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Pharmaceuticals and the Internet

Drug Regulatory Authorities' Perspective

24–25 September 2001, Copenhagen, Denmark

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Executive Summary

This workshop was organized by the Nordic Council on Medicines (NLN) in collaboration with the World Health Organization (WHO). It took place in Copenhagen, Denmark, from 24 to 25 September 2001.

The main objective of this meeting was to identify the minimum quantity of information a drug regulatory authority (DRA) should have on its web site, to define how to assess a DRA web site, and to get guidance on those subjects. A DRA web site is seen as a potential tool to help to fight inappropriate use of the Internet in both the distribution of biased and dangerous drug information and unlawful sale of products.

Many questions remain in relation to the use of the Internet: Do we need more guidelines? What can be done beyond the yellow booklet published by WHO (*Medical products and the Internet: A guide to finding reliable information*)?

Examples of DRA web sites were presented, as well as a proposal by WHO of a model web site for DRAs.

Drug regulatory officials from Belgium, Bulgaria, Denmark, Estonia, Nepal, the Netherlands, Portugal, South Africa, Sweden, and Tunisia, as well as representatives from the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and the International Organisation of Consumers Unions (Consumers International) attended the meeting (see Annex 1).

The organizing committee appointed by the NLN and WHO to plan the conference had the following members:

Nordic Council on Medicines

Dr Ola Westbye, Secretary General
Ms Anna Dahlin
Ms Karia Karlsson

World Health Organization

Dr Lembit Rägo, Department of Essential Drugs and Medicines Policy
Mr Kees de Joncheere, Regional Adviser, Pharmaceuticals, Regional Office for Europe
Ms Elodie Jambert, Department of Essential Drugs and Medicines Policy
Mr Jorg Hetzke, Department of Essential Drugs and Medicines Policy
Dr Wilbert Bannenberg, Technical Adviser, Pharmaceuticals (making a presentation of behalf of the South African authorities)

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Overview of activities by the World Health Organization

Dr Lembit Rügo

Department of Essential Drugs and Medicines Policy, World Health Organization, Geneva

The Fiftieth World Health Assembly requested the Director-General of the World Health Organization (WHO) to collect information on the various aspects and consequences of using the Internet in collaboration with drug regulatory authorities (DRAs), national and international enforcement agencies, consumer groups, professional associations, and the pharmaceutical industry and to convene a WHO ad hoc working group to consider and review the relevant issues [1]. The Fifty-First World Health Assembly requested the Director-General of WHO to review existing legislation, regulations, and guidelines on the Internet and to educate Internet users by developing a guide on medical products and the Internet [2]. In response to this, WHO published the booklet *Medical Products and the Internet: A Guide to Finding Reliable Information* [3], which, in addition to English, is available in many other languages, such as Spanish, Italian, Estonian, etc. The guide was intended to serve as a model for Member States to adapt into locally meaningful advice for Internet users in order to help them obtain reliable, independent, and comparable information on medicinal products.

Since then WHO has been keeping communications open with regulatory authorities, industry, consumers, and other involved parties. WHO has prepared a draft Model Web Site for drug regulatory authorities in order to improve access to the regulatory information. It has also made efforts, in collaboration with the World Intellectual Property Organization (WIPO), to control the use of international nonproprietary names (INNs) of drugs as domain names on the Internet. WHO, along with the pharmaceutical industry, is of the opinion that the system designed to facilitate universal identification of active pharmaceutical substances is threatened by companies and individuals registering INNs as Internet domain names. Examples of this include www.sanquinavir.com, www.omeprazole.com, and www.paroxetine.com. There is also the fear of *cybersquatters* registering a large number of INNs in the hope of selling them for profit, as has been the case with names of countries and personalities. After discussions with WHO and the pharmaceutical industry, WIPO has suggested a ban on the registration of exact INNs because “without any external control over the veracity and reliability of the information relating to the INN, there are risks of confusion posed to health professionals and consumers” [4].

WHO has also discussed with its partners further steps to be taken to minimize the public health risks of Internet sales of pharmaceuticals. To clarify

how WHO Member States regulate e-trade, a questionnaire was prepared and sent to all 191 Member States. Over one-fourth (58) of the countries replied. Only five countries declared that they specifically regulate the promotion and sale of pharmaceuticals through the Internet, but a wide range of sanctions, such as revoking licences, confiscating drugs, imprisonment, and applying financial penalties, was reported. Moreover, very few countries effectively control the export of drugs, which can result in the import of counterfeit or substandard drugs, or of drugs that are unregistered in the receiving country. At the same time, the purchase—and import—of medications via the Internet is often accepted for ‘personal use’. These current practices give good grounds for safety concerns.

Overview of activities by the Nordic Council on Medicines

Dr Ola Westbye

Nordic Council on Medicines, Norway

Much has been done by the Nordic Council on Medicines (NLN) in the area of pharmaceuticals. They have worked on the quality of the information about medicinal products that are available on the Internet. A proposed quality symbol for web sites that meet specific criteria (the 'Nordic Symbol for Reliable Information on Medicines') has been produced. Seminars and conferences have also been organized by NLN on e-medicines, medicines on the Internet, harmonization of the Nordic drug regulatory authorities' administrative practices, etc.

Country Experiences

Sweden: Publication bias of clinical trials

Dr Juliette Säwe

Medical Products Agency, Sweden

Few clinical trials are published in peer-reviewed journals at the time a drug is registered; however, the Medical Products Agency (MPA) is planning to make public on their web site all clinical trial results submitted in the dossier. This is in addition to the evaluation monographs, summaries of products characteristics (SPCs), and patient information leaflets (PILs) that MPA has already published on the Internet. PILs, monographs, and overhead presentations are only available in Swedish (<http://www.mpa.se/mono/monomatris2.shtml>), but the SPCs are also available in English (http://www3.mpa.se/spc/nn_spcindex.html).

Who has access to the information? The industry, the regulators and the scientists. But the different sectors (drug industry, universities, medical agencies, healthcare professionals, patient organizations) have different goals and roles.

Who has the information? The industry and the regulators. The public should know what is in the files, but it can be difficult for the public to gain access to this information. Providing objective, unbiased information is not without difficulty and presents a constant challenge. Medical journals have established rules for publishing trial results in order to avoid such problems, but some doctors still accuse them of not addressing critical issues in an unbiased manner. Even patient organizations are not always an independent source of information because they may get funds from the industry. The problem is that it is the industry that has the information and it is the industry that selects what is published and reported. An example of this is a class study (celecoxib vs. ibuprofen/diclofenac) where celecoxib was shown to be better, even if it is not really better (celecoxib has no advantage over ibuprofen as judged by adverse drug reactions but it may appear to have an advantage if the ibuprofen and diclofenac data are pooled).

To avoid bias, the Declaration of Helsinki (DOH) clearly states that 'Negative results have to be published . . .' (p. 27) [5]. The challenge is to make this information more broadly available. The drug regulatory authorities are in a unique position to do this because they have the information and can cover all drugs. Thus they have the information to put on a web site and are also responsible for making this information (SPCs, PILs, monographs) available.

The Netherlands: Pharmaceuticals and e-commerce

*Dr Hans Heuvelmans**

Public Health Supervisory Service, Health Care Inspectorate, Netherlands

There is nothing specific in the laws and regulations of either the European Union or the Netherlands on Internet matters and e-pharmaceuticals. While quality standards have been harmonized, the individual Member States are responsible for registration, and developing a standardized approach continues to be a challenge. For example, over-the-counter drugs can be obtained from drug stores in the United Kingdom and the Netherlands but not in all European Union countries.

It is also legal in the Netherlands and the United Kingdom to run an 'Internet pharmacy'. The physical prescription needs to be sent to the pharmacy, but all other communication can be done via e-mail or the Internet. Examples of Internet sites targeted towards selling pharmaceuticals in the Netherlands include nine pharmacies, four drug stores, chat boxes, e-auctions, and apotheek.org. The success of these Internet pharmacies is based on the difference in manufacturers' prices and taxation. For example, pharmaceutical prices in Germany are 30% higher than those in the Netherlands. The difference in taxes between countries ranges from 0%–25%, and costs for delivery can range from 20%–50%. Although less than 1% of drug sales are currently handled through the Internet, this can be expected to increase.

The types of activities carried out by the Health Care Inspectorate include monitoring information on pharmaceuticals, the trade in pharmaceuticals—both legal and illegal—and prescriptions. Sales of all kind of products, including controlled substances, are carried out on the Internet, and in addition to legitimate pharmacies and drug stores there are also many charlatans.

Information versus advertising

In the European Union, there are many legal cases against either Member States or companies testing the limits in areas where the regulations are not precise. The number of such cases is expected to increase because there are many areas not clearly covered by law. For example, some pharmacies in the Netherlands sell to Germany, which is legal in the Netherlands but illegal in Germany. These medications are delivered by courier service (as an extension of the pharmacy's service, perhaps).

* Dr Hans Heuvelmans of the Netherlands Inspectorate is the only 'cyber-drug-inspector' among the European agencies.

Measures for information, preparation, cooperation

How should we deal with these activities? What can be done? There are several actions that can be taken. There is information (based on day-to-day practice) that must be prepared, made accessible, and kept up to date. Working in cooperation with the public is important. Effective measures for control must also be taken when necessary. For example, the maximum fine for illegal handling of pharmaceuticals used to be US\$4000 or a prison sentence of six months; the fine is now US\$40 000 or a maximum of six years imprisonment.

One problem, however, is monitoring these activities, which can be a monumental job; at present, only 5% of the mail is screened in the Netherlands and the United States. Another problem is customs control. Inside the European Union there is no customs control, with free movement of products among Member States.

Many companies are trying to do a good job, but there is still a real need to protect and inform the public. While professional guidelines for pharmacy services online have increased, quality seals like those of the Health on the Net (HON) Foundation (<http://www.hon.ch/home.html>) and the Which? Web Trader can help consumers judge the quality of the information on a web site for themselves. A European working group is also currently drafting guidelines on the quality of health-related web sites [6]. The role of the health authority is to explain to consumers what can and cannot be guaranteed, but the question is how far we need to go in protecting the consumer.

In pharmaceuticals and e-commerce, there are both legal and illegal activities that are increasing over time. In order to monitor these activities and to protect consumers adequately, we need international contacts, and we have to use existing agencies such as WHO, FDA, etc.

Discussion and comments

Is there a web site for the public? It is under construction.

Are more specific regulations necessary? There is no need for more specific regulations at the moment. Present legislation is adequate for most issues, but no one can screen all web sites. Most information comes in via complaints.

Rogue web sites abound, and only rarely is one able to stop them. DRAs should concentrate on the physical distribution of drugs from these Internet pharmacies at post-offices and through courier agencies.

Biased information is a problem. The industry—the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and the Association of

the British Pharmaceutical Industry (ABPI), for example—has updated its voluntary codes to include promotion through the Internet [7].

Quality seals are sometimes misused and can be difficult to monitor. WHO and NLN have dropped their efforts, but IFPMA announced they will establish an industry quality seal soon. The HON code is the most widely known.

Denmark: Web site of the Institute for Rational Pharmacotherapy

Ms Karin Friis Bach

Danish Medicines Agency, Denmark

Established in October 1999, the Danish Institute for Rational Pharmacotherapy is part of the Danish Medicines Agency, but is formally independent. The aim of the Institute is to provide information on rational drug use in order to improve prescribing habits. The Danish Medicines Agency publishes SPCs, PILs, and monographs, but the Pharmacotherapy Institute publishes treatment guidelines and comparative reviews (in Danish only) on its web site (www.irf.dk). The Institute has access to all studies submitted to the Agency. Their activities include:

- a monthly newsletter;
- courses for GPs;
- cooperation with local authorities;
- lectures, meetings;
- a web site;
- a list server.

On this web site, you can find:

- general information about the Institute, including working plans, strategies, etc.;
- all publications, including the monthly newsletter;
- information on new drugs (evaluations);
- information about courses;
- summaries of meetings, etc.

The information for new drugs is for selected drugs only. It includes:

- evidence of the drug's effectiveness (summaries of studies) and what is missing;
- a description of adverse drug reactions/interactions and other risks;
- information on prices and reimbursement;
- direct advice on how to use the drugs.

There is also information on prices, e.g., reimbursement status, price changes over time, price comparisons between synonyms or analogues, updated information on prices (searchable by product name, anatomical therapeutic chemical classification [ATC], etc.). Before being published, all information is submitted to the industry for comment.

A list server with more than 300 participants (physicians, pharmacists, industry employees, administrators) is used for providing information on new drugs. It is set up as a chat room, where the participants receive messages and have discussions.

Discussion and comments

There is more promotion than information for consumers. As a result, consumers may receive mixed messages.

Denmark: Danish Medicines Agency web site

Mr Karsten Jørgensen

Danish Medicines Agency, Denmark

This presentation covers both the Danish Medicines Agency web site (www.dkma.dk), which is in English and Danish, and the web site of the European Agency for the Evaluation of Medicinal Products (EMA) (<http://www.emea.eu.int/>).

On the Danish Medicines Agency web site, there is information about the Agency, medicinal products, pharmaceutical companies (an application form for pharmaceutical companies to register products, fees and payment), reimbursement, pharmacy and non-prescription products (pharmacy licensing, pharmacy reimbursement, distributors), e-commerce (medicinal products and customs regulations), extensive statistical information (statistics on medicinal products, a price index for medicinal products, consumption analyses), and medical devices. There is also an explanation of how to handle e-business (with a short introduction) and active feedback where visitors can ask questions, e.g., whether buying a certain medicine through the web is legal. All Legal Acts are on one web page.

“If you want people to comply with your regulations, you have to make them readily available.”

Discussion and comments

Is the daily defined dose (DDD) related to price? Yes.

What is the target audience of the web site? The primary targets are companies and the public; it is less oriented toward doctors and pharmacists.

South Africa: The South African perspective on medicine regulation

Dr Wilbert Bannenberg

World Health Organization, South Africa

The current problem is that Internet pharmacies exist but the control is only on the physical movement of products. Another problem is that there are port health officials at main post offices and airports, but they are able to check only 5% of incoming parcels. There are counterfeit drugs, and 10%–25% of the drugs are stolen. The private sector is where the expensive drugs are found. There are large differences between rich and poor countries and within countries, between urban and rural areas, between hospitals and clinics, white and black segments of the population, and men and women.

A consultation on drugs and the Internet was held by the Medicines Control Council of South Africa (MCC),* and all stakeholders were invited. The conclusions were that more information is needed. What can be done to improve the situation? What are the priorities? What is the impact of code-of-conduct and quality seals?

Much of the information available to consumers is misleading promotional material. The recommendations, therefore, were that information that is unbiased, objective, evidence-based, and comparative should be provided. Consumers have the right to such information, and e-mail and web sites are good communication tools. MCC has to set a good example.

Both good-quality and biased information is spreading fast through the Internet, which is why DRAs should treat dispensing good-quality information as an urgent priority.

Medicine is a combination of product, information, and context:

- The *product* is the chemical substance, the form and dosage, the packaging, the distribution system, and the brand name.
- *Information* is an essential part of a medicine and should be objective. The following questions concerning information may be asked: Is the

* The health sectors in South Africa cover 42 million people, 5.2 million (12%) of whom are HIV positive.

The Medicines Control Council is the DRA for South Africa. It has 24 members and is chaired by Professor Peter Eagles.

information objective? How should the product be used? How should it be prescribed? When should it be stopped?

- The *context* is culture, beliefs, attitude, perception, demand, use, and commercial pressures. The regulatory controls on medicines should focus more on the context, which plays an important role.

There are significant HIV/AIDS-related problems, but there is no advice from the government on how to provide information about HIV care, drugs and treatment guidelines, availability of drugs in the country, etc.

Tunisia

Dr Amor Toumi

Direction de la Pharmacie et du Médicament, Tunisie

The web site for the Tunisian DRA was presented (Figure 1). It is in French.



Figure 1: Home page of Tunisian DRA (<http://www.dpm.tn/>)

Estonia

Dr Maia Uusküla

Bureau of Drug Information and Pharmacovigilance, State Agency of Medicines, Estonia

The web site for the Estonian State Agency of Medicines was presented (Figure 1). It is in both English and Estonian.

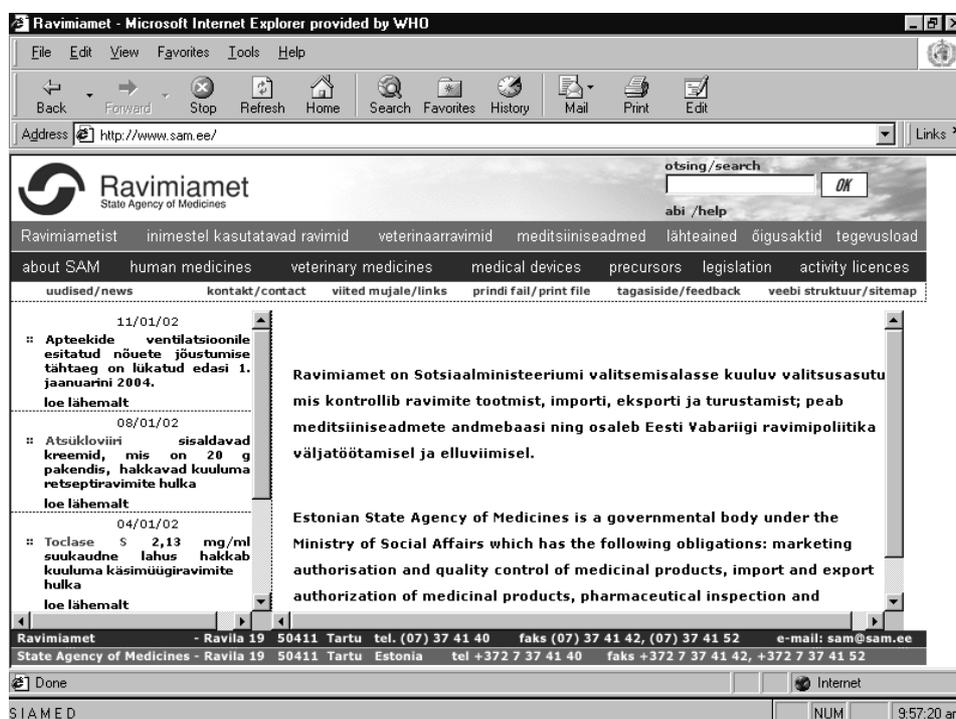


Figure 1: Home page of Estonian DRA (<http://www.sam.ee/>)

Bulgaria: Bulgarian Drug Agency

Rozalina Asenova Kulaksazova

Specialized Drug Information Department, Bulgarian Drug Agency, Bulgaria

The web site of the Bulgarian Drug Agency (BDA; www.bda.bg), was produced in 1998 by the team of the Information Technologies Department and funded by BDA's budget. Access is free and the information from the site can be downloaded. The home page (Figure 1) contains the main menu, a picture of the BDA building and its address with the 'hot line' telephone number. The content is organized in two languages, indicated by Bulgarian and English flags on the upper right corner of the home page. An animated banner below the flags in the upper right corner of the page focuses the attention of visitors on 'hot topics' for discussion, the current one being the mutual recognition facilitating procedure. The main menu has links to specific sections, as described below.

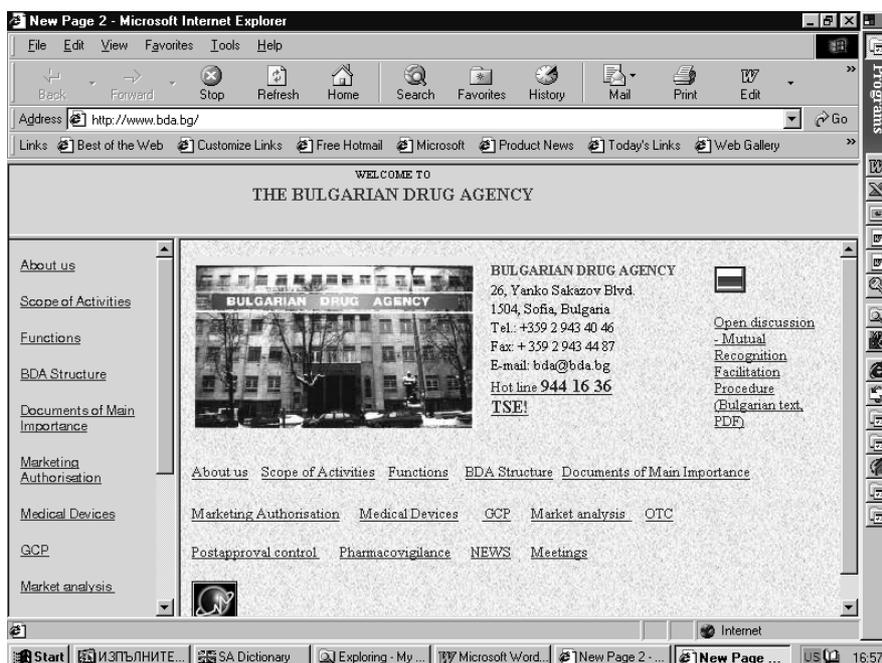


Figure 1: BDA home page

About us

This provides a link to the page that presents the BDA as the government body responsible for regulating the pharmaceutical sector in Bulgaria and for ensuring the quality, efficacy, and safety of the medicinal products sold in the country.

Scope of activities

The page behind this link describes trends and the main activities within the Agency.

Functions

Under *functions*, the tasks entrusted to the Agency and its social responsibilities are described, thus making the services offered by the Agency known to the general public.

BDA structure

This page shows BDA's hierarchical structure, encompassing the Agency and its interrelated components, such as directorates and departments.

Documents of main importance

This is shown in Figure 2. It is the 'legislative' link giving access to basic regulations related to pharmaceuticals.

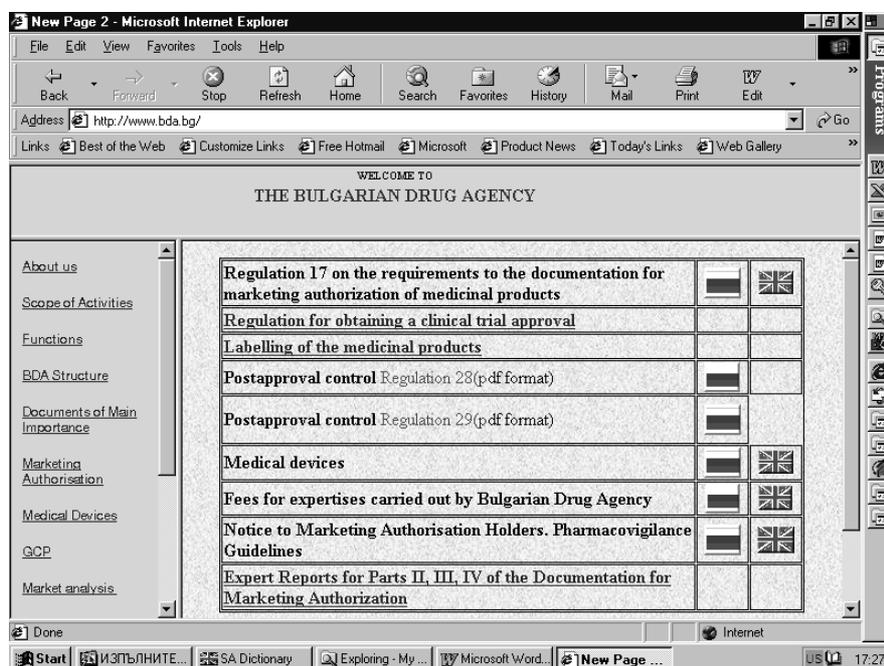


Figure 2: Documents of main importance

Six regulations are on-line, two of which have been translated into English. Three other documents concerning the marketing authorization procedure and

fees payable for the expert work carried out by the Agency are also available in English. The Agency's approved standard operating procedure is currently being set up in Bulgarian. This page is updated on a regular basis.

Marketing authorization

This link has sublinks to the medicinal products with marketing authorization granted during the previous quarter of the current year, the list of medicinal products with suspended marketing authorization, *in vitro* diagnostic medical devices, and the register of drug stores.

It also provides a register of all the medicinal products with effective marketing authorization, as well as a register of licensed wholesalers, in both Bulgarian and English.

Medicinal products can be searched by (Figure 3):

- trade name;
- international nonproprietary name (INN);
- ATC code;
- manufacturer.

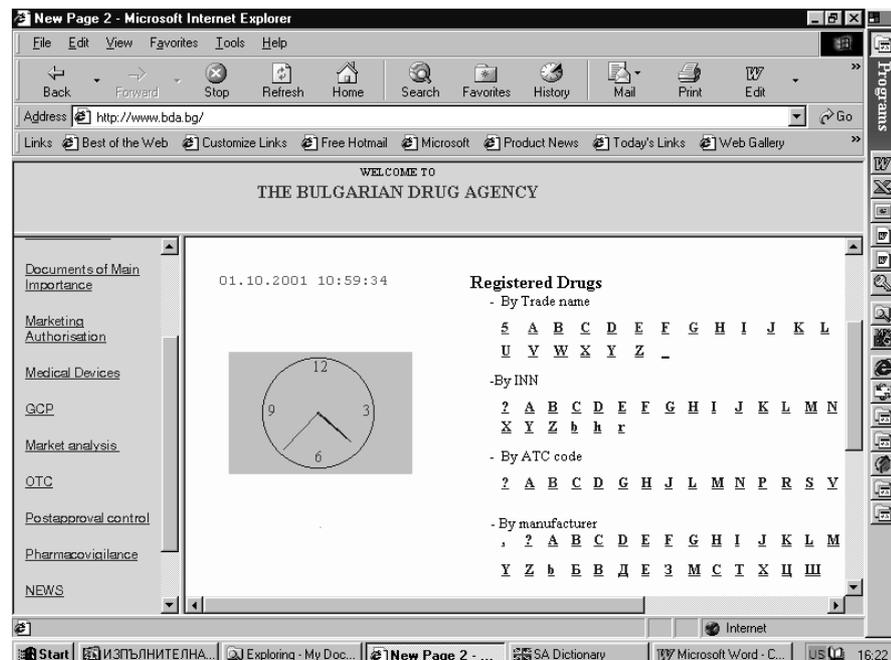


Figure 3: Search criteria

The separate columns can be arranged in alphabetic order. Information for every medicinal product presented on the site includes the items mentioned above plus the pharmaceutical dosage.

The same link presents information on wholesalers. The search can be done in alphabetical order by the type of license they have obtained (full or partial). This information is updated on a weekly basis.

Medical devices

This link gives visitors access to the register of medical devices authorized in Bulgaria. The search can be performed by ATC code or class.

GCP (good clinical practice)

This topic deals with the main documents related to the regulation and notification form and the list of ethics committees with authorized standard operating procedures, in both Bulgarian and English. The page is updated on a regular basis.

Market analysis

Here one can find a pharmaceutical market review, based on statistical data that are updated on an annual basis.

OTC

The main menu also provides access to the list of over-the-counter (OTC) drugs by (1) OTC medicinal products and (2) OTC medical devices, updated on a quarterly basis.

Postapproval control

This information—on recalled medicinal products—is available only in Bulgarian. It contains the product trade name, manufacturer's name, batch number, and grounds for recall for all medicinal products that have been recalled. The page is updated on a regular basis.

Pharmacovigilance

This page provides a description of the reporting system for adverse drug reactions and is available only in Bulgarian. It is updated on a regular basis.

News and meetings

This information is updated on a regular basis.

Analysis of BDA's web site

From the information on BDA's web site, the following conclusions can be drawn:

1. The information provided can be classified according to content.
 - Administrative: About us, Scope of activities, Functions, Marketing authorization links.
 - Legislative: Documents of main importance, GCP.
 - Statistical: Market analysis.
 - Methodological: Pharmacovigilance, News.
 - Information on medicinal products: Marketing authorization, OTC, Postapproval control.
2. The frequency of updating information is one of the basic classification criteria for the information provided on the BDA web site.
 - Information updated on a regular basis: administrative and legislative information.
 - Information updated on a weekly basis: information on medicinal products.
 - Information updated on a quarterly basis: information on medicinal products.
 - Information updated on an annual basis: statistical information.
3. The information can also be classified according to the language in which it is available.
 - only in Bulgarian;
 - in both Bulgarian and English.

The information provided is mainly addressed to specialists working in the pharmaceutical sector and to healthcare professionals.

The tracking system provides statistics on visitors to the web site.

- The average number of daily visitors is 44.
- The average number of weekly visitors is 263 (the highest = 441).
- Visitors from different countries in Europe, North America, Asia, and Australia have visited the web site.

- Over a 65-day period, the highest number of visitors (1100) was from Bulgaria, followed by the United Kingdom (37), and Australia (29).

Discussion and comments

Who is the audience? Consumers/patients, healthcare professionals and professionals in business

How and what information can consumers find on a DRA web site? DRAs put in pieces of information aimed at specific audiences.

The minimum information a DRA web site should contain:

- all registered drugs;
- reference sources;
- all elements required for making an informed decision;
- quality control;
- important adverse drug effects.

Information provides value for money, and drug information is only 1% of the total cost of regulation.

The Danish Consumer Council

Ms Margrethe Nielsen

The Danish Consumer Council, Denmark

Pharmaceuticals represent a very special group of products: they can cure, but they can also hurt. The Danish Consumer Council (DCC) has been involved in international reviews. Apparently, more legislation and guidelines are needed.

The problem for the consumer association is to know how to strengthen consumer protection and to inform and educate consumers and professionals about their rights and obligations. Patients know about their health, and Danish consumers can actually order medicines by using the Internet. They are increasingly better educated and want to take responsibility. They should have access to information that tells them how to use medicinal products safely, e.g., on adverse drug reactions (ADRs), how to use the drug, interactions, etc.

The DCC would like to find the following on the Internet: dispensing by a skilled authorized professional (even if delivered through an e-pharmacy), impartial information, no promotion on prescription drugs, clear policies on how to handle sensitive personal data, and an e-commerce guarantee (giving consumers the right to see and touch the article and to return it within 14 days; however, medicines should not be resold if returned). Selling through the Internet should be licensed as it is in Denmark, because the DCC sees a risk of error with e-commerce, and consumer rights have to be respected.

The DCC has the cooperation of the Industry Association and has established certain criteria that they would like e-commerce to comply with. The DCC can provide a mark that certifies compliance with specific standards.

Swedish Industry Association

Dr Håkan Mandahl

Swedish Industry Association, Sweden

The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) plans to introduce a quality symbol along with the criteria for assessing the DRA web sites. This symbol will be based on international, European and national codes of conduct and is expected to be in the form of a quality seal that can be displayed on all industry sites.

As mentioned, there are at least 40,000 web sites providing health information. The problem for a consumer is to find the right place for good-quality, correct, and up-to-date information. A seal could provide a type of guarantee to the public that a certain site contains information of high quality. It is proposed that the seal be administered by the IFPMA secretariat in Geneva. Complaints will be received by the IFPMA and then referred to the concerned national industry association and their ethical board, which will deal with the complaint and take the necessary actions. In Sweden, for example, companies have to pay about US \$6000 each time they break the rules and 'the verdict' is published in all pharmaceutical and medical papers.

IFPMA view the seal as an addition to what is already in place. It is just one more system to control pharmaceutical information. It can operate globally and nationally, which is often a problem for most other codes applicable on a regional or national basis only. The IFPMA seal is expected to work alongside the others. It should be simple to operate and simple to understand. Of course a lot of promotion is needed until the public gains understanding of and respect for the symbol.

Companies using the seal will have to demonstrate that they fulfil all criteria before they may use it. After being accepted for use of the seal, the idea is that either the public or the health profession or competitors could report the companies to the IFPMA if the information on their Internet site is not correct. In every company there should be at least one person responsible for any information released, which is more or less the situation today.

Introduction to discussion points

Dr Lembit Rõgo

Discussion points

1. Patient/consumer protection in e-commerce:

- effective protection when purchasing on the Internet;
- same degree of protection as in the real marketplace?
- what further actions on the demand side (beyond the booklet *Medical products and the Internet*)?
- role of national governments;
- partnerships (professional associations, Internet service providers);
- Children/minors and e-commerce:
 - vulnerability to advertisements and commercial messages;
 - capability to distinguish between advertising and information;
 - limitations on advertising to children?

2. The role and limitations of national regulatory authorities:

- reaching health professionals and consumers;
- improving visibility and improving provision of information.

3. Minimum information about suppliers and products offered:

- essential details about the supplier: name of company, physical address, phone, fax, e-mail, name and address of the licensing body through which the company is registered or authorized;
- geographic scope of trade;
- safe and proper handling/storage requirements;
- information (or non-availability of information) on regulatory status of products or on safety or warnings in countries of origin and destination;
- reference/links to sources of independent information on product safety, use, and efficacy;
- actual costs of delivery, postage and handling, insurance, and customs taxes and duties;
- information on applicable law and the jurisdiction for settling disputes;

- requirements for disclosure of (liable) representative in importing country?

4. *Intellectual property and e-commerce:*

- international differences in trade names and patent validity;
- challenges to national policies on parallel imports;
- laws and legal rules not harmonized at the international level.

5. *Responsibility of exporters and importers/consumers:*

- is compliance with importing country's regulations the responsibility of the exporter or the importer?
- forbid 'distance shopping' (e.g., Germany)?
- establish direct-to-consumer e-export licences?

6. *Codes of conduct and beyond:*

- 'ethical/fair' trade guidelines/principles;
- is there a role for manufacturers?
- what challenges for pharmacists' associations?
- is there a role/challenge for Internet service providers?
- towards an *ad hoc* global regulation of international e-trade?
- limits to the rights of governments to regulate business to protect consumers and public health?

7. *Observatories:*

- who should/can monitor e-offers?
- label for legitimate suppliers?
- is there a role/challenge for Internet service providers?
- how can we ensure that international harmonization does not reduce the level of protection provided by existing national standards?

Quality aspects

Dr Ola Westbye

The NLN wishes to play a part in improving the quality of drug information published on the Internet in the Nordic region and, at the same time, to make it easier for both professionals and lay people to find reliable information. Quality-assured information is identified by the NLN 'seal of quality' (the symbol for reliable information on medicines). What does quality mean? It is the satisfaction of the consumer. The criteria for using the seal of quality are as follows:

- The information provider must have a documented internal quality-assurance system (procedures manual) of its own for the production and publication of drug information. This system must meet the need for continuous assurance of the validity of the information provided and for updating the information in line with scientific developments in the field.
- Information must immediately be updated when essential new facts emerge, such as significant new research findings or official decisions concerning the medicines in question. Information must be regularly reviewed, at least twice a year. There must be electronic mechanisms to remove information that has not been updated within six months.
- The provider's web site must give the name of an individual who is professionally responsible for the quality of the information published. This person must have a degree in pharmacy, medicine, or veterinary medicine.
- Pharmaceutical companies must participate in the quality-control system organized by the pharmaceutical industry in the country in which the information is published and must follow the guidelines that apply within the industry. Directions and requirements laid down by industry monitoring bodies must be complied with immediately and in full.
- A legally binding court order or judgement must be complied with immediately and in full.
- The producer of a registered medicinal product may only publish information that is consistent with the most recently approved summary of product characteristics (SPC) and package leaflet. If a drug manufacturer provides information concerning a non-registered product, it must be made clear that the product is not approved; the manufacturer may only

give information that can be checked in public sources and must include references that users will be able to find.

- Information must be accompanied by the name of the publisher, the name of the individual responsible for quality, the place of publication, and the date of the most recent revision.
- In other respects, the information must comply with national and internationally recognized standards of good practice, e.g., those of the International Chamber of Commerce.

Pilot study on drug regulatory web sites: Current status and future challenges

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Introduction

The Internet can be a valuable resource for users seeking health information. By its very nature, the Internet was designed to provide a forum for the unrestricted exchange of information, and web sites may contain factual information, opinions, data, ideas, propaganda, self-promotion, and/or commercial material [8]. However, the quality of health information on the Internet is extremely variable and difficult to assess. Unlike traditional print resources, web resources rarely have editors or fact-checkers, and this tends to be even more so for national web pages [9]: the sites are not monitored, edited, regulated or approved. There are no rules or standards governing the type or quality of information that a writer, or an organization, can put on the Internet, and there is no consensus on how to resolve the problem, no uniform guidelines for quality assessment of web-based health information for consumers. Because this could potentially affect health outcomes for millions of people, there is a growing urgency for objective, reproducible, widely accepted criteria that can be used both to evaluate the quality of information on a web site [10] and to prepare a reliable, good-quality, easy-to-use web site.

For most patients, health professionals, policymakers, and pharmaceutical companies, the information available on the web site of a drug regulatory authority (DRA) should be the most appropriate way to obtain information about drugs. If used properly, the Internet allows DRAs to make information about their activities available to other authorities and organizations, as well as to the public and industry. By having a reliable, easy-to-use, accessible, and up-to-date web site, a DRA can increase its efficiency and efficacy, while at the same time being recognised as being more transparent in its regulatory work. While health information proliferates on the Internet, and e-trade increases worldwide, it is crucial for health professionals and patients to have access to reliable information, particularly the list of authorized products in their country. This should also include all laws and regulations related to medicinal products. Such transparency helps to maintain public confidence in pharmaceutical products.

Background

There have been concerns raised by the national authorities of several WHO Member States regarding the issue of cross-border trade of pharmaceuticals through the Internet. In 1999, WHO published a booklet called *Medical products and the Internet: A guide to finding reliable information* [3]. In October 2000, a workshop took place in Geneva, on 'Pharmaceuticals and the Internet'. Some key aspects that were discussed included: What should be done in addition to the existing WHO guidelines? How should illegal e-trade be fought? How should the safety issues be addressed? etc.

The recommendations included countering biased information and malpractice, making more reliable information readily available, and analysing the situation as regards DRA web sites. It was suggested that a WHO Model Web Site for DRAs should be created to ensure the availability of good-quality, reliable information.

In order to assist WHO Member States, WHO has taken the initiative in providing criteria and guidance for existing or new DRA web sites, addressing the following concerns:

- uneven quality of pharmaceutical information available on the Internet;
- e-trade—unregulated and uncontrolled dispensing and self-prescription;
- misleading and biased advice on pharmaceuticals, dietary supplements, etc.

Objectives of the study

The purpose is to propose a WHO Model Web Site as a guide for DRAs to create their own web site or improve it, in order to offer Internet users improved quality and increased availability of health information on the Internet. Before the project could begin, the most important pieces of information that a DRA web site should contain were identified in a list of objective, reproducible criteria.

An assessment was then carried out to provide a brief overview of the quality of the information currently on existing DRA web sites—by analysing their content—in different languages and regions and at different levels of sophistication.

By making pharmaceutical information available on reliable, accessible web sites, DRAs will greatly speed up the work of health professionals involved in drug procurement and supply. Better prescribing by medical doctors will also be facilitated and rational use of drugs improved. Just as important, communication

and a transparent dialogue among DRAs, industry, consumers/patients, and health professionals will be enhanced.

More generally, DRAs will

- increase the transparency of their own activities;
- improve collaboration between DRAs, health professionals, and academics;
- improve the public-health impact of drug regulatory work;
- facilitate networking between DRAs to solve drug regulation problems;
- offer reliable and unbiased drug information to guide Internet users;
- help combat the problem of substandard and counterfeit drugs by offering reliable information.

Methodology

The development of a list of criteria designed to serve as the 'gold standard' to make the analysis was the essential first step. A list of the countries that have a DRA web site was compiled either by searching the web or contacting the ministries of health and DRAs.

In parallel, bibliographic research was undertaken to find relevant articles on how to assess a health-information web site. Many organizations [11] and individuals have published criteria to evaluate health-related information on the Internet. A literature and Internet search found that 'the most frequently-cited criteria were those dealing with content, design and aesthetics of site, disclosure of authors, sponsors or developers, currency of information (includes frequency of update, freshness, maintenance of site), authority of source, and ease of use, and accessibility and availability' [12].

These criteria are very general and do not fully correspond to the evaluation of DRA web sites, which needs more 'specific' criteria. A set of key criteria (general and specific) was developed on different types of drug information (lists of approved drugs; national drug regulations; information on how to ensure safe, efficacious, and rational use of specific drugs; lists of approved companies and their authorized activities, etc.). Twenty-four criteria were identified (six general and 18 specific) and set up as a checklist to assess the quality of information on a DRA web site.

A scoring system ranging from 0 to 2 (0 = inadequate, 1 = intermediate, 2 = good) was used to weight each criterion. To use this scoring system, each criterion was reviewed through content (quantitative aspect), links (selection,

content, etc.), interactivity (mechanism for feedback, forum, etc.), accessibility, and balance of information for targeted users (industry, health professional, public).

General criteria

1. User friendliness

The first impression when looking at a web page and its general appearance [13] are very important.

- Most pages are designed attractively and to entice further exploration.
- Information is presented logically and clearly enough to be successfully manipulated by the intended user and is easy to find.
- Unless the national language is English, French, or Spanish, information is both in the national language and in one of the three widely used languages.
- Spelling and grammar are correct.

2. Navigability

This permits a site to be used effectively and enables the user to get to the important information [14]. Accessibility, logical organization, and internal search engines are essential.

- Users can get the information they need within a reasonable number of clicks (preferably three or fewer) [15].
- Users can move from page to page, link to link, and item to item with ease, without getting lost or confused.
- Users do not need to pay a fee or type in personal information (such as name or e-mail address) before using the site.
- If there are large amounts of information on the site, some kind of search function should be provided.

3. Speed

The home page and most subsequent links (except those from web sites outside the control of the DRA) are displayed in up to 4 to 5 seconds.

4. Site map

- A site map shows logical lines and organization of the site.
- It shows clearly how to navigate through all pages.

- Users can easily find out where to go and how to get there. The ‘buttons’ or menu items are labelled using clear language [16].

5. Search

The site has its own search engine, set up for searching either by key words or with an ‘A-Z’ index. It also permits searches for other sites.

6. Update

The web site includes the date on which it was created and the date of the last update. The site is regularly updated and reviewed. This criterion is very important; if the information has not been updated since the previous year, it is not very reliable.

Specific criteria

1. Mission statement

The mission statement and purposes of the DRAs are clearly stated and easily accessible. Activities and programmes are described.

2. Contact information

Contact persons with names, addresses, phone and fax numbers, and email are readily available for each activity, complete and up to date. It is easy to identify person/service and to reach information.

3. Organizational structure

The structure of the DRA is available, complete, and up to date. It allows information on a department to be obtained by clicking on it.

4. Services

- The site offers information related to the DRA.
- The information is clearly labelled and organized, and easy for users to understand.
- The site does not contain words that try to ‘persuade’ rather than ‘inform’.

5. News, events, and meetings

The site mentions and describes news, events, and meetings planned and has a calendar that is transparent and regularly updated.

6. Safety alerts and adverse drug reactions (pharmacovigilance)

- Safety alerts—patient and health professionals have easy access to the safety alerts *by date and product name*: recalls, suspensions, revocations, and recall procedures. The information is comprehensive, detailed, and chronological. Batch size is also mentioned.
- Adverse drug reactions (ADRs)—the site contains a definition of terms, procedures for reporting adverse drug reactions and adverse drug events, how to report ADRs on-line, links to useful sites, last pharmacovigilance reports, etc.

7. Feedback form for informing the DRA

There should be a facility enabling any user to contact the authority, either to ask questions or to report problems. This feedback form should be easy to download, complete, find, and send back to the DRA.

8. Regulatory guidance on legislation and regulations

Regulatory guidance such as laws, decrees, orders, and any legislative and regulatory material related to pharmacy, drug manufacturing, drug registration processes, commerce, information, promotion and advertising, and e-trade should be available.

9. Instructions for applicants

- Information for applicants should be presented with a sufficient degree of detail to prepare registration of dossiers: composition of the file, fees, document to file for first demand, variations, renewal, extension, transfer of marketing authorization, the drug registration process and procedures, accelerated registration procedures, and norms, standards and guidelines for pharmaceuticals.
- Forms (that can be downloaded) should include a marketing authorization application form, a variation application form, and a template for a summary of product characteristics.
- Information on drug regulation and quality-assurance systems, drug regulatory information, guidelines for good clinical practice for trials on pharmaceutical products, etc., should be included.

10. Medicinal products (human/veterinary medicines)

This criterion is very important. The web site should include the following information, which should be in more than one language and updated monthly.

- the list of authorized drugs in the country, including at least
 - generic name;
 - authorized presentations (form and strength);
 - patient information leaflets ;
 - summary of product characteristics;
- a search facility that permits the user to find items either by brand name, holder of marketing authorization, INN, therapeutic group, or status of marketing authorization;
- the list of cancelled marketing authorizations;
- information about orphan drugs;
- products under special post-marketing surveillance monitoring.

11. Approved manufacturers

Information or statistics on manufacturers in the country should be presented and easily readable: a list of approved manufacturers (name, addresses, contacts), licence status, last inspection date, etc. If charts or graphics are included, their quality should be good and should enhance the content rather than distract from it [17].

12. Import and export

Statistics on import and export; guidance for importers, exporters; WHO type certificate, etc., should be presented and easily readable.

13. Approved wholesalers, distributors, pharmacies

A list of approved wholesalers, distributors, and pharmacies should be provided, with information on their activities and volume of business.

14. Basic statistics on drug consumption

The site should offer information about sales data, manufacturing data, etc.

15. Basic statistics on country profile

The site should contain basic statistics about the country, such as the following:

- population data;
- population income statistics;
- health statistics;

- healthcare facilities, etc.

16. Basic statistics on DRA activities

There should be information on how many new drug applications the DRA has received; the number of pending applications; number of positive or negative decisions; number of applications withdrawn; inspections of pharmacies, wholesalers, and manufacturing sites.

17. Links

The links provided to other pages and sites should meet the following criteria:

- They should include links to sites that are worthwhile and appropriate for the intended audience.
- They should be clearly labelled and serve an easily identified purpose.
- They should give added value to the web site.
- They should be current/unexpired and should operate efficiently.
- They should be grouped in some type of logical order.

Links to the web sites of medical journals and national drug regulatory authorities should be included, along with international links (World Health Organization, European Agency for the Evaluation of Medicinal products, etc.).

18. Publications

- Sources of information cited should be reliable, pertinent, and identifiable.
- Publications can be downloaded with a current bibliography of references.

The publication page can contain, for example, the DRA's bulletin, annual report, quarterly report, cumulative list of recalls, safety alerts (and other decisions that restrict use of medicinal products), guidance materials, latest list of approved products, latest list of approved manufacturers, wholesalers, importers, distributors, medical journals, newsletters, and periodicals, etc.

Results

Only 53 national DRA web sites were found; 51 were evaluated (the sites of Austria and Greece were not assessed in this study). Five of the 53 sites are only available in the national language (Austria, Greece, Italy, China, Portugal).

Broken down by WHO regions, the DRA web sites are distributed as follows (given as percent of countries in the region): EURO (55.8%), WPRO (32.1%), AMRO (19.5%), AFRO (8.5 %), SEARO (30%), and EMRO (4.5%) (see Annex 2). Details of the analysis of the DRA web sites is shown in Table 1.

Findings

- Only 13.7% of the web sites scored ‘good’ on information on medicinal products.
- Only 11.8% scored ‘good’ on safety information.
- Basic statistics: only 7.8% scored ‘good’ on drug consumption information; 5.9% on wholesalers, distributors and pharmacies; 5.9% in manufacturers; 7.8% in import and export in the country; 11.8% on country profile; and 21.6% on DRA activities.
- In 56.9% of the web sites, no feedback form was provided for informing or contacting the authority.
- There was no recent update (during the current year) indicated on 54.9%.
- There was no text search in 56.9%, or the search was not functioning.
- No publications at all were mentioned by 58.8%.
- The links function scored ‘inadequate’ on 51% of the web sites assessed. Also, ‘services’ were rated ‘inadequate’ on 71.4%, although this score is very subjective.
- Only 27.5% had a good site map; 60.8% had no site map at all.
- There were good pages on news and events in 27.5%; 52.9% had nothing related to such topics.
- The best results were found for speed (56.9%), navigability (58.8%), contact information (37.3%), and organizational structure (41.2%).
- The results for ‘instructions for applicants’ were ‘good’ on 47.1% of the sites.
- The results were ‘intermediate’ for mission statement (51%), user friendliness (49%), and regulatory guidance on legislation (39.2%).

Table 1: Percentages of scores of 'inadequate', 'intermediate', and 'good' for the 51 DRA web sites

General Criteria	Inadequate %	Intermediate %	Good %
User friendliness	21.6	49.0	29.4
Navigability	9.8	31.4	58.8
Speed	17.6	25.5	56.9
Site map	60.8	11.8	27.5
Text search	56.9	17.6	25.5
Update	54.9	7.8	37.3
Specific Criteria	Inadequate %	Intermediate %	Good %
Mission statement	17.6	51.0	31.4
Contact information	29.4	33.3	37.3
Organizational structure	31.4	27.5	41.2
Services	70.6	9.8	19.6
News, events, and meeting	52.9	19.6	27.5
Safety alerts and adverse drug reactions	80.4	7.8	11.8
Feedback form for informing DRA	56.9	13.7	29.4
Regulatory guidance on legislation and regulations	33.3	39.2	27.5
Instructions for applicants	27.5	25.5	47.1
Approved manufacturers	84.3	9.8	5.9
Import and export	80.4	11.8	7.8
Approved wholesalers, distributors, pharmacies	74.5	19.6	5.9
Medicinal products (human/veterinary)	52.9	33.3	13.7
Links	51.0	17.6	31.4
Publications	58.8	19.6	21.6
Basic statistics on drug consumption	88.2	3.9	7.8
Basic statistics on country profile	88.2	0.0	11.8
Basic statistics on DRA activities	74.5	3.9	21.6

Discussion

Only a few DRAs across the globe provide their respective information resources to an Internet audience via a web site. Indeed, many DRAs do not have a web site, and even those that have one seem to provide either a small amount of information or such a vast amount of information that it is difficult to navigate through the site. Most web sites do not post approved drug information, and very few provide access to the list of authorized drugs in the country. The quality of health information provided is very heterogeneous and could benefit from improvement.

Lacking drug information, healthcare providers and consumers may be uncertain as to which drugs are approved for treating which conditions, which drugs meet national regulations, and which drugs may be imported. For consumers, these problems are being exacerbated by the growth in pharmaceutical e-trade. Ensuring the rational use of drugs and an efficient drug supply then becomes more difficult. At the same time, lack of drug information can suggest that DRAs are not 'transparent', ultimately leading to a lack of trust in the quality and legitimacy of their work.

Conclusions

DRAs should provide reliable drug information for consumers/patients, health professionals, and public- and private-sector organizations (hospitals, manufacturers, importers, etc.), making it more widely available and easily accessible. And the quality of the information provided has to be improved.

The Internet is a powerful information tool that could be used for exactly this purpose. Indeed, it has proved that it can be a source of valuable, good-quality information on the approved drugs, treatments, and medical products available in different national markets. For many DRAs, this will mean creating a web site. For others, the task will be to improve an existing web site.

The WHO model web site for drug regulatory authorities

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The WHO Model Web Site is based on the list of criteria used to assess DRA web sites (Figure 1). Different sections should be available through the main headings, as described below.

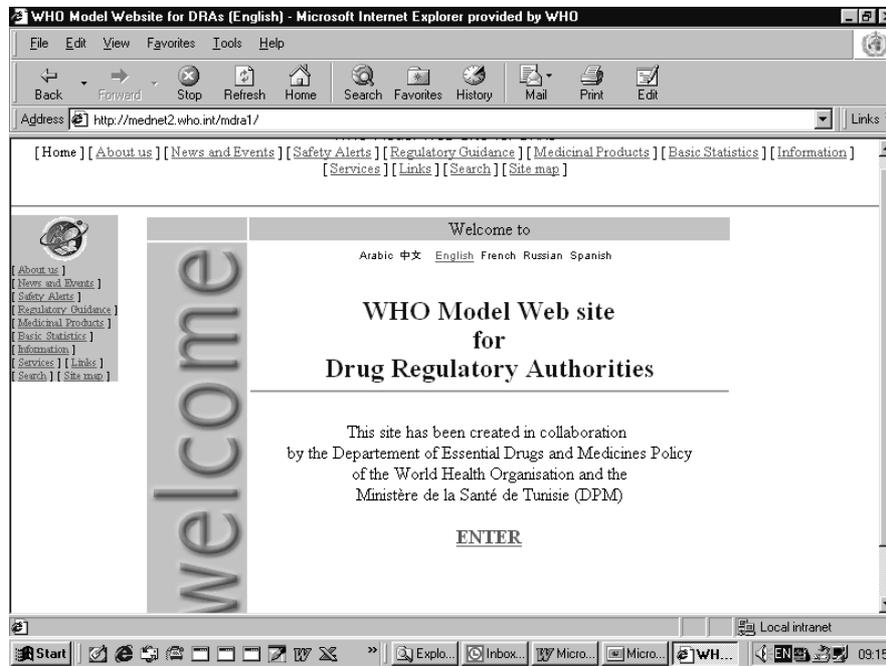


Figure 1: Model home page

About us

In ‘about us’, the users can find a mission statement, contact information, and location (the DRA address, name of the contact person for general enquiries, a map, how to get there, and the opening hours), as well as information about services, the organizational structure, and a help section with frequently asked questions (FAQs).

News, events, and meetings

There should be a calendar that is regularly updated and transparent, along with news, events, and meetings planned.

Safety alerts

Patient and health professionals should have easy access to safety alerts *by date and product name*: recalls, suspensions, revocations, recall procedures. The information should be comprehensive, detailed, and chronological. Batch size should also be mentioned.

The web site should also contain pharmacovigilance information, with a definition of terms, the procedure to report adverse drug reactions and adverse drug events (on-line, etc.), links to useful sites (for example, the WHO International Drug Monitoring Programme), recent pharmacovigilance reports, etc.

Regulatory guidance

Regulatory guidance, such as laws, decrees, and orders and any legislative and regulatory material related to pharmacy, drug manufacturing, drug registration processes, commerce, information, promotion and advertising, and e-trade should be available.

Medicinal products (human and veterinary)

The list of authorized products—both human and veterinary medicinal products—should be available (Figure 2). A list of marketing authorization revo-

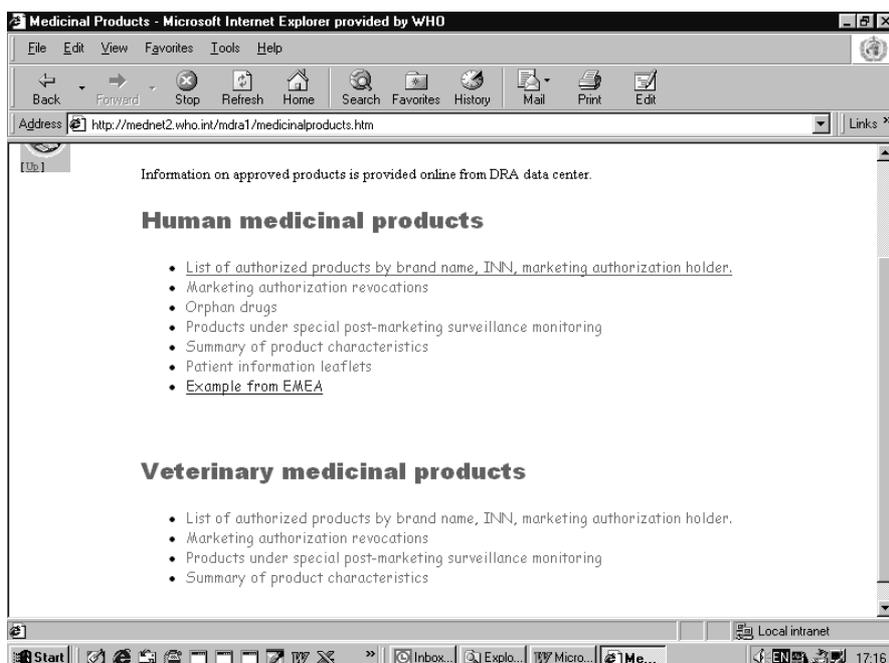


Figure 2: Example of information on approved products

cations, orphan drugs, products under special post-marketing surveillance monitoring, the summary of product characteristics, the patient information leaflets should also be presented on the web site.

There should be a search engine (Figure 3) that permits finding a product by brand name, INN, or marketing authorization holder, among other things.

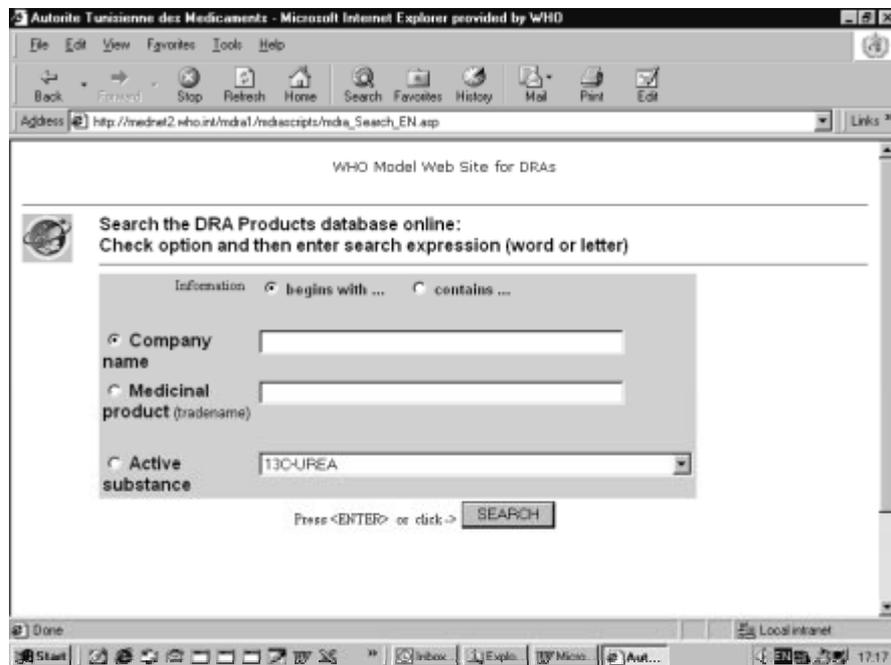


Figure 3: Example of search engine for authorized products

The kind of information available for a product should include generic name, strength, dosage form, packaging, company, etc. (with more information found by clicking on the generic name).

Basic statistics

Statistics about DRA activities, drug consumption, and a country profile should be available (Figure 4).

Information Resources

General information and audience-specific information (for consumers, health professionals, applicants, and manufacturers) should be presented.

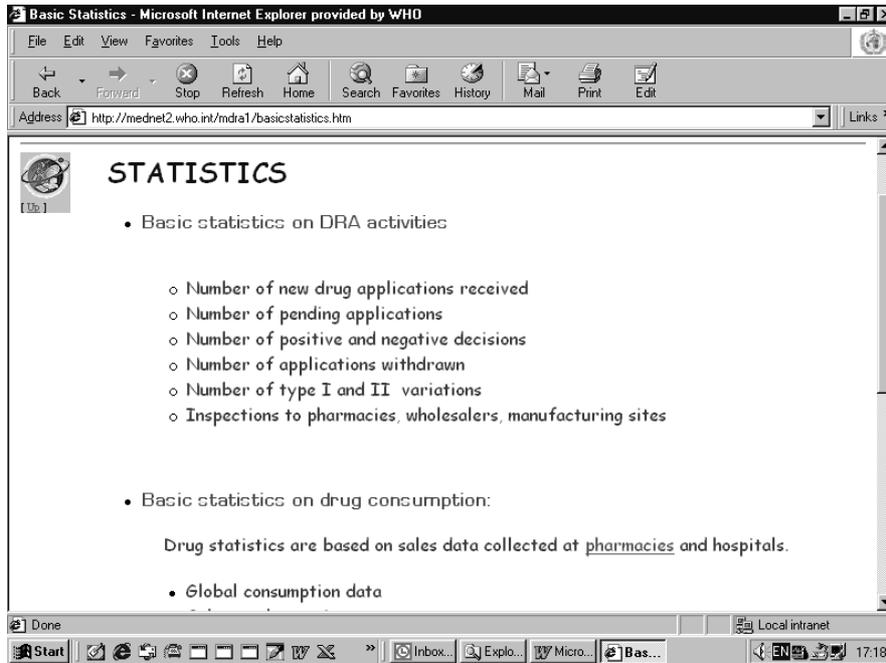


Figure 4: Example of web page related to statistics

General information: E-trade

Information and warnings about buying drugs online should be provided to consumers and patients (Figure 5).

General information: Information exchange and discussion groups

Different links should be provided to permit visitors to join electronic discussion groups, such as edrug (<http://www.healthnet.org.np/>), WHODRA, WHO Mednet, etc.

Audience-specific information: Information for consumers

General information about medicinal products, diseases, and health issues should be made accessible to consumers (Figure 6). Audience-specific information: Information for health professionals

DRA's can provide information for health professionals on safety issues, clinical trials, orphan drugs, medical devices, medicinal products, rational drug use by health professionals, infectious diseases, drugs used in HIV-related infections, etc.

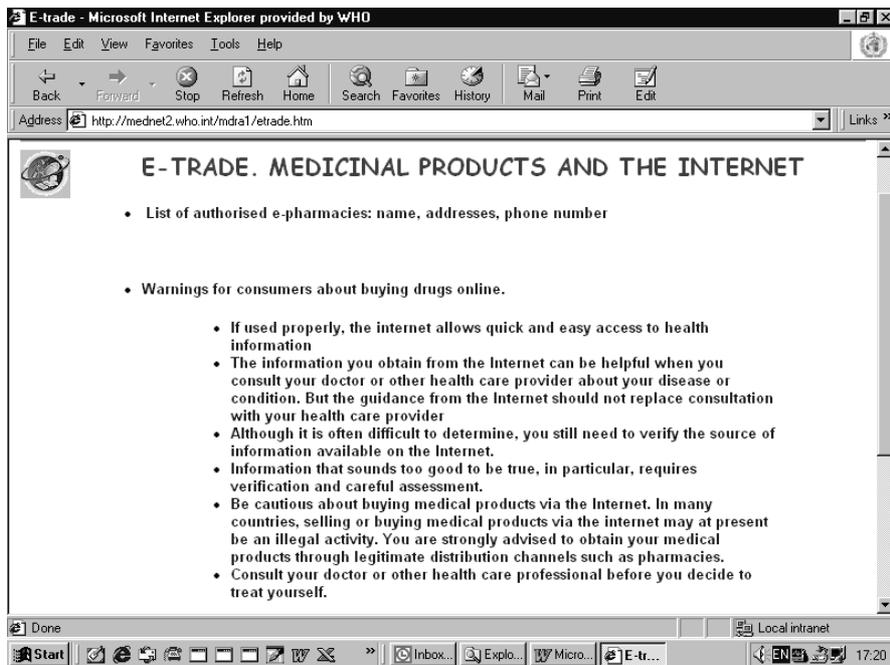


Figure 5: Example of information related to e-trade

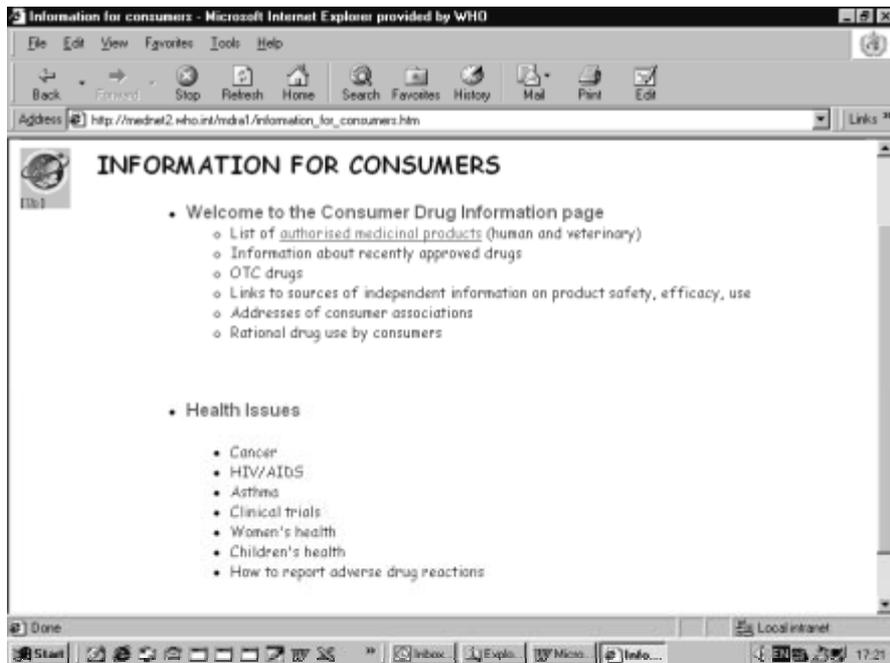


Figure 6: Example of general information for consumers

Audience-specific information: Information for applicants

Information for applicants should be presented with a sufficient degree of detail to enable the preparation of application dossiers: composition of the file, fees, document to file for first demand, variations, renewal, extension, transfer of marketing authorization, norms, standards and guidelines for pharmaceuticals, drug registration processes and procedures, and accelerated registration procedures (Figure 7).

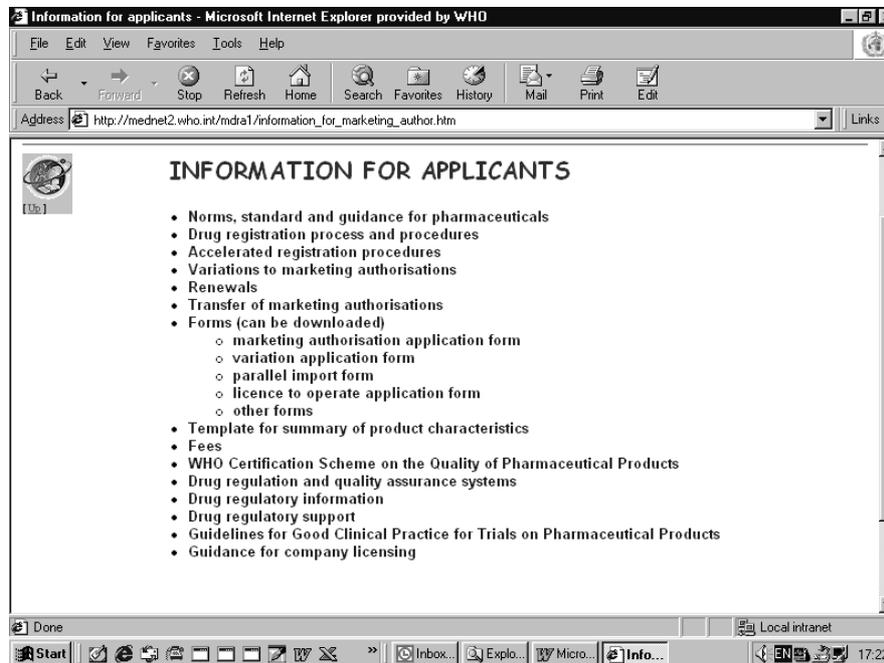


Figure 7: Example of information for applicants

Information on drug regulation and quality-assurance systems should also be included, as well as guidelines for good clinical practice for trials on pharmaceutical products, etc.

Audience-specific information: Information on pharmacies

A list of approved wholesalers, distributors, and pharmacies (with addresses, phone numbers, licence status, last inspection date, etc.) should be presented along with information on their activities and volume of business.

Audience-specific information: Information on pharmaceutical companies

Information or statistics on manufacturers in the country should be presented and easily readable: a list of approved manufacturers (name, addresses, contacts), licence status, last inspection date, GMP certificate, etc.). If charts or graphics are included, their quality should be good and should enhance the content rather than distract from it.

Links

A selection of Internet links to other DRA web sites, EMEA, and medical journals should be provided, as well as international links related to medicines, such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), WHO, etc., and European links to such sites as the European Commission, European national agencies, etc.

Search

The site should have its own search engine, that permits searchers either by key words or with an 'A-Z' index. It should also permit searches for other sites (Figure 8).

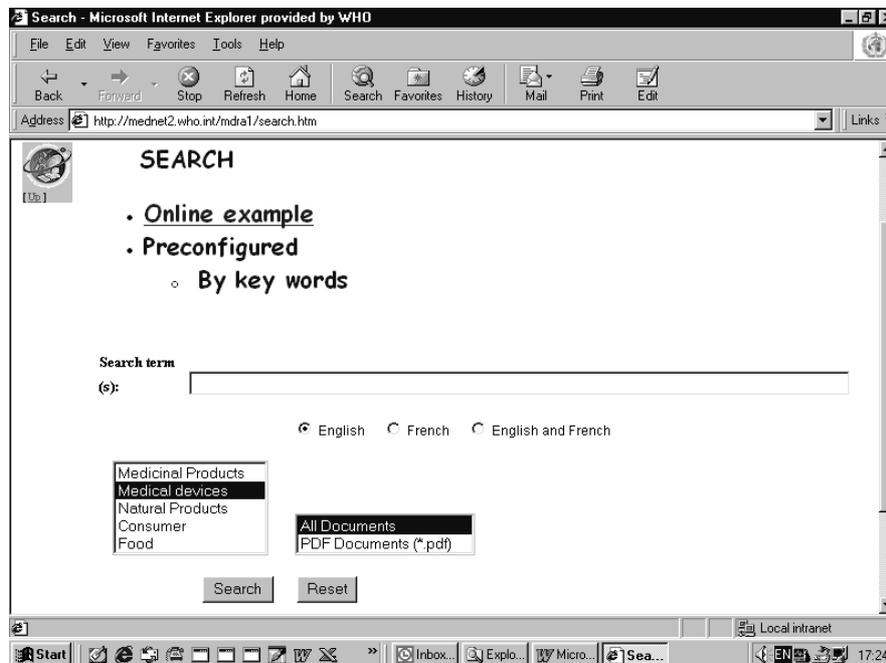


Figure 8: Example of search engine

Publications

The documents produced by the DRA should be able to be downloaded and consulted (Figure 9).

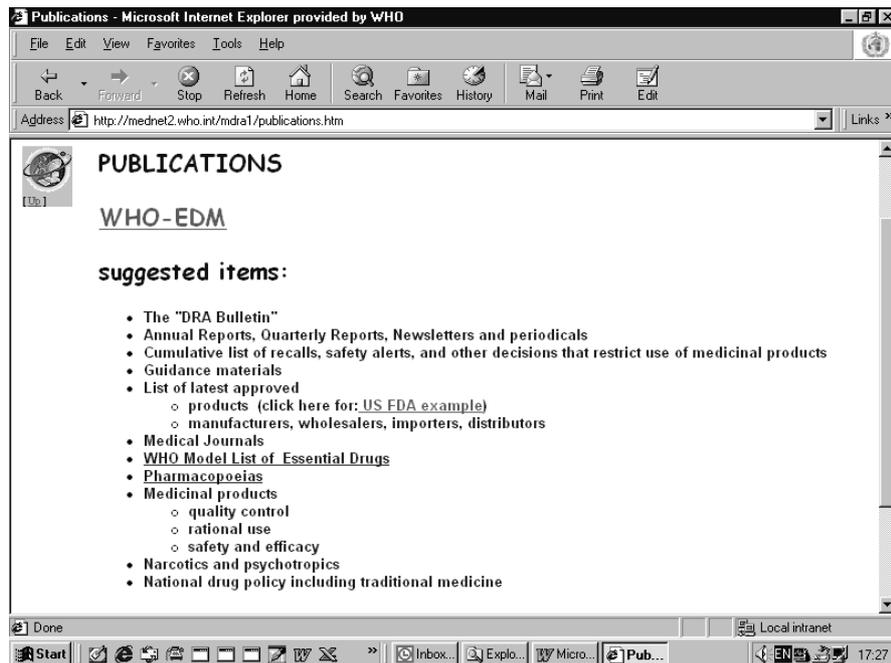


Figure 9: Example of publications web page

Site map

A site map shows logical lines and the organization of the site. It should clearly show how to navigate through all pages (Figure 10). Users should easily be able to find out where to go and how to get there. The 'buttons' or menu items should be labelled using clear language.

Discussion and comments: Review of WHO Model Web Site

The WHO Model Web Site is too detailed. WHO has to define its priorities for the site: i.e., the minimum block of information—the minimum list you need to provide. Suggested minimum content should include information about the DRA itself, information for consumers/patients, and relevant legislation.

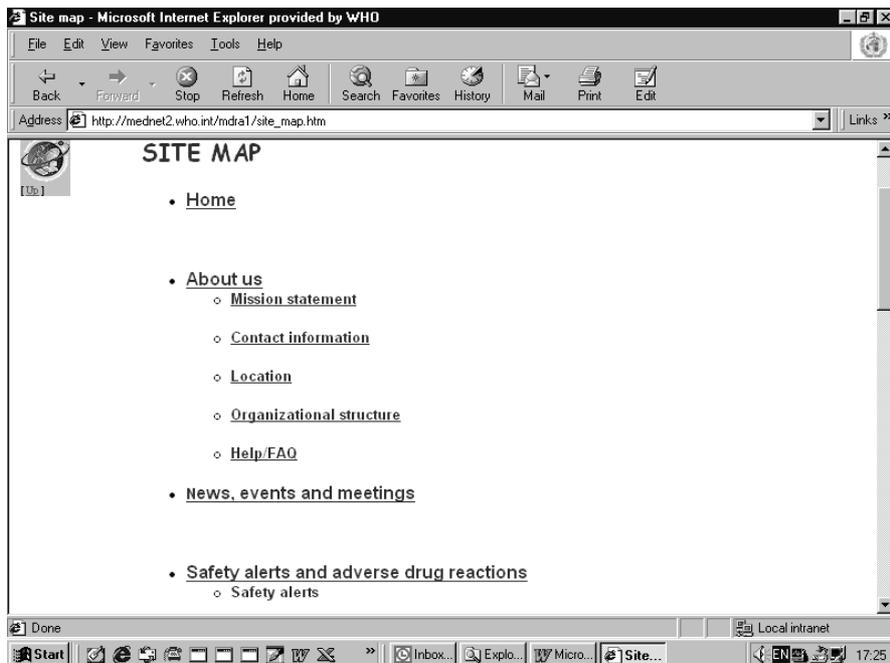


Figure 10: Example of a site map

In the discussion, participants proposed diversifying the WHO model into three levels:

1. *basic*: only information on decisions by the DRA that are their ‘core’ business (registration database, SPCs, PILs, monographs, DRA decisions, etc.);
2. *intermediate*: useful additional information (drug information, treatment guidelines, prices, addresses, etc.);
3. *expanded*: information that is ‘nice to have’.

General changes suggested for the WHO Model Web Site

- Delete ‘services’ from the main menu and move under ‘contacts/about us’.
- Separate news from events and meetings.
- Contact information should include information on external contacts to related agencies (such as anti-poison services) and medical institutes in addition to internal contact information.

- Guidance should be provided on where and how to find reliable information.
- Information should be grouped by interest (patients and consumers, business and healthcare professionals), and by level (e.g., with different colours).
- The heading 'safety alerts' is too long. 'Alerts' should be removed from the heading so that it says 'safety' only.
- Complaints—what should be done about complaints?
- Publications—everything the authority publishes should be on the web site, regardless of whether it must be paid for or is free.
- Medicinal products should be replaced by 'authorized products'. For the countries that have WHO's Model System for Computer-assisted Drug Registration (SIAMED), the list of authorized products should be directly linked to SIAMED. Information about immunological products should be provided (allergy, etc.). The definition of terms for 'drugs' or 'medicines' should be discussed and should be clear to everybody. Advice on veterinary drugs should also be presented.
- A good site map is essential. Entry points for the different users should be easily accessible, with shortcuts by major needs or target groups (consumers, healthcare professionals, businesses).
- 'Regulatory guidance' should be replaced by 'laws and regulations' and should contain legal documents, etc., as well as the legal framework on which DRA activities are based and the procedures for decision making.
- The entire supply system should be described. The drug supply system should have links.
- For a quality web site, you need qualified staff and sufficient resources: Denmark's DRA has one IT person and one coordinator who runs the site; in addition, all staff prepare and provide technical information.
- The idea of a customizable site was suggested: i.e., a site that could be configured for basic, intermediate, and advanced users. One can think of a personalization system where a person logs on by identifying her/himself as belonging to a user group. The Swedish Pharma Industry uses interactive identification, for example. The Swedish industry site asks the user to choose an interface for one of the following: regulator, patient, health provider, or 'general' user.

Updating

- The date of creation and last update must be mentioned.
- Rapid upgrading is essential.
- Information can be categorized by how often it should be updated: immediately, quarterly, and once a year.

Information for consumers

- The health issues contained too much information.
- Legislation is also important to consumers.
- Links to sources of reliable information and other institutions could be provided (e.g., to WHO's disease-oriented pages).

The mission statement

Simply stating the mission is not enough. The plenum suggested a minimum set of information on the DRA, which should include the following:

- Who we are. What we produce and provide. What the web site contains.
- A list of contact information showing what the DRA is doing, with a description of its activities (e.g., what the DRA is responsible for and what it is not responsible for). The prime lines of responsibility, duties of the authority; comments on basic responsibilities.
- DRAs should state clearly what they want to show on the web site: only information exclusively available to the DRA, with links to originators/holders of other information.
- Rational therapy information should be provided (i.e., how to use the medicines).
- List of registered drugs.
- Changes in drug status: e.g., when a drug changes from prescription to OTC, etc.

Quality assurance

Any site should be based on a documented quality-assurance system. There was a discussion on quality labels for Internet web sites dealing with medicines, as proposed by the Nordic Council on Medicines; a further label is now being implemented by IFPMA.

Maintenance issues

A web site will only be successful if:

- It is based on a functional regulatory body with clearly structured information;
- It knows its audience;
- It routinely maintains its data;
- It has dedicated support staff.

Language

A site should be presented in its national language and English.

Missing information

- Specific consumer information is missing.
- Treatment guidelines and disease information are missing.
- Links to psychotropic drugs are missing.
- Basic WHO information, such as a *WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce*, is missing.
- The model web site can be used to add a link to SIAMED (which is one advantage of a computerized registration process), and it could also be packaged with WHO reference/guidelines information on health and medicines.
- Other items that could be included:
 - a glossary;
 - address lists for pharmacies, with opening hours;
 - drug side effects;
 - poison information, first aid;
 - training courses for chronic diseases;
 - clear identification of medicines registered, and those marketed.

Practical considerations

MCC was asked whether it would be willing to test the new 'model web site'. The 'new' MCC web site could initially be hosted on WHO's computers, and it is likely that WHO/EDM IT staff could assist in the development. For example,

patient organizations were invited to test the Swedish industry site, which is also designed for use by disabled persons. Usability testing should be carried out, including usability by handicapped people.

The US Food and Drug Administration (FDA) keeps a list of DRA web sites (<http://www.fda.gov/oia/agencies.htm>). MCC should inform the FDA about its web site as it is not yet listed.

Sites must be based on a documented quality-assurance system. The points to consider are quality assurance, internal guidelines, etc. The European Union has developed guidelines on quality criteria for health-related web sites [6]. As the volume of information increases, mechanisms for controlling the quality of this information are required. A content-quality group looks at information posted.

A specially designed contact point for problems (such as counterfeit drugs, problem drugs, and unregistered products) would be useful. A panel could eventually be used for managing feedback.

Concluding discussion

Medical Products and the Internet

The feedback on this publication was that the tone is negative, in that the emphasis is more on what not to do rather than what should be done. There is a great deal of poor-quality information on the Internet, but sources of reliable information should be highlighted and users should be assisted in their search for such sources.

WHO will consider the need to review this document and to give good examples, and will try to meet the needs.

Information

Patients, consumers, and health professionals want to know what the good web sites on health information are.

With respect to medical information available on the Internet, DRAs should provide more information to a wider spectrum of audiences. The main target audiences should be more clearly defined and should be able to obtain specific information relating to their respective areas of interest.

WHO Model Web Site

The WHO Model Web Site was well received so far as concept and purpose are concerned. The following suggestions were made.

- A minimum set of information that is related to the core functions of a DRA should be defined, i.e., information that is uniquely available from DRAs should be made accessible—in so far as confidentiality rules and data security allow.
- The model web site should be pre-configured with WHO guideline information and basic data.
- The model web site could be provided with a standard installation of the WHO Model Drug Registration Software.

WHO should revise its current version of the model web site and then start deploying a new version based on the suggestions made by the audience.

Ideally, WHO could assist a selected number of interested countries in establishing a DRA web site based on the revised WHO model. In a further step, these DRA-initiated model web sites could then be validated by a panel of users from different audiences.

Annexes

Annex 1. List of Participants

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Annex 2. List of DRA web sites

Regional Office for Africa (AFRO)

4 of 49 AFRO countries (8.5%)

Algeria: <http://www.ands.dz/>

Botswana: http://www.gov.bw/government/ministry_of_health.html

Mauritius; <http://ncb.intnet.mu/moh/index.htm>

South Africa: <http://www.health.gov.za/indexdep.htm>

Regional Office for the Americas (AMRO/PAHO)

7 of 36 AMRO countries (19.5%)

Canada: <http://www.hc-sc.gc.ca/hpb-dgps/therapeut/>

Colombia: <http://anticorruccion.gov.co/invima/>

Costa Rica: <http://regcon.netsalud.sa.cr/>

Guatemala: <http://www.mspas.gob.gt/default.html>

Mexico: <http://www.ssa.gob.mx/unidades/dgcis/>

Peru <http://www.minsa.gob.pe/digemid/>

United States of America: <http://www.fda.gov/>

Regional Office for the Eastern Mediterranean (EMRO)

1 of 22 EMRO countries (4.5%)

Morocco:

http://www.sante.gov.ma/ministere/medicament/direction_du_medicament.htm

Regional Office for Europe (EURO)

29 of 52 (included EMEA) EURO countries (55.8%)

Austria: <http://www.bmsg.gv.at/>

Belgium: <http://www.afigp.fgov.be>

Bulgaria: <http://www.bda.bg/>

Czech Republic: <http://www.sukl.cz/>

Denmark: <http://www.dkma.dk/>

EMEA: <http://www.emea.eu.int/>

Estonia: <http://www.sam.ee/>

Finland: <http://www.nam.fi/>

France: <http://agmed.sante.gouv.fr/>
Germany: http://www.bfarm.de/gb_ver/
Greece: <http://www.yyp.gr/>
Hungary: <http://www.ogyi.hu/ENG011.HTM>
Ireland: <http://www.imb.ie/>
Israel: <http://www.health.gov.il/>
Italy: <http://www.sanita.it/farmaci/>
Latvia: <http://www.vza.gov.lv/english/default.html>
Lithuania: <http://www.vvkt.lt/ENG/default.htm>
Luxembourg: http://www.etat.lu/MS/DPM/fr/fr_index.html
Netherlands: <http://www.cbg-meb.nl/>
Norway: <http://www.legemiddelverket.no/eng/reg/regulatory.htm>
Poland: <http://www.il.waw.pl/eng/version.htm>
Portugal: <http://www.infarmed.pt/>
Slovakia: http://www.sukl.sk/sukl_en.htm
Slovenia: http://www.sigov.si/mz/ur-zdrav/english/index_en.htm
Spain: <http://www.msc.es/agemed/main.htm>
Sweden: http://www.mpa.se/ie_index.html
Switzerland: http://www.iks.ch/default_E.asp
Turkey: <http://www.ieg.gov.tr/>
United Kingdom: <http://www.mca.gov.uk/>

Regional Office for South-East Asia (SEARO)

3 of 10 SEARO countries (30%)

India: <http://www.mohfw.nic.in/kk/95/ia/toc.htm>
Korea: <http://www.kfda.go.kr/english/index.html>
Thailand: <http://www.fda.moph.go.th/enginfo.htm>

Regional Office for the Western Pacific (WPRO)

9 of 28 WPRO countries (32.1%)

Australia: <http://www.health.gov.au/tga/>
China: <http://www.sda.gov.cn>

Japan: <http://www.mhlw.go.jp>

Malaysia: <http://www.bpfk.org/html/index.htm>

Mongolia: http://www.pmis.gov.mn/health/Epos_NHP/default.htm

New Zealand: <http://www.medsafe.govt.nz/indexie4.htm>

Philippines: <http://web.doh.gov.ph/BFAD/>

Singapore: <http://www.hsa.gov.sg/cpa/>

Hong Kong: <http://www.info.gov.hk/dh/>

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