

*The International Society of Drug Bulletins (ISDB) is a worldwide network of publications on drugs and therapeutics that are financially and intellectually independent of the pharmaceutical industry.*

## ISDB Committee

### President

**Joe Collier**

*Drug and Therapeutics Bulletin*  
United Kingdom  
[jcollier@sghms.ac.uk](mailto:jcollier@sghms.ac.uk)

### Secretary

**Maria Font**

*Dialogo sui Farmaci*  
Italy  
[maria.font@ulss20.verona.it](mailto:maria.font@ulss20.verona.it)

### Treasurer

**Andrea Tarr**

*Drug and Therapeutics Bulletin*  
United Kingdom  
[andrea.tarr@which.co.uk](mailto:andrea.tarr@which.co.uk)

### Gita Fernando

*Sri Lanka Prescriber*  
Sri Lanka  
[gitaf@celltelnet.lk](mailto:gitaf@celltelnet.lk)

### Etzel Gysling

*Pharma-kritik*  
Switzerland  
[etzel@infomed.org](mailto:etzel@infomed.org)

### Rokuro Hama

*Kusuri-no-Check*  
Japan  
[gec00724@nifty.com](mailto:gec00724@nifty.com)

### Mary Hemming (newsletter editor)

*Therapeutic Guidelines Limited*  
Australia  
[mhemming@tg.com.au](mailto:mhemming@tg.com.au)

### Ksenija Makar-Ausperger

*Bilten o lijekovima and Pharmaca*  
Croatia  
[ksenija.makar-ausperger@zg.hinet.hr](mailto:ksenija.makar-ausperger@zg.hinet.hr)

### José María Récalde-Manrique

*Boletín Terapéutico Andaluz*  
Spain  
[cadime@easp.es](mailto:cadime@easp.es)

### Walter Thimme

*Der Arzneimittelbrief*  
Germany  
[wthimme@zedat.fu-berlin.de](mailto:wthimme@zedat.fu-berlin.de)

## President's report

**Joe Collier** [jcollier@sghms.ac.uk](mailto:jcollier@sghms.ac.uk)

In my report to the society in the last issue of the newsletter, I said that the byword for my presidency would be 'consolidation'. The process of consolidation has now started, and inevitably it is taking time.

Plans are well underway to establish an 'independent' group to review our constitution (see 'Revision of the constitution' on page 7). Darko Vrhovac has agreed to chair the group, and Etzel Gysling will be one of its members. Final details of the membership, and of the group's terms of reference, will be agreed at a meeting of the full ISDB committee in London on 17 and 18 September this year.

There have been important developments regarding the completion of the ISDB manual on 'Starting or strengthening a drug bulletin'. The present plan is that a small editorial team composed of 4 or 5 ISDB members will work on the chapters already submitted with the aim of ensuring consistency, clarity and useability. Each chapter will then be posted on the society's website for comment.

Once the comments are in, we aim to publish a pilot version of the manual jointly

with WHO. Our target publication date is April 2004, which will coincide with a WHO-sponsored meeting (ICIUM-2) taking place in Chiang-Mai, Thailand. There would then be wide consultation on the pilot version, and the comments received would be used in the production of a definitive version of the manual to be published sometime in late 2004. This definitive manual will be available in hard copy and as a PDF file. Danielle Bardelay, Andrew Herxheimer, Rokuro Hama and Andrea Tarr have already agreed to be members of the editorial team, and terms of agreement determining our relationship with WHO on this project are all but complete.

Arrangements have also been made for a meeting between ISDB and WHO with the aim of establishing our areas of common interest and exploring how (in addition to the manual project) we can work together to greatest mutual advantage.

The meeting has been planned in discussion with Hans Hogerzeil (Team Coordinator, Policy, Access and Rational Use, WHO) and is scheduled to take place in Geneva on Friday 3 October.

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*Apart from official reports of the society, the views expressed in this newsletter are solely those of the individual authors and do not necessarily reflect the position of the society.*

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In contrast to these 'positive' developments, it saddens me to announce that in March this year, and after 12 years in print, the Medicines Information Bulletin, published in New Zealand by the National Preferred Medicines Centre (PreMeC), ceased publication of new material (old material will still be available on its website, at least for the time being). Closure occurred because PreMeC's main contract was not renewed by PHARMAC, the government's drug-funding agency. When I discovered that closure was likely, I wrote to PreMeC as ISDB President, saying:

It is with great regret that I learn of the possible demise of the Medicines Information Bulletin, an active member of the International Society of Drug Bulletins (ISDB). The sort of independent information provided by the Medicines Information Bulletin is not a luxury, but an asset hard earned and hard to come by. It takes years to reach the sort of position achieved by PreMeC, and I ask that all options are explored before any decision is made that might lead to its closure.

I was able to write this note because I knew PreMeC 's work well (I had visited its office in November 2002), and knew how its publication fully reflected ISDB's values.

Clearly we should strive to ensure that the society can have a similar feeling of security that all its members reflect ISDB ideals. Displaying the ISDB logo carries a guarantee that the material published meets established high standards. It is for the society to underwrite that guarantee. To this end, at its September meeting the committee will be developing ways of regularly reviewing the membership to ensure ongoing eligibility.

It was for Josef Tukker to head up this review, but sadly he has left *Geneesmiddelenbulletin* and so has resigned from his post as society and membership secretary. In the short time Josef has been secretary, he has proved a most valued colleague and I am sorry that he has had to leave. Nevertheless, we must march on, and it gives me great pleasure to welcome in his place Maria Font (*Dialogo sui Farmaci*, Italy). Apart from being secretary to the society, she will, as membership secretary, lead the membership review.

Finally, I need to remind members that at the September meeting of the committee we will be deciding on the venue of the 2005 General Assembly. If you want to be considered as a possible host, we will need to have your letter of application by Monday 25 August 2003 (see 'Secretary's report' in the next column).

## Secretary's report

Josef Tukker

### Reminder: Call for bids to host the 2005 Workshop and General Assembly

After the first General Assembly in Stockholm in 1986, subsequent assemblies were held in Mannheim in 1989, Tokyo in 1992, Granada in 1996, Amsterdam in 1999, and Dubrovnik in 2002.

All member bulletins of ISDB are invited to make a bid for organising and hosting the Workshop and General Assembly in 2005. The committee would highly recommend a country outside Europe, and preferably a country with visa rules that are easy to comply with for participants from developing countries. It should be remembered that ISDB is a worldwide organisation and that so far the majority of the meetings have been in Europe.

The bid should include the following:

- venue location
- venue features and services
- site accessibility (by air, car and train)
- suggested accommodation (including proximity to the venue)
- experience of the local staff in organising such a meeting
- estimated costs (preferably in US\$).

The meeting should take place in July, August or September of 2005. Please submit your letter of application to my successor, Maria Font ([maria.font@ulss20.verona.it](mailto:maria.font@ulss20.verona.it)), by Monday 25 August 2003. The final decision will be made by the full committee at its meeting in September.

## Treasurer's report

Andrea Tarr [andrea.tarr@which.co.uk](mailto:andrea.tarr@which.co.uk)

### ISDB membership fees

Recently, you should have received a request for payment of the ISDB membership fee for 2003. Thanks to all the members who have paid promptly. Payment of the fee is necessary in order to remain a member or a recognised correspondent of ISDB. There are three categories of ISDB membership to ensure that there is no financial barrier to membership of the society and, for those unable to pay, it is possible to apply for exemption.

## Coordinator's report

Andrea Tarr [andrea.tarr@which.co.uk](mailto:andrea.tarr@which.co.uk)

### Regional meetings

#### ISDB Western Europe Pharmacovigilance Workshop

A meeting in western Europe is being planned for 31 October–1 November 2003 in Berlin, Germany, on the topic 'Getting the most out of pharmacovigilance'. The program for the workshop is on page 14.

#### Middle East & West Asia Region

A meeting/workshop is being planned for members in the Middle East & West Asia region, to take place in Kathmandu, Nepal, on 19-21 February 2004. This will replace the regional workshop that was being planned for December 2003 in Colombo, Sri Lanka, but which unfortunately had to be cancelled for local reasons.

The program for the meeting/workshop in Kathmandu will be announced later this year. To register your interest in attending, please contact Bimal Shrestha, *Drug Bulletin of Nepal*, at [dda@healthnet.org.np](mailto:dda@healthnet.org.np).

If you are interested in organising an ISDB meeting/workshop in one of the other regions (Africa, America, East Asia & Pacific, or Central & Eastern Europe), please contact Andrea Tarr. See 'Future meetings' on page 5 for further details.

### Committee meetings

A committee meeting is planned for 17-18 September in London. A draft agenda is being prepared by the executive group and will be emailed to all members of the society for their input.

### Newsletter submissions

The third issue of the newsletter for 2003 will be published in November. The deadline for contributions is 30 September.

Please forward submissions or enquiries to Mary Hemming at [mhemming@tg.com.au](mailto:mhemming@tg.com.au).

# Brief outline of the work and workings of ISDB

Andrea Tarr [andrea.tarr@which.co.uk](mailto:andrea.tarr@which.co.uk)

This paper has been prepared as a ready-to-use summary of information that members of the society can use to inform other organisations and individuals about ISDB. If you wish to have the paper in electronic format, please contact Andrea Tarr.

## Introduction

The International Society of Drug Bulletins (ISDB) is a worldwide network of bulletins on drugs and therapeutics which are financially and intellectually independent of the pharmaceutical industry. Founded in 1986 with the support of the World Health Organization (WHO) Regional Office for Europe, the overall aim of ISDB is to encourage and assist the development of independent drug bulletins worldwide and to facilitate cooperation amongst them. Independent drug bulletins are recognised as an important tool in promoting rational drug use.

## Membership of ISDB

ISDB has two categories of members: full members and recognised correspondents. Full members fulfil the criteria set out in the constitution. That is, they must:

- adopt editorial procedures and an organisational structure that will, in the opinion of the committee or the society in general meeting, ensure their independence and the quality of their content
- contain no advertising relating to therapeutic or diagnostic activities
- allow the quality of their contents and the independence of their editorial system to be periodically assessed by the society.

Recognised correspondents are either drug bulletins that fulfil some but not all membership criteria, or are bulletins, organisations or individuals that simply support the goals of ISDB.

There are currently 56 full members and 29 recognised correspondents from 48 countries (see below). Membership is diverse not only in terms of organisational characteristics, but also in terms of the type of content and frequency of publication. Organisationally, there is variation in age, structure, circulation figures and funding. For example, some bulletins receive financial and practical support from government departments, while others rely totally on private subscription. With respect to content, some publications focus on very specific issues (eg adverse drug reactions or poisoning), while others publish articles on a wide range of topics, such as disease management, therapeutic choices and policy issues.

## Management of ISDB business

The society is run by a committee, the members of which are appointed by election at the 3-yearly general assembly. In exceptional circumstances committee members can be coopted.

For the period 2002–2005, the committee members are:

- Joe Collier (*Drug and Therapeutics Bulletin*, United Kingdom)—president
- Josef Tukker (*Geneesmiddelenbulletin*, The Netherlands)—general secretary and membership secretary (succeeded by Maria Font in July 2003)
- Andrea Tarr (*Drug and Therapeutics Bulletin*, United Kingdom)—treasurer
- Gita Fernando (*Sri Lanka Prescriber*, Sri Lanka)
- Maria Font (*Dialogo sui Farmaci*, Italy)—webmaster (and general secretary and membership secretary from July 2003)
- Etzel Gysling (*Pharma-kritik*, Switzerland)
- Rokuro Hama (*Kusuri-no-Check*, Japan)
- Mary Hemming (*Therapeutic Guidelines*, Australia)—newsletter editor
- Ksenija Makar-Ausperger (*Bilten o lijekovima & Pharmaca*, Croatia)
- José María Récalde-Manrique (*Boletín Terapéutico Andaluz*, Spain)
- Walter Thimme (*Der Arzneimittelbrief*, Germany)

The primary aims of the committee are to help strengthen the work of established bulletins, to bring new bulletins into the membership, and to empower bulletins to influence local practice in the use of drugs and therapeutics.

## Countries in which there are ISDB member bulletins, presented by region

AFRICA	AMERICA	EAST ASIA & PACIFIC	MIDDLE EAST & WEST ASIA	CENTRAL & EASTERN EUROPE	WESTERN EUROPE
Burkina Faso	Canada	Australia	India	Armenia	Austria
Eritrea	Nicaragua	China (Hong Kong)	Israel	Bosnia & Herzegovina	Belgium
Ghana	Panama	Indonesia	Nepal	Croatia	France
Kenya	Peru	Japan	Pakistan	Czech Republic	Germany
Madagascar	USA	Malaysia	Sri Lanka	Estonia	Italy
Nigeria		New Zealand		Latvia	The Netherlands
Zimbabwe		Philippines		Lithuania	Norway
		Singapore		Moldova	Spain
				Poland	Sweden
				Republic of Georgia	Switzerland
				Romania	United Kingdom
				Slovenia	

The day-to-day business of the society is carried out by an executive group of the committee, consisting of the president, secretary and treasurer. The society employs a coordinator (Andrea Tarr) for half a day per week, whose responsibilities include coordinating communication within the committee and the society. Regional coordinators (to represent the 6 'regions' of the world) will be appointed from the committee later this year. They will be expected to play a crucial role in the consolidation and expansion of the organisation, for example by providing help with identifying new members, evaluating current members and new applicants, organising regional meetings, and assisting with contacting bulletins in the region.

## Sources of funding

The primary sources of funding for ISDB are the annual membership fees and members' donations. The membership fee is not fixed, but is a suggested amount (ranging from £5 to £600) based on the member's overall budget. Members who cannot afford to pay even the lowest rate can apply for exemption. The total annual income of the society is around £10 000. Other funding, which has traditionally been on an ad hoc basis, has come from WHO or, for the general assembly, from local bodies (eg ministries, city councils).

## Work of the society

### Newsletter

ISDB publishes a newsletter to inform members of the society's business. It is distributed free-of-charge by email (and by post to those who have no Internet access) to all members and recognised correspondents. It is planned to publish three issues per year. The newsletter is edited and prepared on behalf of ISDB by Mary Hemming (*Therapeutic Guidelines*, Australia).

### Website ([www.isdbweb.org](http://www.isdbweb.org))

The constitution, a list of members, links to members' websites, and details about how to join the society are available on the ISDB website. The website is maintained on behalf of the society by Maria Font (*Dialogo sui Farmaci*, Italy).

### Meetings

Since it was established, ISDB has held regular meetings (see below). There are several different styles of meeting: general

assemblies; regional and local workshops dealing with various issues for established and new bulletins; formal training courses; and meetings to develop ISDB policy. Several meetings have received financial support from WHO (eg East Asia & Pacific regional meeting, 1997; Central & Eastern Europe regional meeting, 1998).

### Past meetings

1986	Stockholm, Sweden <i>General assembly and workshop</i>
1989	Mannheim, Germany <i>General assembly and workshop</i>
1991	Reggio, Italy <i>Workshop</i>
1992	Algiers, Algeria <i>Workshop</i>
1992	Tokyo, Japan <i>General assembly and workshop</i>
1994	Budapest, Hungary <i>Workshop</i>
1995	Manila, Philippines <i>Regional meeting</i>
1996	Granada, Spain <i>General assembly and workshop</i>
1997	Penang, Malaysia <i>Regional meeting</i>
1998	Riga, Latvia <i>Regional meeting</i>
1999	Amsterdam, Netherlands <i>General assembly and workshop</i>
2000	London, UK <i>Editors' training course</i>
2001	Paris, France <i>Working group meeting</i>
2002	Dubrovnik, Croatia <i>General assembly and workshop</i>

### General assemblies

The meeting of all the full members (the general assembly) is the governing body of the society. ISDB holds a general assembly every 3 years at which members elect a new committee and make other decisions about the society. The general assembly is usually combined with a series of workshops at which members meet and exchange ideas and information.

### Regional and local workshops

These meetings provide an opportunity for participants to exchange experiences and acquire the skills necessary to develop and run a high quality drug bulletin. At these meetings, people working on well-established bulletins can share their experience with those starting new ones.

For example, the Central and Eastern Europe regional meeting in Riga, Latvia, in 1998 involved around 35 participants from Armenia, the Czech Republic, Slovenia, Poland, Croatia, Kazakhstan, Kyrgyzstan, Moldova, Estonia, Tajikistan, Bosnia and Herzegovina, the Netherlands, France, and the UK. Participants discussed ways to strengthen the regional network and improve the quality of drug information in order to promote the essential drug concept and rational use of drugs. Workshops focused on practical skills, such as the development of an editorial policy, improvement of the readability of a drug bulletin, independence and financial sustainability, access to reliable sources of information, and cooperation in sharing these sources, for example by using electronic communication. Participants also analysed different ways to start a new drug bulletin, given the scarcity of resources available in the region. They agreed on different methods of cooperation and mutual support that would play a significant role in providing independent information on drugs for health professionals and consumers.

### Training courses

An editors' training course was held in London in 2000. Six editors, from drug bulletins in Sri Lanka, Romania, Lithuania and Germany, attended. The course covered the responsibilities of members of the team; deciding on the topics of articles; choosing and commissioning external authors; the consultation process; editing; verification; sources of information; and different types of evidence.

### Meeting to develop ISDB policy

During 2001, editors from several established bulletins collaborated in a working group to deliberate on the issue of 'What is a real innovation in the use of medicines?' This work culminated in a meeting in Paris and publication of the 'ISDB declaration on therapeutic advance in the use of medicines' (the Paris declaration). This document is available, in several different languages, on the ISDB website.

### Ad hoc visits and support

To support the development of new drug bulletins, several ISDB members have hosted visits from editors starting new bulletins to help them gain experience. Some established bulletins provide support to developing bulletins (eg *Prescrire*, a French member bulletin, supports bulletins in French-speaking African countries, including Algeria, Burkina Faso and Madagascar).

## Future meetings

It is expected that at least one meeting will be organised in each ISDB region during the next 2 to 3 years. ISDB has allocated funds to help support these meetings: a total of around £6000 to help support five regional meetings during the years 2003–2005, and around £10 000 for the General Assembly in 2005. For a regional meeting to be eligible for ISDB funding, it must involve the active participation of at least five ISDB members, of which at least four are based in the region itself. Moreover, the organisers will need to produce a report of the meeting with some assessment of the participants' views of the meeting's content, perceived value, organisational arrangements, and so on. Once funding is agreed, the money will be guaranteed, with up to 25% paid in advance.

A meeting in western Europe is being planned for 31 October–1 November 2003 in Berlin, Germany: the ISDB Western Europe Pharmacovigilance Workshop—Getting the most out of pharmacovigilance (see pages 14 and 15).

A workshop in the Middle East & West Asia region is being planned for 19–21 February 2004 in Kathmandu, Nepal (see the Coordinator's report on page 2).

## Manual on 'Starting or strengthening a drug bulletin'

Apart from the meetings organised by ISDB and the informal contacts between members, there are few opportunities for people working on independent bulletins to share experiences. There is also a lack of written information about the work of drug

bulletins. This means that it is difficult for those involved in new bulletins to benefit from the work of others. To fill this gap, a project to develop and publish a manual on 'Starting or strengthening a drug bulletin' was started in 1998 by ISDB in collaboration with WHO. The original aim of the manual was to draw from the experience of those involved in independent drug bulletins and to present that experience—and reflect the diversity to be found among bulletins—in the form of a practical tool to help those involved in starting a new bulletin, or to help strengthen an existing bulletin.

Unfortunately, work on the manual ceased in September 1999. However, the ISDB committee has now arranged for work on the project to be resumed, and it is expected that the manual will be published in 2004.

# Minutes of the executive group meeting

## 14 March 2003, Drug and Therapeutics Bulletin Office, London

*The draft agenda had been mailed to all members of the committee 3 weeks prior to the meeting. Responses were received from Gita Fernando, Maria Font, Etzel Gysling, Mary Hemming, Ksenija Makar-Ausperger, José María Récalde-Manrique, Walter Thimme, and were, as appropriate, either incorporated as a redrafted agenda or considered in discussion.*

*Present: Joe Collier (president), Josef Tukker (secretary), Andrea Tarr (treasurer)*

## Report of activities since last meeting

### The president

- visited Berlin and met the editors-in-chief of the 4 German member bulletins
- met with Kathy Holloway (Medical Officer, Department of Essential Drugs and Medicines Policy, WHO) in London in January, and with Hans Hogerzeil (Team Coordinator, Policy, Access and Rational Use, WHO) in London in February. A report of the meeting prepared by Hans Hogerzeil is reproduced in Appendix 1 on page 7
- after hearing that PreMeC (a member bulletin in New Zealand) was threatened with closure, and following discussion by phone and email, the president sent a letter in support of PreMeC to Patricia Logan, its general manager. The letter was used in PreMeC's 'survival' campaign
- prepared president's report for the newsletter.

### The secretary

- contacted several potential new members in Bulgaria, Romania, Tanzania and Kyrgyzstan

- continued work on current membership list, particularly concentrating on issues surrounding incorrect entries
- prepared secretary's report for the newsletter.

### The treasurer

- prepared the financial report for 2002, and a draft budget for 2002–2005
- prepared treasurer's report for newsletter.

### The coordinator

- attended the meeting with Joe Collier and Kathy Holloway in London
- drafted a proposal for completing the ISDB manual, 'Starting or strengthening a drug bulletin', and contacted all original authors setting out the proposal and asking if they would be prepared to bring their chapters up to date.

## Review of roles/titles

### Membership secretary

It was noted that the constitution requires that there should be a membership secretary responsible for membership issues. It is proposed that Josef Tukker formally takes on this role, and so becomes membership

secretary as well as general secretary. As such he will be responsible for managing the review of members and evaluation of new members, as well as keeping the membership list up to date. It is envisaged that the role of membership secretary will involve a considerable amount of work. Assistance with the work would be needed from the ISDB coordinator and from regional coordinators, when identified.

### ISDB coordinator

It was felt important to clarify that the coordinator is not a role represented on the committee. To this end, the list of roles of the committee originally circulated to members after the last meeting will need amending. If possible, this amended list would be the one that would appear in the forthcoming (March 2003) issue of the ISDB newsletter.

### Executive group/executive committee

To avoid confusion, and to be fully consistent with the written constitution of the society, it is proposed that the group consisting of the president, secretary and treasurer be named the 'executive group', rather than 'executive committee', which had been used previously.

'Executive group' will be the term used in the ISDB newsletter.

## Appointment of treasurer

It is a constitutional requirement that the society should have a treasurer, and that the treasurer must be a member of the committee. It is also permitted under the constitution that members can be coopted on to the committee, although the constitution does not stipulate mechanisms of, and eligibility for, cooption.

However, concerns have been raised that cooption of Andrea Tarr as treasurer was contrary to the constitution, particularly as it meant that two members on the committee would come from the same bulletin. This is an important issue and needs resolution. Accordingly the executive group went through in detail the events and procedures that led to the present position. During the General Assembly in Dubrovnik nobody from the newly elected committee was prepared to stand as treasurer. It was then agreed by the society at large that Andrea Tarr could continue as interim treasurer for 3 months. Towards the end of the 3 months, and after full consideration of constitutional issues, volunteers for treasurer were again sought from the committee, with a note that Andrea Tarr would be prepared to continue if names did not come forward. No volunteers were forthcoming, so Andrea Tarr was formally appointed as treasurer. Commensurate with the duties of the post and its constitutional role, she was then coopted to the committee. The cooption followed full consultation by the executive group with the membership of the committee.

## Communication within ISDB

It was decided that this item, which was to consider in detail how to facilitate ways of communicating between members of ISDB, should be addressed by the full committee at its meeting in September 2003.

## Regional coordinators

There is a requirement in the constitution for the society to have regional coordinators (representing the 6 'regions' of the world). They are expected to play a role in the consolidation and expansion of the organisation. It was proposed that regional coordinators be appointed from the committee and their roles defined at the meeting of the full committee in September 2003.

Suggested responsibilities for regional coordinators are:

- identifying new members
- helping evaluate current members and new applicants
- helping organise regional meetings
- assisting in contacting bulletins in the region.

## Membership fees

It was decided that the treasurer should ask all members to pay their 2003 fees as soon as the March newsletter (which contained a notice about fee collection) had been distributed. A review of membership fees for 2004 should be an item for discussion at the September 2003 full committee meeting.

## Regional meetings

A detailed agenda for the Berlin meeting has been received. It was noted that Joe Collier, as president, would give a brief welcoming address. The group felt that the meeting proposals met the criteria for a regional meeting and so would make the organisers eligible for financial support from ISDB (up to £2000), if needed. Andrea Tarr will contact the organisers about this.

The executive group was told that the meeting being arranged for Colombo had been cancelled. The coordinator will explore possibilities for there to be an alternative meeting in the region during the same period.

## Membership applications

The executive group proposes that all new applications for membership are considered by the full committee at the September 2003 meeting. So far, we have received one new application (from Kazakhstan). Josef Tukker will contact two US publications (*Medical Letter* and *Prescriber's Letter*) to ask whether they are interested in joining ISDB.

## How can we identify potential new members?

The issue of identifying new members of ISDB will be put on the agenda for the September 2003 meeting of the full committee. This is a potential role for regional coordinators. Regional representatives of WHO may also be able to help identify new members. Joe Collier will ask contacts at WHO for contact details of regional officers.

## The re-evaluation of current members

This has already been identified as an item for discussion at the full committee meeting in September. Josef Tukker (as membership secretary) will develop a proposal for a procedure for evaluating current members. This will be presented and tested at the committee meeting in September.

## ISDB manual on 'Starting or strengthening a drug bulletin'

The ISDB coordinator (Andrea Tarr) had prepared an outline of a plan to revive the ISDB manual project, which had begun several years ago in collaboration with WHO, but had stopped in 1999. Andrea Tarr had contacted the original authors of the manual chapters, setting out broad plans for proceeding with a view to publishing the manual towards the end of this year. The proposals had been warmly received by the majority of the authors—responses from those remaining would be sought.

## Full committee meeting

A full committee meeting is planned for 17-18 September in London. It is hoped that any committee members who cannot attend will be able to participate through telephone conference or video link at some time during the meeting. A draft agenda for the 2-day meeting will be prepared by the executive group and circulated to all other members of the committee for their input. Other members of the society will be invited via email to make comments or suggestions about the meeting.

## Meeting with WHO

It is proposed that a group representing ISDB meets in Geneva with members of WHO's Policy, Access and Rational Use team (part of the Department of Essential Drugs and Medicines Policy). The proposed date for the meeting is Friday 19 September 2003. This has yet to be agreed. A tentative program has been proposed, but will be subject to discussion and negotiation with WHO. The contents of the ISDB side of the meeting will be finalised later, preferably at the September committee meeting. Areas identified for discussion are:

- What is ISDB and what is its importance?
- What does ISDB want from WHO?

- What can WHO gain from closer links with ISDB?
- How can ISDB and WHO collaborate and to what ends?
- the ISDB manual project.

## Revision of the constitution

It has been proposed to set up an 'independent' expert group, made up of members of the society, to review the current constitution and advise on ways it might be revised. The recommendations of the group would be presented to the General Assembly in 2005. It is proposed that the following people be invited by Joe Collier to be members of the group: Bozidar Vrhovac, Etzel Gysling and John Dowden.

## Summary of the proposals for consideration by the full committee

- a. That Josef Tukker formally becomes membership secretary, as well as general secretary.
- b. That the group consisting of the president, secretary and treasurer will be named the 'executive group' rather than 'executive committee'.
- c. To set up an 'independent' expert group, made up of members of the society, to review the current constitution and advise on ways it might be revised.

(See Appendix 2 for the committee's response to these proposals.)

## Appendix 1. Report by Dr Hans Hogerzeil (Team Coordinator, Policy, Access and Rational Use, WHO) of a meeting with Joe Collier in London on 3 February 2003

I met with Professor Joe Collier, newly elected president of ISDB. ISDB has about 56 members in 37 countries. It issues about 3 newsletters per year. It has five regions; each region is supposed to hold one 2- to 3-day training meeting every three years. Once every three years there is a global assembly; the next one is planned for 2005. Other office bearers are Josef Tukker (secretary) and Andrea Tarr (treasurer and ISDB coordinator). The total budget is roughly US\$15 000 per year.

Most outcomes of the earlier meeting between Dr K Holloway and Dr Collier were confirmed and do not need to be repeated

here. Especially, the following points were reconfirmed:

1. WHO is very willing to support ISDB, both technically and financially. A first concrete moment could be the planned regional training meeting in Sri Lanka later in 2003; this will be discussed with Kris Weerasuriya from WHO/SEARO (South East Asia Regional Office). WHO could perhaps contribute by funding a small number of extra participants, or a WHO resource person.
2. The work on the draft manual on establishing and running a drug bulletin in developing countries will be taken up again. ISDB will prepare and discuss a plan for finalisation of the manual at its next committee meeting in March and will submit this plan to WHO soon after. WHO is eager to see the manual completed.
3. Joe Collier and other members of the ISDB committee intend to visit Geneva in September to present ISDB, and the case of drug bulletins in general, to WHO colleagues and discuss further collaboration.
4. ISDB could send a delegation to ICIUM-2 in April 2004 in Chiang-Mai, Thailand, to present recent developments and any research on drug bulletins in developing countries.
5. ISDB would like to be involved and/or consulted on important WHO policies regarding bulletins and drug information.

## Appendix 2. ISDB committee members' responses to executive group proposals

- a. That Josef Tukker formally becomes membership secretary, as well as general secretary.  
Agree: 10  
No reply: 1
- b. That the group consisting of the president, secretary and treasurer will be named the 'executive group' rather than 'executive committee'.  
Agree: 10  
No reply: 1
- c. To set up an 'independent' expert group, made up of members of the society, to review the current constitution and advise on ways it might be revised.  
Agree: 9  
Disagree: 1  
Defer for discussion at full committee meeting: 1

# Drug marketing and irrational drug use in developing countries

Gopal Dabade, *BUKO Pharma-Kampagne* dabade\_pal@yahoo.com

This paper is based on a presentation given at the 2002 ISDB Workshop and General Assembly in Dubrovnik.

## 'Children in the sights of the pharmaceutical industry'

In 1995, BUKO Pharma-Kampagne, Germany, along with the Doctors' Initiative of Terre des Hommes, a non-government organisation working for the worldwide improvement of rights and living conditions for children, began a study of the drugs that are promoted for use in children by German pharmaceutical companies.

The study focused on drugs being marketed to developing countries like India, Pakistan, Mexico, Brazil, Kenya, the Philippines and Thailand. The results suggested that several drugs, including vitamin combinations, cough syrups, antiarrhoeals and appetite stimulants, were being marketed for irrational uses.

The researchers concluded that the German drug industry was contributing little to the health of children in developing countries. In fact, on several occasions the industry appeared to be causing more harm than good, by encouraging people to spend their meagre economic resources purchasing totally useless medicines.

BUKO Pharma-Kampagne decided to publish details of the study in order to expose cases of inappropriate marketing by German pharmaceutical companies.

The paper was titled 'Kinder im Visier der Pharmaindustrie' (Children in the Sights of the Pharmaceutical Industry).<sup>1</sup>

Three examples of drugs found to be inappropriately marketed for use in children were Bayer's Tonic, Bayer's aspirin, and E. Merck's pyritinol.

## India: Bayer's Tonic for 'rejuvenation and energy' in children

Until recently, Bayer's Tonic was marketed in India for 'rejuvenation and energy' for children. Each 15 mL of Bayer's Tonic contains the following:

- liver fraction 2 (12 mg) derived from 300 mg of fresh liver
- sodium acid phosphate I.P. 506 mg
- concentrated yeast extract 178.5 mg
- alcohol I.P. 1.65 mL
- flavoured syrupy base q.s.

The alcohol content of Bayer's Tonic is 10.5% (by volume) and Bayer recommended that it be taken three times daily. If given to a malnourished child, this could possibly initiate cirrhosis of the liver. The drug is therefore potentially very dangerous, as most children in India are suffering from some degree of malnourishment or under-nourishment, depending on the economic status of the family.

When this case was described in our BUKO Pharma-Kampagne publication, Bayer was quick to respond by saying that it would stop marketing the drug for children and that it would put a warning on the bottle saying 'Keep out of reach of children'. BUKO Pharma-Kampagne's objectives were not fully achieved, however, as the use of the drug in adults is just as irrational as it is in children, although the danger to the liver would be less.

The interesting point is that, although several other Bayer products were criticised in the BUKO Pharma-Kampagne publication, the company only responded to the issue of Bayer's Tonic, which has a huge market in India. Perhaps they believed that admitting their error would be better than letting an ongoing dispute spoil the image of such a profitable drug.

## South America: Bayer's aspirin for pain and fever in children

Bayer markets aspirin for use in children in several South American countries such as Chile, Uruguay and Argentina. The fact that Reye's syndrome is often associated with the use of aspirin in children has been more or less sidelined in the promotional material of the pharmaceutical company.

Since 1988, Bayer has recommended in Germany that aspirin should not be used in children. However, the company has continued to promote the drug aggressively in developing countries for pain and fever in children, thus reflecting a double standard.

When approached about this dubious marketing practice, Bayer responded with a drawn-out battle of letters and face-to-face meetings lasting almost three years. Their main argument was that BUKO Pharma-Kampagne and Terres des Hommes were exaggerating the adverse effects of aspirin in children. But, when details of the case were finally published in an attempt to expose the double-standard, the company was quick to reply. However, Bayer failed to explain why it continued to recommend aspirin for children in developing countries but not in developed countries. Their contention was that there was not much evidence for Reye's syndrome in developing countries.

- STIMULATES APPETITE
- OVERCOMES THAT 'TIRED FEELING'
- REVIVES VIGOUR
- RESTORES THE SENSE OF WELL-BEING
- AND OF COURSE TASTES SO-O-O GOOD!

# Bayer's TONIC

### INDICATIONS

- LOSS OF APPETITE
- GENERAL DEBILITY
- CONVALESCENCE AFTER ILLNESS OR SURGERY

**DOSAGE** 15 ml (1 tablespoonful or 3 teaspoonfuls) twice daily

**Bayer's TONIC** should be taken preferably before meals

**AVAILABILITY** Bottle of 300 ml

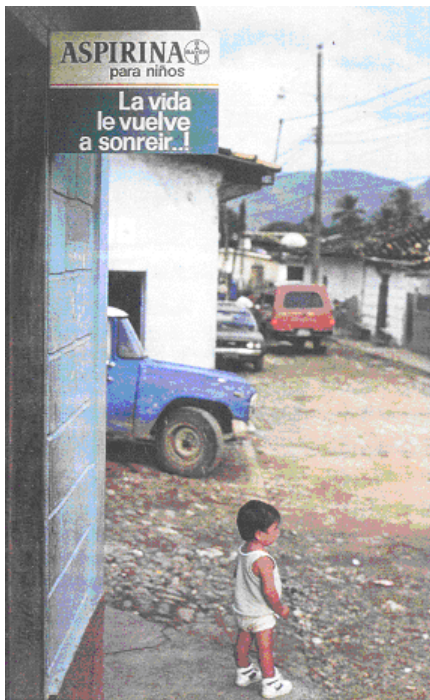
**COMPOSITION**  
Each 15 ml contains: Liver Fraction 2 (12 mg) derived from 0.3 g of fresh liver, Sodium Acid Phosphate I.P. 506 mg, Concentrated Yeast Extract 178.5 mg, Alcohol I.P. 1.65 ml, Flavoured syrupy base q.s. (Alcohol content 10.5% v/v)

For further information please contact:  
**Bayer (India) Limited**  
Pharmaceutical Division  
P.O. Box 1436, Bombay 400 021  
Regd. T. Ms of Bayer Leverkusen, Germany  
Regd. User: Bayer (India) Limited

6/87/6/41000



Bayer's Tonic is also expensive. The money spent on buying a bottle (around 40 rupees, which is almost a day's wage for a person working on a farm) could purchase 1 kg of vegetables, 1 kg of rice, 1 kg of carrots, and 1 banana. This food would be much more nourishing than the contents of a bottle of Bayer's Tonic.



Aspirin for children: 'Life goes on with a smile'

### India: E. Merck's pyritinol as a 'memory miracle' for children

Until recently, E. Merck promoted pyritinol (Encephabol) as a 'memory miracle' (or brain tonic for memory and growth) for children in India.

The company has claimed that pyritinol improves oxygen consumption and glucose uptake by brain cells.<sup>2</sup> Despite these claims, and despite the drug having been available for thirty years, pyritinol fails to receive a mention in authoritative texts of pharmacology.

In 1986, a paper on drug marketing in the developing world in the *Lancet* reported that:

There is no scientific evidence for this drug's efficacy. I have seen this drug prescribed for children with disabilities including cerebral palsy, mental retardation, epilepsy and behavioural problems in Syria, India, Sri Lanka, Malaysia, Singapore, and Indonesia.<sup>3</sup>

In 1987, the World Health Organization (WHO) Regional Office for Europe pointed out that the effectiveness of pyritinol had not been demonstrated.<sup>4</sup>

In 1988, the Medical Lobby for Appropriate Marketing (MaLAM) was unable to find a single published clinical trial of the efficacy of pyritinol 'for any indication'.<sup>5</sup>

BUKO Pharma-Kampagne highlighted E. Merck's marketing of Encephabol in the

September 2001 issue of *Pharma-Brief*<sup>6</sup>, the widely circulated bulletin on the German pharmaceutical industry, discussing one of the advertisements for the drug in India.

E. Merck responded by saying that it was a 'technical mistake' that Encephabol was promoted as a 'memory miracle' and that the situation would be rectified.

### Campaigning against irrational drug use in developing countries

It is unfortunate that promotional literature aimed at developing countries often bypasses scrutiny by the regulatory authority, a problem made worse because:

- most drugs are available over-the-counter without a prescription
- many patients do not have enough money to consult a doctor, so they often seek medical advice from a pharmacist instead
- doctors mostly depend on information supplied by the drug industry, as there is no other source of information
- drug regulations are weak.

It is therefore up to organisations like BUKO Pharma-Kampagne to challenge drug companies about cases of inappropriate marketing and irrational drug use.

Unfortunately, these campaigns generally produce little change. Getting rid of an advertisement containing inappropriate claims is a positive step, but it will not necessarily stop a drug being used irrationally.

A more successful example of a campaign against irrational drug use is the case of the drug Insogen Plus, a combination antidiabetic manufactured by the German company Byk Gulden. Insogen Plus contains phenformin, a drug that is banned in Germany and many other countries because of the risk of lactic acidosis. Nevertheless, Byk Gulden continued to promote and sell Insogen Plus in Mexico.

BUKO Pharma-Kampagne discovered this drug during their 1992 survey on German drugs in developing countries, which was published under the title 'Zweite Wahl für die Dritte Welt' (Second Quality for the Third World) in 1994.<sup>7</sup>

BUKO Pharma-Kampagne wrote to Byk Gulden about Insogen Plus but received no response. Then BUKO Pharma-Kampagne

was approached by a German television station, which asked for a 'bad example' from the survey of a drug that was manufactured by a German company and sold in a developing country. BUKO Pharma-Kampagne told the television reporters about Insogen Plus, and a documentary was shown shortly after on the regional news. Byk Gulden reacted immediately by asking for a meeting.

A few days later the same documentary was telecast on the main nationwide news program. The very next day BUKO Pharma-Kampagne got an urgent fax from Byk Gulden saying that they wanted to discuss the matter. BUKO Pharma-Kampagne agreed on the condition that Byk Gulden would be willing to take appropriate action following the discussion. A few days later BUKO Pharma-Kampagne received written confirmation that Insogen Plus would be withdrawn from the market in Mexico.

The lesson is that it can be useful to confront pharmaceutical companies with cases of inappropriate drug marketing and irrational drug use, but only if there is enough public pressure to make them want to act.

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# Global harmonisation of drug registration requirements: a technical and political issue

**Patrice Trouiller**, Ministry of Health, Antananarivo, Madagascar, and Neglected Diseases Group, Médecins Sans Frontières, Geneva, Switzerland [pat.trouiller@netclub.mg](mailto:pat.trouiller@netclub.mg)

**Wilbert Bannenberg**, Public Health Consultant, Health Research for Action, Reet, Belgium, and Neglected Diseases Group, Médecins Sans Frontières, Geneva, Switzerland [wilbertb@wanadoo.nl](mailto:wilbertb@wanadoo.nl)

**Peter Folb**, Department of Pharmacology, University of Cape Town, South Africa, and the World Health Organization Collaborating Centre for Drug Policy [pfolb@uctgsh1.uct.ac.za](mailto:pfolb@uctgsh1.uct.ac.za)

*This paper is based on a poster titled 'Dissemination of high tech quality standards: regulatory imperialism?', which was prepared by Ragnar Salmen, Kirsten Myhr and Patrice Trouiller, and a report commissioned by Médecins Sans Frontières titled 'Legal and regulatory issues affecting drug development for neglected diseases: harmonization of technical requirements for registration of pharmaceuticals for human use', which was written by Patrice Trouiller, Peter Folb and Kisantha Weerasuriya and is available at [www.accessmed-msf.org/ndg/documents.asp](http://www.accessmed-msf.org/ndg/documents.asp).*

## Introduction

Increasing affluence in many areas, including Europe, North America, and the Far East, has led to the marketplace becoming both more competitive and more global. At the same time, there have been moves to reduce barriers to trade by harmonising many regulations, including those relating to pharmaceuticals. These efforts initially developed on a regional basis, with the EU (European Union) representing one example, and afterwards on an inter-regional basis, the ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) being a prominent example.

In addition, the creation of the World Trade Organization signalled a drive towards market harmonisation at the global level. Globalisation is leading to complex interdependence of economies across national borders, and gives rise to increasing convergence of structures and attitudes between countries. However, the implications of globalisation for the pharmaceutical industry are just beginning to be understood.

A necessary prerequisite for globalisation is the development of quality control systems. Developing these systems requires an increase in spending on research and development; therefore, only those companies that can afford to spend a large proportion of their budget on research and development will reap the economic rewards of globalised pharmaceutical standards. Transnational corporations, which have strong financial and technological capabilities, are highly competitive in the global market. Companies with weaker

financial and technological capabilities are unable to compete. The danger is that meeting drug standards will become so demanding that only large producers will be successful, and smaller enterprises will be forced out of business.

In theory, the movement toward harmonisation of requirements at the global level could improve product quality, safety and efficacy, which in turn would improve international public health. However, if most countries become largely dependent on imported pharmaceuticals, and lose their ability to develop and produce pharmaceuticals locally or regionally, their specific needs and demands will be diluted in the global agenda. These concerns currently range from economic accessibility to existing drugs (eg antiretrovirals) to the availability of new drugs for specific diseases (eg antimalarials).

## Regional harmonisation

Harmonisation of various elements of drug regulatory activities has been undertaken in the last decade as an initiative of various intergovernmental organisations at a regional and inter-regional level. The driving force behind these efforts was the increase in global trade in pharmaceutical products, along with the growing complexity of technical regulations related to drug safety, efficacy and quality.

A prerequisite for the initiation of any harmonised approach to drug regulation is the existence in each of the countries involved of a drug regulatory system (eg a drug registration authority). Countries that only have a rudimentary drug regulatory system, or lack such a system, will not benefit from the harmonisation process.

Harmonisation activities related to drug regulation are now being pursued all over the world. The following initiatives are noteworthy:

- in Asia, the activities of ASEAN (the Association of South East Asian Nations) and the GCC (Gulf Cooperation Council)
- in America, the activities of PANDRHA (the Pan American Network for Drug Regulatory Harmonization), which also includes CAN (the Andean Community), CARICOM (the Caribbean Community) and MERCOSUR (the Common Market of the South)
- in Africa, the activities of AFDRAN (the African Drug Regulatory Authorities Network) and SADC (the Southern African Development Community)
- in EU countries, the activities of the European Medicines Evaluation Agency (EMEA), the Pan European Regulatory Forum (PERF), and CADREAC (the Collaboration Agreement between Drug Regulatory Authorities in European Union Associated Countries).

## International Conference on Harmonisation

A special status in drug regulatory harmonisation has been attained by the ICH. The ICH initiative, which began in 1990, includes drug regulatory authorities of the EU, Japan and USA on the one hand, and the research-based pharmaceutical industry associations of those countries on the other hand (the International Federation of Pharmaceutical Manufacturers Associations, or IFPMA).

Forty-five guidelines describing technical requirements related to the process of drug registration have been produced by groups

of specialists drawn from the regulatory authorities and pharmaceutical companies of the ICH countries. Regulatory authorities of the ICH countries now implement these guidelines, most of which represent an up-to-date approach to drug testing and registration. The costs required to fully implement the guidelines can be considerable, but it is argued that they are offset by the time saved when registering new drugs.

## Expansion of ICH guidelines to non-ICH countries

A new situation concerning ICH activities has arisen since 1997 due to the creation, within the ICH Steering Committee, of the ICH Global Coordination Group. The aim of the group and the new ICH policy is to expand the use of ICH guidelines to include non-ICH countries and generic products. This expansion is intended to make the ICH guidelines the 'global standard' in the area of drug regulation. It will also have important consequences for the production of generic drugs (eg guidelines related to raw materials and impurities).

The ICH guidelines were originally aimed at new drugs marketed in high-income countries. They describe high safety and quality requirements as appropriate for drugs intended to improve quality of life. In practice, however, the 'judicialisation' of public life prevailing in Western countries means that these requirements are effectively based on the risk of legal action taking place if a drug was found to be unsafe. Paradoxically, in several cases the World Health Organization (WHO) safety and quality requirements are more strict than the corresponding requirements applied by the ICH.

It appears that the intention of the ICH expansion process is not simply to improve the availability of new drugs to worldwide markets, nor to decrease the cost and duration of the research and development process for countries involved. Rather, the process seems to be based more on meeting the requirements of the ICH countries than satisfying global concerns—a form of 'global unilateralism'. In fact, the ICH process conflicts with WHO policy, because the ICH starting position was essentially commercial while the WHO approach is guided by international public health concerns. In addition, while WHO and 17 countries are observers of the ICH process,

there are still 175 non-ICH countries unable to get a word in edgeways.

## Is global harmonisation a nonsensical constraint?

Another issue of importance that has not been examined closely is that the current trend in global harmonisation of regulatory requirements, exemplified by the ICH, could be more of a hindrance than a help to evaluating and making available certain medicinal products, such as drugs for neglected diseases. Harmonising and then globalising standards, guidelines and practices for similar medicinal products from different countries will only be successful in lowering technical barriers to trade if there is no technical uncertainty involved.

For many technologies and products, technical specifications and other precise criteria can be used with certainty. This is the case with most industrial products; however, a recurring feature of medicinal products and corresponding regulations is that the underpinning science is characterised by considerable uncertainty regarding, for instance, data sets from toxicology, clinical trials, and pharmacovigilance studies. These extensive uncertainties in drug testing partly account for the fact that scientists belonging to different national regulatory authorities can review the same data about the safety of a drug but reach entirely contradictory conclusions. Different examples demonstrate that this is not merely an academic issue (eg the case of the RotaShield® vaccine).

The consequences of this technical uncertainty have not been extensively analysed, even though they are of critical importance, particularly in terms of the evaluation and availability of new drugs for diseases of no specific interest to the major regulatory authorities. In other words, can we separate the technical aspects of drug testing and marketing—which are fraught with a number of scientific and technical uncertainties—from the social and epidemiological context in which a drug will be used?

## Conclusion

The crucial question is whether the current drug regulation system, which is increasingly globally driven and dominated by a limited number of regulatory authorities and multinational corporations, places the

interests of industry and trade over and above the interests of patients and international public health.

Firstly, the global expansion of ICH requirements may lead to a considerable increase in the requirements imposed on local manufacturers in non-ICH countries, where the drug market is often based on well-established products and is linked in many cases to the manufacture of generic versions of essential drugs. If these manufacturers were unable to meet what may be deemed unreasonable requirements, the adverse impact of the withdrawal of these essential drugs on the health of the population would be far more dramatic than that of any hypothetical risk posed by failing to achieve the ICH technology-driven standards.

Secondly, in the present globalised marketplace, a domestic decision made by one country, or a group of countries, can have profound implications for the rest of the world, especially if this country is considered—rightly or wrongly—to have the best scientific and medical knowledge. Such a set-up is by nature asymmetrical and will usually result in negative consequences for the less powerful countries.

## Overdose: the case against the drug companies<sup>1</sup>

Reviewed by Andrew Herxheimer

In this valuable book, Jay Cohen, an academic physician based in San Diego, outlines his concerns that many official drug dosage recommendations are too high and take no account of the normal biological variations between people. This situation leads to vast numbers of avoidable adverse effects, deprives people in whom lower doses would work of effective treatments, wastes money, and is counter-educational in terms of the rational use of drugs.

Cohen analyses the commercial and regulatory causes of this situation, and discusses what needs to be done to solve the problem. Unfortunately, Cohen focuses heavily on the US, largely ignoring the rest of the world. Nevertheless, I strongly recommend the book as a source of themes, ideas and examples for all ISDB members.

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## Drug promotion, misinformation and economics: failures of the therapeutic chain

According to a recently published editorial<sup>1</sup> written by Albert Figueras and Joan-Ramon Laporte (from the WHO Collaborating Centre for Research and Training in Pharmacology in Barcelona, Spain), the potential causes of therapeutic failure depend on a complex interplay of social as well as medical factors.

The therapeutic chain includes development, regulation, marketing, distribution, prescription, dispensing, and use of a drug—failures can occur at each and every point.

Members are encouraged to read the whole article, but some of the more important issues raised are:

- The methods and objectives of medical research are driven mainly by industrial priorities and regulatory requirements, rather than what is important in the context of clinical practice.

- Marketing approval tends to be granted on the basis of superiority over placebo, with efficacy being measured by endpoints of varying clinical relevance.
  - Marketing budgets are larger than the research and development costs.
  - The trade related intellectual property rights agreement of the World Trade Organization has a negative effect on the equitable access of populations to drugs.
  - Less developed countries have poorer standards of drug regulation, quality control, education, and drug and therapeutic information, so the probability of therapeutic failure is high.
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## BMJ theme issue: the relationship between doctors and the pharmaceutical industry

The 31 May 2003 issue of the *BMJ* was a theme issue exploring the relationship between doctors and the pharmaceutical industry. There are many extremely interesting and relevant articles in this issue, all of which are well worth reading.

A two-part article by Ray Moynihan describes relationships existing between doctors and the pharmaceutical industry, eg free lunches, pens, funds for research, consultancies, support for professional societies.<sup>1,2</sup>

Andrew Herxheimer writes about new associations that are developing, such as those between the pharmaceutical industry and patients' organisations.<sup>3</sup> Grants from companies can help patients' organisations 'grow and be more influential but can also distort and misrepresent their agendas'.

In an article on public relations, Bob Burton and Andy Rowell describe the third party technique—separating the message from an apparently self-interested messenger.<sup>4</sup> Hence the importance of opinion leaders.

Silvio Garattini and others provide a guide to ethics committees on trial protocols that do more to market a drug than to advance understanding.<sup>5</sup>

A systematic review by Joel Lexchin and colleagues shows that drug studies funded by the pharmaceutical industry are more likely to be associated with outcomes that are favourable to the sponsor's product than research funded by other sources.<sup>6</sup>

Other articles examined rules and guidelines on doctors' relations with drug companies<sup>7</sup>, and the role of pharmaceutical advertising in medical journals.<sup>8</sup>

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## Evidence b(i)ased medicine: review of a study carried out by the Medical Products Agency

Also part of the BMJ theme issue covering the relationship between doctors and the pharmaceutical industry is an article by Björn Beermann and colleagues of the Medical Products Agency (MPA) in Sweden.<sup>1</sup> This paper deserves special mention as the study was the subject of a presentation by Björn Beermann at the 2002 ISDB Workshop and General Assembly.

The study investigated the relative impact on publication bias caused by multiple publication, selective publication, and selective reporting in studies sponsored by drug companies.

The researchers examined 42 placebo-controlled studies submitted to the MPA as a basis for securing marketing approval for 5 selective serotonin reuptake inhibitors. When applying for marketing approval for a new drug, applicants must submit complete reports of all studies (published and unpublished) carried out on the drug, including those containing unfavourable results. The researchers then identified 38 published versions of the submitted studies and compared the results.

The study found evidence of duplicate publication, selective publication and selective reporting, with selective reporting (the tendency to publish only the more favourable results) being the major cause for bias in the published data. For example, although both intention to treat analyses and per protocol analyses were available in the submissions to the MPA, only 24% of stand-alone publications (a published article reporting results from a single submitted study) reported the usually less favourable intention to treat results.

The authors acknowledge that the results of their study 'should not be used to dispute the value of systematic literature reviews and meta-analyses in general'. However, they caution that 'for anyone who relies on published data alone to choose a specific drug, our results should be a cause for concern. Without access to all studies (positive as well as negative, published as well as unpublished) and without access to alternative analyses (intention to treat as well as per protocol), any attempt to recommend a specific drug is likely to be based on biased evidence.'

1. Melander H, Ahlqvist-Rastad J, Meijer G, Beermann B. Evidence b(i)ased medicine—selective reporting from studies sponsored by pharmaceutical industry: review of studies in new drug applications. *BMJ* 2003;326:1171-3. Available from: <http://bmj.com/cgi/reprint/326/7400/1171.pdf>.

## Gefitinib should not be approved, Public Citizen tells FDA

In the March 2003 edition of the ISDB Newsletter, Rokuro Hama and Keiko Sakaguchi discussed the controversy in Japan over the approval of the new anti-cancer drug gefitinib (Iressa, AstraZeneca).

The US watchdog group, Public Citizen, took note of the situation in Japan and on 1 May wrote a letter to the Food and Drug Administration (FDA) attempting to dissuade them from approving the drug for use in the US.<sup>1,2</sup> Clinical trials that had already been conducted showed no benefit associated with gefitinib, Public Citizen said.

'The FDA would be putting patients in jeopardy by approving a drug that is already showing itself to be ineffective and dangerous,' said Dr Sidney Wolfe, director of Public Citizen's Health Research Group.

Nevertheless, on 5 May 2003, the FDA approved gefitinib under an accelerated approval for the third-line treatment of non-small cell lung cancer.

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2. Cancer drug Iressa should not be approved, Public Citizen tells FDA [press release]. 2003 May 1. Available from: <http://www.citizen.org/pressroom/release.cfm?ID=1417>.

## Gefitinib 'hardly a wonder drug' according to *New Scientist*

A recent article in *New Scientist* by Sylvia Pagán Westphal discussed the controversial approval of gefitinib (Iressa) in the US.<sup>1</sup>

Westphal described how the Food and Drug Administration (FDA) approved gefitinib in May 2003 despite there being little scientific evidence that it works and growing concern about a potentially fatal adverse effect, interstitial lung disease (ILD). She said that

the FDA appeared to give in to pressure from patient groups and the drug's manufacturer, AstraZeneca, by accelerating the approval process.

The FDA claims that it did not find out about the significant safety concerns associated with Iressa until after a crucial meeting in September last year.

1. Westphal SP. Hardly a wonder drug. *New Sci* 2003 May 24:12-3.

# ISDB Europe Regional Workshop

## Getting the most out of pharmacovigilance

Date	Friday 31 October and Saturday 1 November 2003
Organisers	Arznei-Telegramm, Arzneimittelbrief, Pharma-Brief, Arzneiverordnung in der Praxis
Location	Arznei-Telegramm Office, Bergstr. 38A (Water Tower), D-12169 BERLIN (Steglitz)
Language	English
Issues to be addressed	<i>What is the state of the art and how can it be improved?</i> <i>Which national systems are good examples to learn from?</i> <i>How can the generation of signals be improved?</i> <i>How can transparency of signal processing be improved?</i> <i>How can information on administrative handling of data be obtained?</i> <i>How can participation in the decision-making process be established?</i> <i>How can transparency of the decision-making process be ensured?</i> <i>What is the role of ISDB journals in drug safety evaluation?</i> <i>What does ISDB expect from national and European legislators?</i> <i>How can freedom of information be achieved and guaranteed?</i>

## Updated agenda

### Friday 31 October

8.30–8.50	<b>Registration of participants</b>		c) International (WHO) —Mary Couper	15.45–17.00	<b>Workshop 3</b> <b>Chair: Wolfgang Becker-Brüser</b> <i>Arznei-telegramm</i> <b>Recent events in pharmacovigilance and what we can learn from them</b> a) Gefitinib (Iressa): What happens with ADR data from clinical studies? —Rokuro Hama b) Paroxetin (Seroxat): New ways to get information about ADRs—Andrew Herxheimer c) Hexavalent vaccines: What to do with weak ADR signals —Wolfgang Becker-Brüser d) Professional or patient reporting of ADRs, or both? —Charles Medawar
8.50–9.00	<b>Welcome addresses</b> <b>ISDB president:</b> <b>Joe Collier</b> <b>Host:</b> <b>Wolfgang Becker-Brüser</b>	11.00–11.30	<b>Coffee break</b>		
9.00–9.15	<b>Who is who?</b> Short introduction of the workshop participants	11.30–12.30	<b>Workshop 2</b> <b>Chair: Walter Thimme</b> <i>Arzneimittelbrief</i> <b>Systematic monitoring of ADR data</b> What can we learn from different countries? What can be achieved by pharmacovigilance centres? a) France—Elisabeth Polard b) Germany (Bremer Modell) —Hans Wille		
9.15–10.00	<b>Lecture</b> <b>P.S. Schönhöfer</b> <b>How can data on adverse drug reactions (ADRs) be obtained and what are the problems?</b> What sort of data do we need? What are the best methods for obtaining data? What are the shortcomings and pitfalls of ADR monitoring and processing? How is an early discussion of new ADRs best organised?	12.30–13.00	<b>Discussion</b>	17.00–18.00	<b>Discussion</b>
10.00–11.00	<b>Workshop 1</b> <b>Chairs: Heiner Berthold / Bruno Müller-Oerlinghausen</b> <i>Arzneiverordnung in der Praxis</i> <b>Spontaneous ADR monitoring system</b> What can we learn from different countries regarding spontaneous reporting? a) UK—Helen Barnett b) Sweden—Björn Beerman	13.00–14.00	<b>Lunch</b>	<b>Evening</b>	<b>Documentation</b> Drafting of reports and resolution by rapporteurs
		14.00–14.45	<b>Lecture</b> <b>Chair: Jörg Schaaber</b> <i>Pharma-Brief</i> <b>EMA in focus: the role and policy of EMA with respect to detection, reporting, processing and decision-making in drug safety issues and events</b> a) Are EU authorities willing and able to communicate with ISDB bulletins? —Rudolf Bass b) Lobbying in European parliament and EU administration		<b>Saturday 1 November</b>
		14.45–15.15	<b>Discussion</b>	9.00–12.00	<b>Discussion of draft ISDB Europe resolution on pharmacovigilance</b> ISDB members and recognised correspondents only
		15.15–15.45	<b>Coffee break</b>	12.00	<b>Close and farewell</b>

For more information, please email Wolfgang Becker-Brüser at [ati@berlin.snafu.de](mailto:ati@berlin.snafu.de). If you would like to register for the workshop or reserve a hotel room, please fill out the form on page 15.

# Workshop registration and hotel reservation

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## A. Workshop registration

- I wish to participate in the ISDB Europe Regional Workshop on Friday 31 October and Saturday 1 November 2003

Name 

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Street 

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Postcode 

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 City 

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Country 

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Bulletin/organisation 

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Phone 

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 Fax 

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 Email 

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## B. Hotel reservation

We have booked rooms in a hotel a few bus stations away from the *Arznei-Telegramm* office (for passionate walkers it is within walking distance).

- I would like to make a hotel reservation

Name 

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Bulletin/organisation 

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\_\_\_ Single room(s) (€85 per room)

\_\_\_ Double room(s) (€90 per room)

From (check-in date) 

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 To (check-out date) 

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Date 

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 Signature 

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Please fill in this form and fax to (+49 30) 79 49 02 20