President’s report

Joe Collier  jcollier@sghms.ac.uk

In many ways this has been my quietest few months as president since I took over in 2002. Apart from hosting the meeting of the executive group in late May, I have been working on the ISDB/WHO Essential Medicines Project, and have met with Bozidar Vrhovac to discuss progress on the review of our constitution (Bozidar chairs the review group). In the WHO Medicines Review Project, we now have reviewers for all of the topics (single drugs and sections), with authors signed up from Australia, Belgium, Canada, Croatia, Germany, India, Israel, Italy, and the UK. Work seems to be going to plan, although coordinating the project has consumed rather more time than I had expected. Turning to the ISDB constitutional review, the full committee will be presented with the working group’s proposals at its meeting in Verona in September 2004.

In contrast with my quiet ‘public’ arena, there has been the personal turmoil of stepping down as editor of the UK Drug and Therapeutics Bulletin at the end of June. Some 40 colleagues, old and new, attended a dinner to wave me goodbye. After 35 years with DTB (I edited my first article in 1969 and took over editorship in 1992!), it was all rather sad. But, I have no doubt it was the right decision as it will give me a few years to explore other interests before I fully retire from my university post in 2007. When I offered my resignation, the Consumers’ Association (publishers of DTB) asked if I would continue to represent DTB at ISDB. This I was delighted to do, and as you will know, my colleagues on the ISDB Committee asked if I would also stay on as president until the 2005 Melbourne General Assembly (many of you will remember that, in the 1990s, Andrew Herxheimer remained ISDB president for several years after his retirement). I feel honoured and flattered that my colleagues on the committee have asked me to continue in this way.

Before closing, I should remind you that planning for the 2005 General Assembly starts in earnest in Verona. If you have any ideas about the format or contents of the Melbourne meeting (see p.2 for dates etc. and p.9 for proposed program), please let a member of the committee know as soon as possible, and at least by the beginning of September.

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

© 2004 International Society of Drug Bulletins
Three more applications are under review.

The ISDB committee executive group (president, general and membership secretary, and treasurer) met in London on 21 May 2004.

Membership news

Review of current members: As reported in the last issue of the newsletter, a program to evaluate existing full members of ISDB (as required by the constitution) has begun with a review of the bulletins based in Spain: Boletín Terapéutico Andaluz, Butlleti Groc, Boletin de Uso Racional del Medicamento from Spain, Farmaka I Fokus from Sweden, and Drug Bulletin from Kazakhstan (the latter was mistakenly reported to have been granted recognised correspondent status in the last issue of the newsletter). The recognised correspondents are Arzneimittel, therapie, kritik from Germany and Drug Information Bulletin from Nepal.

The review of current members is also helping to provide information for the ISDB database of member bulletins.

New membership applications: There are three new full members and two recognised correspondents to welcome to the society. The full members are Boletin de Uso Racional del Medicamento from Spain, Farmaka I Fokus from Sweden, and Drug Bulletin from Kazakhstan (the latter was mistakenly reported to have been granted recognised correspondent status in the last issue of the newsletter). The recognised correspondents are Arzneimittel, therapie, kritik from Germany and Drug Information Bulletin from Nepal.

Three more applications are under review.

Website

There are important new features for ISDB members on the ISDB website <www.isdweb.org>.

The ISDB website now includes an area for members only. Access to the area is protected by a password, which is available to members on application through the website. There are three features of the members-only area:

Forum: This is an interactive area where members can take part in discussion about a particular topic, or post a query or an alert for other members. Andrea Tarr will act as administrator and coordinator of the forum.

Library: Members can post articles they think will be of interest to other ISDB members.

Members can post articles they think will be of interest to other ISDB members.

I welcome any comments you have on these new features, or on other parts of the website.

Treasurer’s report

Andrea Tarr
andrea.tarr@virgin.net

Membership fees: Requests for membership fees were sent out by email at the beginning of May. Thanks to all those members who have already paid.

Finance report: An interim finance report was prepared for the committee in May. It includes the expected income and expenditure in connection with the ISDB/WHO Essential Medicines Project.

Database of ISDB bulletins’ indexes: This area will contain indexes of articles published by ISDB member bulletins. Indexes will be grouped according to language: English, French and Spanish. The database has the potential to be a valuable resource for ISDB members, but its success depends on ISDB members regularly providing their bulletin indexes for inclusion in the database. It is also hoped that some bulletins will be able to provide access to the fully published articles via the index. The database will be prepared by staff at Dialogo sui Farmaci, Italy. Please contact Maria Font, webmaster, to arrange for your bulletin index to be included in the database.

Library: Members can post articles they think will be of interest to other ISDB members.

I welcome any comments you have on these new features, or on other parts of the website.

ISDB General Assembly 2005

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<tr>
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<td>11 September from 3 pm (registration)</td>
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<td></td>
<td>12–14 September 9.00 am – 5.00 pm</td>
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Why was your bulletin started?

Our organisation came into existence in 1992 in the wake of tragedies occurring due to use of Imodium (loperamide hydrochloride) drops, an antidiarrhoeal that resulted in post-diarrhoeal ileus in children. During the campaign against this sometimes fatal medicine, it was realised that there were several other medicines being sold on the Pakistani market that could create havoc and that there was no independent information about these (or other) drugs.

So, ‘Association for Rational Use of Medications in Pakistan’ (ARUMP) was formed, and a newsletter named TheNetwork’s News Letter started. Although initially it was to be just a newsletter about organisational activities, it soon became a source of credible independent information about medicines; the only one of its kind in the country.

It helped take the concept of rational use of medications to prestigious institutions such as the College of Physicians and Surgeons Pakistan. When ARUMP started its campaign to ban some drugs, its effective messages resulted in incidents of pharmacy holders in some peripheral cities burning the whole stock of some drugs, such as chlormezanone.

Later, the publication was renamed TheNetwork’s Drug Bulletin and after some years, ARUMP became ‘TheNetwork for Consumer Protection in Pakistan’.

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

The first issue of TheNetwork’s News Letter was published in February 1992. It was, and it still is, a bimonthly publication. With this periodicity and zeal, 12 years have flown by.

Who receives the bulletin?

Drug Bulletin’s readership includes: policy-makers, journalists, doctors, pharmacists, paramedical staff, civil society organisations, industry, health researchers, students of medical colleges, health activists and workers and consumers of health care products and services.

It is primarily distributed through surface mail. Briefs of important articles published in the last 4 issues are also available on our website <www.thenetwork.org.pk>.

Recently, TheNetwork has decided to link this publication (along with three others) with its membership drive. Consumers are encouraged to become members of the organisation and get this publication free.

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

I graduated in medicine from Rawalpindi Medical College in 1988, and then did postgraduate studies in paediatrics with the College of Physicians and Surgeons Pakistan. I am presently pursuing a Masters in Health Communications.

In addition to editing TheNetwork’s Drug Bulletin, I am also responsible for bringing out a bimonthly health magazine Sehat aur Sarfeen in Urdu, our national language. Currently, this publication is distributed to about 8000 readers all over the country.

My role at the bulletin is that of editor. I oversee the entire publication process, from content planning to writing and commissioning, to interacting with the illustrator to the final design of the print copy.

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

With me on the editorial team are 2 other members. One of them, Nabeela Aslam, is a journalist with a masters degree in English Literature, and the other, Usman Tariq, is the graphic designer. We usually outsource the illustrations.

Apart from this 3-member team, we also have at hand the expert advice and...
Do you liaise with other like-minded organisations in your area?

TheNetwork for Consumer Protection in Pakistan has many focus areas, one of them being pharmaceuticals. Our pharmaceutical work includes projects on promoting rational use of drugs, essential medicines, drug pricing, banned drugs, and Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Working in tandem, the drug bulletin team and the pharmaceutical project team at times liaise with the Ministry of Health, WHO and some of the professional bodies and individuals in the health sector. But overall, we find it hard to make easy partners due to the deep penetration of the pharmaceutical industry in the health sector.

What kind of material do you cover in your bulletin?

The publication process has evolved over the 12 years; each publication now has the following 5 sections:

• **Cover story**: a feature article on a selected topical subject.
  - Exploratory studies recently undertaken by TheNetwork and published in the bulletin include types of spoons used by consumers to administer syrup medications, the state of drug management systems in the country, and adherence of general practitioners to DOTS (Directly Observed Therapy Short course) strategy for treatment of patients with tuberculosis. [DOTS is the WHO recommended strategy for global tuberculosis control.]
  - Other issues covered include some interventions, such as developing standard operating procedures for storage and dispensing of drugs and prescription handling, and conducting the first international Promoting Rational Drug Use course in Pakistan.

• **Campaign update**: International drug market sources are scanned for decisions about banning, or withdrawing drugs, and proposed changes to labelling or product information. This is viewed from the local perspective and any discrepancy is reported in the bulletin and issues taken up with the appropriate authorities.

• **National drug market information**: is surveyed periodically for essential medicines that have not been available.

• **Drug news and media watch**: Important news items on drugs (with special emphasis on banned drugs, unethical promotional practices, drug pricing etc.) are reported.

• **Health policy**: Public health policy and relevant international developments are critically analysed.

• **Dialogue**: Readers’ section in which requested information is provided and concerns published.

What are your main challenges for the future?

Economic sustainability and impact assessment were, and will be, a challenge. Publications like this—that do not accept any advertisements and keep a critical eye on the pharmaceutical industry and its backdoor relationship with the Ministry of Health—always have economic problems. Presently though, we do have funding for 3 years, but beyond that, we see a struggle again.

Also, in a country where there is no process of continued medical education of health professionals and where professionals are more attuned to the promotional enticements of industry, it is a challenge to get health professionals to respond to our readership survey questionnaires. At present, we are working on supplementing our postal readership survey with periodic meetings of readers in our geographical focus area to better understand the impact of the bulletin.
Increasing pressures on drug budgets at hospital, regional and national levels have focused attention on the role of pharmacoeconomic analyses to support drug selection decisions. These may be decisions to list a drug on a formulary for primary care, a hospital or managed care scheme; or to include a drug for reimbursement or subsidisation by insurance or national health plans. As the name suggests, pharmacoeconomics is the application of the principles of economics to pharmaceuticals and the emerging discipline has its own jargon, which can sometimes act as a barrier to its use. However, the principles that underpin the techniques used are relatively straightforward.

Pharmacoeconomics is not about cost savings, rather it is the discipline of studying the relationship between the benefits of a drug treatment (improved efficacy, better side effect profile etc.) and the costs of the drug. Implicit in this statement is the importance of the clinical evidence about a drug and this information is always considered first. It is the clinical evidence that determines which kind of economic analysis is appropriate.

If a drug being considered for listing or subsidisation offers no benefits over existing treatments, then the rational economic decision is to pay no more for the drug, and cost-minimisation analysis is the appropriate form of economic analysis. Where the two therapies are considered clinically equivalent in efficacy and safety, only the costs of the interventions need to be compared. However, the cost of the intervention is not simply the acquisition cost of the drug. There may be differences between therapies in the administration equipment required, the amount of health professional time for drug administration and the drug monitoring and tests required. These differences in direct medical costs for each drug need to be included in the economic analysis to determine an ‘equivalent’ price for the new and the established therapies. While conceptually straightforward, there are a number of technical issues that need to be addressed in performing a cost-minimisation analysis—identifying the appropriate comparator treatment for the new drug, establishing the clinical equivalence of the drugs and equi-effective doses of the therapies, and deciding which costs (other than drug costs) need to be included in the analysis.

Where the clinical evidence identifies a benefit of treatment over existing therapies, cost-effectiveness analysis is the appropriate form of economic evaluation. A cost-effectiveness analysis is based on quantifying the differences in the benefits of the new drug compared to an existing treatment and the differences in costs between the new and existing therapy. What is derived is an incremental cost-effectiveness ratio (ICER) that is a measure of the extra cost required to obtain the extra benefit(s) with the new drug. The outcome of a cost-effectiveness analysis may be expressed in terms such as cost per life saved or cost per life-year gained, or in clinical terms such as cost per additional cure, or cost per stroke avoided. Sometimes it is appropriate to consider changes in quality of life as well as quantity of life, so the outcome life-years can be adjusted by a quality weight. The outcome becomes a cost per quality adjusted life-year (QALY), and this is referred to as a cost-utility analysis.

Cost–benefit analysis requires that the benefits of a treatment be quantified in monetary terms. However, there are ethical difficulties in assigning a monetary value to outcomes such as a life saved or a life-year gained. Therefore cost–benefit analysis has a limited role in pharmacoeconomics. While the basic methods are conceptually straightforward, assembling the data to perform a reliable economic evaluation can be difficult. There are numerous texts and published papers addressing various aspects of the techniques, and some of the methods are still in evolution. Published economic evaluations are often of limited value to decision makers—the perspective of the analysis (hospital, societal, third-party payer etc.) may not be relevant, the methods of delivering care and subsequent costs applied may be different to the local context, and often there are no relevant studies available at the time decisions need to be made. In an increasing number of jurisdictions, authorities are requiring that economic evaluations be provided as part of an application to list or subsidise a drug. Guidelines for the preparation and standard reporting of pharmacoeconomic studies are available, and these are an attempt to make economic evaluations sufficiently transparent that they can be used with some confidence by decision makers.

Decision-making is a complex process and the decision to list or subsidise a drug will not rest solely on the results of a pharmacoeconomic analysis. What is accepted as ‘cost-effective’ will depend on the setting and reflect the community’s ability to pay for health care. The ethical and social values of the community will also influence decision-making. A drug used by a small number of patients for whom there are no other treatment options may not be ‘cost-effective’, but the community may still believe it is worth funding the drug. This does not diminish the value of pharmacoeconomic analyses, as the decision is informed by knowledge of the trade-off between the benefits and the costs of the drug.

Pharmacoeconomic analyses are likely to play an increasingly important role in drug selection decisions in the future as new drugs with substantially increased costs but offering only small clinical gains seek their place in the pharmaceutical marketplace.

Suggested reading:
Conference reports

International conference on patient safety, pharmacovigilance and ADR reporting
26–28 May 2004, Bricheni, Moldova

Natalia Cebotarenco  druginfo@mtc.md

The consumer organisations DrugInfo Moldova (a member of ISDB) and Swedish Consumer Institute for Medicines and Health (KILEN) held a conference on ‘Quality and Safety of Medicines—Patient Safety’ in Bricheni, Moldova, 26–28 May 2004.

Government and consumer representatives from Moldova, Kyrgyzstan, Ukraine, Uzbekistan, Tajikistan and Kazakhstan worked together to improve reporting of adverse drug reactions in their countries by health professionals and consumers, in the interests of patient safety. This was the first conference of its kind for these countries, which are undergoing major challenges to public health, and where access to medicines and safety issues are critical.

A greeting letter to participants from Dr Mary R Couper, Quality Assurance and Safety: Medicines, Essential Drugs and Medicines Policy, WHO, Geneva, mentioned that the conference coincided with a new initiative—the WHO’s Patient Safety Alliance. This will cover all aspects of patient safety in health care facilities, including safe drug use. WHO believes that consumers have a vital role to play in reporting adverse reactions to medicines.

The conference was structured to provide participants with the tools and inspiration needed to establish systems that capitalise on consumers’ experiences. Participants examined experience with such schemes in various countries and the role of such approaches in complementing existing professional-based systems for the reporting of adverse drug reactions. The participants emphasised that present reporting systems do not give enough information about adverse drug effects. DrugInfo Moldova presented the results of a survey they conducted during one week in May 2004 in Moldova. The main goal of the consumer survey was to describe consumers’ awareness and attitudes to the safety of medicines. During the last three years, 14 adverse drug reactions were registered through the professional-based system according to official data; these were mainly reactions to vaccination. But what is the rate in reality?

Three hundred and four consumers were surveyed in three polyclinics of Chisinau, the capital of Moldova. Results indicate that 83.2% of respondents believed that any medicine may have a risk of harm; moreover, 74.7% of respondents said they had had an adverse drug reaction during their lifetime and 96.6% of them had stopped taking medicines for that reason. In 58.6% of these cases the decision was made by the physician, in 4.9% by the pharmacist and 36.5% of consumers stopped taking medicines without informing their doctors. In response to the question ‘Who provides information about safety of medicines to you’, only 53.9% of consumers indicated that physicians talked with them about adverse drug reactions, 7% indicated that pharmacists focused their attention on possible adverse drug reactions, 7% indicated that pharmacists focused their attention on possible adverse drug reactions, and 3.7% highlighted the role of the nurse. However, 35.5% of consumers tried to find information from different sources by themselves.

During ‘small groups discussions’ the participants explored the problems around safety of medicines and pharmacovigilance and their needs and possibilities for establishing systems for a medicine safety program. The participants also made a personal plan for their safety of medicine program in their own homes—how to establish reporting facilities for professionals and consumers—and how to collaborate with each other. The enormous interest among the participants and their great delight at exchanging experiences about working conditions, medicine problems etc. was striking.

One of the problems expressed by many of the participants was their huge lack of equipment, like computers and Internet access. KILEN, as the collaborating partner...
in this conference and project, will start a subscription in aid of computers in Sweden and forward them to organisations in need.

The conference ended with a discussion and adoption of the Bricheni Declaration that set out the problems and issues to be tackled. It is in Russian and will be translated into English. The Bricheni Declaration will work as a platform for future engagement and work in the region. Hopefully this is the start of a three-year project which aims to involve professionals and consumers in ‘safety thinking’ when it comes to medicines and to encourage organisations to start working in the field of pharmacovigilance.

ISDB at ICIUM 2004* report

Mary Hemming  mhemming@tg.com.au

From 30 March to 2 April 2004, around 450 multidisciplinary researchers, national and international policy makers, patient advocates and clinicians, representing nearly 80 countries, gathered in Chiang Mai, Thailand, for the second International Conference on Improving Use of Medicines (ICIUM 2004). To ensure an interactive conference across multiple interest areas, the number of participants at ICIUM 2004 had been restricted.

The first ICIUM conference in 1997 was a milestone, and resulted in consensus on interventions to improve medicine use and a definitive global research agenda to increase understanding of issues that impact on the appropriate use of medicines. Participants at ICIUM 2004 reported on and reviewed the advances made since that first meeting. At the same time, there was concern expressed over the continued, widespread improper use of medicines. While agreeing that the unprecedented level of funding now available to increase availability of medicines in nonindustrialised nations is essential, they cautioned that the increased access to quality drugs is beneficial only if the medicines are used properly.

The program for the meeting was ‘overflowing’. Sessions, mostly concurrent, started at 7.45 am each day and yet there was still no time allocated to view the many posters on display. The conference organisers were aware that time constraints had resulted in some important areas being omitted from the program. So on the first day of the conference the organisers offered to make rooms available in the evenings for people to hold impromptu sessions on areas of interest. Andrew Herxheimer and I (acting as ISDB representative) responded quickly and we managed to secure a room for an hour to hold a session on ISDB.

A notice about the session was displayed, and approximately 20 people (including a few current ISDB members) attended the session at which I was able to talk about ISDB and its work. The following people attended:

- Zaheer-U-Din Baber, School of Pharmacy, University College Sedaya International, Kuala Lumpur, Malaysia
- Dr Douglas Ball, Faculty of Pharmacy, Kuwait University, Kuwait
- Natalia Cebotarenco, DrugInfo, Moldova
- Suntharee T Chaisumritchoke, Faculty of Pharmaceutical Sciences, Chulalonkkorn University, Bangkok, Thailand
- Margaret Ewen, HAI, The Netherlands
- Anwar Gilani, Professor of Pharmacology, The Aga Khan University, Karachi, Pakistan
- Ambrose O Isah, Clinical Pharmacologist, Department of Medicine, College of Medical Sciences, Benin City, Nigeria
- Niyada Kiatying-Angsulee, Faculty of Pharmaceutical Sciences, Chulalonkkorn University, Bangkok, Thailand
- Maneerat Layton, Faculty of Pharmaceutical Sciences, Khon Kaen University, Thailand
- Pranaya Mishra, Department of Pharmacology, Manipal College of Medical Sciences, Nepal
- Kirsten Myhr, RELIS Ost Drug Information Centre, Oslo, Norway
- Waris Qidwai, Associate Professor, Family Medicine, Aga Khan University, Karachi, Pakistan
- Klara Tiscoki, Faculty of Pharmacy, Kuwait University, Kuwait

At the meeting copies of various ISDB documents were distributed to attendees. The documents were:

- the paper that describes ISDB and its activities (prepared by Andrea Tarr and published in a previous newsletter)
- an issue of an ISDB Newsletter
- a membership application form.

Apart from this dedicated session, the work of ISDB was mentioned on several occasions by different speakers in the various plenary sessions. Most of these references were made by WHO personnel, who at other times were also actively directing people to me to find out more about ISDB.

* ICIUM 2004 is part of a global effort to improve the use of medicines, particularly in nonindustrialised countries. The ICIUM 2004 Conference was collaboratively organised by the Boston University School of Public Health Center for International Health, Harvard Medical School Department of Ambulatory Care & Prevention, International Network for Rational Use of Drugs, Management Sciences for Health through its Rational Pharmaceutical Management Plus (RPM Plus) and Strategies for Enhancing Access to Medicines (SEAM) Programs, the Thai Network for Rational Use of Drugs, and the World Health Organization Department of Essential Drugs and Medicines Policy.

Major support for the conference was provided by the Bill & Melinda Gates Foundation, Canadian International Development Agency, Swedish International Development Cooperation Agency, US Agency for International Development, World Health Organization (WHO)—Geneva, WHO Country Office for Thailand, and WHO Regional Office for South-East Asia (SEARO). In addition, more than 20 other organisations contributed to the success of the conference by sponsoring attendance of multiple participants.
Letter to the editor

The demise of the Drug Information Newsletter

Ti Teow Yee (editor-in-chief of DIN from 1983 until its demise in 2004) tityee@singnet.com.sg

The demise of a 22-year-old drug bulletin occurred this year, not due to a lack of readership or funds. When publication of the Drug Information Newsletter (DIN) was discontinued it was financially sound with a readership of about 3000. By all indications it was well received by its subscribers and this was one of the reasons why it survived 22 years. To understand the fate of this drug bulletin, perhaps it is worthwhile to trace its history.

The DIN was started 22 years ago by a few members of the Department of Pharmacology at the National University of Singapore who believed strongly in the need for getting unbiased, evidence-based information about drugs and drug usage to the practitioners. However, to be an independent drug bulletin, financial support had to come from outside the pharmaceutical industry. DIN was started with a grant from the Singapore Turf Club, which in those days regularly donated to university research/educational projects. Initially the bulletin was sent to all medical and dental practitioners and pharmacists free of charge. A survey of the readership was done a few years after its launch and the response to the bulletin was good.

When the grant ran out, DIN was put on subscription. DIN was published quarterly and consisted of 4 pages in 2 sheets of paper which were conjoined. The subscription rate was S$10 per year which would cover the cost of printing and postage. Clerical work (typing and mailing the bulletin, maintaining the record of subscribers) and accounting were done by the office staff of the Department of Pharmacology and were not factored into the cost of publication. After a trial period of a year we found that the work involved in maintaining the bulletin on subscription was too much for the department’s clerical staff to handle. The solution to this was to approach the Singapore Medical Association and the Pharmacy Association to buy the bulletin in bulk and send it to their members with their other monthly mail.

Fortunately, both associations saw the need for an independent drug bulletin and supported us since. Practitioners who were not members of either association could subscribe individually. This arrangement was ideal for us as we did not have to advertise, maintain a record of a large number of subscribers, handle the finance and mail the bulletin. The administrative work was reduced substantially.

However, our problem was to get committed persons to join the editorial board. Over the years we tried to recruit new members to the editorial board but without much success. I am sure all the readers of this article are familiar with the time and energy involved in producing an issue. First, a topic that was relevant to local practice was selected and an appropriate author identified. A member of the editorial board would then approach the potential author and discuss the focus of the topic. Once the manuscript was submitted the editorial work would begin. There was not only a lack of persons who were willing to serve on the editorial board; we also had increasing difficulties getting authors to contribute to the bulletin.

The main reason for this is the increasing focus by the university on publishing in international refereed journals and thus staff members are under the stress of ‘publish in international refereed journals, or perish’. No credit is given for publications in a local drug bulletin and neither is the work on the editorial board of DIN recognised. Therefore, the work done for DIN is not rewarding professionally (in terms of promotion) or financially. It is little wonder we could not find new members for the editorial board.

Over the years the members of the editorial board have gradually dwindled, due mainly to retirement. By this year there were only two members left and as such we were forced to discontinue the publication of DIN.

Could the closure have been avoided? Under the present circumstances I do not think so.

[This article is a personal view.]

[Editor’s note: We welcome letters (up to 400–500 words) from ISDB members on this or other issues that might be of interest to readers.]

Media round-up

Are statements made in medical promotional leaflets correct?

Wolfgang Becker-Brueser has kindly provided this summary of an article1 published in Arznei-Telegramm, 13 February 2004. The full article (in German) is available at <www.di-em.de/data/at_2004_35_21.pdf>.

Medical decisions are determined more by information that is produced and distributed by pharmaceutical industry representatives (‘promotional’ literature) than by critical independent judgment of scientific literature. In order to investigate the reliability of promotional medical information, the authors asked general practitioners (GPs), randomly selected from the North Rhine area, to participate in a study to evaluate the material they receive. Of the 54 GPs approached, 43 (80%) took part and each was asked to collect all printed information given or sent to them by the pharmaceutical industry in June 2003. A total of 293 different promotional leaflets were collected during this period. Of these, 118 did not contain any medical statements (eg they contained travel information, or...
The 175 evaluated promotional leaflets contained a total of 520 different definite medical statements. Of these 520 statements, 218 (42%) included at least one transparent reference. These statements were evaluated to assess their congruency with the cited literature; 41 of the promotional claims were consistent with the references (ie 8% of the total 520 promotional claims), or 19% of the 218 promotional claims giving at least one transparent bibliographical reference.

The study showed that information in 94% of the promotional leaflets distributed by the pharmaceutical industry containing at least one medical statement is not supported by traceable or valid scientific data. The conclusion was that information in promotional literature about pharmacological products’ safety and efficacy is distorted, which means that the quality of doctors’ prescribing behaviour could be jeopardised. Taking into account the resulting potential medical dangers and growing economical burden for the population, governments and administrations must take fast and decisive steps to eliminate inappropriate advertising claims.


Regulating the regulators

Joe Collier has written a very interesting review1, published in The Lancet, on a book written by Charles Medawar and Anita Hardon entitled Medicines out of control? Antidepressants and the conspiracy of goodwill.2

Both authors are well known consumer advocates in public health issues. In this book, they look at drug regulation and, using selective serotonin reuptake inhibitors (SSRIs) as an example, discuss the way they were introduced and marketed. It appears that the interests of public health were not always the most important objective. The role of pharmaceutical companies, regulatory bodies and governments is explored.

Collier considers the book is ‘beautifully written, painstakingly researched, thoroughly referenced, powerfully and persuasively argued, and eerily up to date’.

This book sounds like fascinating reading for anyone interested in the area of drug regulation.


Draft agenda for ISDB committee meeting

Verona, Italy, 15–16 September 2004

This is the draft agenda for the next meeting of the ISDB committee. ISDB members are invited to comment on agenda items and suggest additional topics for discussion by the committee. Please send your comments to Andrea Tarr (ISDB coordinator: <andrea.tarr@virgin.net>) by 6 September 2004.

Wednesday 15 September

9.30 Welcome

9.50–11.50 Reports from ‘officers’ of the Society, and discussion

12.00–1.15 Reports from the regions

Europe (including pharmacovigilance workshop and declaration)
(Walter Thimme)

West Asia and Middle East (Gita Fernando)

East Asia and Pacific (Rokuro Hama)

Central and Eastern Europe (Ksenja Makar-Ausperger)

America (Benoit Marchand)

Discussion about the role of the regions and regional meetings

Tuesday 18 September

9.00–1.00 Planning for the General Assembly, September 2005

Structure of sessions and content

Lectures and workshops

Business meeting (the general assembly of members)

Time for the new committee to meet

Social program

General organisation

Sponsors

Help for members with travel costs, decide criteria for giving help

Opening and closing ceremony

Is there a need for sub-committees to look after different components?

Satellite meetings for the regions

2.00–3.00 Conflicts of interest and relationships with outside bodies

3.00 Any other business

Dates of next committee meetings

3.30 Close