients are marked in its database as 'not medically confirmed'. When necessary Lareb asks a patient or consumer for permission to contact the person's doctor.

Unlike health professionals, patients can submit reports only electronically via the Lareb website; reports on paper or by telephone are not accepted. This ensures that all reports include the details required for an adequate analysis. The website has separate sections for patients and health professionals.

The scheme was introduced with an extensive information campaign – leaflets in community pharmacies, articles in journals for patients and consumers, as well as promotion on the Internet.

The experience from three years from April 2004 was analysed (de Langen et al 2008). Reports from patients (n=2522) were compared with reports from GPs, specialists and pharmacists, looking at the most frequently reported ADRs, their seriousness (using the CIOMS V criteria), and the outcome. The leading drug classes were statins, selective serotonin reuptake inhibitor (SSRI) antidepressants, beta-blockers, anticoagulants, and proton-pump inhibitors. The top-ranking 5 SOC [System/Organ/Class] categories were the same; seriousness did not differ, but patients reported more life-threatening ADRs and more

disability (which official ADR reporting systems do not record). Patients noted outcomes and non-recovery more often than did health professionals.¹

Follow up of reports was possible in 70% of cases where it was needed. People cooperate willingly; altruism appears to be a major motive.

The Lareb Board now includes 3 patient representatives. Patient reporting is firmly established as an essential component of Dutch pharmacovigilance.

IVM, the Dutch Institute for Appropriate Use of Medicines* is an independent organisation that promotes the appropriate, efficient, safe and economic use of medicines. In 2004, it launched a website 'MeldpuntMedicijnen.nl' [Reporting point for medicines] to allow patients to report their experiences using medicines. The texts of the reports are posted by drug name in date order. For example on 6 Dec 2009 the site listed 222 reports of adverse effects from paroxetine, 175 from venlafaxine, both antidepressants. Reports of adverse events are passed on to Lareb, but IVM is independent of Lareb.

*Instituut voor Verantwoord Medicijngebruik [www.medicijngebruik.nl]

Denmark

From June 2003 a new law allowed patients or relatives to report ADRs. Denmark was the first EU Member State to introduce direct patient reporting.

ADRs can be reported to the Danish Medicines Agency [DMA] by telephone, post or through their website. Patients' reports are handled together with reports from professionals, by the same staff; patients' stories take longer to analyse. The DMA tries to get medical confirmation of patients' reports; the website asks for permission to contact the reporter when necessary.

The DMA receives several hundred reports a year from patients. In 2008 the sources of the 2925 reports were as follows:

Sources	Number of reports received	Percentage of total
Physicians	2104	71.93%
Pharmacists	53	1.82%
Other professionals, e.g. nurses, dentists	172	5.88%
Patients	565	19.31%
Others, e.g. carers, consumers	31	1.06%

One PhD thesis has compared reports from professionals and patients. Discrepancies were noted particularly in neurological ADRs, but not in other categories.

Reports published in the media have stimulated consumer reporting, eg on oral contraceptives (1997), Human Papilloma Virus vaccine (2008), thyroxine (2009).

From 2006 onwards the finding of severe nephrogenic systemic fibrosis after the use of a gadolinium contrast medium for magnetic resonance imaging caused alarm in several countries. In Denmark 20 cases were reported - this led to a National Action Plan to reduce barriers to ADR reporting, which was launched early in 2009. People affected by a change in the formulation of Eltroxin (thyroxine) have posted some of their experiences on Facebook, so new social media are starting to play a role in sharing information about the consequences of medicine use.

The Danish Society for Patient Safety [DSPS] is the Danish component of the WHO Patient Safety Programme, part of which concerns the detection and avoidance of medication errors. It aims to put the patient in the centre of its work. DSPS also contributes reports to the DMA database, to help deal with the grey area between medication errors and ADRs. Medication errors occurring in hospitals must be reported by staff to a database hosted by the Danish National Board of Health. Since 2009 the law on reporting also includes primary care and in future patients may report medication errors as well. Until 2009 DSPS worked only in hospitals because the Danish Patient Safety Law did not apply in primary care; now it does.

Reports of medical errors are analysed differently from ADR reports, using 'root cause analysis'. This examines the factors and processes that led up to the error as well as the individual circumstances such as the patient's medical history and the nature and timing of the effects.

Italy

Since 2004 patients can download special form to report an ADR from the AIFA (Italian Drug Regulatory Agency) website (www.agenziafarmaco.it). The completed form is mailed to the local health district's pharmacovigilance centre. The response from citizens has been small – around 50 reports/year in 2007 and 2008.

To put this into perspective, since 2006 the number of reports from doctors and nurses has risen to about 1100/month (90% are from doctors). Reports from industry are mandatory, but few.

Letters from patients too have led to regulatory action, eg on photosensitivity to topical ketoprofen (a non-steroidal anti-inflammatory drug) , and on the packaging of paracetamol for children.

In August 2009 an electronic form was introduced, which also helps local pharmacovigilance staff to contact the patient or the doctor concerned.

The consumer organisation Altroconsumo has invited people to use its website to report their experiences with medicines intensively monitored by AIFA and other agencies – anti-inflammatory coxibs, the immunosuppressant creams tacrolimus and pimecrolimus, and isotretinoin used in acne. Altroconsumo concludes: *If adequately stimulated, patients respond in great numbers and provide accurate and detailed reports.* They can provide useful information not only on adverse effects, but also about other problems with the treatment, such as inadequate prescriptions and incorrect use – information which would otherwise be very difficult to collect.

Sweden

Patient reporting of ADRs was begun in Sweden by Kilen, a non-profit organisation working on issues of dependence, side effects and injuries related to medicines, particularly psychotropic drugs. It focused mainly on informing and educating the public and on helping affected people personally, but also in 1997 established a database of experiences of medicines in the Nordic countries to enable consumers to share such experiences. In 2000 Kilen organised the first International Conference on Consumer Reports on Medicines in Sigtuna. This was important in getting the idea of consumer reporting known and more widely accepted, but it took until 2008 to integrate it in practice with the very different activity of formal pharmacovigilance in the context of medicines regulation.

In June 2008 the Swedish Medical Products Agency (MPA) added an interactive section on its website enabling patients and consumers to report ADRs on the site, and explaining how to do it. Reports can be corrected as they are being written, and are acknowledged as correct or incomplete. Patients are asked whether they will accept follow up if the MPA expert considers this desirable.

In the first 12 months about 500 reports were received. The first 200, and then the second 200 were analysed and compared with reports from professionals. They were largely about similar products, but more of the reports from patients concerned psychiatric disorders and neuroleptics. Professionals reported more ADRs related to vaccines.

It has not been decided whether the narrative part of ADR reports will be made accessible - for example a statement that an antihistamine lozenge used against travel sickness caused an unpleasant prickling feeling.

Pharmaceutical companies note patient reports that they receive in the regular Periodic or other Safety Update Reports, but do not submit individual reports to the authorities unless they are serious and medically confirmed.

An important ADR recently reported by patients, initially in Norway, concerned severe liver reactions to Fotodol, a herbal product that is used both medicinally and as a food additive. Laboratory analysis by the MPA found that it contained nimesulide, a non-steroid anti-inflammatory drug (NSAID) known to damage the liver.

Belgium

Neither European nor Belgian law requires health authorities to have a reporting system for patients, so the Federal Agency for Medicines and Health Products (FAMHP) does not actively promote direct patient reporting. It “prefers to stimulate patients to discuss their concerns with their treating ... professional.” But when FHAMP receives reports from patients on the yellow card used by professionals, it analyses them in the same way as reports from professionals.

However, in 2006 the national consumer organisation, Test-Achats/Test-Aankoop (TA), established a direct patient reporting system. The TA system is run by a pharmacist who has been trained at FHAMP and maintains contact with FHAMP. The system is publicised in the consumer magazine, on the TA website, on the websites of the biggest sickness funds, the National Institute for Health and Disability Insurance, and in leaflets distributed through 100 pharmacies run by mutual funds. In 2007, TA agreed to share the data from the system with FHAMP. FHAMP responds to the consumer reports and provides TA with an anonymised overview of every 100 reports. Once a year, TA and FHAMP publish a press release about the results of direct patient reporting.

Consumers can download a report form **in French** from <http://www.test-achats.be/dossiers/mediccomplaint/fr/mediccomplaint.aspx?ext=1> or **in Flemish** from http://quask.euroconsumers.org/FormServer/meldformulier_ta. These forms can also be requested from the TA call centre.

Between 2006 and Nov 2009 T-A had received 762 reports; it now gets about 21 reports a month. About 75% of the reports concern adverse effects, the others relate to prices, medicine information leaflets, etc.

Recently FAMHP started a working group with Belgian patient organisations, primarily to enhance the transparency of FAMHP towards the public and to investigate the possibility of a direct patient reporting tool.

United Kingdom

Before 2005 the Medicines agency (MHRA) did not formally accept or use ADR reports from patients. Then policy changed, and a small pilot scheme began with leaflets to General Practitioner surgeries, press releases and articles in the media. The results were disappointing, and in 2006-7 the National Institute of Health Research [NIHR] commissioned a wide-ranging evaluation of patient reporting. It is being undertaken by a strong multi-disciplinary team from several academic institutions, led by Prof Tony Avery at Nottingham Medical School. The report is due in 2010. The Evaluation Team has an independent Advisory Group.^a

In February 2008 more substantial efforts were made to raise awareness among all age groups and to increase the number of reports. New Yellow Cards – (all cards for reporting ADRs are yellow and have a distinctive format) for patients were distributed to all pharmacies in the UK, a web reporting system was set up, and the scheme was freshly promoted to the public. Now in late 2009 the MHRA receives an average of about 100 reports/month from patients.

The reports are analysed together with the reports from professionals. Qualitative analysis is not done; it is not part of the training of UK pharmacovigilance staff.

When follow up is necessary patients are asked for permission to contact their doctor. Reports are not routinely sent to the manufacturer unless the patient requests it.

All reports are copied to the Eudravigilance database and the Uppsala Monitoring Centre, but without the narrative part because the system is not built for free text.

The reports have contributed some signals, 'aha' experiences [sudden insights], quality of life experiences - and also to regulatory activity. 'A soft' benefit is that the patient is fully part of

^a Andrew Herxheimer is a member of this Group

the process. The implementation of direct reporting has led to a revision of the form: it now enables reporters to give more reasons for considering a reaction 'serious'.

United States of America

Patients have been able to report ADRs directly since the reporting system began in the 1960s. They may do so by downloading a form from a website and then completing it, or do it directly on the website. They can also report by phone or by letter, but letters are now uncommon. The number of reports has increased over time. At present the Food and Drug Administration receives around 500,000 reports a year, which includes both direct reports and reports from manufacturers. In 2008 FDA received 154,000 reports from physicians, 27,000 from pharmacists, 88,000 from other health professionals including nurses, and 227,000 from consumers (many of them submitted by manufacturers).

The reviewers are mostly clinical pharmacists or physicians. They are trained to assess qualitative data in reports.

All these reports are used for regulatory decision making, changes in the mandatory information about the product, etc.

Reports from consumers are analysed and used in the same ways as the others, except that occasionally an official may call the health professional to confirm the event.

Images of individual reports (with personal information removed) are available for a fee to outside researchers, including manufacturers, through Freedom of Information requests.

In an important survey by Golomb et al patients taking a statin (94% of them from the USA) who had discussed a possible ADR with their physician were asked how the physician had responded. A great many physicians had denied the possibility. The authors concluded that the yield of ADR reporting systems would be boosted if patients were encouraged to report such ADRs themselves. ²

Countries Not Actively Collecting Patient Reports

France

Patients in France are at present not encouraged to report ADRs. Members of the public who send a report to pharmacovigilance centre are asked for medical validation. European law requires such validation before a report can be submitted as a suspected ADR to the EUDRA [European Drug Regulatory Authorities] database. It states: "Reports that are not medically validated should be kept within a national agency or a pharmaceutical company."

In 2004/05 the French regulatory agency (AFSSAPS) initiated a partnership with a number of patient organisations [POs]. AFSSAPS carried out a pilot study of patient reporting with good support from the POs and their members.³ Of 200 report forms distributed, 130 were returned sufficiently complete but 12 were excluded because the patient refused to have them confirmed by a doctor. Of the doctors asked for confirmation fewer than half responded, and of these 58% confirmed the ADR. Of the 118 reports 84% noted that the ADR had impaired the quality of life; 55% reported a 'serious' reaction. No unexpected or new ADRs were found. A strength of the reports was the good account they gave of quality of life (which the current pharmacovigilance system does not take into account). As might be expected, the kinds of ADR (system, organ, class) reported varied with the type of Patient Organisation.

In June 2009 a new law was introduced enabling patients to report ADRs. A decree to put this into practice is expected to be published by April 2010. Future patient reporting will probably not be organised with POs because the members of POs represent only a small and very skewed proportion of the population.

Germany

The German Medicines Agency BfArM has an elaborate pharmacovigilance system which receives reports from pharmaceutical firms and physicians and other health professionals.

It works closely with the Drug Commission of the German Medical Association, with which it shares the ADR database. It also receives reports from the Adverse Effects Network of the Arznei-telegramm, an independent drug bulletin.

BfArM usually accepts reports of observed adverse effects only from health professionals since it must evaluate the most detailed medical information. Patients are therefore requested to ask a doctor they trust to complete the reporting form.

The identity (and gender) of patients and of reporting professionals is subject to the Data Protection Law. Any follow up must therefore be arranged through the reporting professional, if possible.

The possibility of allowing direct reporting by consumers does not appear to have been publicly discussed.

Ireland

The Irish Medicines Board (IMB) has always accepted reports directly from patients/ consumers, but if it considers confirmation necessary it requests permission to contact a

health professional involved in the patient's care for additional information. Such an interaction with a professional takes place only with explicit written permission from the patient/ consumer and is based on their nomination of a professional. These cases were then classified with the numbers of reports provided by the various health professional groups, and up to 2007 were not listed separately. Since 2007 the IMB lists patient/ consumer reports separately; around 100 such reports were received in 2007-08.

The main reason for this approach to involving a professional is to ensure that all relevant information about medical history, predisposing factors, other medications, pathological investigations, etc, are available to allow comprehensive evaluation of a case. The IMB also considers it essential that professionals directly caring for a person are aware of problems experienced with treatment, so that they can intervene appropriately, eg by modifying dosage, changing potentially interacting medicines, referring the patient to a specialist, etc.

The IMB is not planning to change these arrangements.

Portugal

INFARMED, the Portuguese National Authority of Medicines and Health Products, does not accept ADR reports from patients and consumers. Whether to do so, and how, has been discussed within INFARMED, but no decisions have been taken.

The European Medicines Agency (EMA)

The European Medicines Agency depends entirely on reports from the national drug regulatory agencies of the member states, and has no policy of its own on direct reporting by patients/consumers. If direct patient reporting were to be accepted in all member states, it would have important implications for the structure and management of the Eudravigilance database.

Brief Literature Review

Two published reviews have dealt with patient reporting of suspected adverse drug reactions (ADRs). The first reported the outcomes of a seminar on Patients' reporting of adverse reactions held in May 2005 by Health Action International Europe, with speakers from the Netherlands, Denmark and the UK.⁴

The second, by Blenkinsopp *et al* (2006), reviewed accounts of international experience from six countries, and seven studies interviewing or surveying patients in hospital or primary care.⁵ However none of the studies concerned *spontaneous* reporting by patients, where patients themselves decide to report an adverse event that a drug may have caused. Patient reports identified possible new ADRs that had not previously been reported by health professionals. They conclude:

The quality of patient reports appears to be similar to that of health professional reports. There is some evidence that patients report an ADR when they consider that their health professional has not paid attention to their concerns. Patient reports may, at least initially, be more time consuming to process.

We discuss the papers under four important questions about spontaneous direct reporting by patients:

- a) How do the reports compare with reports from professionals?
- b) Do they lead to earlier detection of ADRs?
- c) Do patients' reports give further or clearer descriptive detail about the ADRs?
- d) Do they describe how the ADR affects the person's life?

How do the reports compare with reports from professionals?

Four studies have compared spontaneous patient reports with reports from professionals. Two of them examined patient reports that followed a television programme, one in the United Kingdom on the adverse effects of paroxetine,⁶ the other in the Netherlands in 2007 on the benefits and harms of statins.⁷

The first compared a collection of 1374 emails sent to the broadcaster with Yellow Card reports of similar ADRs sent to the MHRA in the years before the programme. The authors concluded that the "reports from users and relatives...communicated information that professional reporters can never be expected to provide. They were far richer, and described suicidality and withdrawal symptoms much more clearly and intelligibly than the Yellow Card reports."

The second study was from Lareb, which received all the Dutch reports. The TV programme led to a peak in patient reporting but not in reports from professionals. The two groups did not differ in the seriousness of the ADRs or drug cessation. Patients noted non-recovery from the ADR more often than professionals. The programme had led almost 30 patients to discontinue the medicine; many felt that they had received too little information and that health professionals had not adequately addressed their concerns.

A different kind of study compared patients' ADR enquiries to a Dutch medicines information line with reports sent to Lareb.⁸ The callers were younger and more often asked about psychotropic drugs. A further study followed, comparing telephone questions with reports that Lareb received from pharmacists in the same period in 1994.⁹ The differences were small – the pharmacists reported relatively fewer possible psychiatric ADRs and fewer ADR associated with the use of antidepressants than the callers mentioned. Neither paper remarked on the quality of the reports.

Do patient reports lead to earlier detection of ADRs?

Mitchell et al examined whether patients could be a direct source of information on ADRs.¹⁰ In their ingenious experiment patients being treated with amoxicillin or co-trimoxazole were given one form for reporting **events**, and another inviting them to report **ADRs**. Later telephone interviews confirmed that the reports of events were reliable and valid. Most of the events reported were related to the patient's illness, indicating the 'noise' to be expected in a system where patients report all events. But patients were conservative in attributing events to their treatment, and their ADR reports had low sensitivity.

The Dutch telephone medicines information service was also used earlier than the study described above⁸ to see how rapidly ADRs to a newly introduced antidepressant, paroxetine, were reported by patients and by health professionals.¹¹ They found that the mean time lag for all suspected reactions to paroxetine was 229 days less for the telephone service than for Lareb. The mean difference in time lag was even greater (273 days) for nine reactions that had not been mentioned in the patient information leaflet.

Do patients' reports give further or clearer descriptive detail about the ADRs?

Do they describe how the ADR affects the person's life?

The evidence is that if patients have space to report ADRs they will give much more detail and describe reactions more clearly than professionals who have little space on forms and are pressed for time. This emerged in the work of Medawar and Herxheimer⁶ and in the French pilot study cited above³.

Patients also do not hesitate to report how an ADR has affected and is still affecting their life, whereas professionals rarely know about this, and tend not to ask.

Gains and Costs

Gains to pharmacovigilance and to medicine from direct patient and consumer reporting

1. **Faster accumulation of knowledge** of ADRs than can be achieved with reports from only health professionals in the population.
2. **Directness** – it comes straight from the person who has experienced the effects, with no intermediary.
3. Reports are in **non-technical language** and this makes it easier to use them in information for patients.
4. They give **more detail**.
5. The **effect on the person's life and his family or carers** is often explicit.

Gains to the community, to public health, and to the relationships between patients and professionals

6. The patient is an **active participant**, not a passive recipient of advice and care.
7. Reporting is a **learning experience** – in reflection and in self-expression. This becomes an important informal part of education, especially on health matters. It contributes to health literacy.
8. Patient and consumer reports **describe the burden of ADRs for individuals**, a major component of health that is missing from public health estimates of disease burden in populations. This is a key gain, since policy makers often focus on a macro approach based on numbers, neglecting the micro approach that shows the human side.

Costs

1. The pharmacovigilance systems must be restructured to enable direct patient reports to be appropriately handled. That will require more staff, new training and time. To be able to analyse patient reports, pharmacovigilance staff need to learn to analyse qualitative data.

2. Physicians, pharmacists, nurses and other health professionals will need to improve their roles as 'information intermediaries' with patients and the public. They should accept a greater role in teaching patients, carers and consumers how to think about medicines and to use them well, for example how to weigh their expected benefits against possible harms and disadvantages.

Policy Recommendations

Promotion of reporting by patients and consumers

- Those with experience in running patients' reporting systems should assess which techniques to promote their systems have been most effective, with particular attention to mechanisms for encouraging reporting by the elderly and by users of minority languages.
- Piloting ways of stimulating and encouraging patients and professionals to prepare ADR reports **in collaboration with one another**.

Connecting information from patient reports to adverse reaction data held by pharmaceutical companies

- Authorities and organisations active in the field of patient reporting should provide updates on their interactions with the pharmaceutical industry (exchange of data and analyses) and circulate the outcomes of any engagement with industry, be it in joint working groups or other multi-stakeholder platforms.

Ensuring high-quality data analysis and data compatibility

- Certain core quantitative data should be pooled across different countries and future systems designed with such compatibility in mind;
- Patient and consumer organisations should be encouraged to take on responsibility for analysing qualitative data and should invest in systems for responding promptly to those making reports. Europe-wide patient and consumer organisations should facilitate exchange among their national member organisations.

Communicating with countries with no established system of consumer reporting

- Outreach to groups in countries not covered in this report should be coordinated. These groups should be asked to indicate:

- a. What other existing or planned systems of patient reporting there are in their country;
- b. The extent of enthusiasm and capacity they have for being involved in work on patient reporting.

Communicating with national and European authorities

- Partner organisations should be encouraged to use this document for advocacy to their governments, demonstrating the value of patients and consumer reporting systems and pressing for such a system to be developed and tested in their country;
- The European Medicines Agency should convene a meeting with all stakeholders to discuss patients' and consumer reporting;
- Communication with national and European authorities should stress the principle of public access to pharmacovigilance data, whether from patients or from professionals.

Supporting pharmacovigilance activities by allocating adequate financial and human resources

- To develop a proactive pharmacovigilance structure that meets public health needs, pharmacovigilance systems must receive adequate funding from public bodies.

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