



NEWSLETTER

Vol. 16, N°1, January 2002

WELCOME TO A NEW FULL MEMBER

KUSURI-NO-CHECK (Check-your-pills in English) from Japan has been granted full membership.

The bulletin is financed by subscribers, personal donation and donation from the former *Information Centre for Drug Induced Sufferings (ICADIS)*.

The bulletin is aimed both at professionals (about a third of subscribers) and the public.

The editors intend to publish twice a year the Japanese translation of *Therapeutic Guidelines*, and booklets on hot issues, as supplements to *Kusuri-no-check*.

In future *Kusuri-no-check* website will feature some of its articles in English, including a weekly comment on major Japanese newspapers.

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COLUMN

The ISDB Declaration on Therapeutic Advance in the Use of Medicines

A Working Group of more than 20 editors involved in new drug evaluation met in Paris in November 15-16 2001 to put the finishing touch to an ISDB Declaration on 'what constitutes a genuine Therapeutic Advance as considered from the viewpoint of patients and society'.

Drafting of the Declaration began in spring 2001, and several drafts were made, taking into account comments of the Working Group and of 13 reviewers. The Declaration has been circulated to all ISDB members, and a majority of them endorsed it. It is available in two formats: an off print attached to this newsletter, and an electronic version (PDF) that you already received. The electronic format is designed to allow you to reprint all or parts of the document in your bulletins.

A Press Release is also available on request. It will be attached to the Declaration when sent to the media.

We have started a dissemination campaign aimed at the parties involved: health professionals and editors of independent drug bulletins, the public and their information providers, international health organisations, policy makers and regulators, as well as the pharmaceutical industry.

We strongly encourage you to use and disseminate this Declaration in your country or internationally. It can be used either as an editorial aid or a bargaining lever. We would appreciate it if you could forward us reactions to and follow up reports on the Declaration.

Further copies of the off print are available on request to the ISDB President Christophe Kopp.

E-mail address: christophe.kopp@wanadoo.fr

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KUSURI-NO-CHECK-WA-INOCHI-NO CHECK: A NEW ISDB FULL MEMBER

We reprint a paper by Gilles Bardelay, Director general of *la revue Prescrire*, published in the 5th issue of the new Japanese bulletin aimed at patients and the public.

Thanks to *Kusuri-no-check*, Japan takes the lead

Throughout the world, the quality of health care is determined by a shifting balance of power between four major players.

The first corresponds to the group most immediately concerned by the quality of health care, namely patients and their relatives. This is also the largest and, often, the most poorly informed group, and is influenced by opinion-makers such as the media. Patients express needs, fears and desires. And, when it comes to their health, they have certain habits, perceptions, beliefs, and demands.

The second major player is represented by health care professionals in both the private and public sectors, who have their own media, unions, and training organisations. Their opinions and actions influence patients and consumers, who in turn exert continuous pressure on them.

Policy makers, regulators, administrators in health ministries and welfare organisations, who set the ground rules, constitute the third player. Their role is essential. Society expects them to manage day-to-day affairs equitably and also to pave the way for improvements. They have a major influence on the behaviour of the first two players, but must also take the views and needs of the latter into account.

Thus, patients, health care professionals and regulators create a dynamic marketplace in health care. It is in the drug market that the fourth player, the drugs and medical devices companies exert their influence.

Industry is the most dynamic and

flexible player. Its aim being to sell a maximum of its merchandise, private enterprise strives to ensure that the other three players perceive their products as indispensable – regardless of the means employed.

How do the other three players react? Do they try to sort the wheat from the chaff; the useful, beneficial and innovative from the superfluous? And how susceptible are they to marketing ploys, gifts, sponsoring, and advertising?

Without an independent information system truly acting on their behalf, patients and health care professionals will always be the playthings of the industrial sector, and will be regularly caught off guard by health disasters. A sound, independent media is required to convey relevant, balanced information.

The drugs industry is increasingly targeting the general public directly, thereby bypassing health care professionals. But patients, bombarded as they are with frequently conflicting reports, are starting to demand reliable information.

We are entering a new era of health information sharing between patients and health care professionals, based on equal access to the same independent information sources. This can only make both parties more responsible.

Kusuri-no-check is a ground-breaker in this movement, and its example should be followed in every country.

[See page 1 for details about *Kusuri-no-check*]

Hold that needle!

For many, the sight of a syringe holds the same magical power as some traditional medical practices. What they do not realise is that the hand that holds the syringe is the last link in a thriving industrial chain that starts with the manufacture of injectable drugs and injecting materials, and ends with the trade in mystical therapeutic practices.

Since the 1960s, injections have become widespread, even in the most remote and poorest regions. A syringe and a few blunted needles, and, occasionally, a pot of boiling water to sterilise them, were enough to make a visit to the doctor rhyme with injection. Just about everyone and everything was injected.

Unfortunately, the results are now all too visible. In Africa, the World Health Organisation estimates that at least several tens of thousands of people have been infected by HIV in this way, and that several hundreds of thousands have been infected by HBV.

Given the scale of the problem, half-measures are not enough. Few patients really need injections. The entire chain must be broken up, including the sale and promotion of useless injectable drugs; the distribution of injectable drugs without the necessary sterile materials or means of sterilisation; and promotion of the parenteral route in situations where the oral route is perfectly adequate.

A sustained effort is required to make people more aware of the grave risks associated with needless injections.

[Taken from *la revue Prescrire* October 2001]

Getting information from the FDA

We reprint here extracts from a speech delivered for the ISDB meeting on therapeutic advance by Amanda Frost (*Public Citizen Health Research Group*) on the US Freedom of Information Act (FOIA), and a paper from *la revue Prescrire* on the FDA website.

As quite rightly put in *Worst Pills, Best Pills News* November 2001: “... it is impossible to conduct a valid independent assessment of the therapeutic value of a new drug without including the FDA reviews of the drug. The FDA reviews all studies submitted by a manufacturer, some of which may never be published because they do not shine the most favorable light on the product. Drug manufacturers are very adept at managing the information published about their products.”

Note that unpublished data and publication bias will be the subjects of debate and communications at our next General Assembly in September 2002 in Dubrovnik (Croatia).

OPEN GOVERNMENT LAWS IN THE UNITED STATES NOVEMBER 15, 2001

I am a lawyer for Public Citizen, a non-profit consumer advocacy organization with approximately 150,000 members. Public Citizen was founded in 1971 by Ralph Nader, and since that date has focused significant attention on fighting government secrecy. In particular, my organization has used open government laws to obtain information about the safety and effectiveness of drugs and medical devices and about the procedures that the US federal government follows to ensure the health and safety of such products. I am here today to talk to you about how you can use and benefit from the open government

laws in place in the United States.

In the late 1960s and early 1970s Congress passed a series of open government laws designed to open up government to public view. The principle underlying all these laws is that the more citizens know about their government, the better they will be governed. My talk today will focus on the Freedom of Information Act, which provides access to the records of federal agencies, but I will also touch on other laws that permit public access to government information. My goal is to explain how these laws work so that you can know when and how to use them to obtain information from the US government.

I. FOIA

FOIA was enacted in 1966 and went into effect in 1967. Although it has been amended several times over the years, its basic framework has remained the same. The statute establishes the presumption that all records of federal agencies are accessible to the public unless they are specifically exempted from disclosure by FOIA itself or another statute. To accomplish this goal, FOIA sets up a tripartite system for providing public access to government information:

First, agencies must public basic information about themselves, such as their structure, rules of procedure, function, and the substantive rules and statements of policy that they have issued, in the federal register, a government publication that is available to all, and that is available on line (1).

Second, agencies must make available for public inspection and copying certain basic agency records, such as final opinion in agency adjudication, statements of policy and interpretations not published in the federal register, and staff manuals about matters that affect

the public. To fulfill this task, agencies are required to establish physical rooms, called “reading rooms,” where the public can access the information. In addition, as a result of amendments in 1996 that take into account the development of the internet, the information must now also be available on the web (2). The 1996 amendments also require that agencies post on their web documents that were requested in the past and which the agency thinks are “likely to become the subject of subsequent requests for substantially the same records.” If an agency fails to comply by making information about its rules, policies and procedures publicly available, it will not be permitted to enforce those rules or policies against an unwitting member of the public.

Third, and most interesting to the general public and to this audience, records which are neither published in the federal register nor made available in reading rooms can be requested by members of the public. Although the law uses the term “records,” it defines that term to include graphs, pictures, photographs, slides, and any other physical piece of information that the government has in its possession. “Any person” may make a FOIA request. That includes individuals, partnerships, corporations, associations, and other organizations, foreigners, foreign corporations, foreign governments, and prisoners. Moreover, the requester need not provide any reason for the request (3). The agency is required to provide the records requested if they are in the agency’s possession unless the documents fall into one of the narrowly defined exemptions to disclosure. (...)

How To Make a FOIA Request

First, check the agency’s web site. As explained above, each agency’s ►►

► website will contain a great deal of information about the agency's mission, structure, personnel, and also information about its current policies, regulations, and results of agency adjudication. Most helpful is a 1996 amendment to FOIA requiring that agencies post on their website all documents that have been, or are likely to be, subject to frequent FOIA requests. (A good, if frivolous, example is that the FBI now posts on its website documents relating to Elvis Presley, which are frequently the subject of FOIA requests). This amendment makes life easier for agencies and requesters. It saves agencies from having to respond multiple times to the same request and provides requesters with immediate access to documents they are seeking. Each agency's website has a search engine that can be used when searching for records. As well, the 1996 amendments to FOIA also require agencies to provide an index of the documents in their possession.

In short, spend some time looking around the agency's website before making a request for records, since there is a chance the information you are seeking is already online.

If the records you are seeking are not on the web, then you must make a FOIA request. Although my talk here will hopefully make clear how this process works, you can also follow the guidelines provided for making such requests on an agency's website. Each agency, including the FDA, posts a "FOIA handbook" that walks potential requesters through the process. If you are making a request, you may want to skim that handbook first, although it is not necessary.

You must send your request to the FOI office for the agency that you believe possesses the records. The FDA's web site provides its address. You can also get the address of other federal agencies at the web site for the Department of Justice. www.usdoj.gov. One of the most difficult tasks for some requesters is finding which agency has the records they are seeking. For example, someone seeking records on disposal of nuclear waste might be unsure about whether the relevant records are kept by the Environmental Protection

Agency, the Department of Defense, or the Department of Energy.

As a result of 1996 amendments to FOIA, each agency must list an index of the records that they hold, and this index can be very useful in determining where to target a FOIA request. As you can see from FDA's website, it provides a very detailed index of the records it holds on new drugs and medical devices. This index can be useful in informing requesters of the type of information they might be able to receive with a FOIA request.

I also recommend sending a request for records to any and all agencies that might have the records to ensure that your request produces all materials held by the government.

Letters seeking records from the government do not need to follow any particular form, and certainly do not need to be drafted by a lawyer. There are a few things that every request letter should contain.

First, you must identify your request as a "FOIA request" in the header or in the first few sentences.

Second, you need to "reasonably describe" the records you want. FOIA does not require that you identify the exact records you are seeking. Agency employees are supposed to conduct a search "reasonably calculated" to locate your request, as liberally construed. However, I recommend that you describe the records you are seeking as specifically as possible by providing the subject of the records, the date they were created, the author of the records, and any other identifying information you may have. (Of course, if you are seeking "any and all records" the agency may have on a certain subject, then such specificity will not be possible or desirable.) The more specific you can be, the faster you will obtain a response. In fact, many agencies have established two tiers of requests: Very specific requests that are easy to answer are given the "fast track" while broad or vague requests are put on slower track.

FOIA provides the public with the right to access government information, but does not impose on the government any obligation to create new records or answer questions in response to an

information request. Thus, do not ask the agency to answer questions or create documents that do not exist. Also phrase your request in terms of asking for documents that already exist.

Third, you should also specify in your letter the form in which you are seeking the records. The 1996 amendments to FOIA requires agencies to provide records to requesters "in any form or format requested by the person if the record is readily reproducible by the agency in that form or format." This can be helpful, especially if you are seeking data in an electronic form so that you can analyze the data yourself. In my experience, agencies are generally very willing to provide data in electronic format if they store it that way themselves.

Fourth, FOIA is not free, and thus your letter should address the question of the costs of your request. FOIA establishes different fee structures for different types of requesters. Commercial requesters must pay for all agency time spent searching for and reviewing the records requested, and the cost of copying and delivering those records. Requesters who are not seeking to profit from their requests do not need to pay for the first two hours of agency time and the first 100 pages of copies. Requesters who plan to distribute the information requested widely to the public, and who do so without any motive for personal profit, may qualify for a waiver from all the usual fees.

If you are not seeking a fee waiver, your letter should state you are willing to pay the costs of search, copying and the time spent by agency reviewing the documents to determine whether the information is covered by an exemption. If you are only willing to pay up to a certain limit, you should state what that limit is.

If you are seeking a fee waiver, you should inform the agency of that in your initial letter. To obtain a fee waiver, you must state that your request is in the "public interest" because it is likely to contribute significantly to the public understanding of the government's activities and is not primarily in the commercial interest of the requester. The FDA is particularly good about granting such requests for waivers, and

FEDERAL ADVISORY COMMITTEE ACT

Federal agencies rely on committees of outside experts to advise them, and the Federal Advisory Committee Act (FACA) regulates this process. Before FACA, agencies were abusing this process by consulting biased individuals (frequently employees of regulated entities) to provide secret recommendations and advice that the agency then used to justify its policy decisions. FACA seeks to control agency use of outside experts and to ensure that the process is both fair and transparent. FACA ensures that government information provided to the outside experts is automatically made available to the public, without the need to file a FOIA request.

FACA requires that agencies provide the public access to, and infor-

mation about, the Committees that they have established. Agencies must disclose the names of who they have appointed to such committees and must ensure that they don't have a conflict of interest (or must explain why they have waived any conflict that does exist). All materials that the committee considers are to be made available to the public at or before the meeting. The date and location of the meetings are to be announced at least 15 days in advance, and the public must be allowed to view the meetings. In addition, the public must have a chance to participate, either through written comments or through an oral presentation.

FDA relies heavily on advisory committee to help review new drug

applications, and as a result of such committees the public can gain access to information about drugs under consideration. As stated, most of the material that the advisory committee relies upon to make its decision about the drug must be provided to the public at or before the meeting. In addition, transcripts or minutes from committee meetings are to be made public, and the committees must make publicly available their final report with their opinions. The FDA now provides all this material - advisory committee materials, transcripts, minutes and reports - on its web site.

[Already published in ISDB Newsletter May 2000: "Freedom of Information Act" by A. Frost]

my organization has rarely had any trouble receiving fee waivers from the FDA. However, certain agencies have begun demanding a great deal of information from requesters before granting fee waivers, making the fee waiver process difficult and time-consuming.

Agencies have 20 business days to respond to requests, although it can take additional time under "unusual circumstances." Moreover, most agencies (including FDA) are backlogged, and thus it can take longer. Right now, FDA's median response time for simple requests is 11 days, but for more complicated requests the agency averages 65 days. Requesters should fax requests, if possible, because the clock only starts running for the agency on the date it receives the request. The requester can ask for requests to be expedited if you can show "exceptional need or urgency," but expedition is rarely granted.

Possible Agency Responses to FOIA Requests

An agency denies a FOIA request

when it 1) claims it cannot locate records responsive to the request; 2) refuses to disclose some or all of the records requested it claims they are exempt from disclosure; 3) denies the request for a fee waiver; or 4) fails to respond altogether. Any agency response denying a requester access to some or all of the records must explain why the request was denied and provide the requester with information about how to appeal the denial.

FOIA has nine exemptions, and if the information requested falls within an exemption it may be withheld by the agency, although in most cases the agency may exercise its discretion to release information even if an exemption applies. The exemptions are to be interpreted narrowly, and if information does not qualify for an exemption, it must be disclosed. Below is a brief summary of the nine exemptions and an explanation of how they are defined by FOIA and interpreted by courts. I have minimized my discussion of exemptions that are less relevant to this audience,

and focused on those exemptions must often asserted by FDA in response to requests for information about drugs.

Exemption 1: Exemption 1 of FOIA protects from disclosure national security information concerning the national defense or foreign policy, provided that it has been properly classified in accordance with the substantive and procedural requirements of an executive order.

Exemption 2: Exemption 2 of FOIA exempts from disclosure records related solely to the internal personnel rules and practices of an agency. This exemption covers internal matters of relatively little significance, such as personnel rules regarding parking facilities or regulation of lunch hours, which are considered so trivial as to not be worthy of public interest. The exemption also covers information about significant internal operations that might, if disclosed, enable members of the public to evade agency regulations or statutes or impede the effectiveness of agency law enforcement activities. ▶▶

► **Exemption 3:** Exemption 3 incorporates the disclosure prohibitions that are contained in other federal statutes. This exemption permits Congress to enact additional statutes expressly prohibiting disclosure of information that would not qualify for a FOIA exemption. Congress has only rarely exercised this authority, however, so relatively few statutes qualify as exemption 3 withholding statutes.

Exemption 4: Exemption 4 applies to 1) trade secrets, and 2) “confidential commercial information.” Trade secret has been defined by the DC Circuit narrowly: “unpatented, secret, commercially valuable plan, appliance, formula or process which is used for the making, preparing, compounding, treating, or processing of articles or materials which are trade commodities.” *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280 (D.C. Cir. 1983). Confidential commercial information is defined as information which is a) commercial or financial, and b) obtained from a person, and c) privileged or confidential. *National Parks v. Morton*, 498 F.2d 765 (D.C. Cir. 1975).

Exemption 4 is the exemption most often asserted by FDA in response to FOIA requests for information about new or recently approved drugs. This exemption is intended to protect the interests of both the government and submitters of information. Its existence encourages submitters to furnish voluntarily useful commercial or financial information to the government and it correspondingly provides the government with the assurance that such information will be reliable. The exemption also affords protection to those submitters who are required to furnish commercial or financial information to the government by safeguarding them from the competitive disadvantage that could result from disclosure. Unlike other exemptions, agency has no discretion to disclose information that is “trade secret” or “confidential commercial information” because another federal statute, the Trade Secrets Act, prohibits disclosure.

Usually, agencies do not assert exemption 4 as a basis for withholding information until after they consult with the submitter of information and deter-

mining that the submitter does not want the information released. In most cases, the submitter will then intervene in any litigation and defend nondisclosure, while the agency will take a relatively minor role in the litigation. The agency’s role is diminished in such cases because it is the submitter, not the agency, that is concerned about disclosure. If, however, an agency chooses to disclose information over the submitter’s exemption, the submitter can file a “reverse-FOIA” lawsuit, in which it seeks to prove that the information qualifies for exemption 4. Thus, even if an agency wishes to disclose information, the requester may have to wait months or years until the legal challenge brought by the submitter has reached its conclusion.

Exemption 5: Exemption 5 covers inter-agency or intra-agency memoranda or letters that would not be available by law to a party in litigation with the agency. Exemption 5 has been read to incorporate the privileges available to private parties in civil litigation, such as the attorney-client privilege, the deliberative process privilege, and the attorney work-product privilege.

The most significant of these privileges is the deliberative-process privilege, which prohibits disclosure of non-final opinions of agency personnel. The privilege is designed to protect the decision-making process by ensuring that agency staff can deliberate openly and frankly about a problem without fear that their preliminary opinions will be subject to public disclosure. The deliberative process privilege is limited by the fact that 1) it covers only those agency opinions that are kept within the executive branch; once an opinion is shared with outsiders, it is no longer privileged; 2) it covers only agency opinions, and not the facts that underlie those opinions; and 3) it covers only non-final agency deliberations.

Exemption 6: Exemption 6 permits the government to withhold all information about individuals that would constitute a clearly unwarranted invasion of personal privacy. For example, information on an individual’s personnel or medical files would usually qualify. In

every case, the court has to weigh the individual’s interest in retaining their privacy against the agency’s interest in disclosure.

FDA will not disclose information that identifies patients or participants in drug trials. Normally, I advise my client to make clear to the FDA that they are seeking only the data about the drug’s effects, and are not seeking information that would reveal the identity of the patients/trial participants.

Exemption 7: Exemption 7 protects from disclosure records compiled for law enforcement purposes, but only to the extent that the production of such information 1) could reasonably be expected to interfere with enforcement proceedings, 2) would deprive a person of a right to a fair trial or an impartial adjudication, 3) would reasonably be expected to constitute an unwarranted invasion of personal privacy, 4) could reasonably be expected to disclose the identity of a confidential source, 5) would disclose techniques and procedures for law enforcement investigations or prosecutions, or 6) could reasonably be expected to endanger the life or physical safety of any individual.

Exemption 8: Exemption 8 protects matters that are contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions.

Exemption 9: Exemption 9 covers “geological and geophysical information and data, including maps, concerning wells” (9). This exemption is rarely asserted.

Agency must provide all “reasonably segregable” information in the requested records. That means that even if some of the information qualifies for an exemption, the rest of the information should be disclosed. My organization has frequently objected on the ground that it has been denied an entire document when in fact only a small percentage of the information in the document is exempt from disclosure. Agencies such as FDA still frequently fail to carefully distinguish between exempt and non-

exempt information, so it is up to the requester to carefully review the material received, and the exemptions asserted, in order to determine whether the agency has wrongly withheld nonexempt information.

Appealing Agency Denials

As stated, an agency that denies some or all of the information requested must inform the requester of their right to appeal and must provide the requester with the address of the office to which an appeal should be directed. Appeal letters are reviewed by higher up agency officials with more discretion, including discretion to waive exemptions. For example, the appeal letters for FDA are reviewed by a special office in the Department of Health and Human Services (the umbrella agency for FDA). The original reviewer of each FOIA request is usually a very low level (and poorly paid) federal employee with little discretion and possibly with little understanding of how FOIA should work. Appeals are reviewed by individuals with a great deal more experience with FOIA and with discretion to waive exemptions.

Thus, appeal letters should contain all political and legal arguments in your favor. It is helpful to explain to the agency any legal basis for objecting to their denial. Sometimes the agency denies us records of a type similar to those that we have previously received from them. In such cases, I recommend explaining to the agency that the denial violates their previous policy, and, if possible, including a copy of the records provided in response to a previous request to prove the point.

My final word of advice about FOIA requests is to remember that you are not limited to simply writing the request, but can also call and speak to the person handling your request in person. Such conversations can be very useful in helping to identify the records you are seeking or explaining why you merit a fee waiver. The FOIA office at FDA knows my organization well (too well, they might argue!), but this kind of personal contact has made a big difference in the speed and nature of the response to your request. So do not hesitate ►►

MedWatch

The FDA safety information and adverse event reporting program

<http://www.fda.gov/medwatch/index.html>

MedWatch is the name of the FDA's safety information and adverse event reporting program for drugs, biological products, medical devices and dietary supplements sold on the US market.

Strong points. Pharmacovigilance alerts and new warnings on adverse effects are readily accessible.

The *Safety Information* section provides pharmacovigilance alerts and explanatory documents (letters, reports, etc.). It has five subsections, entitled biological products, dietary supplements, drugs, medical devices, and "miscellaneous". A brief summary of pharmacovigilance data appears on screen, with hypertext links to detailed documents, circulars addressed to health professionals, reports, etc. Alerts are archived by year and in alphabetical order.

All modifications to summaries of product characteristics (SPC) for drugs marketed in the US are published online. These modifications cover all the different sections of the SPC, i.e. adverse effects, precautions for use, warnings, contraindications, indications, dosage and mode of administration, and interactions, as well as clinical pharmacology, oncogenicity, etc. The new text is marked clearly in bold, underlined characters. A hypertext link is provided if the text containing the data that led to the modifications is available on the FDA website. SPC modifications are archived by

date and in alphabetical order.

The standard adverse effect form can be downloaded. Health professionals and members of the public can notify adverse effects online.

The MedWatch site encourages comments and questions on product documents and reports, and provides an online form for this purpose.

One section provides a list of product or batch withdrawals, each accompanied by the reason. Most involve manufacturing problems (inappropriate packaging, failure to respect good manufacturing practices, etc.), illegal copies – which are relatively frequent in the United States (identifiers are provided), batch withdrawals of blood-derived medicinal products (identification of a risk factor in a donor, such as an infection, ongoing drug therapy, an underlying health disorder; and labeling errors, etc.), and lack of conformity of medical devices.

Weak points. MedWatch only covers drugs marketed in the United States. A drug marketed elsewhere may also be available in the United States but may have a different brand name, indication or dose strength.

Short-cuts. The *What's New* page shows the last two weeks' alerts. Automatic e-mail alerts can be received by subscribing to the MedWatch mailing list.

[Taken from *la revue Prescrire* October 2001]

Pay your membership fee!

You will soon receive a request for your membership fee for 2002. Please pay as soon as possible. ISDB's activities depend on your contribution.

LOOKING OVER THE FDA WEBSITE

The Food and Drug Administration (FDA) evaluates the risks and benefits of health products (drugs, medical devices, screening tests, etc.) and monitors the safety of foodstuffs and some consumer products that carry a potential health risk (portable phones, microwave ovens, etc.).

The FDA website is well designed and currently provides online access to some 140 000 administrative or technical documents.

Each main FDA department has its own subsite on the FDA server.

Strong points. The home page makes it easy to access the information sought, with separate internal links to pages for:

- consumers, patients, health professionals, manufacturers, journalists, women, elderly people and children (*Information for*);

- publications (*Reference room*);

- news (*FDA news*);

- product types (*Products FDA regulates*);
- clinical trials, commissions, surveillance, etc. (*FDA activities*);

- FDA contact pages: to report a problem, request a public document, etc. (*Let us hear from you*).

Departments with their own subsites include:

- Center for Drug Assessment and Research (CDER)**, which is responsible for assessing new drugs in terms of manufacturing quality, efficacy, safety and information leaflets, and gives its opinion on whether a new product warrants marketing authorisation in the US. The CDER home page can be found at <http://www.fda.gov/cder/index.html>.

- Center for Biologics Assessment and Research (CBER)** is responsible for evaluating the efficacy and safety of therapeutic products of microbiological, plant, animal or human origin, such as blood and blood products, vaccines, monoclonal antibodies, enzymes and interferons, genes, xenografts, allergens, etc. Laboratory tests for infectious agents are also dealt with by CBER. The home page can be found at <http://www.fda.gov/cber/index.html>.

- Center for Devices and Radiological Health (CDRH)** is responsible for assessing the safety and efficacy of medical devices (prostheses and orthoses, blood

glucose monitors, surgical robots, etc.), and the safety of radiation-emitting devices (microwave ovens, video screens, cellular phones, radiological equipment, etc.). American surveillance data on materials, including public alerts, are gathered together under the heading *Postmarket issues*. The CDRH home page can be found at <http://www.fda.gov/cdrh/index.html>.

- Medwatch (see inset page 7) is a general FDA department responsible for pharmacovigilance and materials surveillance; the home page can be found at <http://www.fda.gov/medwatch/index.html>

- Center for Food Safety and Applied Nutrition (CFSAN)** is charged with monitoring the safety of foodstuffs consumed by the American population (with the exception of meat, poultry and eggs). The prevention of foodborne illnesses is thus one of its main responsibilities. CFSAN is also responsible for the safety of food additives and dietary supplements, milk formulas and other foods used for human therapeutics, and cosmetics. The CFSAN home page can be found at <http://vm.cfsan.fda.gov>.

- Limitations.** The FDA has the legal obligation to make available on its website the information it holds. The limitations of the website reflect those of the FDA itself.

- In brief.** The web page entitled *FDA Manuals and Publications* provides easy access to all the documentation present on the site. The different types of document are classified and can be accessed via a short list of key words given in alphabetical order. Each FDA department also offers a specific list of its online documents.

- Three search modes are provided at the bottom of the home page: a precise plan of the site (*Site map*), an A to Z key word index (*A-Z index*) and an internal search engine (*Search*). Information contained in the site's database cannot be accessed using these three search modes: each database must be searched individually.

- The home page for health professionals (*Health professionals*) has links to all the FDA website pages likely to interest them: this is a time-saver for the health professional who just wants to browse.

- The visitor seeking specific information can use the advanced search mode (*Advanced Search*) to find all the pages containing a string of closely related or unconnected words, and can choose to search



the entire text or simply the titles and/or keywords. A specific search can be made for documents posted online the previous day or week. The information contained in databases cannot be accessed in this way. The user is advised to type words entirely in lowercase or uppercase letters, and to place each word inside quotation marks to optimise the search (click on *Search tips* for more details).

Users can subscribe to various mailing lists (FDA News Digest, FDA Consumer, MedWatch "What's new", etc.). Links to these services are found at the bottom of the home page (*Subscribe to FDA's E-mail lists*).

Site created in 1995

Publisher(s). US Food and Drug Administration.

Funding is stated. The site is financed by FDA, whose provisional budget for 2002 is \$ 1 414 391 000 (approximately 40% from the public coffers and 60% from industry dues).

Advertising. None.

Fate of users' personal details. FDA states that it never communicates to third parties any personal information volunteered, such as e-mail addresses, which must be given to subscribe to FDA mailing lists, or personal details required to notify surveillance problems.

Update policy. New documents are posted online each day. Documents published on the FDA website are updated regularly and modifications can be posted daily.

Author(s). The FDA employs 9 000 people, including chemists, microbiologists, clinicians, veterinarians, lawyers, biomedical engineers, health inspectors, pharmacy inspectors, etc., and also has a number of advisory committees comprising experts in the various areas the FDA covers. The authors of online documents may be agency employees or outside experts.

[Taken from *la revue Prescrire* October 2001]

► to contact FDA's FOIA office personally if you have not received an answer to your response or are not satisfied with the response you have received.

Shelby Amendments

Before concluding my discussion of FOIA, I want to say a brief word about the Shelby Amendments to FOIA, which are only a few years old and to my knowledge have not yet been widely used. Under FOIA, agencies are nor-

mally only required to provide access to records in their possession. However, the Shelby Amendments make records of certain government research grantees (often academic institutions) subject to FOIA as well. These amendments thus may provide a rich source of information about the data underlying government funded research, and should be kept in mind when seeking information relating to government-funded private research.

DRUGS AGENCIES' WEBSITES UNDER SCRUTINY

National drugs agencies must guarantee the transparency of their decisions, and have a duty to inform not only political authorities and the pharmaceutical industry, but also health professionals and citizens (1).

The most appropriate medium through which to convey this information to the public is now the internet: costs are minimised; daily updates can be made; and decision-making can be traced.

The quality of drugs agencies' websites reflects the quality of their work, and their willingness and capacity to inform and thereby fulfil their public health mission.

First impressions of websites are usually based on their user-friendliness, i.e. accessibility, rapidity, compatibility with popular browsers and software, and layout.

In particular, all information posted

on drugs agency websites must be regularly updated, and dates on which information is posted must be clearly stated.

What matters most, however, is whether these sites provide clear answers to legitimate questions on national drugs policies.

The criteria we used to evaluate drugs agency websites are listed on page 10. They may not be comprehensive, but they represent the bottom line.

We regularly assess websites of regulatory agencies and other important websites in our French edition.

[Taken from *la revue Prescrire* June 2001]

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1- "Statement of the International Working Group on Transparency and Accountability in Drug Regulation" Uppsala, 11-14 September 1996 Available on request.

LIST OF ISDB FULL MEMBERS AND RECOGNISED CORRESPONDENTS ON THE INTERNET, UPDATED DECEMBER 2001.

The following list may not be complete or have errors, please send your details or amendments to christophe.kopp@wanadoo.fr

Arnei-telegramm (Germany)
<http://www.arnei-telegramm.de>

Australian Prescriber (Australia)
<http://www.australianprescriber.com>

Belgisch Centrum voor Farmacotherapeutische Informatie (Belgium)
<http://www.bcfi.be>

Boletín Terapéutico Andaluz (Spain)
<http://www.easp.es>

Bulleti d'Informacio Farmacoterapèutica (Spain)
<http://www.csbcn.org/public/bif>

Der Arzneimittelbrief (Germany)
<http://www.arneimittelbrief.de/ambstart/starfs.html>

Dialogo sui Farmaci (Italy)
<http://www.dialogosuifarmaci.org>

Dossier du CNHIM (France)
<http://www.cnhim.org>

Drug and Therapeutics Bulletin (United Kingdom)
<http://www.which.net/health/dtb/main.html>

Drugs Moldova (Moldova)
<http://www.aiha.com/english/general/projects/drugs.htm>

Farmakon (Slovenia)
<http://www2.arnes.si/~ljslfd1>

Focus (Italy)
<http://www.sfm.univr.it>

Geneesmiddelenbrief (Belgium)
<http://www.farmaka.be>

Geneesmiddelenbulletin (the Netherlands)
<http://www.geneesmiddelenbulletin.nl>

Health Action International
<http://www.haiweb.org>



Prescrire's criteria for assessing drugs agency websites

1- Organisation of the agency

- Organisational flow chart: positions and contact details of managerial personnel; lists of experts; conflicts of interest
- Calendar of meetings, with precise minutes, and whether or not meetings are open to the public
- Detailed annual activity reports
- Board of Directors' reports; financial controllers' reports; etc.
- Budgets

2- Regulatory matters

- All regulatory texts defining the role and objectives of the agency, its commissions and its task forces
- All decisions and recommendations signed by the directors
- Lists of generics, drugs with special status, controlled drugs (opioids), blood-derived products, etc.
- List of banned advertisements, with the reasons for prohibition

3- Assessment reports

- Summaries of Product Characteristics (SPC), including information for professionals, patient information leaflets and pack labelling, with precise details of any wording changes
- Assessment reports submitted in support of applications for marketing authorisation (with dates of drafting and submission, clearly mentioning updates (a))
- Reports of discussions by commissions and specialised task forces (or transcriptions of recorded meetings)
- Register of ongoing and completed clinical trials. Comparative assessment of drug cost-effectiveness: work of ad hoc commissions; access to all reports made by these commissions, to evaluations of "services rendered" relative to other available products, and the reports on which they are based
- Clinical guidelines; vaccination calendars; etc.

4- Pharmacovigilance

- Pharmacovigilance decisions, and the data on which they are based: alerts, warnings, packaging modifications, batch withdrawals (industrial problems), circulars (to manufacturers, pharmacovigilance centres, health professionals, etc.), market

withdrawals and suspensions of marketing authorisation

- Changes to SPCs relating to adverse effects, interactions, pregnancy, warnings, restricted indications, dose regimens, overdose, special clinical settings
- Reports of completed pharmacovigilance surveys

-Reports of commission meetings on pharmacovigilance, pharmacodependence, drug interactions, pregnancy and breast-feeding, etc.

- Drugs subject to special monitoring (list of ongoing surveys, lists of monitored drugs)

- Pharmacovigilance bulletins (national and regional pharmacovigilance centres)

- Reports of spontaneous notifications by prescribers and pharmacovigilance studies

-List of pharmacovigilance and pharmacodependence centres, etc.

- Downloadable notification forms for reporting adverse effects (for drugs, medical devices, herbal products, etc.)

5- Consumption, Usage, Pricing

- Data on consumption
- Data on usage: non compliance, dependence, off-licence indications, prescriptions not observing the SPC
- Market withdrawals, stock shortages
- Regularly updated details of price of drug reimbursed by the public health insurance system

6- Other products

Drugs agencies' responsibilities are rarely limited to proprietary medicinal products: their websites must also, depending on regulations and the missions of the different institutions, include:

- extemporaneous preparations made in community or hospital pharmacy;
- medicinal plants;
- blood-derived products;
- medical devices;
- dietary products.

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a- For instance the European Public Assessment Reports (EPARs) of the European Agency, and Drug Reviews of the US Food and Drug Administration. No such reports exist in France.

► Information from Lakemedelsverket (Sweden)

<http://www.mpa.se>

INRUD

<http://www.msh.org/inrud>

Informazioni sui Farmaci (Italy)

<http://www.fcr.re.it>

Kusuri-no-check (Japan)

<http://www.npojip.org>

La Lettre du GRAS (Belgium)

<http://www.ulb.ac.be/esp/gras/index.html>

MaLAM (Australia)

<http://www.malam.asn.au>

Nytt om Legemidler (Norway)

<http://www.slk.no>

Pharmainformation (Austria)

<http://info.uibk.ac.at/c/c5/c515/pharmainfo.html>

Pharma-Brief (Germany)

<http://www.epo.de/bukopharma>

Pharma Selecta (Holland)

<http://www.pharmaselecta.nl>

Pharma-Kritik (Switzerland)

<http://www.infomed.org/pharmakritik-e>

Prescriber Update (New Zealand)

<http://www.medsafe.govt.nz/Profs/PUarticles.htm>

PRN Bulletin (Malaysia)

<http://prn.usm.my/bulletin/>

Rational Drug Bulletin (India)

<http://www.healthlibrary.com/reading/rdb/index.htm>

Ravimiinfo Estonia (Eronia)

<http://www.sam.ee/bull.html>

Therapeutic Guidelines (Australia)

<http://www.tg.com.au>

Therapeutics Initiative (Canada)

<http://www.interchange.ubc.ca/jauca>

WHO/EDM

<http://www.who.int/medicines>

Worst Pills Best Pills (United States)

<http://www.citizen.org/hrg/NEWSLETTERS/pillnews.htm>

COMMITTEE MEETING MINUTES PARIS 17 NOVEMBER 2001

9.00 am to 15 pm - La Revue Prescrire - 73 Boulevard Voltaire -Paris

Present:

Andrew Herxheimer - Andrea Tarr - Bozidar Vrhovac - Christophe Kopp - Dzulkifli Abdul Razak - Gita Fernando - Hirokuni Beppu - Jose Recalde - Ksenija Makar-Ausperger - Maria Font

Organization of next General Assembly in Dubrovnik: The committee has discussed dates and prepared a draft programme and discussed the general organisation of the 2002 GA. Dates: 19 to 21 September. University premises will be used to host the meeting. A local travel agent has been appointed to take care of accommodation booking. We do not know yet what will be the cost of the meeting and therefore whether we need to find any external funding.

Andrea will write up the provisional programme for circulation to the committee and members for further development. Ksenija will ensure that enough rooms are booked at the University to host the main meetings and workshops, and will investigate a convenient place for having lunches (the University does not allow food on the premises). Ksenija will send to the committee an estimate of the cost of hosting the GA. Ksenija and Darko will ask their Ministry of Health for support/representation.

ISDB manual: all material has been received from the WHO but has not been yet reviewed by Danielle and Christophe. They will do so in the next few weeks and then report to the committee.

An application for membership has been received from Rokuro Hama for the Japanese consumer/health professional bulletin Kusuri no check. As it is in Japanese, Maria will ask Hiro for his judgement on the content and advise the committee before we make a decision to grant full membership (see p. 1-2).

Health Information Forum. The committee wondered if it is possible to ask the major scientific journals for a reduced subscription rate for ISDB members. It was felt that it would be too difficult to do this with individual journals. It was decided that it would be more worthwhile to circulate the contact details of the Health Information

Forum (an organisation that aims to make published scientific information accessible to all). Andrea to find the details for circulation to all members.

Financial report: Andrea gave a summary of the 2001 financial report. Total income so far £9300, total expenditure so far £3500, leaving a balance of about £5800. There is a surplus of £14000 from previous years and so there is a total fund of £19800 available. A more detailed report will be prepared at the end of the year. Nearly all of the full members have paid the membership fee, but many recognised correspondents have not responded.

Follow-up of the Paris Declaration. It will be circulated to the working group and then it will be sent by email to all members to ask their approval within a deadline. The declaration will then be disseminated as agreed at the declaration meeting (see column p. 1).

Web site: As a result of the difficulties with communication about the web site under the present arrangements, and consequent delays in completing the web site, the committee agreed to look for a new provider. Andrea and Maria presented an estimate of costs for creating a new ISDB web site with an ISDB-specific domain name. The committee agreed that Maria will ask to an Italian company to prepare the new web site which should be ready at the end of December. The cost of the new web site (isdbweb.org) will be around 1.704 Euro including bimonthly update and visitors counting. The annual cost for the second year would be of 370 Euro.

COLOPHON

Editor: Christophe Kopp
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The following people contributed to this newsletter: Gilles Bardelay (*la revue Prescrire*), Maria Font (*Dialogo sui farmaci*), Amanda Frost (*Public Citizen Health Research Group*), Andrea Tarr (the *DTB*),

The ISDB Newsletter is sent free of charge to ISDB members and corresponding members.

ISDB



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IMPORTANT A date for your diary!

**GENERAL ASSEMBLY
19-21 SEPTEMBER, 2002
DUBROVNIK, CROATIA**

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