



## Column

## Melbourne GA and Perspectives

In this first editorial I'd like to thank the organizers of the GA, the colleagues of the past committee and all the members who supported the new committee and myself as Chair of it. I feel honoured for this but I also realize the challenge of steering the society for the next three years.

During the introduction of the new committee in Melbourne it was said that we wanted to give a new style to ISDB, defined by an improved cooperation among bulletins, shared decisions and more attention to the needs of starting bulletins and those from developing countries. The planned actions for the future should reflect this.

ISDB lived in the past 3 years a turbulent period (growth crisis maybe?). True, we are evolving: one third of the current 74 members entered the society in the last 6 years. The presence of electronic bulletins is growing as well as that of patients' bulletins. The ways of doing drug information are changing in a globalized context even more complex than 20 years ago: the influence of pharmaceutical industry on Public Health is growing, from research to continuous medical education and of course on the approval of new drugs. Sadly conflicts of interest are rampant in all health sectors and particularly in drug information. If it's time to untangle health operators from drug companies, an independent drug information is an essential tool, that's our policy and our challenge.

During the last General Assembly in Melbourne, some of these issues were discussed. I'd like to underline three important aspects for the next future.

The first is that the ISDB Assembly decided finally to approve some needed changes in the Constitution but maintain a coherence with the original mission of ISDB (see page 2).

The second is the presentation, during the GA, of the first edition of the Manual "*Starting and strengthening a drug bulletin*" in collaboration with WHO. This project, initiated many years ago, has finally been completed. It is a text of high quality, that will help people producing drug information bulletins without industry funding (available on the ISDB Website).

The third aspect is the new committee, constituted by 10 members that represents all the continents and particularly developing countries. The committee defined a program for the next three years. This program will include campaigning as a regular activity, more collaboration among bulletins and collective actions, for instance fighting direct-to-consumer advertising and misleading promotion; assessing ICH guidelines and registration requirements in developed and developing countries.

Other objectives like supporting bulletins in trouble, comparing transparency indicators of regulatory agencies and reviewing the WHO essential drug list have also been proposed (see minutes page 2).

A first informal executive group meeting was held in Paris on 15-16 December to define the proposals that emerged in Melbourne during the first committee meeting.

Intensifying and improving cooperation will be the most intelligent way to operate in the future.

Maria Font  
*Dialogo sui Farmaci*  
ISDB Chair

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# General Assembly in Melbourne

## New ISDB Committee

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Dialogo sui Farmaci  
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maria.font@ulss20.verona.it

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Burkina Faso  
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### *Other european countries coordinator*

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Farmakoterapeutiké Informace  
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### **Pijus Sarkar**

Bodhi & Asukh Bisukh  
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fha@cal.vsnl.net.in

The General Assembly in Melbourne was a success (see results of the feedback questionnaire page 3). Speeches and reports will be posted on ISDB website.

## A New Committee has been elected

It represents all the continents (see full list opposite).

### **Executive Committee :**

Maria Font has been elected **Chairman**, Christophe Kopp **Secretary**, and Jörg Schaaber **Treasurer**.

### **Regional coordinators:**

**Western Europe** Jörg Schaaber  
**America** Benoit Marchand  
**Asia Pacific** Zahed Masud  
**Africa** Clotaire Naga  
**Eastern Europe** Blanka Pospíšilová

## The ISDB Constitution has been amended

Following years of discussion and a lively debate in Melbourne the ISDB we have now a slightly amended Constitution, that maintains a coherence with the original mission of ISDB.

Outdated parts have been cleaned out with approval of the entire Assembly. Minor amendments have been accepted such as the wording 'associate member' instead of 'recognised correspondent'. A number of proposed amendments have been challenged, then put to vote and finally rejected by the required majority.

In short the definition of a drug bulletin, notably publication frequency, remains unchanged (4 issues a year).

Members who cannot attend General Assemblies will still have the possibility to give a proxy to another member. A major change has been accepted, which provides for full membership to bulletins aimed at patients or published electronically.

So the Constitution debate is over thanks to this Melbourne GA.

## Minutes of the first Committee meeting

Melbourne, 16 September 2005

The 10 new committee members attending the meeting were:

Maria Font, Sharon Hart, Rokuro Hama, Christophe Kopp, Benoit Marchand, Zahed Masud, Clotaire Nanga, Blanka Pospíšilová, Pijus Sarkar, Jörg Schaaber.

First the ex-President reported on a number of issues that need to be dealt with by the new Committee. Then we started listing a number of priorities, related to ISDB administration on the one hand, to campaigning on the other hand. Corresponding responsibilities were given to committee members: names of committee members appearing below are those in charge of a topic, but we stressed the need to work collectively, always looking for input from other members before implementing a project.

## ISDB administration

**Secretary will announce new committee members** on ISDB forum (done); Sharon Hart will prepare a press release to the same effect, to be sent to Scrip. The press release will state the key ISDB priorities for the coming 3 years.

**The amended ISDB constitution** is due to be registered in London (Sharon Hart) after approval of the draft by Committee members. The new constitution will be posted on ISDB website with amendments in bold.

**Coordination with previous Treasurer** was ensured. Treasurer will take over the accounts from the previous administration and prepare the next budget. A new ISDB account has to be opened in Germany (Euro currency).

**Benoît Marchand will prepare a questionnaire for evaluating the Melbourne GA**, with a view to planning the next one. Secretary will distribute it and gather the responses for analysis to be published in Newsletter (see page 4).

**Secretary will prepare a Newsletter** by end of December 2005, using input from all members, and taking into account priority actions. He will be assisted by Florence Vandeveldt at *La revue Prescrire*. ► ►

## ► Website maintenance and update: Maria Font.

The ISDB/WHO manual is due to be posted on ISDB website; each chapter will be downloadable separately for convenient use; registration will be required before downloading (Maria Font). Treasurer will approach the WHO contact in charge of the manual during the previous administration in order to see what had been decided, then report to the committee for decision. The need for further reprints of the manual was considered, which should not mention the EU logo. According to la revue Prescrire, one reprint could cost 6 euros only (with new cover and binder); decision postponed.

**Secretary will continue evaluating quality of member Bulletins.** Benoit Marchand is due to review the evaluation questionnaire for possible refinements (as suggested in workshops), such as the presence/absence of Correction and 'Letters to editors' sections in Bulletins, or publication of annual financial reports. The ISDB draft document on conflict of interest should also be considered.

**Secretary will distribute to other committee members an application** received in Melbourne from a Nepalese colleague (previously recognised correspondent).

**Secretary will urge members to send each issue of their Bulletin** regularly to the ISDB library, now located at: La revue Prescrire, 83 Bd Voltaire 75011 Paris, France.

Members having an electronic Bulletin can send it by email to [docuserv@easynet.fr](mailto:docuserv@easynet.fr) (with copy to [christophe.kopp@wanadoo.fr](mailto:christophe.kopp@wanadoo.fr)).

**Regional coordinators** should map members and blank spots worldwide.

## ISDB programme

The new committee has set up **two campaigning objectives:**

- fighting direct-to-consumer advertising and misleading promotion;
- assessing ICH guidelines and registration requirements in structured and non-structured countries, with a view to improving drug application dossiers (Rokuro Hama and Pijus Sarkar).

**WHO medical reviews.** The previous committee had dealings with WHO that need to be reassessed. The new committee has to decide if it wants to continue with a system whereby ISDB Bulletins carried out medical reviews of candidate drugs for the WHO essential drug list. No decision was made during the meeting. If the committee ever decides positively, a strict method and review system involving a panel of ISDB members (and a training phase) would be needed, so as to ensure

good quality of ISDB-made medical reviews and ISDB credibility. Christophe Kopp will take stock of the previous workings and make proposals to the committee.

## On the agenda

The committee had no time dealing with a number of important issues raised during workshops. These issues are also on the ISDB agenda:

**Solidarity and support.** Training at other bulletins. Developing editorial skills. Financial support (eg for expanding distribution). Support to go to meetings.

**Transparency indicators** of regulatory agencies. The project is to design a multi-item questionnaire for evaluating access to key documents from regulatory agencies in as many countries as possible. Results could be formatted as a transparency indicator and presented at each ISDB general assembly. The aim is ultimately to put pressure on secretive and failing regulatory agencies.

## Future Meetings

**An Executive committee** is due on 15-16 December 2005 and another full committee meeting in May 2006.

**Next general assembly.** 2 candidates have applied: Benoit Marchand in Managua (Nicaragua); and Clotilde Nanga in Ouagadougou (Burkina Faso).

**Christophe Kopp**  
ISDB Secretary

**Don't forget to send each issue of your Bulletin to the ISDB library!**

(either by post or by email if you make an electronic edition)

The library is located at the ISDB Secretariat:

Post address:

La revue Prescrire  
DOCUMENTATION  
83 boulevard Voltaire  
75558 PARIS CEDEX 11  
France

Email addresses:

[docuserv@easynet.fr](mailto:docuserv@easynet.fr)  
with copy to [christophe.kopp@wanadoo.fr](mailto:christophe.kopp@wanadoo.fr)

**Thanks in advance!**

## Welcome to New Full Members!

**During the GA, 3 applications for full membership were successfully reviewed. All 3 Bulletins were accepted as full members.**

### Asukh Bisukh

#### INDIA (Language: English)

Bulletin for patients from India.

*Asukh Bisukh*, belonging to the same organisation as *Bodhi*, will result in a new bulletin belonging to the same membership.

Contact: **Pijus Sarkar**

([pha@cal.vsnl.net.in](mailto:pha@cal.vsnl.net.in))

P 254 - Block B

Lake Town

Calcutta 700 089 - India

### Arzneiverordnung in der Praxis (AVP)

#### GERMANY (Language: German)

AVP comes back! AVP was one of the ISDB founder. It was a recognised correspondent, and is now again full member.

Website: [www.akdae.de](http://www.akdae.de)

Contact: **Heiner Berthold**

([heiner.berthold@dgn.de](mailto:heiner.berthold@dgn.de))

Arzneimittelkommission der deutschen Ärzteschaft

Herbert-Lewin-Platz 1

10623 Berlin - Germany

### Boletín Fármacos

#### ARGENTINA-USA (Language: Spanish)

Electronic Bulletin (see page 8 Conversation with Martín Cañas).

Web Site: [www.boletinfarmacos.org](http://www.boletinfarmacos.org)

Contact: **Martín Cañas**

([macanas@netverk.com](mailto:macanas@netverk.com))

or **Nuria Homedes**

([nhomedes@utep.edu](mailto:nhomedes@utep.edu))

1100 North Stanton Suite 110 El Paso  
Texas 79902 - USA

## Feedback on the ISDB General Assembly in Melbourne... and ideas for the next one

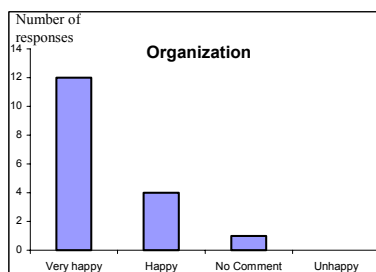
In order to help the new committee to organize the next GA, a feedback was asked to the Melbourne GA participants.

### Methods

A questionnaire was sent by the Committee to the GA participants. Satisfaction was assessed through 3 items (Organization, Content, Social event), and 3 open questions were asked: What was the main strength of the GA? What would you have preferred to be different? Any suggestions for the next GA? The responses were anonymously analysed.

### Results

Three main themes emerge from the different responses to the open questions: Melbourne GA was a success, it was a pleasure to meet and exchange ideas, and we received a lot of ideas in the field of "content and methods" for the next GA. We pick up some quotes reflecting the main proposals.

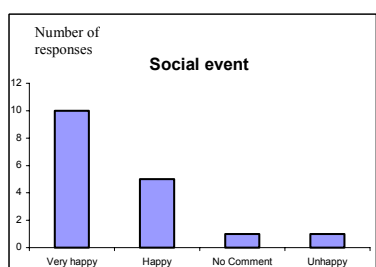


#### 1. Organization and social events: a success.

As you can see on the histograms, the organization was well appreciated "The reliable and thoughtful team of volunteers", "TG did a good job", "Discipline and time control": thanks again! The social event were appreciated as well.

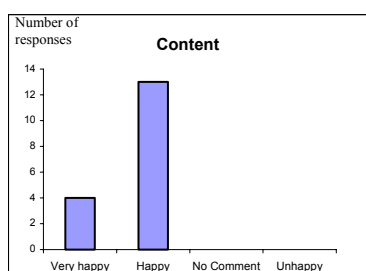
#### Interesting ideas for the next GA.

"start with a funny social event that helps people (...) to mix. Why not to bring something typical of their country (food or drink, or music)?";  
 "a photo group should be included in the program (because of the time it takes to organize!)";  
 "improve internet facilities", "need of PCs for working outside and within workshops, and showing web-sites to colleagues (...)";  
 "make available a summary of the conferences, before the meeting", "provide all the speeches and reports in a CD-Rom that is distributed at the end of the GA".



#### 2. The pleasure of meeting .

Exchanges of experiences, meeting together was a great pleasure : "the most important thing is to see other members of the ISDB and to informally discuss several aspects of our activities", the "strong, not only pharmacological/therapeutic, but also ideological and political commitment of many ISDB members" was appreciated, as well as the "feeling of freedom during the debates", "meeting people from different countries";



"learning about and sharing experiences of the different bulletins", "meeting many friends around the world working in similar fields and exchanging views", "made historical amendments in the ISDB constitution" ("with (fortunately!) only short discussion about it"), "Meeting people involved in the same area", "opportunity to discover new experiences, particularly initiatives towards people and drug consumer", etc.

**Interesting ideas for the next GA.** "It would be preferable that the new members present themselves at the end of the first day, so the old members would have the opportunity of knowing them from the beginning of the meeting";

"all participants should bring a copy of their bulletin", and "provide a poster explaining what their bulletin is, who it is for, how the content is determined and edited, editorial policies, etc.";

"the new committee should be elected earlier in the meeting so that they can start to work together"; etc.

#### 3. Content and methods: a lot of ideas.

**Workshops: good interactive work opportunities, if well prepared.**

The workshops "gave the opportunity to intensive discussions and considering practical actions to improve the quality of bulletins", "more workshops are needed in order to debate some issues in smaller group". The fact that the workshop were "not always very effective" was underlined. A solution could be : "give more detailed headlines for the topics of the working groups, so that participants see what they can expect".

**A question:** "The interests of ISDB journals (e.g. in Europe and in Asia) are very different. How to deal with this within ISDB?"; "Perhaps sometimes it could be interesting that bulletins from developing countries meet together (for instance to discuss the topics on bulletin in needs, etc.)"

#### Speech quality: heterogeneous.

On the one hand, there is a lot of compliments about the presentations : "Several presentations (Keynote address) were excellent (...) and very helpful", "well prepared", etc. But, on the other hand, some problems are underlined: "ask speakers to circulate their powerpoints to committee members before GA in order to make them more understandable and friendly".

#### A wish: "to discuss more in depth some strategic issues".

"More attention to the "changing world" should be paid (...): Globalization, information technologies and other are radically changing the panorama of information on medicines and therapeutics"; wish to discuss "marketing strategies of bulletins in the era of internet".

"Reinforcing the concept that bulletins are only a part of drug information and the need for drug bulletin teams to be involved in broader drug information strategies, working with press, mass media and other network involved in drug policies issues and drug information, to take advantage of electronic communication, Reinforcing the idea that ISDB should play a proactive role in international drug policy debate".

Thank you for your constructive comments, good ideas and suggestions for the next GA!

The Committee

## Website updates

The new committee has been included in the section "About ISDB". The home page has also been updated.

Many members' addresses have been updated in Members' area.

The Bulletin Index has been modified so as to include language as criteria of selection for bulletins in the web.

All full members and 'associate members' (a wording replacing 'recognised correspondents' in the amended Constitution) have received the user name and password to get access to the restricted area.

The web is updated regularly at least once weekly.

Maria Font

### New!

#### The manual is online!

**The ISDB-WHO Manual "Starting and strengthening a drug bulletin" is available as full text and in separate chapters.**

**Thank again to Andrea Tarr for the coordination of the project!**

#### GA Presentations: soon on the Website!

**The presentations are to be sent by Therapeutics Guidelines (host of Melbourne GA) to Maria Font (webmaster). They will be put on the website together with the reports that where sent by the rapporteurs.**

## Important!

### Please check your addresses and e-mails!

In spite of our efforts, there might still be mistakes in addresses or e-mail addresses on the Website.

We need an updated database so that we can work together.

Please check your details and send the modifications to [dialogo1@ulss20.verona.it](mailto:dialogo1@ulss20.verona.it), with copy to [maria.font@ulss20.verona.it](mailto:maria.font@ulss20.verona.it).

### Special call to coordinators:

Please make sure that all the ISDB bulletins from your region are on the website, and send your report to the secretary ([christophe.kopp@wanadoo.fr](mailto:christophe.kopp@wanadoo.fr)).

## Colophon

Editor: Christophe Kopp  
Coordinator and lay-out: Florence Vandeveld

The following people contributed to this newsletter:

Maria Font, Jörg Schaaber, Dick Bijl, Philip Sax, Martín Cañas, John Dowden, Walter Thimme, Clotaire Nanga, Leo Offerhaus, Jeremy Smith, Ciprian Jauca.

Thanks to Therapeutics Guidelines for sending documents from the previous administration.

### A new and convenient software

As you can notice, the Newsletter has a new look. Unfortunately, we couldn't use the nice template, that was elaborated by Therapeutics Guidelines, because we didn't have the appropriate software.

We've used an easy and flexible software ("Publisher 2002"). You don't need any training to be able to use it properly. Witness, only one software-naïve editor laid out this Newsletter. It is also a cheap software (less than 150 euros), and we'll be happy to give it (together with template) to the following Newsletter's editor in 3 years.

### Newsletter's weight

Our objective is that the Newsletter should be technically as light as possible for people to download it easily, even if they don't have any broadband internet connection. That is why you won't find glamour pictures, the weight being too high to permit rapid downloading.

### Content: sections in line with Committee's priorities

You will find the usual sections, accompanied by new sections featuring actions and campaigning towards better healthcare.

The main sections are:

**-News of ISDB** (Past and future meetings, News of the Website, Committee minutes and activities, General Assembly).

**-News of ISDB members:** Conversation with, Bulletins Roundup; this new section will promote any interesting items or actions found in ISDB member Bulletins.

**-Ongoing campaigns** will launch or relay campaigns such as "No Thanks", "INN use", and tackle political issues.

**-Regulatory Watchdog** will follow up on drug registration and agencies' performance.

**-Conflict of interests** will try and raise awareness on these endemic problems affecting healthcare professionals, regulatory agencies, national bodies, as well as international organisations.

**-Editorial methods** will relay good ideas for improving bulletin editorial process.

**-Good sources** will highlight useful websites or books.

### Contribute to the Newsletter!

Feel free to send papers (English language and word file) for the Newsletter to Christophe Kopp ([christophe.kopp@wanadoo.fr](mailto:christophe.kopp@wanadoo.fr)) with copy to [fvandeveld@prescrire.org](mailto:fvandeveld@prescrire.org).

### EMERGENCY!

## Call for help from an ISDB colleague

The following letter, and request for help, comes from Ayyaz Kiani who is the head of advocacy at The Network for Consumer Protection in Pakistan (ISDB member).

Following the earthquake, the Network for Consumer Protection in Pakistan created a camp, together with other NGOs. If you can help maintain this camp please contact Ayyaz. Here is his message dated 21<sup>st</sup> of October 2005.

Dear Friends

The government rescue and relief work in quake hit areas in Pakistan (and perhaps also in India?) has only just started to trickle in. The rescue effort has suffered due to inertia, landslides which wiped out roads and bridges, and a lack of helicopters to ferry in vital heavy lifting equipment. Anger has started to build as help failed to arrive. In many places, people dug with their bare hands in an attempt to reach friends and relatives trapped in the rubble (...).

100,000 people have died in Pakistan and India in the Saturday earthquake. Hardest hit was the area around the Pakistani Kashmir capital of Muzaffarabad. Entire towns and villages along a wide area covering most of Pakistani Kashmir and northern districts of NWFP have been flattened. More than 4 million people are in urgent need of shelter.

The Network for Consumer Protection's staff has been involved in providing relief goods especially tents, food, warm clothing and bedding, medicines, raising funds through our relief camp, providing technical support to the partner groups, monitoring markets

for prices and availability of essential goods and publishing relief related information in the print media and electronic media including FM radio.

While it is heartening to see the immense outpouring of sympathy by people who have contributed whichever way they can. But people have a short memory and one wonders how many of them would be still around to help after the media moves on to another story. So what is likely to happen, we are afraid, is that in a little while, people will forget about it, and when it will come to the reconstruction phase, a lot of money will be pilfered, there will be corruption. We will need civil society to put in place some long-term measures to monitor the relief effort.

As the first spate of emergency is over there is need to provide rehab centers and half way homes near hospitals for those homeless who are being discharged from hospitals in cities. Together with another NGO partner, Punjab Lok Sujag, and "Abbottonnians" a group of medicos of the teaching hospital (visit url: [www.wamcrelief.com](http://www.wamcrelief.com)) we are setting such a camp in Abbottabad comprising of 250 beds.

This camp comprises eight large size tents

with a total capacity to house 250 beds. The Network and Punjab Lok Sujag will install the camp complete with beds and bedding, appropriate flooring, light and heating arrangement, toilets and bathrooms and a kitchen. The camp will be set up and operated over a period of next two weeks and handed over to the Abbottonnians to run till the need for such a camp is over.

If you would like to contribute please remit the funds to ABN AMRO Bank New York (Swift Address ABNAUS33) for account of ABN AMRO Bank Karachi (Swift Address ABNAPKKA) for further credit to account # 311442005 of The Network for Consumer Protection in Pakistan with ABN AMRO Bank Islamabad (Swift Address BNAPKKAISB).

Best regards,

Ayyaz Kiani

[ayyaz@thenetwork.org.pk](mailto:ayyaz@thenetwork.org.pk)

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## Gute Pillen - Schlechte Pillen : A new drug bulletin for German public

The new bulletin *Gute Pillen – Schlechte Pillen* (Good pills – bad pills) is published by a cooperation of the editors of 3 German members of ISDB: *arznei-telegramm*, *Arzneimittelbrief* and the *Pharma-Brief*, who discussed the project during the preparations for the ISDB Berlin Declaration on Pharmacovigilance. Since in Germany there was no independent drug bulletin, we felt that there was an urgent need for better impartial information for the general public. We decided to combine efforts, utilizing the fact that all 3 publications are well-known. Thus, in May, 2004, we began to make plans for the project, founding a Limited Liability Company, with the 3 bulletins serving as the partners. The publishing house of *Arzneimittelbrief* prefinances the marketing, paper, printing and distribution, the editors prefinance the production of the texts and the layout, as well as the organisation of the editorial process. The costs for the first year are estimated at 75,000 Euro.

On October 19<sup>th</sup>, 2005, the first issue of this new drug bulletin for laypersons was presented to the public. The press was invited to the Water Tower Building at the Bergstraße in Berlin, where *arznei-telegramm* has its office. Hours before the presentation, however, we already received the first applications for subscription. One month later, nearly 2000 subscriptions were registered. We have received many letters of approval, including quite a long one from the German Secretary of Health. There were, however, some expressions of scepticism: Some doctors disliked our criticism on the overuse of hormone replacement therapy which is still common in Germany.

Each issue has one leading article on a disease or a health-related topic. Thus, in the first issue „The Common Cold“ was discussed, whereas the second issue features „Preparing for a visit to a doctor's office“. Doctors can purchase extra copies of the main article individually as a „Patientenbrief“

(treatment note), for use in their hospital or private practice. In addition to the main articles, the following headings and columns are planned: editorial, drug therapy (new drugs, ineffective drugs, alternative drugs, adverse drug reactions, misleading advertising and drug prices), national and international drug policies, and „Letters to the Editor“.

In addition to the press conference, the marketing strategy involves pilot mailings, inserts to the 3 independent German bulletins on drugs, as well as actively contacting health officials, insurance companies and others, requesting and inviting their cooperation.

A representative opinion poll in Germany has shown that the print media are the most frequently used source of health information, followed by advice received from friends, relatives and the internet. There is a chance, that we, too, can find at least a niche. Let's try.

Walter Thimme

[wthimme@zedat.fu-berlin.de](mailto:wthimme@zedat.fu-berlin.de)

## Conversation with Clotaire Nanga, La Lettre du CEDIM

Clotaire Nanga is a new Committee member, and editor in chief of La lettre du CEDIM. Its aim is to promote reliable information on drugs and therapeutics in Burkina Faso (West Africa).

### Why was your bulletin started?

The bulletin, "La Lettre du CEDIM" is edited by the Drug Information Centre [CEDIM], a department from the ministry of health (Burkina Faso, West Africa). This centre was set up in 1990 as a result of co-operation between Burkina Faso and Italy. The activities started in 1991.

2 main reasons explain the establishment of this centre:

- In Burkina Faso as in most other sub-Saharan countries, the major part of the «prescribers» is nurses. Those kinds of staff have no solid training about drug matters. Thus, they need to be permanently trained in order to improve their performance in this area.

- The resolution which is called "Bamako Initiative" has been adopted in 1987 by the African ministries of health. This resolution is a reinforcement of the primary health policy involving local population cooperation intended to improve their access to drugs. This policy should make for a higher availability of drugs, which implies a higher use by the people and thus, a higher risk related to the use of those drugs. This is more likely to happen in a country as Burkina Faso where more than 80% of the inhabitants are illiterate and the ratio physician/inhabitant, very low.

CEDIM was created in this context to assess constantly the medical literature and bring a technical support to national and regional therapeutic committees. It also aims at keeping up with the problems created by the use of drugs, managing training and information programmes and promoting the rational use of drugs.

### How long has the bulletin been going, and how often do you publish? Who receives the bulletin?

The bulletin has been published every three months from 1991 to 1997. After the withdrawal of the Italian government, the bulletin stopped being edited for about 2 years, given financial difficulties.

It resumed in 2000 when the WHO (world

*Periodicity:* Every three months

*Number:* 2500

*Price:* Freely distributed to all the health units including political leaders and partners.

health organisation) agrees to provide the necessary funding.

### What is your background and What is your role with the bulletin?

I'm a pharmacist, since 1996. I have worked as a hospital pharmacist (the greatest hospital of Burkina Faso, over 1 000 beds) for 3 years. After that, I've been in Senegal (another West African country) to study health project management where I've got an MBA. After that, I went back to my country where I'm in charge of CEDIM. I also hold a master degree in pharmacology.

I've participated to WHO international trainings on the rational use of drugs. I've also been to "La revue Prescrire" (Paris, France) to learn how to write medical or pharmaceutical information paper. I'm now the main editor of the bulletin "La Lettre du CEDIM". I also write articles for "La revue Prescrire" where I'm a junior editor.

### What staff and resources do you have to produce the bulletin?

CEDIM has a low number of permanent employees: 1 pharmacist, 1 assistant (bachelor degree + 3), 1 secretary, 1 office boy. However, 16 university lecturers or hospital practitioners (editorial committee) help us to achieve the final draft of our bulletin. We are waiting for another pharmacist by the end of this year.

The financial resources of CEDIM are provided by the government of Burkina Faso (about 30 000 \$ for all expenses, without the salaries and other fees like phone calls, electricity, water etc.)

The World Health Organization (WHO) gives also money to CEDIM every 2 years (about 30 000 \$ to 40 000 \$). With this money, we buy books, subscribe to medical journals, go to trainings, buy computers, etc. But the money we get (from government and WHO) is very insufficient to work well.

### Do you liaise with other like-minded organisations in your area?

In Africa, there are a very few drug bulletins. The only one I know is in Eritrea. The Centre (CEDIM) has traditional partners as "La revue Prescrire" with which we are still working, and Institute Mario Negri (Italy).

### What kind of material do you cover in your bulletin?

In every issue, we give topical information on drugs, drug problems, etc.

We give also information about common diseases in our area and how to avoid them, what is their treatment. We give pharmacological information on the most prescribed drugs in Burkina Faso.

### What are your main challenges for the future?

In reminder, when I arrived in the centre in 2002, nothing was working: no Internet connexion, no paper to print, no printer's ink. The work was stopped. Our subscription to journals was stopped. There was only 1 worker (an assistant) in the centre. Now, we are 4 permanent staff, and another pharmacist will join us soon.

The centre aims to contribute to improve the quality of healthcare in Burkina Faso and in Africa, by giving quality information on drugs and diseases. So the first objective was to wake up the centre (I think it is done now) and to show the possibilities of CEDIM (trainings, information, research on drug problems, etc.)

We have organized an international course at Ouagadougou (Burkina Faso) in collaboration with WHO and another organization and we want to organize other courses for African physicians, pharmacists and nurses. We also want to establish relationship and partnership with other African drug bulletins, and to contribute to create other similar centre in African. This is to contribute to improve rational use of drugs.

We have difficulties to release money allocated by our government and WHO. We cannot every time buy all we want; where we want (the procedures are complicated). We must find a solution to improve the funds management.

Another objective is to change La Lettre du CEDIM to a real instrument of continuous training for all medical staff. I want that CEDIM and his bulletin become a regional reference, model in drug information. But now, I must assure the permanence of the center.

Clotaire NANGA  
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## Conversation with Martín Cañas, Boletín Farmacos

**Martín Cañas is editor with Boletín Farmacos. Its aim is to promote the appropriate use of medicines in Argentina. Boletín Farmacos is a new ISDB full member.**

### How started Boletín Farmacos?

A group of academics and advocates for the appropriate use of pharmaceuticals in Latin America met during the First International Conference on Improving Use of Medicines that took place in Chiang Mai, Thailand in April 1997. At that time the group committed to the publication of an electronic bulletin as a means of increasing coordination and communication among the members of the advocacy and research network (RUAMAL) and raising awareness of the issues surrounding the use of pharmaceuticals among Spanish speakers. The first issue of *Boletín Farmacos* was published in January 1998 using a university of Texas webpage dedicated to Latin American issues. In April 2001 we acquired our current domain [www.boletinfarmacos.org](http://www.boletinfarmacos.org). The number of the issues per year has been gradually increasing from two in 1998 to five in 2003 and thereafter.

Since January 2003 the Bulletin is co-edited with the Borja Institute of Bioethics from Barcelona, Spain; and in 2005 we were incorporated as an NGO "Salud y Farmacos" in the USA and as a Foundation in Argentina.

### What staff and resources do you have to produce the bulletin?

Except for the last two years (2004 and 2005) the publication has been sustained with the work of volunteers and individual donations. In 2003 we received a grant from a Dutch Foundation, which wants to remain anonymous, through the Borja Institute of Bioethics.

A group of four physicians and two social scientists regularly contribute to the elaboration of each Bulletin. In addition, we have an Editorial Board composed of 28 experts representing different Spanish speaking countries, international institutions and academic centers. We also contract the services of a webmaster and translators.

### Who receives the bulletin?

The electronic format of the bulletin is placed in the internet and can be freely accessed from anywhere in the world. The information gathered by our server indicates that about 2000 persons access our webpage

daily, most to of them from computers located in 25 countries, mainly in the region of the Americas but also Spain, Australia and New Zealand. A recent user survey indicated that most readers are physicians (75%), pharmacists, nurses, and employees of regulatory agencies and ministries of health, academic institutions and the pharmaceutical industry. Most of our readers use the bulletin to gather information they can use in clinical practice (76%), and some use it to do research and to enhance their teaching.

Our webpage includes easy-to print versions of each issue and, according to some of our readers, printed copies of the bulletin are placed in university libraries and made available to hospital employees. In addition, and because we do not have copyrights, we know that other publishers reproduce our information in their publications.

### Do you liaise with other like-minded organisations in your area?

We have strong ties with the Drug Utilization Research Group of Latin America (DURGLA), Health Action International (AIS-HAI), the Argentinean Group for the Adequate use of Medicines (GAPURMED), and several universities and regulatory agencies in the Latin American Region.

### What kind of material do you cover in your bulletin?

The bulletin has different sections including: editorial, news, adverse drug reactions (drug interactions, warnings, label changes, market withdrawals), research articles, ethics, regulation and policy, pharmacy, issues related to trade and intellectual property protection, economy and pharmaceutical prices, summaries of new books and publications, links to other websites.

We commission the editorial to well known activists and promoters of the appropriate use of pharmaceuticals. The research articles are usually submitted by Latin American researchers and occasionally we request the permission to translate and publish articles originally published in English, French or Portuguese that can be of interest of our Spanish readers. The information of the rest of the sections is obtained from scanning 30 academic journals, adverse drug reaction bul-

letins, warnings issued by regulatory agencies and Dear doctor letters, newspapers, and web-based discussion groups.

All original research articles published in the Bulletin are peer-reviewed.

### What are your main challenges for the future?

Increase our level of funding so that we can increase our subscriptions to relevant newsletters and journals, have enough resources to translate key information written in languages other than Spanish, maintain the quality and breath of the bulletin, and continue to make it available free of charge. We also want to engage in innovative research and advocacy that can have an influence in policy-making for the Region and in fostering the conditions that may improve the use of pharmaceuticals by prescribers, pharmacists (including pharmacy clerks), and the community at large.

Boletín Farmacos calls for research papers, news and articles on any topic related to the promotion and the appropriate use of drugs, drug policies, ethics and drugs, controversial drugs, recommended and questioned practices for the use and promotion of drugs. It also publishes news about conferences and workshops on topics relevant to its mission.

**Martín Cañas**  
macanas@netverk.com.ar

## Influence of bulletins in Society : Geneesmiddelenbulletin (Gebu) tackles political issues

The last Newsletter, in July, presented the difficulties faced by « Gebu », and its strategie for change. What's new? This text shows that working collaboration with *Butletí Groc* gave the opportunity to 'Gebu' to tackle political issues.

In the beginning of 2005, after a hectic period in which the minister of public health wanted to close down the Dutch Geneesmiddelenbulletin, we moved from Utrecht to Diemen near Amsterdam where we are now housed within the building of the Health Insurance Board (CVZ).

A few months after my appointment as editor-in-chief of the Geneesmiddelenbulletin my colleague and staff member Dr Anton Kerst attended me to an article that was published in our Spanish sister-bulletin *Butletí Groc*, the bulletin of the Catalan Institute of Pharmacology. The article, 'Gastó en medicamentos e innovación terapéutica', was about therapeutic renewal and the costs of medicines. According to Dr Anton Kerst this article could very well be published in our bulletin. He offered to translate the article. I agreed, also because there was a shortage of new articles and only after the editor prof dr Joan-Ramon Laporte had given his written permission to translate it and to work it up for the Dutch situation. This I felt would be necessary because in the article a top-7 list of drugs with the highest costs in Spain is used and there might be some differences with that of the Netherlands. Also I felt it would be necessary that our referees could add their criticisms and opinions. Dr Laporte agreed on this and we could use the article for translation and working it up, without costs. The latter, the use of articles without costs, I feel is important, underlining solidarity in the ISDB.

### The contents of the original article

Dr Anton Kerst started to translate the article, which deals with the fact that in the top-7 of drugs that generate the most costs the majority of drugs are new drugs and still patented. These drugs are heavily promoted and are responsible for a great deal of drug-costs. There is hardly any evidence for the efficacy on hard endpoints of these drugs. The drugs and groups of drugs that are discussed are statins, atypical antipsychotics, SSRI's, drugs for the treatment of osteoporosis and antihypertensives.

### Reactions

#### Referees and industry.

The article in concept was sent to our referees in May and as it is our policy also to

the drug companies whose products are mentioned in the article. The comments varied highly: some were very enthusiastic, others were hesitating and some were quite negative. A remarkable thing happened in that I was called by the medical director of Eli Lilly in the Netherlands. He told me that he was quite shocked by the article and said that this article would harm our reputation as an objective and independent drug bulletin.

#### Editorial committee.

After collecting the comments of all the referees and industries, a discussion in the editorial committee took place in June. It was decided that the article had to be rewritten according to the Dutch top-7-10 list. It was agreed that three groups of drugs should be highlighted in the article: statines, selective serotonin re-uptake inhibitors and proton-pump inhibitors. Furthermore, specific comments on the influence of marketing had to be added as well as a paragraph on the substitution of classic drugs by new ones. In July a second version of the article was discussed in the editorial board and in August 2005, after a second round of referring, the article was printed and distributed in September.

#### Newspaper.

Since a few months there were contacts with Joop Bouma, a journalist working with the Dutch newspaper *Trouw*, who has a specific interest in the marketing activities of the pharmaceutical industry and publishes regularly on this topic. We had agreed that before an issue of the Geneesmiddelenbulletin would be distributed I would send a pdf-file of that particular issue to Bouma. He could then decide whether he would pay attention to one or more topics of interest in his newspaper and in this way alert readers to the Geneesmiddelenbulletin. On 27 August 2005 there was an article in *Trouw* with the headline 'Artsen moeten leren voorschrijven' ('Doctors must learn to prescribe'). In the introduction it is stated that the minister of public health should make money available for independent postgraduate education of doctors and pharmacists. The streamer says that the sale of expensive drugs is caused by marketing.

#### Questions raised in parliament.

The publication in the Geneesmiddelenbulletin got to the attention of members of parliament. In particular, important questions

were whether the minister does regard it to be his task to make money available for the promotion of policies of cheap pharmacotherapy. Also questions on the influence of marketing were asked.

In the past members of the parliament who are also members of the committee of public health had been on the mailing-list of our bulletin. For some reason they were not anymore. After this affaire I have made now arrangements that they receive our bulletin every month.

#### Minister of public health.

Recently the minister has answered the questions by the member Kant in writing.

### Conclusion

Born out of a shortage of articles the translation and working up for the Dutch situation of an article from the *Butletí Groc* set into move quite a lot of interesting mechanisms, finally resulting in attention and support from the media and questions asked in parliament. The minister said that he will guarantee that independent information on drugs, such as the Geneesmiddelenbulletin gives, will be available to the prescriber. That was a reassuring statement.

Dick Bijl  
dbijl@cvz.nl

Diemen, 28 October 2005

1- Geneesmiddelenbulletin, September 2005, *Trouw* 27 August 2005.

### Last minute!

Dick sent an e-mail on 15 November to tell that « the sponsoring of the Gebu by the minister is definite for the future. »

That's a good news indeed!

## BULLETINS ROUNDUP

This section briefly points out articles of interest that were recently published in ISDB member Bulletins. Their choice is the result of random browsing. Please tell us about your actions or papers of interests that we might not detect due to language barrier. For each article we specify if it's available free or not on the internet. If not, ask the relevant ISDB member for it.

### Kusuri-no-Check (Check-up Your Pills to Save Your Life)

► <http://npojip.org/>  
On 12th November 2005, Rokuro Hama presented a paper on "tamiflu-related death from abnormal behaviour in teenage boys, and sudden death observed in infant" at a scientific meeting of Japanese Society for Pediatric Infectious Diseases. Mainichi daily News, one of the major Newspapers in Japan reported on this story and many mass media followed the news. <http://mdn.mainichi-msn.co.jp/national/news/p20051112p2a00m0na030000c.html>  
See Rokuro's paper in e-BMJ on the same issue at <http://bmj.bmjournals.com/cgi/eletters/328/7433/227>

#### Follow up

► <http://bmj.bmjournals.com/cgi/eletters/331/7526/1203-b#122513>

Rokuro posted a **letter to BMJ** in response to "*strange the conclusion of not only Roche but also pediatric advisory board of FDA*" following his first communications about oseltamivir's harms.

Rokuro's letter is entitled "Limited benefit and potential harm of oseltamivir including sudden death and death from abnormal behavior".

Rokuro concludes in his letter to e-bmj as following: "*We should not overlook these potentially harmful effects in addition to the limited benefit of oseltamivir not only in daily practice but also in stockpiling oseltamivir. Please look at it to consider the harm/benefit balance of Tamiflu for daily practice and for considering stockpiling.*"

For more details 2 posters (English versions) are available (see following links):

► <http://www.npojip.org/english/no59.html>  
<http://www.npojip.org/english/no61.html>

### Therapeutics Initiative

► <http://www.ti.ubc.ca/>  
In Therapeutics Letter 56, August 2005 we can find a short review of anti-Alzheimer agents: "Drugs for Alzheimer's Disease"  
Available free

### Worst Pills Best Pills

► <http://www.worstpills.org/>  
In its September 2005 issue, Worst Pills Best Pills carries a paper and a warning on "Asthma Medicines That Can Cause Asthma Attacks: Do Not Use SEREVENT, ADVAIR or FORADIL".  
SEREVENT=salmeterol  
ADVAIR =fluticasone  
FORADIL=formeterol  
Also in the same issue: "Drug Watch – The FDA's New Drug Safety Web Site"  
Available on subscription only

### Butlletí Groc

► [http://www.icf.uab.es/informacion/boletines/bg/asp/bg\\_e.asp](http://www.icf.uab.es/informacion/boletines/bg/asp/bg_e.asp)  
In its May – June 2005 issue Butlletí Groc published a review on the toxicity of the much hyped anticytokine drugs approved in rheumatoid arthritis and psoriasis: "Toxicidad de los fármacos biológicos en la artritis reumatoide y la psoriasis".  
Available free  
Language: Spanish

### Ricerca&Pratica

► <http://www.ricercaepratica.it/>  
In its September-October 2005

issue Ricerca&Pratica featured an editorial commenting on a national report on drug use in Italy "Rapporto 2004 sul consumo dei farmaci in Italia".  
Available free  
Language: Italian

### La revue Prescrire

► [www.prescrire.org](http://www.prescrire.org)  
La revue Prescrire has published a 64-page Supplement to its December issue that deals with medical errors and how to benefit from them: "Éviter l'Évitable – Tirer partie des erreurs pour mieux soigner".  
Available on request to ISDB members  
Language: French

### Pharma-Brief

► <http://www.bukopharma.de>  
In its September issue, Pharma-Brief featured an article about conflicts of interest in the European Patient's Forum "Europäische PatientInnen von Industrie gekauft? - EU PatientInnenverband im Zweilicht" (for more information see also page 14).  
With the same issue, a supplement about AIDS (20 pages).  
Available free  
Language: German

### Rational Drug Bulletin

► <http://www.cdmubengal.org/>  
Noteworthy: an article on the huge proportion of irrational "Fixed-dose combinations and the Indian pharmaceutical market".  
Language: English

### Informazioni sui Farmaci

► <http://www.informazioni.suifarmaci.it/database/fcr/sids.nsf?OpenDatabase>  
Worth a visit: a website section for the public, including a series of patient-friendly articles on commonly used drug substances (Schede profilo farmaci), on diagnosis and treatment of diseases (Articoli per il paziente), and recommended books (Opuscoli divulgativi).  
Available free  
Language: Italian

# Ongoing campaigns

## International non proprietary name (INN)

### Calling a drug by its real name

A campaign promoting the use of International Nonproprietary Names (INNs) (Campagne DCI in French) has just been launched in France. It has been relayed in Spain (Andalusia) by *Boletín Terapéutico Andaluz*, that already campaigned on this issue, and in Italy by the organization *No Grazie*. The campaign is supported by Medicines in Europe Forum.

It will last several months, targeting the public and health professionals. Leaflets explaining why the use of INNs is so important will be distributed regularly (in French, translated in English for a wider audience). The material will be freely available once translated on [www.prescrire.org](http://www.prescrire.org). Details on the campaign is included in *Prescrire International* December 2005.

**Feel free to use the material in your country, and let us know about the outcome!**

Contact :

[christophe.kopp@wanadoo.fr](mailto:christophe.kopp@wanadoo.fr)

**Links to the INN campaign:**

► <http://www.prescrire.org/cahiers/dossierDciCampagne1.php>;

► <http://www.nograziepagioio.it/>

## No Thanks!

### A New Website 'Gezonde Sceptis'

The new website 'Gezonde Sceptis' [www.gezondesceptis.nl](http://www.gezondesceptis.nl) has been developed by the Dutch Institute for the Proper Use of Medicine (DGV), in response to similar initiatives in Australia (Healthy Skepticism:

[www.healthyskepticism.org/](http://www.healthyskepticism.org/)), the USA No Free Lunch ([www.nofreelunch.org/](http://www.nofreelunch.org/)) and the UK ([www.nofreelunch-uk.org/](http://www.nofreelunch-uk.org/)), France (Non Merci: [www.prescrire.org/](http://www.prescrire.org/)) and Italy ([www.nograziepagioio.it/](http://www.nograziepagioio.it/)).

NoFreeLunch is focused on gifts for doctors from drug companies. Healthy Skepticism has a wider focus on countering misleading drug promotion.

## ISDB project

### Assessing transparency of regulatory agencies

In a poster in Melbourne, Kusuri no check and Prescrire proposed to design and implement a Transparency Indicator, measuring transparency of drug regulatory agencies.

The objectives are:

- to assess the degree of regulatory agencies' transparency,
- to design a rating system of best and worst regulatory agencies in order to make them more transparent and accountable to the professionals and the public.

## DTCA

### Buko Pharma-Kampagne fights against DTCA

**In Melbourne, Jörg Schaaber described how BUKO Pharma-Kampagne works. Here is an extract of his keynote address 'Communicating with patients and the public: The BUKO way'.**

DTCA (Direct to Consumer Advertising) means the promotion of prescription only drugs directly to the consumer. DTCA is legal only in the US and New Zealand. There was an attempt by the European Commission to introduce DTCA in the EU. ISDB and HAI groups were aware of it early enough, so it was possible to intervene in time. I would not claim that BUKO played a key role in the DTCA campaign. But we were part of it and it taught us important lessons.

A small network of interested bulletins and groups developed on the initiative by Prescrire called "Medicines in Europe Forum". Good material was produced by Health Action International (HAI). Prescrire did an in-depth analysis of the EU proposal and suggested improvements. So we had a sound basis for our work. BUKO managed to establish contact to key Members of the European Parliament. A number of European groups and bulletins also approached MPs of national parliaments. BUKO achieved that the German parliament passed a resolution by a very large majority that explicitly excluded DTCA. The press work went well.

It was important to show bad examples – and to stop them. We found in a German gay magazine an illegal DTCA

ad from BMS. The slogan was "Live your future" and promoted three AIDS drugs (Videx, Zerit, Sustiva). We stopped that ad with the help of the consumers union.

It was important to counteract the often subtle industry strategy to promote the introduction of DTCA. One example from Germany: the industry association VFA tried to promote DTCA by organizing a conference for patient groups disguised as "Information through the internet". We invited ourselves to the conference together with an independent patient group and exposed the true aim of the meeting. We used the following quote of the (British) industry strategy to show what this meeting was really about: "The ABPI battle plan is to deploy ground troops in the form of patient support groups, sympathetic medical opinion and healthcare professionals – known as 'stakeholders' – which will lead the debate on the informed patient issue. This will have the effect of weakening political, ideological and professional defences. Then the ABPI will follow through precision strikes on specific regulatory enclaves in both Whitehall and Brussels." After hearing this, the attending patient groups were rather unhappy and the meeting was not very successful for industry and though a number of press people was attending the meeting little (if at all) was reported on the meeting.

The crucial element of this successful campaign was that a number of ISDB-bulletins and HAI groups worked together in a cooperative way. Everybody used the best of his or her skills, information exchange worked. Key stakeholders in different EU-member states were informed why DTCA is bad for public health. Where useful joint action was helpful, like visiting the rapporteur in the EU parliament committee for the legislation together with Prescrire. As the contact to politicians developed very well a number of additional improvements besides the continued ban on DTCA could be introduced into the law.

**Jörg Schaaber**  
[jschaaber@bukopharma.de](mailto:jschaaber@bukopharma.de)

### Regulations in the EU pipeline

#### Be ready to tackle a number of problematic regulations!

-Regulation for medicines in children  
-Regulation on 'conditional marketing authorization'  
-Regulation on 'advanced therapies', i.e. human tissue engineering products as well as gene therapy products and somatic cell therapy products.

We'll keep you posted on all these coming regulations that will have huge public health implications in the European Union and elsewhere.

There are several possibilities for you to influence the drafts when they are in the long and complicated legislative process: first by commenting on drafts when they are open to public consultation, second by lobbying your national COREPER ambassadors.

#### What is COREPER?

COREPER, from French *Comité des représentants permanents*, is the Committee of Permanent Representatives in the European Union, made up of the head or deputy head of mission from the EU member states in Brussels. Its defined role is to prepare the agenda for the different ministerial Councils of the European Union meetings; it may also take some procedural decisions. It oversees and coordinates the work of some 250 committees and working parties made up of civil servants from the member states who work on issues at the technical level to be discussed later by COREPER and the Council. It is chaired by the Presidency of the Council.

There are in fact two committees:

- COREPER I is made up of deputy heads of mission and deals largely with social and economic issues;
- COREPER II is made up of heads of mission and deals largely with political, financial and foreign policy issues.

So getting to know your COREPER names is key: go to [http://www.europa.eu.int/idea/](http://www.europa.eu.int/idea/en/rechent.htm)

[en/rechent.htm](http://www.europa.eu.int/idea/en/rechent.htm), write COREPER in entity name, and you'll find the list with national members of COREPER.

### An example of successful campaigning on transparency

EU pharma laws are tools that can help us improve the situation. Witness article 126b of the new Directive 2004/27/EC that was successfully amended by Medicines in Europe Forum so as to provide for greater transparency:

**"(...) the Member States shall ensure that the competent authority makes publicly accessible its rules of procedure and those of its committees, agendas for its meetings and records of its meetings, accompanied by decisions taken, details of votes and explanations of votes, including minority opinions."**

We need to watch and enforce total implementation of favourable provisions such as this article 126b in each EU countries.

More details available at [www.prescrire.org](http://www.prescrire.org).

### Drug regulation in Israel

PHARMA Drug Bulletin has published in its October-November 2005 issue an assessment of the drug regulatory process in Israel. We reprint extracts relevant to drug evaluation and transparency problems. The full article is available from [Philip Sax](mailto:saxp@netvision.net.il) ([saxp@netvision.net.il](mailto:saxp@netvision.net.il))

The purpose of this Bulletin is to provide, for the first time, an analysis and overview of the governance and regulation of medicines in Israel. It describes the main developments in the various modes of governance and regulation in the pharmaceutical domain. In doing so, it examines the characteristics and nature of relations between state and non-state actors and between public and private sectors, particularly between government and industry. Regarding the latter, a distinguished commentator on the political economy of health care had this to say:<sup>1</sup> "More than most other investor-owned industries, the drug industry is a creature of government, because it cannot exist for long without government protection of its economic turf."

During the last decade, government in Israel has been increasingly active in the drug policy domain. Not only more active than in the past, but also more active than in any other area of health policy. This has particularly been the case since the introduction of National Health Insurance (NHI) in 1995, which promoted government, especially the Ministries of

Health (MoH) and Finance (MoF), to a much more central role as regulator in this policy domain. As a result, the state became responsible for the issue of universal access to a defined basket of health care services.

The following analysis uniquely examines developments in three core regulatory areas involved in key issues in the pharmaceutical policy domain in Israel: reimbursement (issue of access and equity), product regulation (safety, quality and efficacy) and industrial policy (competitiveness and innovativeness). (For ISDB Newsletter readers we extract here only the section on product regulation.)

#### Product regulation

Product safety controls are administered by the Pharmaceutical Administration (PA) of the MoH. The PA falls within the framework of responsibility of the Directorate of Medical Technology & Infrastructure, which is also responsible for administration of the basket and all drug reimbursement issues. The PA undertakes assessments, similar to regulatory agencies in other de-

veloped countries, to ensure that medicines made available for marketing in Israel or exported, meet appropriate standards. These activities are carried out within the framework of a broad and long-standing government policy that drugs are made available in a timely fashion and the industry is free of unnecessary regulatory burdens. The PA is also responsible for monitoring the safe use of drugs on the market once they have been approved, as well as the approval and control of clinical trials.

The regulation of drugs is based on complex risk-benefit assessments. The high commercial stakes that companies have in the regulatory process, and their technical and other resources, mean that the multinational research-based industry tends to dominate the process.<sup>2</sup> For example, drug regulatory agencies require minimal evidentiary standards of efficacy: proving that a new drug is superior to a usually irrelevant comparison treatment (such as placebo) in achieving a potentially irrelevant outcome (such as a surrogate measure).<sup>3</sup> ▶ ▶

## ► Approval Times

In the past decade there has been a convergence in the philosophy and practices of regulatory agencies.<sup>4</sup> Global interdependencies have dictated that the time taken to process marketing applications must approximate international best practice. The lag between first global launch of a new product and its launch in Israel has in the past been substantial: annual averages ranged between 4 to 8 years during the decade up to 1993. It declined continuously thereafter so that in the early 2000s it was about 1.5 years (IMS-Health). Today it is of the order of 8-12 months, with the faster approvals given for potentially life-saving drugs.

One can put forward a number of explanations for this decline in new product launch lag:

- Government has moved from being an arms-length regulator to having a more partnership role with industry.
- Increased reliance on overseas regulatory agencies, in particular the USA's FDA and the European Medicine Evaluation Agency (EMA). (The latter, established in 1995, has been perceived to be more trust-oriented and less adversarial *vis a vis* industry than the FDA).
- Increased local presence and activity of multinational research-based companies, many of whom set up marketing subsidiaries in the mid-1990s, following the Oslo peace agreement and Israel's signature to the TRIP's agreement on protection of intellectual property rights.

The decline in the new product launch lag, including faster regulatory approvals by the reference overseas regulatory agencies themselves, raises the question as to whether there has been an underlying shift in regulatory approach. Has there been a shift to an approach that a new drug is considered safe, unless proven otherwise, from an earlier approach that a new drug is considered potentially harmful until proven safe? Reduced processing times in overseas reference agencies is being driven by competition between national regulatory agencies for regulatory fees from industry.<sup>5</sup> In the light of the Vioxx controversy and other recent disclosures of regulatory failings, the FDA has been criticised for a decline in regulatory stringency, since the adoption of user fees in 1993, over an industry with a natural proclivity to accept greater risks. (delete gap) The product regulatory approach in Israel has traditionally been a trust-oriented one, even after being seriously tested by the Remedix baby milk controversy, which exposed some of the problematics of this approach. An example of the trust-based drug regulatory approach is its reliance on summary clinical information only. Much

of the clinical data provided to government in order to get marketing approval remains secret and inaccessible to the medical community and to the public.

It should be noted that relatively few countries (e.g. UK, Japan, Canada, Australia, Sweden and Switzerland) have regulatory agencies that carry out their own evaluations independently of FDA/ EMA regulatory decisions. The Israel regulator also on occasion operates independently, for example, when the PA comes to granting one of the first approvals worldwide of a new drug (e.g. Teva's Copaxone and Azilect) developed in Israel or of fast-tracking a new potentially life-saving medicine.

The PA's normal procedure, though, is to commence evaluation of new product submissions only after the evaluation has been carried out and authorisation granted by one of the overseas agencies, usually the FDA and/or EMA. As a result, new drugs are usually marketed here up to 18 months later than in those countries. Cost containment concerns are believed to be behind this government policy. Apart from containing NHI drug basket costs, the MoH is itself a major provider of health services, working within a tight budgetary framework including a drug budget for its own hospitals. The research-based industry is lobbying for change so that approval is given automatically, or within 90 days, once an overseas reference regulatory agency has approved the same product, as in many other countries. This proposal is opposed by the MoH, claiming that it would endanger public health.

## Closed Regulatory Process

Developments in product regulatory policy are a feature not only of Israel but other countries as well. Abroad, they are often highlighted as part of a government review or at least are accompanied by a declaration of change in policy. In contrast, in Israel we have almost no idea as to the goals, performance and output of the regulator. The MoH does not release data as to its activities, e.g. number and type of new product submissions, approvals and average approval time, nor information on product recalls. Such data should also include the extent (if any?) of negative opinions with, for example, refusals to approve. Furthermore, unlike most national health agencies, the MoH rarely issues advice, even on safety issues, to prescribers, pharmacists, and to their patients, invariably leaving this to the sole responsibility of the individual companies.

This key public health regulation process is closed, excluding and non-accountable. Industry has managed not only to gain influence over drug regulation but also to persuade government and its regulatory agency that other interested parties, such as consumer organisations, patients' associations and the wider

medical and scientific community, should have few or no rights of access to this regulatory process (...).

## Discussion

Government has multifaceted and often conflicting roles in its regulation of the pharmaceutical domain: industry's regulator (safety); industry's sponsor (competitiveness); industry's customer (MoH hospitals);, as well as reimbursement agency (universal access and copayments) and sick fund supervision (budgets and efficiency). The common thread across the areas of product safety regulation, health policy and support of industry expansion is a trust-based exchange among a narrow range of stakeholders, with a blurring of public-private boundaries.

Product safety and efficacy controls and health policy interests are being increasingly influenced and shaped by economic objectives – most recent example is the sale of medicines in non-pharmacy outlets – and the imperative of industry competitiveness and sick fund efficiency. There will always be a trade-off between health promotion and other interests; at present that trade-off appears to be favouring the latter.

Policy networks in this sector are highly integrated and framed by the logic of business and of sick fund efficiency. Membership tends to be exclusive, closed rather than open, and continuous. There is little evidence of the state encouraging empowerment of patient interests in order to advance regulatory norms of the public interest. Likewise in industrial policy, there is little evidence of the empowerment of groups representing the R&D community. Are existing institutions capable of handling regulatory challenges, or is there a need to create a new institutional structure? Would a more independent, less centralised structure be the answer in the Israeli context? (...).

Philip Sax  
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## PATIENT ORGANISATIONS

### European Patients' Forum: Secrecy & conflict of interest

► [www.haiweb.org](http://www.haiweb.org) (homepage)

A short report "Does the European Patients' Forum represent patient or industry interests?" presents a case study in the need for mandatory financial disclosure. The report reveals how the European Patients' Forum legitimacy has been taken for granted despite its lack of transparency and close links to the pharmaceutical industry.

HAI Europe argues that the case of the European Patients' Forum demonstrates the need for rules on financial disclosure - who is funding NGOs and lobbyists - to be made mandatory, not voluntary. The European Transparency Initiative proposed by Commissioner Kallas must be based on clear and enforceable rules on financial disclosure.

HAI Europe also argues that the Commission and the European Medicines Agency should reconsider their relationship with the European Patients' Forum. It is vital that the voice of patients is heard when decisions are being taken about medicines and health. The Commission and the European Medicines Agency should consult with groups which are accountable, transparent and independent of pharmaceutical industry financing.

Jeremy Smith

### Australia: Drug firms enlist patients as allies

Reprinted from:

The Sydney Morning Herald (November 28, 2005)

► <http://www.smh.com.au/news/health/drug-firms-enlist-patients-as-allies/2005/11/27/1133026350317.html>

The pharmaceutical industry lobby plans to expand its influence by funding grassroots patient groups to campaign for government subsidies for new medicines.

New guidelines setting out possibilities for collaboration between the drug companies and patient groups suggest that in return for providing money for activities such as patient mail-outs, manufacturers may be able to expect "support when applying for Pharmaceutical Benefits Scheme listing of medicines". But they should be careful the relationship is not seen to compromise integrity, according to the guidelines developed

jointly by Medicines Australia, which represents the \$5 billion Australian industry, and Consumers' Health Forum, a peak body for patient organisations.

"In practice it is more likely that the health consumer organisation will appear to have lost its independence," says the document, to be released today. (...)

"Effective relationships may influence the way in which public criticisms of partners may be made," it says. "Parties should agree about the way in which differences of opinion will be handled in the media." (...) Helen Hopkins, the executive director of Consumers' Health Forum, said the guidelines would benefit mainly smaller patient groups that needed to raise their profile but might be unsure how to engage with multinational pharmaceutical giants. She said the question of accepting industry cash was fraught, but "if we walk away and say, 'This should never happen', that leaves [smaller] groups more vulnerable". But David Henry, professor of clinical pharmacology at the University of Newcastle, said the document amounted to a "recipe book" for the industry to pursue its commercial agenda via patients, in the wake of tough new rules that curtail drug makers' courtship of doctors. Patient groups "are going to become a lobbying front", he said. "It's a serious mistake by the consumer movement. The industry doesn't [offer funding] out of the goodness of its heart." (...)

Julie Robotham  
Medical Editor

## WORLD HEALTH ORGANISATION

### Eli Lilly Finances World Health Organisation (WHO) promoting psychotropic drugs

Reprinted from: Alliance for Human Research Protection

► <http://www.ahrp.org/> (Sat, 20 Aug 2005)

The credibility of the World Health Organization (WHO) is in doubt since its financial ties to Eli Lilly and Johnson and Johnson.

The reach of Big Pharma is indeed all-encompassing. NOTHING written in the mental health field by professional associations, such as the American Psychiatric Association, or government agencies, such as the National Institute of Mental Health, or "non-profit" NGOs

such as the Mental Health Association, or even the WHO is to be trusted because all of these organizations are under the influence of Big Pharma.

The Final Report - "Nations for Mental Health" - issued by the WHO Mental Health Policy and Service Development, Department of Mental Health and Substance Dependence (2002), was underwritten by Eli Lilly and Johnson & Johnson.

([http://www.who.int/mental\\_health/meda/en/400.pdf](http://www.who.int/mental_health/meda/en/400.pdf))

Acknowledgements:

"WHO gratefully acknowledges the financial support of Nations for Mental Health by the Eli Lilly and Company Foundation, the Johnson and Johnson Corporate Contributions Europe Committee, the Government of Italy, the Government of Japan, the Government of Norway, the Government of Australia and the Brocher Foundation."

The introduction states:

"Nations for Mental Health was to pursue the following goals:

1. To raise awareness of the people and governments of the world to the effects of mental health problems and substance abuse on the psychosocial well being of the world's underserved populations.
2. To stimulate innovative approaches to the promotion of mental health and the prevention and control of mental disorders.
3. To generate the human capital able to lead innovation in the mental health promotion and care provision.
4. To promote service development at country level through technical demonstration projects."

A three-step approach was envisaged to create a process leading to put mental health in the political agenda.

The first step was to increase the general awareness of the importance of mental health through a series of key high profile events to focus public attention.

Second, it was planned that efforts would be devoted to building the will of the key political authorities to participate.

Third, and finally, efforts were directed towards securing political commitments by decision-makers (e.g., legislative measures, policy undertakings, and performance of specific initiatives in favour of mental health, such as a campaign to destigmatize mental disorders).

Alliances with the scientific community and policy-makers were seen as achievable in the context of demonstration

projects and through the effects of awareness-raising efforts. Nations for Mental Health is, therefore, a covert promotional marketing tool masquerading as an objective credible source of information.

**Reminder:** Eli Lilly and Johnson & Johnson are not charities. Lilly and J & J are in business to increase drug sales and profits. They manufacture blockbuster drugs such as: Prozac°, Cymbalta°, Straterra°, Zyprexa° (Lilly) and Risperdal° (J & J). When pharmaceutical companies provide "gifts" to individual physicians, government or Not for profit organizations—they do so for but one purpose only: That purpose is to promote their drugs so that sales will increase. Drug manufacturers love to fund "anti-stigma" campaigns - thereby ensuring an ever increasing customer base. Every one who accepts financial support from a pharmaceutical company - no matter what the stated "educational" goal - becomes a promoter of the company's drugs - whether the recipients acknowledge that fact or not.

### Levofloxacin on WHO essential drugs list

At the Melbourne General Assembly a member from *la revue Prescrire* asked why the 14th list of essential medicines includes the non-essential substance levofloxacin, which is an isomer of ofloxacin, already on the list. And he wondered whether it could be due to commercial interference or, why not, an anti-generic ploy.

As an echo to this question, we reprint a message posted on E-Drug by Leo Offerhaus (pharmacologist) on 19 October 2005.

« Dear E-druggers,  
Why another (patented) quinolone for tuberculosis treatment when ofloxacin is already on the WHO list for the same indication? Are there any comparative trials? Published? Where? And has ofloxacin -which has a number of disturbing CNS side effects - ever been critically compared with older off-patent quinolones? What about development of resistance? It is alright if hard data are available, otherwise it is just another gimmick to push the N-th me-too drug.

Patients are not helped with empty promises.

Best wishes,

Leo Offerhaus, Netherlands »  
offerhausl@euronet.nl

## PHARMA COMPAGNIES

### Misleading data from Glaxo on Serevent°

► <http://www.citizen.org>

Peter Lurie is deputy director of Public Citizen's Health Research Group, which publishes the ISDB full member bulletin 'Worst Pills Best Pills'. He is the co-author of the letter to the Lancet "Absent greater transparency at the FDA, we will never know how often this kind of self-serving data analysis occurs." He sent a message on the e-drug forum that we reprint below.

*In today's Lancet, Sid Wolfe and I have a letter detailing how Glaxo mislead the U.S. FDA about the drug Serevent (salmeterol) through misleading statistical analyses. The analyses involve a 28-week randomised controlled trial called SMART in which salmeterol was compared to placebo and showed increases in a variety of asthma-related outcomes, including death. In essence, the company added into its dataset data on adverse events collected passively during the 6 months after the trial was over. The result was that all four of the major outcome variables were biased toward the null: the drug appeared to be less dangerous in Glaxo's analysis than in the per-protocol 28-week analysis. You can read our press release at: [http://www.citizen.org/hot\\_issues/issue.cfm?ID=1209](http://www.citizen.org/hot_issues/issue.cfm?ID=1209)  
The full letter appears on the Lancet website at <http://www.thelancet.com/journals/lancet/section?volume=366&issue=9493&section=Correspondence>*

Peter Lurie  
plurie@citizen.org

Public Citizen listed Serevent as a "Do Not Use" drug in its Worst Pills, Best Pills newsletter ([www.worstpills.org](http://www.worstpills.org)) in March 2003 because of the interim study results.

Salmeterol was dispensed more than 2.1 million times in U.S. pharmacies in 2004. The combination product, Advair, was dispensed more than 16.1 million times in U.S. pharmacies that year.

### Serono admits Aids drug charges

Reprinted from : BBC NEWS  
► <http://news.bbc.co.uk/go/pr/fr/-/2/hi/business/4350814.stm>

The payout relates to allegations that it offered kickbacks to doctors to write prescriptions for the drug to boost sagging sales.

The settlement was agreed with the US Justice Department.

Serostim is a US approved growth hormone used to treat muscle wasting in Aids

patients.

Serostim° was backed by the Federal and Drug Administration (FDA) regulators in 1996 at about the same time the FDA approved protease inhibitor drugs.

#### Out of date

Protease inhibitors revolutionised treatment for HIV and Aids and made patients less prone to muscle wasting, and therefore less in need of drugs such as Serostim°.

Four former Serono executives were indicted in April on charges of offering illegal payments to doctors for prescribing the drug. The company made more than \$90m profit during the period of illegal promotion, the Justice Department said. "Serono abused the system of testing and approval, and put its desire to sell more drugs above the interest of patients," said US Attorney General Alberto Gonzales. Serono Labs will be excluded from all federal health care programs for at least five years.

#### Similar cases

The Serono settlement is the latest in a series of 'whistleblower' claims that have cost major drug firms more than \$3bn in recent years.

Last month, UK giant GlaxoSmithKline announced it would payout \$150m to settle allegations that it overcharged the US government for two anti-nausea drugs.

Meanwhile, US federal and state officials are said to be probing 150 price and marketing fraud cases involving more than 500 drugs.

## HEALTH PROFESSIONALS

### Cash interests taint drug advice

Reprinted from: AHRP

► [www.ahrp.org](http://www.ahrp.org)

An investigation by the journal, NATURE (the largest of its kind) reveals that not only do conflicts of interest taint the conduct and outcome of clinical trials, the authors who formulate clinical practice guidelines have financial ties to the "relevant drug companies." The investigation found that one third of guideline authors declared financial ties to "relevant drug companies, with around 70% of panels being affected."

The authors, Rosie Taylor and Jim Giles note, "These links with pharmaceutical companies are more worrying than the financial conflicts known to plague clinical trials and reviews, say public-health experts, because the guidelines have such a direct effect on the drugs that doctors prescribe."

For full survey results, see [www.nature.com/news/2005/051017/full/4371070a.html](http://www.nature.com/news/2005/051017/full/4371070a.html)

### The T-score

The Australian Prescriber uses a simple rating system to assess transparency of drug regulatory agencies and pharma companies.

#### REPRINT EXTRACTS

### 'Two-way transparency'

For several years there have been complaints about the transparency of the Australian drug regulatory system. Pharmaceutical companies complain about the transparency of decisions to approve or reject a product for marketing or subsidy, while clinicians complain that they cannot access the data used to make those decisions.

The Pharmaceutical Benefits Advisory Committee has been working with the pharmaceutical industry to address some of these criticisms. Greater transparency of the operation of the Pharmaceutical Benefits Scheme (PBS) was also a key feature of the free trade agreement between Australia and the USA.

While the pharmaceutical industry has achieved some of its goals, much of the clinical data it provides to government remains secret. The Editorial Executive Committee believes that clinical information which could be used to help patients should not be kept as 'commercial-in-confidence'. (1/2).

In view of the pharmaceutical indus-

try's interest in greater transparency, the Editorial Executive Committee has been inviting companies to supply the information that supported the approval of their products in Australia. This information can then be used in the preparation of the New Drugs section of Australian Prescriber and enhances the evidence base for these comments.

While there has been a range of responses (Table 1), the Editorial Executive Committee is pleased that some companies are willing to provide information for independent review. Companies have also been supplying information to assist the National Prescribing Service in preparing its RADAR review of new listings on the PBS. We hope this is the beginning of a trend which will lead to increased transparency in drug regulation.

*The Australian Prescriber*  
(Aust Prescr 2005;28:103)

[http://www.australianprescriber.com/index.php?content=/magazines/vol28no4/103\\_transparency.htm](http://www.australianprescriber.com/index.php?content=/magazines/vol28no4/103_transparency.htm)

Table 1: T-score

T T T	Manufacturer provided all requested information
T T	Manufacturer provided some data
T	Manufacturer had no objection to providing data but did not actually provide it
Crossed T	Manufacturer declined to supply data
X	Manufacturer did not respond to request

#### References

1. Eadie M. The secrecy of drug regulatory information. Aust Prescr 2002;25:78-9.
2. Marley J. Cost-effectiveness: the need to know. Aust Prescr 1996;19:58-9.

In this section we'll present any kind of pictogrammes that aim to make reading more friendly or to draw attention to a key point.

### Geneesmiddelenbulletin

The Dutch Bulletin Geneesmiddelenbulletin includes pictogrammes for rating new drugs and new indications.

► <http://www.geneesmiddelenbulletin.nl/>

- ++ an important extension of the pharmaceutical arsenal.
- + a useful drug.
- +/- a drug with a questionable benefit or a drug of which the value can not yet be judged.
- a drug without any added value.
- a drug with extra risks that does not add anything to the therapeutic options.

Please help us and send us your pictogrammes with translation in English!

#### MAKING THE WORDS WORK FOR YOU

"Making the Words work for you" is the title of an interesting presentation made by Andrew Herxheimer in Melbourne.

He particularly insisted on the use of "Harm" instead of "Risk" in the communication about "benefits and harms" of interventions in health.

The Editorial "Communicating with Patients about Harms and Risks" from Bodhi (India), which is signed by Andrew makes a clear picture about this vocabulary problem, and points out the importance of vocabulary when health professionals talk to patients.

Ref. Bodhi issue 63 (March-April 2005) 1-3.

### Happy birthday Andrew!

Andrew Herxheimer was the 1st ISDB president. On the occasion of his 80th birthday, Friends and Colleagues from Health Action International and ISDB met in London during the weekend of 4-6 November and highlighted his achievements.

A seminar was held on 4 November on a number of issues close to Andrew's heart.

More details at:  
[http://www.haiweb.org/01\\_about\\_Andrew\\_Herxheimer.htm](http://www.haiweb.org/01_about_Andrew_Herxheimer.htm)

### DIPEX.org

#### Personal experiences of health and illness

► <http://www.dipex.org>

Translated from *Rev Prescrire* September 2005; 25 (264): 628-629

**DIPEX (Database of Personal Experiences of Health and Illness), a resource based on a qualitative research protocol, gathers information designed to reflect the entire range of patients' experiences as they go through diagnosis and treatment in common primary care settings.**

The site is mainly intended for patients and their friends and relatives. DIPEX focuses on situations frequently encountered in primary care, and gathers medical information designed to meet patients' real needs. Patients' reports are chosen to reflect the entire range of diagnostic and therapeutic experiences, as well as the repercussions of illness and medical procedures on daily life.

Produced by a social science research team hosted by Oxford University's Department of Primary Care, this multimedia database is also a useful resource for health care professionals. It is especially helpful for students, teachers, and all other health care professionals seeking to better understand and take into account their patients' viewpoints in order to improve both the technical and human aspects of their work.

The DIPEX site allows patients to share their personal experiences, offers practical medical information, provides support and decision aids for patients and their loved ones, and encourages better communication between patients and health care professionals.

#### Situations frequently encountered in primary care

In May 2005 the DIPEX website included patients' experiences on cancer (breast, cervical, ovarian, colon, lung, prostate and testicular), cardiovascular disorders (congenital malformations, coronary thrombosis, heart failure, arterial hypertension), psychiatric conditions (depression), neurological disorders (neuropathic pain, epilepsy), screening (antenatal, cervical), and other common health concerns (dying, teenage sexuality, and caring for a relative who has dementia).

#### A standard layout

Each DIPEX module has an "Introduction" providing an overview of its contents.

The "Experiences" section makes it possible to examine the contents of the interviews (divided into major topics and subtopics — "Talking about"), or the full interviews ("Individuals"). Extracts from the inter-

views, organised by patient category and topic, can be read (transcriptions), listened to (audio files) or watched (video files). The "text" versions are particularly useful for visitors whose first language is not English, as some of the patients' regional accents can be hard to understand.

The question-and-answer section ("Q&As") lists questions that patients frequently ask. These were identified by DIPEX editors from the literature and the scores of interviews they have conducted. A brief answer is provided for each question.

The "Information" section provides general information on specific health problems, their diagnosis, and available treatments. Most of these texts are written by the DIPEX team, in collaboration with health organisations or scientific societies. The "Resources" section provides links to the websites of relevant institutions (patient groups, specialised medical societies, self-help groups, etc;) and to reliable references dealing with the relevant topic.

The glossary section ("Glossary") is particularly original: the definitions are not taken straight from the dictionary but from extracts of interviews, using a vocabulary in tune with patients' concerns.

The persons (DIPEX editors and members of the steering committee) and organisations (partners and funding sources) having contributed to each topic are listed in the "Credits" section.

#### Rich bibliography

48 pages of international references on the experience of illness, including novels, clinical trials and scientific publications, can be downloaded from <http://www.dipex.org/documents/Bibliography.pdf>.

#### Limitations

The experiences described on the DIPEX website are those of people living in Britain.

DIPEX currently covers only about twenty health issues. There are plans to increase this number to about 100 by 2010, funds permitting.

#### Shortcuts

Clicking the "page back" button on a page devoted to a specific health issue does not return the visitor to the DIPEX home page: the horizontal menu bar situated at the top of each page is used to navigate in the main DIPEX site, and to find a new set of patient experiences. ►►

## ► Search engine

The site offers two search engines: simple and advanced. The "advanced search" engine can be used to search for specific health issues, interviews, general news, Q&As, or references.

## Site created in 2001

### Publishers)

DIPEX, a non-profit organisation.

### Funding

DIPEX is a non-profit organisation (charity) and is supported by grants and subsidies. The DIPEX project is subsidised by the British Heart Foundation, CancerBACUP, the UK Department of Health, Macmillan Cancer Relief, NHS Direct, Cancer Research UK and The National Electronic Library for Health.

Each DIPEX health issue receives its own funding. For example, the "Teenage Sexuality" and "Depression" issues are subsidised by the UK Ministry of Health, while the "Antenatal Screening" and "Cervical Cancer Screening" issues are supported by the British National Screening Committee.

### Advertising None

### Confidentiality

Visitors do not need to disclose any personal information unless they wish to become members of DIPEX. Membership is required to participate in thematic discussion forums, to receive a quarterly electronic newsletter, and to be informed when a new health issue is covered on the site.

### Editorial policy

The DIPEX team includes social science researchers. The patients are selected with the aim of covering a broad range of experiences.

A multidisciplinary steering committee, specifically dealing with each DIPEX health issue, verifies that the main patient categories, treatments and perspectives are covered.

Interviewees are recruited through general practitioners, hospital practitioners, and patient groups.

DIPEX considers that, for a given health issue, between 40 and 50 interviews are required to cover the range of individual experiences. The interviews are semi-structured, and are conducted at home (or elsewhere, if the interviewee prefers). The interviews are audio recorded, and, if the interviewee agrees, are also filmed.

Each recording is fully transcribed and then qualitatively analysed, in order to identify recurrent or particularly significant experiences. The DIPEX team regularly publishes its analyses in scientific journals (BMJ, The Lancet, etc.).

Extracts must first be approved by the patient before being posted online.

## Update policy

"Yearly" (no further details).

## Author(s)

The DIPEX team is composed of a dozen researchers. In addition to patients' experiences (extracts of transcriptions) and content analyses, the DIPEX team provides general information on specific health problems, generally written in close cooperation with health organisations or scientific societies.

Information sources are listed at the top of each information page on the DIPEX site and dates of the documents are listed at the bottom of the page.

Information updated on 5 July 2005

## BOOK

### **Selling Sickness: How the world's biggest pharmaceutical companies are turning us all into patients**

by Alan Cassels and Ray Moynihan

**"Disease mongering by pharmaceutical companies threatens to bankrupt Canada's public health system" is one of the key messages of this book.**

**Ciprian Jauca (Therapeutic Initiative, ISDB full member in Canada) reported on this book.**

Daily media articles say that the Canadian public health system is in jeopardy, and fingers are pointed at everything from doctor shortages to government mismanagement and bureaucratic greed.

But the authors of the book 'Selling Sickness' point the finger at another cause: drug company funded disease creation. Using their dominating influence in the world of medical science, drug companies are working to widen the very boundaries that define illness. Mild problems are painted as serious disease, so shyness becomes a sign of social anxiety disorder and pre-menstrual stress a mental illness redefined as pre-menstrual dysphoric disorder. Everyday sexual difficulties are seen as sexual dysfunctions, the natural change of life is a disease of hormone deficiency called menopause, and distracted office workers now have adult ADD. Just being 'at risk' by having an elevated blood pressure or cholesterol level has become a 'disease' in its own right.

"Too often the aim is to lower the bar and turn healthy people into patients," says Alan Cassels, drug policy researcher at the University of Victoria in British Columbia. "And lowering the bar makes more and

more of us candidates for the latest pills promoted by the pharmaceutical industry."

Selling Sickness reveals how expanding the boundaries of illness and lowering the threshold for treatments is creating millions of new patients and billions in new profits, in turn threatening to bankrupt national healthcare systems all over the world. "From their domination of guideline committees, their involvement in physician 'education' and their marketing of fear to consumers, the pharmaceutical industry is using its immense power to drive more and more of us towards another prescription," warns Cassels. And, he notes, "a health system that allows drug companies to play a role in defining who is sick is fundamentally unhealthy."

(...) As the authors of Selling Sickness note, with plenty of detail, pharmaceutical company marketing executives don't sit down and actually write the rules for how to diagnose illness, but they increasingly underwrite those who do.

The industry now routinely sponsors key medical meetings, in Canada and around the world, where disease definitions are debated and updated. (...) Added to this is the fact that the bulk of clinical trials on new medication is funded directly by the drug manufacturers rather than the public or not-for-profit sources. And that this research is then disseminated at scientific meetings, events and conferences sponsored by the pharmaceutical industry, and often hosted by medical societies or patient groups that are themselves partially underwritten by drug companies.

(...) While direct-to-consumer advertising of prescription drugs is illegal in Canada, drug manufacturers here mount 'disease awareness campaigns,' which constantly urge you to 'see your doctor' for practically everything. "There are many different promotional strategies used in the selling of sickness, but the common factor amongst them all is the marketing of fear," says Cassels. (...)

Selling Sickness tells us that we need the pendulum to swing back towards a rational and appropriate use of pharmaceuticals for everyone who is sick.

"Our health care system will collapse if we continue to allow for-profit enterprises to define who is sick and who needs treatment," says Cassels.

"Now is the time to start having the conversation about whether we want to continue to allow pharmaceutical greed, not appropriate need, to be driving our health care expenditures."

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