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Drug Safety Information Through the Internet

The Experience of an Italian Website

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Abstract

Background: The Internet may play a crucial role in the prompt provision of updated drug safety information. Nevertheless, limited knowledge of the English language among healthcare professionals or suboptimal search skills constitute barriers to widespread and appropriate use of the Internet for this purpose in Italy. In order to provide accurate information on drug safety and to promote the reporting of adverse drug reactions, in 1999 the clinical section of the Italian Society of Pharmacology created the website www.farmacovigilanza.org, financially supported by a non-profit foundation. The website promptly and independently provides news published in the international literature on drug safety, translated into Italian. The site also contains specific sections dedicated to adverse reactions to herbal products and cosmetic preparations.

Objectives: The aim of this paper was to describe the number and characteristics of users and the most intensively visited sections of the website. Furthermore, in September 2006, 300 registered users who had accessed a registered users area aimed specifically at health professionals more than 20 times in the preceding 12 months received a ten-item multiple choice questionnaire via e-mail, to assess satisfaction with the accuracy and promptness of information provided, text comprehension and other information sources for drug-related issues. We hereby describe the results of the survey, after careful analysis of the questionnaires.

Results: Up until July 2007, the site had over 600 000 direct accesses and 9760 healthcare professionals registered to use the site. A total of 108 responses to the e-mailed questionnaire were received (response rate = 36%), of which 103 were analysed; five were excluded due to missing information. Overall, the

majority of responders judged the information on the site as objective and understandable. More than 85% of participants declared that the site has influenced their opinion and attitudes toward the safety of medicines. In particular, responders said that they pay more attention to drug interactions and to the safety profile of newly marketed drugs, and spend more time on communicating the risks of drugs used by their patients. Specifically, responders stated that they pay more attention to drug interactions (87.7%), newly marketed drugs (68.5%), herbal remedies (56.2%), drugs in patients at increased risk (42.5%), drugs in pregnant women (42.5%) and cosmetics (13.7%).
Conclusions: The website www.farmacovigilanza.org appears to be an effective tool that provides users of the site with independent, relevant and reliable safety information. It was found to influence (and possibly improve) the quality of prescribing of a large proportion of the general practitioners who responded to our questionnaire, and our results indicate a high appreciation of the information found on the website. Moreover, the survey disclosed that there is a substantial need for such information in the national language by healthcare professionals. We think that our approach can serve as a model for similar initiatives in countries elsewhere in the world.

Background

The Internet offers a great opportunity to improve the manner in which pharmacovigilance is achieved and practised; it may also represent an early warning system for potential drug-related issues. Several experiences worldwide have already shown the potential of this technology for these purposes. One of the largest is Vigimed, a worldwide e-mail discussion group maintained by the Uppsala Monitoring Centre (UMC), within the WHO International Drug Monitoring Programme.[1] This tool allows rapid exchange of information and opinions on drug safety matters between national pharmacovigilance centres around the world. Several other independent websites specifically dedicated to drug safety issues are also accessible to the public (such as www.worstpills.org, maintained by the nonprofit organization Public Citizen); some of them require a fee for registration or may not provide sufficient guarantees about the quality of the information released.[2]

Healthcare professionals may fail, however, to fully benefit from such sources of information; in fact, given the large amount of drug-related topics available on the Internet, it may require time to browse the Internet, and the information they find may not meet their needs. In addition, those who are not from English speaking countries may find it difficult to manage information in English, which is the primary language used by the scientific community.

In June 1999, the Clinical Section of the Italian Society of Pharmacology created the website http://www.farmacovigilanza.org – now supported by the non-profit Foundation 'Gianfranco Ferro' – to provide accurate information on drug safety and rational drug use; it also aims to promote the reporting of adverse drug reactions (ADRs) among healthcare professionals, although it is not intended to allow them to report suspected ADRs through it.

Seven years after its creation, we wanted to evaluate the number and characteristics of website users and the most intensively visited sections. Therefore, in September 2006 a questionnaire was electronically mailed to registered users who had commonly accessed the website, to learn their opinions on the quality and the reliability of information provided, and to discover their needs and sources of information for

drug safety issues. In particular, the objectives of the survey were to:

- explore the reasons for using this website;
- assess visitors' satisfaction with this service;
- investigate the self-reported use and impact of the information received;
- explore visitor behaviour in searching for and selecting drug safety information.

Materials and Methods

Access to the website is free of charge, but registration is required to gain access to areas specifically aimed at health professionals. Registered members receive a monthly e-mail (listing all new content) and have access to an online course on pharmacovigilance for the purposes of continuing medical education. Moreover, healthcare professionals can submit specific queries on drug-related issues by e-mail in order to receive personalized answers or advice.

The website offers constantly updated abstracts of articles and case reports published in the international literature and translated into Italian. The electronic version of *Focus* (http://www.farmacovigilanza.org/focus/), an Italian drug safety bulletin affiliated with the International Society of Drug Bulletins (ISDB) [http://www.isdbweb.org/pag/bulletin.php], is also available.

News from international regulatory agencies (the US FDA, the European Medicines Agency [EMEA], the UK Medicines and Healthcare Regulatory Agency [MHRA], the Australian Therapeutic Goods Administration [TGA], etc.) is translated; the original source and the date of publication are always shown. A list of common iatrogenic diseases ('Patologie iatrogene') is also provided, linked to a list of drugs that might be responsible for causing them. A specific section ('Fitovigilanza') provides information on herbal remedies and contains single-herb monographs, lessons, articles and news about side effects of herbs and drug-herb interactions. In the past few years, new sections have been added to provide more complete information: a section ('Alterazioni dei parametri di laboratorio indotte da farmaci') is dedicated to drugs that might alter laboratory tests, and a new area ('Cosmetovigilanza') contains reviews, news and links concerned with adverse cosmetic reactions. Additionally, a special section ('Appropriatezza della diagnosi di ADR') is dedicated to improving the quality of adverse reaction reporting and the selection of the most appropriate adverse reaction terms, according to the definitions of the CIOMS, a non-governmental organization established jointly by the WHO and UNESCO.[3]

The material for the website updates is selected and prepared on a regular basis by an editorial staff composed of clinical pharmacologists, toxicologists, pharmacists and biologists (mainly from an academic setting), who contribute on a voluntary basis. Furthermore, medical doctors and pharmacists doing PhDs or specializing in pharmacology or toxicology are invited to translate and summarize the articles selected for the website as a part of their clinical training. Special care is taken to ensure that both the language and the style of the information, as well as its presentation, are tailored to meet the needs of healthcare professionals.

A link to a web log analyser (LiveStats.XSP®, version 8) was set up in order to obtain detailed traffic reports, as to the most visited pages, accesses per country, per continent, and visitor characteristics. Furthermore, 300 registered users who had accessed the registered users' area more than 20 times in the preceding 12 months received a ten-item multiple choice questionnaire via e-mail. Inclusion criteria required that participants had either a medical or pharmaceutical degree at the time of registration. Researchers with a medical/pharmaceutical degree were only included if they worked in a clinical setting (e.g. a university hospital). Users working in the pharmaceutical industry or clinical research organizations, medical students, regulators and medical journalists were excluded from the analysis. Moreover, users who were directly or indirectly collaborating with the website were not eligible for the study. Different indicators were considered in this survey, e.g. satisfaction with the accuracy and promptness of information provided, text comprehension. For this purpose, participants were asked to quantify satisfaction

using a non-validated rating scale ranging from a minimum of 1 (inadequate) to a maximum of 5 (excellent). Non-responders were reminded to answer 2 weeks after the first e-mail. Responders were allowed to choose from the list of sections available on the website those that they visited more frequently; there were no limits to the number of sections to choose from. Responses were analysed using descriptive statistics, while answers to open questions were analysed thematically.

We used absolute frequencies and relative frequencies (expressed in %); the mean value and standard deviation (SD) was used for variables quantifying the level of satisfaction for the website. Data analyses were performed using Microsoft Office® 2003 Excel® software (Microsoft, Redmond, WA, USA).

Results

Accesses to the Website

Up until July 2007, the website http://www.farmacovigilanza.org had had 671 780 direct accesses and an average of 120 000 hits per month. Over 9700 healthcare professionals were registered for access to the 'restricted' area, with an average of 185 new registrations per month in the 6 months leading up to September 2006. Community pharmacists (n = 1625), hospital physicians (n = 1287) and general practitioners (n = 1226) are the three most represented categories (figure 1) other than an amalgamation of other users such as medical journalists and regulators. While all registered users were from Italy, 86.6% of website visits came from Europe, the most represented countries being Italy (87.6%), Sweden (4.7%), France (1.6%), Switzerland (1.5%) and Germany (0.9%). Accesses from non-European countries came mainly from North America (12.7%). The remaining 0.7% was equally distributed between Asia, Oceania and Africa.

Moreover, 2736 healthcare professionals subscribed to the continuing education pharmacovigilance training course. Of these, 78 successfully completed the course by passing the final exam. Overall, responders gave their preferences to the following sections: summaries of selected articles and case reports from the international literature (89.3%), news from regulatory agencies (75.7%), 'Fitovigilanza' [safety of complementary and alternative medicines] (61.2%), 'Patologie iatrogene' [list of iatrogenic diseases together with drugs that might be responsible for causing them] (57.3%), 'Appropriatezza della diagnosi di ADR' [definitions of adverse drug reactions and basic requirements for their use] (32.0%), 'Alterazioni dei parametri di laboratorio indotte da farmaci' [drug-induced lab-test alterations] (15.5%) and 'Cosmetovigilanza' [adverse reactions to cosmetic products] (9.7%). The sum exceeds 100% because responders could choose an unrestricted number of sections. The first two sections were equally chosen by different professions, while the sections covering herbal side effects were mainly preferred by hospital physicians (70.0%) and by community pharmacists (69.2%); the 'patologie iatrogene' section was mostly favoured by hospital physicians (90.0%), while the cosmetovigilance area was principally visited by community pharmacists (15.4%) and researchers (12.5%).

Responses to the Questionnaire

A total of 108 responses to the questionnaire were received (response rate = 36%); five of them had to be excluded due to considerable missing information (more than five items left unanswered).

The response rates to the questionnaires categorized by occupation are shown in table I. The characteristics of the responders are shown in figure 2. The majority of the participants in the survey (41%) worked as community or hospital pharmacists, while 36% were physicians (general practitioners, hospital physicians or specialists). Researchers (both pharmacists and medical doctors) accounted for 23% of the sample. Visitor ratings of the website are shown in table II. The majority of responders judged that the content provided was objective and understandable (the rating was 4.5 ± 0.5 and 4.6 ± 0.6 out of 5, respectively). The lowest score was for the prompt provision of information (3.9 ± 0.8 out of 5). The overall judgement on the quality of

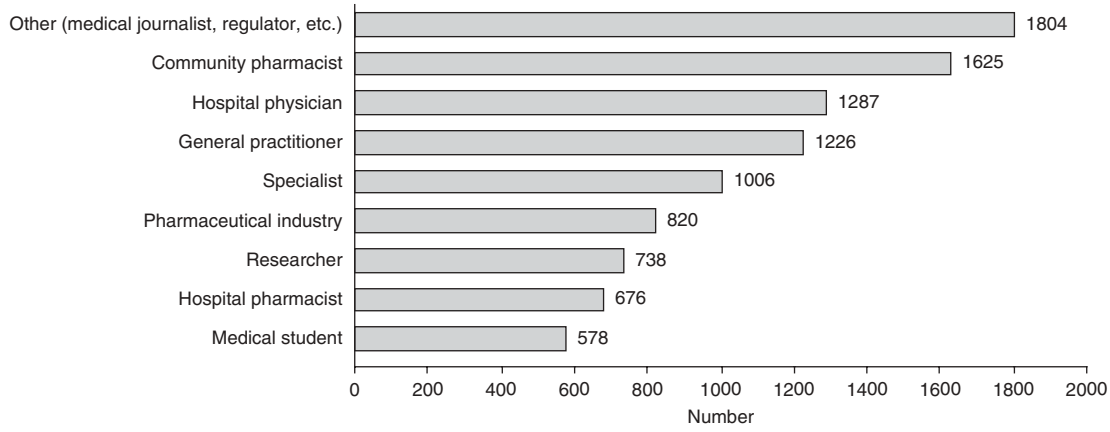

Fig. 1. Profile of registered users of the website up until July 2007 (total = 9760).

information provided by the website was 4.2 ± 0.4 out of 5.

Over 85% of responders stated that the website had influenced their opinion and attitudes toward the safety of drugs. When asked what kind of action, if any, they had taken as a result of reading the information, responders answered that they paid more attention to the safety profile of drugs (83.0%), and spent more time on communicating the risks of drug use to patients (76.1%) or had started to report suspected adverse drug reactions (13.6%).

When asked to what aspect of the safety profile of drugs they have become more focused on, responders stated that they pay more attention to drug interactions (87.7%), newly marketed drugs (68.5%), herbal remedies (56.2%), drugs in patients at increased risk (42.5%), drugs in pregnant women (42.5%) and cosmetics (13.7%). Furthermore, over 82% of participants were also interested in information not necessarily linked to their professional field.

A list of alternative sources of drug safety information used by responders to the questionnaire is shown in table III. Overall, 64 participants (62.1%) use scientific publications (either online or paper journals, bibliographic references in MEDLINE, textbooks), while independent bulletins are consulted by 41.7% of participants. Almost 37% of responders reported using official sources to solve their drug-related doubts, and 33% used one or more generalist websites or search engines. Finally, 28.2% of participants reported that they utilize online databases, such as Drugdex® System, (Thomson Healthcare, Greenwood Village, CO, USA), to find information on medicines, while 11.7% retrieve drug safety information from meetings, by consulting an expert of the company concerned, or from other sources.

Discussion

This study explored the influence of www.farmacovigilanza.org – an Italian website focused on drug safety issues – on healthcare professionals, using both a log file analysis of users and an online questionnaire. The large number of frequent visitors and subscribers and their apparent positive appreciation are sufficiently indicative of its

Table I. Response rate to the questionnaire[a]

Occupation	No. of users contacted	No. of responders (%)
Community pharmacists	83	26 (31.3)
Researchers	58	24 (41.4)
Hospital pharmacists	52	16 (30.8)
General practitioners	42	18 (42.9)
Hospital physicians	33	10 (30.3)
Specialists	32	9 (28.1)
Total	**300**	**103 (34.3)**

a There were initially 108 responses to the questionnaire; five were excluded due to considerable missing information.

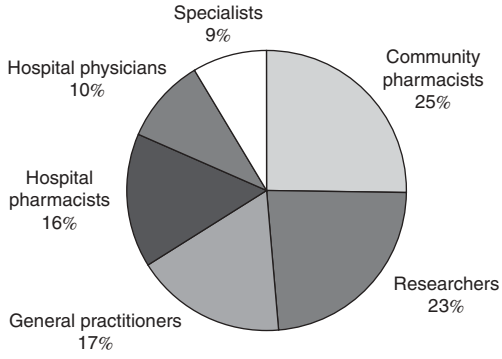

Fig. 2. Characteristics of responders to the questionnaire (n = 103).

usefulness and effectiveness in improving the quality of prescribing to a considerable proportion of healthcare professionals in Italy.

To our knowledge, this is the first investigation performed so far in Italy aimed at exploring the impact of an online independent drug information source on health professionals' practice. Although no terms of comparison are available, our survey suggests a large-scale knowledge of the website in Italy. Considering that up until 2006, according to the WHO Statistical Information System,[4] the number of practising physicians in Italy was 215 000 (37 per 10 000 population), and the number of pharmacists was 44 000 (8 per 10 000 population), we can estimate that about 3.7% of the target population was registered with the website. Its appreciation is further confirmed by the absence of sponsorship and initiatives for promotion since it was set up in 1999. The medical staff responsible for its contents work on a voluntary basis, while the costs for hosting the site on the Internet and for its periodic updates are entirely covered by the non-profit foundation 'Gianfranco Ferro'. This organisation has the primary objective of supporting activities in the field of pharmacovigilance for healthcare professionals; since it does not operate to generate profit, it is financially sustained by donations from the private and public sectors.

There are a number of limitations to be considered in this study. The most important is the selection bias deriving from interviewing only frequent visitors, i.e. those most likely to have a good opinion of the site, which may have influenced the results. Also, candidates for the survey were chosen using very restrictive selection criteria, since we were able to keep track of only those users who had access to the restricted area of the website. However, a considerable proportion of the material presented on the website is accessible without registration, so we may have missed many frequent users; in addition, the population selected for the survey may, for this reason, differ in their features (and answers) from the general population of users. Another drawback is that we drew our conclusions only on people who completed and returned the questionnaire, without having the possibility of obtaining the opinions or reasons for not responding of non-responders, who might have a negative opinion about the website. However, this is unlikely to be the case, since visitors eligible for the survey were those who had most often entered the website. Finally, users contacted for the investigation

Table II. Visitors' evaluation of the website according to five elements[a]

Occupation	Objective	Punctual	Comprehensive	Accurate	Understandable	Global rating
Community pharmacists	4.3 (0.5)	3.7 (0.9)	3.8 (0.7)	4.0 (0.5)	4.4 (0.6)	4.0 (0.4)
Hospital pharmacists	4.3 (0.6)	3.6 (0.9)	4.3 (0.7)	4.1 (0.8)	4.5 (0.5)	4.2 (0.5)
General practitioners	4.8 (0.4)	4.0 (0.9)	4.3 (0.5)	4.5 (0.5)	4.7 (0.5)	4.5 (0.4)
Hospital physicians	4.4 (0.5)	3.8 (0.9)	4.0 (0.7)	4.0 (0.7)	4.5 (0.8)	4.1 (0.5)
Specialists	4.6 (0.5)	4.2 (0.7)	4.2 (0.7)	4.2 (0.4)	4.7 (0.5)	4.4 (0.4)
Researchers	4.6 (0.6)	4.2 (0.6)	3.8 (0.5)	4.2 (0.6)	4.6 (0.6)	4.3 (0.4)
Weighted averages	4.5 (0.5)	3.9 (0.8)	4.0 (0.6)	4.2 (0.6)	4.6 (0.6)	4.2 (0.4)

a Participants to the questionnaire were asked to provide a rating from 1 to 5 (1 = inadequate; 2 = average; 3 = sufficient; 4 = good; 5 = excellent). Mean values ± SD are reported.

Table III. Other sources of information on drug safety used by different categories of responders

Source	Community pharmacists (n = 26) [n (%)]	Hospital pharmacists (n = 16) [n (%)]	GPs (n = 18) [n (%)]	Hospital physicians (n = 10) [n (%)]	Specialists (n = 9) [n (%)]	Researchers (n = 24) [n (%)]	Total (n = 103) [n (%)]
Scientific publications (either online or traditional journals, bibliographic references on MEDLINE, textbooks)	15 (57.7)	12 (75.0)	8 (44.4)	8 (80.0)	4 (44.4)	17 (70.8)	64 (62.1)
Independent bulletins (either online or paper)	15 (57.7)	6 (37.5)	5 (27.8)	4 (40.0)	1 (11.1)	12 (50.0)	43 (41.7)
Official sources (e.g. domestic and international regulatory agencies, Ministry of Health or official drug reference book)	11 (42.3)	2 (12.5)	10 (55.6)	3 (30.0)	1 (11.1)	11 (45.8)	38 (36.9)
Generalist websites, search engines and metasearches	1 (3.8)	7 (43.8)	8 (44.4)	0 (0.0)	9 (100.0)	9 (37.5)	34 (33.0)
Specific databases (e.g. Drugdex®)	18 (69.2)	3 (18.8)	5 (27.8)	0 (0.0)	2 (22.2)	1 (4.2)	29 (28.2)
Other (meetings, consultation with experts or pharmaceutical companies)	3 (11.5)	4 (25.0)	0 (0.0)	1 (10.0)	1 (11.1)	3 (12.5)	12 (11.7)

GPs = general practitioners.

were quite different in their workplace and also in their background regarding drug safety issues. For this reason, and because of the low number of responders, the study findings are not generalizable to the entire population of users. Nevertheless, the purpose of this consultation was to draw a general outline about drug safety related problems from different points of view, and to analyse the range of visitor opinions. In this respect, our results suggest an overall underestimation of the risks associated with drugs and herbal product use among healthcare professionals – given their changing behaviours following website consultation for the majority of participants.

As shown in table II, how understandable the information on our website was, was given a high score by the visitors, although the rating scale used to quantify the level of satisfaction is not validated. According to healthcare professionals, a major advantage of the website is that the information is pre-selected and translated; this is indirectly confirmed by the higher number of registered users working as community pharmacists (16.7%) and hospital physicians (13.2%) rather than as researchers (7.6%). In fact, the majority of responses showed that the consultations of the website had influenced the attitude towards medicines in daily practice and increased concern about safety issues, as well as the provision of information to patients and the reporting of suspected adverse drug reactions, especially regarding newly marketed medicines, drug interactions and herbal remedies. Most responders appeared to prefer information originating from scientific journals, bibliographic databases or independent bulletins. Likewise, responders preferred official sources and generalist websites (table III). A smaller number of participants, on the other hand, preferred information given by pharmaceutical companies or expert consultants.

Interestingly, these results overall suggest that many users consulted sources of drug safety information (such as MEDLINE or DrugDex®) that might require a working knowledge of English. This might be due to the fact that the majority of responders use the website to access a range of pre-selected documents otherwise neglected or time-consuming to retrieve.

The opportunity given by the Internet to have access to updated information makes this tool increasingly important as a source of drug-related information. Nevertheless, despite the drug information overload on the Internet, drug safety information is not always overtly commu-

nicated to the medical community. A study by Tatsioni et al.[5] showed that major warnings issued by the FDA on severe and life-threatening drug toxicity were less likely to be reported in undated websites or in those with unclassifiable site owners. In addition, the authors found that only one-third of the top ten web pages identified by seven different search engines specifically mentioned major adverse effects that were covered by FDA warnings. In spite of this shortage of information, additional data are continuously released that modify the benefit-risk profile of drugs available on the market. New drug-drug interactions or unlabelled adverse drug reactions are published daily in the literature, but it may take time before they become more widely known. In this context, the Internet can be a potential source of prompt and value-added information. A major concern with the Internet is the potential of websites to disseminate inaccurate or incomplete health information to healthcare professionals and patients. Several studies and a systematic review have already documented the variable quality of consumer health information on the Internet.[6-11]

Most national pharmacovigilance centres are linked with regulatory agencies. Because of priorities arising from the regulatory requirements and procedures (e.g. the assessment of Periodic Safety Update Reports), the communication and negotiation with pharmaceutical companies and judicial procedures, national centres may not have the time to cover all possible issues related to the safety of medicines. For instance, preliminary signals or unconfirmed case reports not requiring regulatory decisions are often not brought to the attention of healthcare professionals.[1] As a result, the recognition and reporting of similar experiences may be delayed. Also, safety data provided by pharmaceutical companies may be company property and need to be kept confidential by the regulator. A regulatory committee that has previously approved a given medicine may, in the assessment of a subsequent safety problem, not be entirely unbiased. The withdrawal of rofecoxib from the market and the ensuing debate on the role of the FDA may serve as an example of such limitations.[12-18] An Internet-driven independent information service such as our website (www.farmacovigilanza.org) can serve as an additional and complementary source of updated, comprehensive, clear and useful information, focusing on issues and problems that matter in medical and pharmaceutical practice. However, independent information is not necessarily reliable and/or valuable; the former can be achieved by referring to the original source of the information and the latter by understanding the needs that exist in the target audience, as is suggested in the joint declaration that was released in 2007 by the main associations promoting independent health information.[19] The opportunities provided by the Internet to independent organisations for the provision of rational, unbiased and practice-oriented information are unprecedented. Our findings show that a website such as ours could have the potential to reach very large numbers of healthcare providers as well as patients, improve the prescribing and use of medicines, and increase the effectiveness of pharmacovigilance.

Conclusions

The website www.farmacovigilanza.org appears to be an effective tool that, in a comprehensive and practice-oriented way, focuses the attention of drug prescribers and other healthcare professionals on independent, relevant and reliable safety information. It was found to influence (and possibly improve) the quality of prescribing of a large proportion of the general practitioners who responded to our questionnaire. Despite bias in our survey, as the questionnaire was only sent to frequent visitors to the website, our results indicate a high appreciation of the information found. Moreover, the survey disclosed that there is a substantial need for such information in the national language by healthcare professionals. We think that our approach can serve as a model for similar initiatives in countries elsewhere in the world.

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