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A new committee for 2012–2015

ISDB members elected a new committee at the General Assembly in Vancouver in March. The new committee members (together with the name of the organisations they represent, and their countries) are as follows:

- Natalia Cebotarenco (*Cito!*, Moldova)
- John Dowden (*Australian Prescriber*, Australia)
- Juan Erviti (*Boletin de Información Terapéutica de Navarra*, Spain)
- Maria Font (*Dialogo sui Farmaci*, Italy)
- Mary Hemming (*Therapeutic Guidelines*, Australia)
- Ciprian Jauca (*Therapeutics Initiative*, Canada)
- Benoit Marchand (*Boletin AIS-COIME*, Nicaragua)
- Zahed Masud (*Drug and Health Bulletin*, Bangladesh)
- Jörg Schaaber (*Pharma-Brief, BUKO Pharma-Kampagne*, Germany)
- Isidro Sia (*RDU Update*, Philippines)
- Florence Vandevelde (*Prescrire*, France)

Jörg Schaaber was once again elected as President, and Isidro Sia as Treasurer. Juan Erviti is the general secretary and Maria Font the membership secretary. Mary Hemming, John Dowden and Jörg Schaaber

together form the newsletter editorial committee. In addition, Mary Hemming will manage the membership database and assist the membership secretary with assessment of new members. Ciprian Jauca in conjunction with Chris Adlaparvar from *Therapeutics Initiative* will take over the management of the website. Florence Vandevelde together with Teresa Alves of *Prescrire* will handle press communications.

The regional coordinators are as follows:

- Natalia Cebotarenco – East Europe & Africa
- Ciprian Jauca – North America
- Benoit Marchand – Latin America & Caribbean
- Zahed Masud – Central & West Asia
- Isidro Sia – East Asia Pacific
- Florence Vandevelde – Europe.

Contents

The 2012 ISDB general assembly

Members of ISDB (55 participants representing 31 bulletins from 25 countries) gathered for the 9th ISDB General Assembly in March. The meeting was hosted by the Canadian group *Therapeutics Initiative* at Loon Lake Research and Education Centre, about 1 hour east of Vancouver, British Columbia. The delegates met, ate and slept in cabin-style buildings on the edge of a lake in the middle of a pine forest. This proved to be a beautiful and tranquil location for the meeting.

The programme, which had as its theme '*ISDB: fit for the future! Independence & sustainability*', was a mixture of ISDB business, presentations from society members and external speakers, and workshops in which delegates could share knowledge and experience. There was also time for outdoor activities (including the choice of a more, or less, challenging walk around the lake, or canoeing), campfire theatricals, toasted marshmallows, cultural exchanges (with demonstrations of aboriginal ritual dances, and salsa and samba dancing), movies, and great food (pancakes and maple syrup for breakfast was a wonderful start to the day!). Those who wanted to could limber up before breakfast in the gymnasium with a programme of joint mobilisation led by Shane Heins.

The future of ISDB

Where are we now?

ISDB now has active members in almost every continent. However, the number of members has not been increasing in recent years. Also, a closer look at the distribution of members shows that there are still major countries (such as China, Russia, Korea) that, as far as we know, have no independent bulletin. Another striking fact is that India, with its huge population and large number of potential readers (around 852,000 qualified doctors), has only two functional bulletins. This is in contrast to Europe, the home of most ISDB members and where some countries (eg Spain) have several independent bulletins. This picture represents one of the challenges facing ISDB: how to be relevant to the various needs of countries and bulletins all over the world.

Taking India as an example, the impediments to the existence of drug bulletins appear multiple: a large number of languages, a dominant private sector, lack of prescription audit, lack of control over misinformation, no consumer pressure (because most people are illiterate), no scope for non-drug therapy (because of a strong cultural expectation for drug treatment), no mechanism for reward or punishment in relation to prescribing, an insensitive government and an indifferent medical community. There is a need to educate and empower consumers so that they question and put pressure on prescribers. Bulletin readers have to feel the need for what bulletins are offering; they must see that there is something in it for them (perhaps in terms of time or money gained). There is no point publishing in a vacuum. This is a theme that was responded to well by a presentation on Australia's Therapeutic Guidelines Ltd on making your publication relevant to subscribers (see the website for more on this).

There was a feeling that the strong European representation in ISDB has tended to result in the society's work and output being rather eurocentric and as a result is only of limited usefulness to bulletins in other parts of the world. For the future, ISDB needs to think about how to be more relevant to bulletins outside Europe. This might include strengthening the society's regional support network.

How will ISDB develop?

During the meeting, members had an opportunity to share their thoughts on how ISDB can develop over the next few years.

There was strong agreement on the future priorities of ISDB:

The future of ISDB (cont.)

- to continue to focus on rational use of medicines and independence of industry
- to continue to support the formation, continuity and improvement in the quality of smaller bulletins
- to be an effective counter power to industry with respect to information for health professionals and the public.

There was also a consensus among members that ISDB needs to grow its membership in order to become stronger, but that growth should not be at the expense of reducing the quality of information and independence. It was agreed that the wording of the constitution, with its focus on print bulletins, might be a barrier to expanding the membership, particularly now that publishing increasingly involves digital communication.

The supportive role of ISDB (particularly in terms of training and knowledge sharing) could be strengthened by bolstering the structure (maybe by founding an ISDB office or a coordinator), by collaborating with other organisations (such as the Cochrane collaboration) and by developing the website.

ISDB should aim to become a reference source for the media and continue its lobbying work, but extend this beyond Europe.

Work priorities for ISDB over the next three years

On a practical level, these main themes of support (a stronger structure, and expansion of the membership) were translated into projects for working groups (with named coordinators for some, see below). Also, there are other working groups that will continue work begun under the previous committee.

New working groups

- Communication using new technologies – Coordinator: Ciprian Jauca. This group will also look at the possibility of hosting small member bulletins on the ISDB website.
- Review of the constitution to help broaden membership – Coordinator: To be decided.
- Quality information for consumers – Coordinators: Natalia Cebotarenco, Dulce Calvo. The objectives of this group are to share information and experience, and develop a training programme in each country.
- Joint drug assessments or sharing of members' drug assessments – Coordinator: To be decided.

Working groups to be continued

- Development of the ISDB conflict of interests policy – John Dowden.
- EU lobbying – Florence Vandevelde. To include direct to consumer advertising (DTCA), pharmacovigilance, medical devices, price transparency. There needs to be exploration of ways to extend lobbying work to the rest of the world.
- Clinical trials in developing countries – Nuria Homedes.

A report on the last three years

Officers of the outgoing committee (Jörg Schaaber, president; Isidro Sia, treasurer; Florence Vandevelde, secretary; Maria Font, webmaster) reported on the work of the committee and achievements of ISDB over the last three years. The work of the committee (which was organised through once yearly meetings in person and many phone conferences in between) was summarised as follows:

- creation of working groups and supervision of their work
- recruitment of new members
- assessment of existing members
- support of members in trouble. A letter of support was sent in respect of several bulletins, the existence of which was threatened: *Therapeutics Initiative* (Canada), *Geneesmiddelenbulletin* (Netherlands) *Notas Terapeuticas* (Spain)
- preparation of position papers on DTCA, pharmacovigilance, transparency and conflict of interest
- communications to the press
- organisation of and/or attendance at meetings in Brussels (related to informing the European Parliament, the EU Commission and the public).

The working groups were set up at the general assembly in Nicaragua in December 2008. Their tasks were to deal with the following topics: DTCA; developing a Conflict of Interest policy for ISDB; clinical trials in developing countries; access to data from the Uppsala adverse effects monitoring centre; and collaboration on drug assessments. Of these, the group working on DTCA had been the most active and has helped achieve very important results in helping to delay proposed changes to the law on DTCA in Europe. In this respect, collaboration with other groups (including HAI and the Medicines in Europe Forum) has been crucial.

The treasurer's report was approved by the membership. The webmaster reported on the improvements made to the website since the last general assembly, particularly to the

A report on the last three years (cont.)

interactive area. These included making access to the forum easier; automatic data update; restricting access to newsletters to members only; updating the ISDB booklet (English and Spanish versions).

Evaluation of website use showed that the forum and the library of full text articles are not used very much by members. A discussion following the presentation of the report at the meeting brought out some suggested improvements to the website: sending out automatic update information (eg RSS feeds) once a month to alert people to changes on the site; including a new searching tool for the library; a new drugs section with links to bulletins' evaluations. It is hoped that the website forum will be used more by members in the future, for example to exchange news, perform mini surveys, or ask about other bulletins' practices.

Included in the role of the secretary over the last three years were the tasks of monitoring the quality of bulletins and editing the newsletter. During that time, ISDB admitted two new full members and two associate members; an application for full membership from another bulletin was unsuccessful. There were also some members switched from full to associate membership and vice versa. There is now a membership master file to keep an up-to-date record of membership details, and an assessment guide has been designed for assessing the quality, frequency and independence of member bulletins. Only one issue of the newsletter had been published in each of the last three years. The newsletter is important as an archive and a record of the minutes of the committee and for sharing members' news. It is hoped that the newsletter can be published more frequently and it is recognised that the Society would need to employ someone (a native English speaker) to help with this.

Training and sharing

One of the key roles of ISDB is to support the development of member bulletins. To this end, a training workshop was held in Columbia (4–5 November 2009) that involved 28 participants from seven Latin American countries. On a different level, the Australian member *Therapeutic Guidelines* provided individual training to a Cuban member.

ISDB is also an important forum for sharing ideas. A pharmacovigilance workshop was held in Germany, involving 22 participants from 14 countries and four continents. Members considered harm, in terms of what is important and how to communicate harm. On pharmacovigilance, ISDB has been working on getting access to the largest database, WHO Vigibase, on which there has been some success, although this needs follow up. There has also been some progress on access to EMA pharmacovigilance data.

Developing a conflict of interest policy

A key role of ISDB is to identify biased drug information and provide appropriate antidotes. A major source of bias arises from pharmaceutical and medical device companies that have competing interests in providing information to prescribers, policy makers, and consumers. It is therefore important for ISDB members to recognise and effectively manage conflicts of interest.

Of course, no full member bulletin of ISDB carries advertisements. Apart from this common point, somewhat surprisingly, relatively few members have formal conflict of interest policies for their own publications, and the ISDB manual '*Starting and Strengthening a Drug Bulletin*' provides little guidance on disclosure of competing interests. As a result of this ambiguity, ISDB members have been left to develop their own policies, resulting in a patchwork of solutions. During ISDB's general assembly in late 2008, it was decided that ISDB's own practices in this area should be transparent, uniform, and stringent. An ISDB working party on conflicts of interests was convened to examine the problem, survey existing practices, and develop policy recommendations. The survey results were presented at the general assembly by David Menkes, coordinator of the working group.

The survey of ISDB member bulletins was, after some effort, satisfactory in its response rate (48/60, 80 per cent) and highly informative. Overall, responding bulletins endorsed the importance of disclosure for authors, editors and reviewers, but varied in how conflicts of interest, once declared or detected, were dealt with. These differences can be understood, in part, as reflecting the varied contexts and resources available to bulletins around the world.

The next step is for ISDB members to debate the implications for an ISDB policy, including:

- the requirements for membership and membership renewal
- reporting and management of conflicts of interests once detected
- visibility of overall conflicts of interests policy on the main ISDB website (eg should individual bulletin policies also be visible on their websites?)
- whether there should be consequences if a bulletin does not adhere to the agreed policy as regards to its membership status (eg switch to associate membership)?
- how to assist bulletins that require help to develop and implement effective conflict of interest policies
- how to monitor uptake, adherence, and impacts of conflict of interest policies on ISDB's mission.

One approach is to base ISDB policy on International Committee of Medical Journal Editors (ICMJE) methodology (http://www.icmje.org/ethical_4conflicts.html) and to adapt that organisation's conflict of interest disclosure forms for:

a. bulletin staff (editors, internal authors and reviewers)

b. external authors and reviewers.

Overall, ISDB needs to think about competing interests in a way that is manageable. A newly formed conflict of interest working group (coordinated by John Dowden) will continue the development of this important policy work.

More from the ISDB General Assembly on the website

You can find reports on other aspects of the ISDB meeting on the website. These include:

- more details of the conflicts of interest survey and the ICMJE forms
- reports from the other working groups on lobbying Europe; direct-to-consumer advertising; and clinical trials in South America
- practical information on bulletin work, including practical tips from Australia's *Therapeutic Guidelines* on tailoring your information to the needs of your audience; and an account of 30 years' experience of new drug assessments, describing the process of evaluation by writers and editors at France's *Prescrire*, and the trends in new drugs observed over that time
- summaries of presentations by external speakers on: bias in reports of drug studies; the new process of comparative drugs assessment in Germany; how the pharmaceutical industry manages key opinion leaders and their publications; an analysis of how institutional practices, incentives and protections compromise the benefits and harms of drugs; surrogate endpoints – do we really need them; and the drug industry's invisible influence on prescribers
- practical points from the skills training workshops on: creating a website for your bulletin and how to make it an effective tool for communication; why and how to make the content of your bulletin fit for new technologies; making your bulletin fit for CME; writing for lay people; building alliances and coalitions; and critical appraisal skills.

The staff of Kusuri-no-Check are from left Keiko Sakaguchi, Michiko Kishishita, Rokuro Hama and Yukiko Umeki.

Harakiri

Contributed by Clotaire Nanga, Editor, La Lettre du CEDIM (Centre de Documentation et d'Information sur le Médicament), Burkina Faso

From 27 to 29 September 2011, a roundtable on fake drugs was held in Ouagadougou. It was organised by a group of partners including the Ministry of Health of Burkina Faso, the French Ministry of Foreign Affairs, and the Chirac Foundation. International organisations and pharmaceutical companies were also present. The objective of this roundtable was to 'contribute to the adoption of a sub-regional strategy, creating the conditions necessary for the establishment of a platform for coordination of the technical and financial partners in the fight against fake drugs'.

'Fake medicines' is a fuzzy term that can help to tackle counterfeit drugs and, to some extent, to satisfy policy makers and health professionals in Africa, by including street drugs. Did pharmaceutical companies come to Ouagadougou for street drugs? Certainly not, they aren't philanthropists. What is at stake is broader.

On the issue of fake drugs, not everyone has the same understanding. Drug manufacturers maintain a degree of confusion between counterfeit medicines, drugs with manufacturing defects (workmanship), generic medicines and parallel imports of medicines. Manufacturing defects can be a problem when it comes to anti-infective drugs or drugs with a narrow therapeutic margin, but the other issues involve intellectual property and market protection.

For *CEDIM*, the goal is straightforward. We need to ensure people's access to quality medicines and we must get patients to buy all their medicines in pharmacies. And we must ensure that drugs sold in pharmacies are not substandard. In order to achieve these objectives, the level of technical quality control in laboratories should be raised, checks after the marketing of drugs should be reinforced, and offenders must be penalised without complacency.

The role of these countries is not to support marketing strategies and market protection tactics of firms from developed countries. Intellectual property issues are not the priority of poor countries who should refuse to deal with drug companies that hinder the production of new generics or impose costly means of authenticating their drugs. Giving up to these companies is self-defeating. The decrease in production of generics increases prices. The rising price of medicines impedes access to quality medicines. Lack of access to quality medicines leads to the use of counterfeit drugs and street drugs. This is a vicious circle.

We must remember that it is not the breach of intellectual property that kills, but the poor quality of medicines and the inflexible rules of intellectual property.

Policy makers who want to address access to quality medicines must remember that we no longer need statements or declarations of good intentions. What counts is action!

Conversations with some ISDB members

Keiko Sakaguchi, *Kusuri-no-Check*, Japan

Can you explain the name of your bulletin?

The full name of our bulletin is 'Kusuri-no-check-wa-inochi-no-check', which means 'check-up your medicine to save your life'.

Why was your bulletin started?

We started *Kusuri-no-Check* because we thought that consumers in Japan should have a reliable and independent source of medical information to allow them to have better communication with health professionals.

We think *Kusuri-no-Check* forms an essential bridge between medical consumers and medical professionals.

How long has your bulletin been going, how often do you publish it and who receives it?

Kusuri-no-Check was started in January 2001, so it has been going for 11 years. It is published four times a year.

Subscribers to the bulletin include medical consumers, doctors, pharmacists, and other health professionals.

Conversations with some ISDB members (cont.)

Who are the people involved in the production of Kusuri-no-Check?

The editor-in-chief is Keiko Sakaguchi.

There is an editorial board that has seven members: four medical doctors (including Rokuro Hama), two pharmacists and one victim of an adverse drug reaction (subacute myelo-opticoneuropathy from clioquinol). There are seven advisers to the editorial board: three medical doctors, one pharmacist, one professor/journalist, one journalist and one victim.

Four people (including Rokuro Hama and Keiko Sakaguchi) work to put the material together for the bulletin. Other people involved in the production of the bulletin are three illustrators and one book designer.

What resources do you have to produce the bulletin?

All the funding to produce the bulletin comes from subscription fees and contributions from readers.

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

We liaise with several groups in Japan. For specific articles aimed at professionals, we liaise with 'The Informed Prescriber' but other organisations we liaise with include: 'Yakuhiren' (victims of drug disasters, Kyoto), 'Med watcher' (Tokyo), 'Idea Four' (breast cancer patients, Tokyo) and 'Medical Care and Human Rights' (HIV patients, Osaka).

What kind of issues do you cover in your bulletin?

We mainly publish articles based on individual diseases and/or drugs. Some of the important topics have included:

- Diabetes, with a focus on the role of a suitable diet to reduce the need for medications.
- Cholesterol, to explain that cholesterol is essential to maintain a healthy body and to advise of the harm of hypocholesterolaemic agents.
- Hypertension, warning consumers of the possible harm of being exposed to unnecessary antihypertensive therapy if guidelines published by WHO/ISH or The Japanese Society of Hypertension are followed.

In addition to the many articles on specific diseases or commonly used drugs that we prepared we have also published articles such as the risk/benefit of fluoride, drug prices and their value, interviews with victims of adverse drug events.

Kusuri-no-Check also includes a correspondence column, questions from readers, and book reviews.

What are your main challenges for the future?

1. In the future we hope to include an article on the assessment of a new drug in every issue. We already publish an assessment of relevant medicines when we focus on a specific disease or drug.
2. We are planning to re-edit all the interviews conducted by the editor with victims from drug disasters and publish them in a compendium of drug disasters.
3. We have just started a development program to train successors to assess efficacy and harm of drugs and write articles for the bulletin.
4. We are investigating harm of drugs that are currently on the market such as oseltamivir and gefitinib.

Professor Kumud K. Kafle, Chief Editor, *Drug & Therapeutics Letter*, Nepal

Why was your bulletin started?

We began our bulletin to provide updated information on medicines and therapeutics.

How long has your bulletin been going, how often do you publish it and who receives it?

We have been producing the *Drug and Therapeutics Letter* for 19 years. We currently publish four issues per year.

Our bulletin goes to all departments of Tribhuvan University Teaching Hospital, which is located in Kathmandu. It also goes to 30 other institutions including medical schools, dental schools, hospitals, WHO and our drug regulatory department.

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

The Drug Information Unit of the Department of Clinical Pharmacology, Institute of Medicine, at Tribhuvan University Teaching Hospital produces the bulletin. The unit has computer equipment, internet access, printer and photocopying equipment. We involve the faculties and postgraduate residents of the department in the production

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

Yes, we liaise with the regulatory body, the Department of Drug Administration.

What kind of issues do you cover in your bulletin?

In the bulletin we discuss the management of common health problems and provide brief information on services provided by the department.

What are your main challenges for the future?

We do not see any specific challenges.

Please add any other comments you might like to have included in the article about your work.

The publication of the bulletin including printing and distribution is supported by the Tribhuvan University Teaching Hospital. It also supports our membership fee of ISDB.

Professor Kumud K. Kafle, bottom row, second from left.

Future events of interest

Independence forum – October 29, 2012; Melbourne, Australia

This Forum, hosted by Therapeutic Guidelines Ltd, will bring together national and international experts and ethicists to discuss the influences that have the potential to compromise the quality of therapeutic advice for prescribers.

Topics to be discussed include:

- What is independence?
- Has the Evidence-Based Medicine movement been captured by commercial interests?
- Is new thinking about sources of research funding needed?
- What degrees of separation should be maintained between experts involved in guideline development and their interests?

The meeting will be of interest to everyone involved in the development of guidelines, health professionals who use guidelines as a basis for their decision-making, people working in areas to improve the quality of health care, university lecturers, and health policy makers.

Speakers will include Silvio Garattini (Director, Mario Negri Institute for Pharmacological Research, Italy), Barbara Mintzes (Therapeutics Initiative, Canada), Paul Komesaroff (Director of the Monash Centre for the Study of Ethics in Medicine and Society) and Ian Kerridge (Centre for Values, Ethics & Law in Medicine, University of Sydney).

Send an email to independence@tg.org.au to register your interest.

Selling Sickness Congress, 20–23 February 2013; Washington, USA

First, there was the 2006 Inaugural Congress on Disease Mongering in Australia which marked a watershed in networking among health care reformers and drug industry critics. Then, the 2010 Selling Sickness conference in Amsterdam expanded the network and updated the work. Now, Selling Sickness 2013: People before Profits is coming to Washington, DC in 2013.

Selling Sickness 2013 will bring together academic scholars, healthcare reformers, consumer advocates and progressive health journalists to examine the global tide of disease mongering. The conference will be designed to encourage audience participation and increase collaboration among the conference attendees. There will be invited keynote addresses, panels, workshops and an exhibits room celebrating the scores of exciting US and international groups working on aspects of disease mongering and selling sickness.

The conference will include topics pertaining to disease mongering such as: misleading marketing; ethics in professional education; journalistic standards; social media; over-treatment; new models for drug development and testing; whistleblowers; new conflict of interest areas; health screening policies; impact on public health and pocketbook. In addition, the congress organisers are encouraging submissions offering new ideas, research or policy matters relevant to the overall theme. Acceptable presentation formats include brief talks, symposia, roundtable discussions, workshops, or poster presentations.

A unique aspect of Selling Sickness 2013 will be the approval of a statement of principles and policies on disease mongering representing the combined thinking of a team representing the perspectives of consumer activist organisations, health journalists and critical reform scholars. The statement will be prepared during the months leading up to Selling Sickness 2013 and will be discussed at a conference session. Co-sponsoring groups and publications will post, publish, and otherwise disseminate the statement following the conference.

Registration for Selling Sickness 2013 opens in (Northern) Summer 2012. The presentations submission form and full call for presentations will be available from June, 2012. Visit http://sellingsickness.com/ for more information. ISDB is a co-sponsor of this meeting.