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International Society of Drug Bulletins
Newsletter
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President's report

Joe Collier jcollier@sghms.ac.uk

It has been a hectic four months since my last report. Apart from hosting an executive group meeting in London in January, visiting Nepal for a very successful Middle East and West Asia regional meeting in February (see p.7) and trips to Geneva to further our links with the World Health Organization (WHO), there have been two opportunities to implement our policy on helping bulletins 'in need'.

The meeting in Nepal was inspiring, taking place in a beautiful hotel complex dwarfed by the Himalayas along the northern skyline. The meeting was a mixture of plenary talks, workshops, breakout groups and brainstorming sessions. Of particular importance to me was the opportunity to meet, and learn from, editors in the region who, in discussion, shared their experiences and expertise. The meeting reinforced my belief in the strength the society gains from its very diversity, and impressed on me yet again how essential it is that we hold regional meetings whenever possible.

The first episode concerning a bulletin 'in need' was completed in December, and not until after the last newsletter went to press. We learnt that the Dutch government had threatened to withdraw its funding from *Geneesmiddelenbulletin*, which could well have forced the bulletin to close. Both I, and Etzel Gysling, the Western Europe coordinator for ISDB, wrote to the Dutch Minister of Health asking him to review his position and this he did. In December we each received a personal letter from the minister telling us that the monies would continue, at least for the time being.

The second episode involved the Spanish *Butlletí Groc*, which was being taken to court by the multinational company Merck Sharp and Dohme. On behalf of the society I wrote a note supporting *Butlletí Groc* which was widely disseminated on the web. To my great delight the judge dismissed the company's claims (see p.3). While our influence was small, I am sure it helped. Whatever else,

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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.

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the letters, with their wide circulation, will have raised our profile as a serious and concerned society with a voice to be heard.

The fruits of my negotiations with the WHO can be seen on p.4. I do hope members of the society will offer to write the various reviews as outlined. I am in no doubt that such collaboration with the essential medicines arm of WHO can only be seen as an endorsement of our place on the world stage when it comes to the formulation of drug policy.

Finally, I would like to ask you to read the interview on p.5 of the newsletter. You will remember that Benoit joined the ISDB committee in December last year. Here is a chance to learn more about him.

Secretary's report

Maria Font
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In the last three months I have undertaken the following activities as membership secretary:

1. **Evaluation of new applications:**

   Applications for membership were received from three bulletins: one from Kazakhstan, one from Sweden and one from Spain. The Kazakhstan bulletin, *ZdravPlus* (HealthPlus), will be accepted as a recognised correspondent and the other two (*Boletin de Uso Racional del Medicamento* and *Farmaka I Fokus*) will be accepted as full members, on payment of the required fees. With these new members ISDB will have 58 member bulletins.

   Some recognised correspondents have asked about applying to become full members. Other recognised correspondents that we know publish good quality bulletins have been invited to apply for full membership. We expect at least four to five applications in the next month.

2. **Review of current full members:**

   The constitution stipulates that full members must be assessed at least once every three years. The people undertaking these assessments will vary depending on the language and geographical area. When assessments are to be done, we will be asking members to complete a questionnaire that has been developed especially for this purpose. Each evaluation will be based on the 4 most recent issues of a bulletin. We will undertake evaluations by geographical area and language. We have decided to start with the 5 Spanish bulletins.

3. **Membership database:**

   A membership database has been created that contains all the information we have about the different members. This includes names of contact people, addresses and other information such as language, geographical spread, subscription charge (if any) etc. The information is not complete for all bulletins but with everyone's cooperation will be assembled over time.

As webmaster, I have supervised an update of the website over the last two months. In addition, with the help of Etzel Gyzling and Jose Maria Recalde, I am reviewing ways of optimising the website. We are planning to introduce a new area for members that will require members to register to gain access. This area will include the ISDB mailing list so this should allow better communication between members. Other information we hope to include will be an index of the most recent bulletins published and also the ISDB newsletter. We expect this area to be ready for an initial test period from April and after it has been tested it will be available to all members. **If you would like to collaborate with the web group and help with the testing, please contact me.**

Treasurer's report

Andrea Tarr
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A report showing the income and expenditure of ISDB in 2003 has been prepared together with an outline of the expected income and planned expenditure for the remainder of the current committee's term of office (until September 2005). The main change from last year's spending is an increase in the amount allocated for development of the ISDB website, which we hope will become a valuable service and resource for members. Monies will need to be allocated for organising one more regional meeting, and for organising the 2005 General Assembly (the details of which will be discussed by the committee when it meets in September 2004). The 2003 report and the budget for 2004 and 2005 also take account of the funding offered by WHO to help members who cannot find funding for travel, to enable them to participate in ISDB meetings. In deciding the budget, the committee has planned to leave a surplus in the account for the next committee when it takes over in September 2005.

ISDB membership fees

In the past few years, there has been a great variation in the fees paid by members. This is partly because, despite certain defined payment bands, members have been able to choose the amount they pay. This system makes it difficult to predict the likely income from membership fees and may be unfair. The committee recently decided that the fee system should be simplified in an attempt to introduce a more rational arrangement:

- For members from industrialised countries there will now be two tiers of payment depending on the budget of the publishing organisation:
  - For organisations with a budget of £5000–£20 000 (British pounds), the membership fee will be £150.
  - For organisations with a budget of more than £20 000, the membership fee will be £600.
- For members from developing countries, the fee will be £30. There will be an option for these members to apply for exemption if payment is difficult.

Please pay promptly. The society's constitution requires that the membership fee is paid within 2 months of receiving the invoice.

Coordinator's report

Andrea Tarr
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Regional meeting in Nepal

In February, I attended the workshop for members from the Middle East / West Asia region. It was a wonderful opportunity for established ISDB members to meet, and to bring potential new members in contact with the society. (See the report and photographs on pp.7–9.)

ISDB manual

Work on the ISDB manual *A practical guide to starting or strengthening a drug bulletin* is progressing. A poster to promote the manual was displayed at the International Conference on Improving the Use of Medicines (ICIUM) at Chiang Mai, Thailand, which was held on 31 March–2 April.

Four more chapters will soon be ready for circulation to ISDB members. They are: 'Principles of drug use'; 'Planning resources'; 'Design, layout and production' and 'Dissemination'. What the manual needs most, and what you as an ISDB member can provide, is a brief description of the way your bulletin does these things to illustrate the diverse ways in which bulletins go about their day-to-day business.

The manual editorial team* plans to complete the pilot version of the manual in the next few months. WHO will then circulate the pilot version widely before a final version is published, hopefully by the end of this year.

*Danielle Bardelay, Andrew Herxheimer, Rokuro Hama, Benoit Marchand and Andrea Tarr (manual project coordinator)

Dates of committee meetings

The next full committee meeting will be held on 15–16 September 2004, in Verona, Italy. In the meantime, the executive group of the committee (president, membership and general secretary, and treasurer) will meet on 21 May 2004, in London. If there are any issues you want the committee to discuss, please send me your suggestions. In sending your suggestions, remember that in September we will start planning the 2005 General Assembly (see p.4). As usual reports of the meetings will be published in the newsletter.

Letter to the editor

Letter of thanks

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To the Editor,

I would like to thank my many colleagues for their support during the recent court case brought against the Institut Catala de Farmacologia by Merck Sharp and Dohme (MSD). The case related to an article we published in *Butlletí Groc* on irregularities in the analysis and interpretation of the VIGOR trial.[1]

Dr Africa Mediavilla, the President of the Spanish Society of Clinical Pharmacology, gave evidence on our behalf and to support our position we presented approximately 25 submissions. These included letters of support from Professor Joe Collier (as president of ISDB), Dr Graham Dukes, the Major/Rector of the Autonomous University of Barcelona, The Director General of the Catalan Institute of Health, the Chairman of the Catalan Medical Association and more than 700 signatures from general practitioners and other prescribers and pharmacists in Spain, more than 200 from Latin and North America, and some dozens from other European and African countries and Australia.

The hearing took approximately one-and-three-quarter hours, rather longer than the usual 15 to 20 minutes. This worked in our favour as it gave us time to demonstrate and validate the accuracy of the information in the article.

The support we received from hundreds of people around the world was a striking demonstration of solidarity and provided global coverage to what might have been an unfortunate local incident.

At the conclusion of the trial, we released the following statement:

1. The judgment is a victory for all those involved in independent information on medicines and therapeutics with regard to any past, present or future attempt by pharmaceutical companies to meddle in these activities. Pharmaceutical companies should not pretend that a single way of thinking on their products exists. The debate on scientific issues is only possible if there is no pressure or intimidation. Hence the need for freedom of speech for the progress of science and of medical care.
2. The verdict confirms that the facts described in *Butlletí Groc* were true. It also reflects the debate on the ethics of reports and publications on medical research, and it echoes the US FDA warnings (www.pharmcast.com/WarningLetters/Yr2001/Sept2001/Merck0901.htm) to the MSD company on the contents of rofecoxib promotional material, which minimised the risk of adverse cardiovascular effects.
3. The results of scientific research are always subject to interpretation. We believe that the design, conduct and analysis of research done by pharmaceutical companies are not adequately supervised by independent bodies. The lack of transparency in these issues raises doubts on its trust.
4. Many new medicines are presented as improvements over those already available, but do not show any real relevant clinical advantage in terms of efficacy, safety, convenience or cost. Independent information and interpretation are needed in order to ensure that this does not harm patients' health nor the financial health of the National Health System.
5. We wish to express our gratitude and that of all those working in independent medicines and therapeutics information to all the institutions, scientific societies, organisations and thousands of health professionals in Spain and in more than 30 countries who have given us their support.

1. Bombardier C, Laine L, Reicin A, Shapiro D, Burgos-Vargas R, Davis B et al.; VIGOR Study Group. Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis. VIGOR Study Group. N Engl J Med 2000;343(21):1520-8.

Contract with ISDB to undertake drug reviews for WHO—a call for authors

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Following detailed negotiation, an agreement has been signed between ISDB and WHO in which ISDB will receive US$24 200 to provide WHO with a set of reviews for its Essential Medicines Programme. The project reflects the esteem in which WHO holds ISDB, and will be an opportunity to raise our profile internationally as independent, impartial and reliable advisers on drug policy. The arrangements for the project are set out below, and those individuals (or Bulletins) interested in participating should contact me (Joe Collier <jcollier@sghms.ac.uk>) as soon as possible. For the project to meet the tight deadlines, I will need to start commissioning reviews with named authors by late April or early May this year. Below is an outline of the project as agreed.

- The project will be coordinated by me, acting in an independent capacity (so not as ISDB president), and I will be responsible for delivering the drug reviews on time and in the required format.
- Authors drawn from the ISDB membership (acting either as individuals or as bulletins) will be invited to write single-drug reviews or review whole sections. There are twenty, 1–2 page single-drug reviews to be written (considering drugs for possible deletion from the Model List of Essential Medicines), and 3 detailed section reviews (considering drugs for addition or deletion from the list). The topics for the single drug reviews are: aminophylline, atropine, calcium gluconate, clonazepam, codeine, colchicine, cromoglicic acid, ergotamine, ether, imipenem/cilastatin, isoprenaline, local anaesthetic/astringent ointment, nalidixic acid, polygeline, procainamide, quinidine, spectinomycin, theophylline, topical sun protection agents, and silver nitrate eye solution. In each case, the review would be for the indication for the drug as stated in the current essential medicines list (ie ergotamine for the treatment of migraine). The topics for the section reviews are: anaesthesia, cefalosporins and ophthalmology; in each instance the drugs to be considered would be those currently named in the section.
- The single drug reviews need to be completed by 31 October (2004); the section reviews by 30 November (2004). Authors will be provided with details of how the pieces should be drafted to ensure consistency of style and content.
- Reviews, with their recommendations, should be written in English by, and accredited to, ISDB individuals or bulletins. Once submitted to WHO, the reviews will be posted on the WHO website as consultation documents from October/November 2004 for around 3 months. The reviews, together with any comments raised during the consultation period, would then be considered in March 2005 by the WHO Expert Committee on Essential Medicines which would, as appropriate, recommend changes in the Model List of Essential Medicines.
- Authors of the single drug reviews would be paid the equivalent of around US$520 for the 2 days it is estimated they would take to produce (the exact payment would be negotiated and would relate to the author's local economy). For the section reviews, which will take longer, the rate would be around US$2800 (again locally negotiable). It is expected that most of the source material used for the reviews, which would generally be secondary or tertiary material rather than original papers, would be obtainable locally or via the Internet. For papers not readily available there would be funds to enable them to be provided free as part of the project. Where WHO has published information about a product or group of products, this will be provided.
- Authors will be given around 6 weeks to produce and return their initial draft. The drafts will then be seen by independent commentators and after 4 weeks or so authors given around 2 weeks to respond to any points raised. Exact dates and timings etc. will be negotiated with each author when the commission is being agreed.
- Payment will be made to the authors in two stages—50% to be paid when the commissioning contract is signed, and 50% when the review is received Internet-ready by WHO.

I believe this is a very important project and look forward to hearing from those of you who wish to be involved. It would help if those interested in being commissioned to produce drafts would indicate which topics, if any, they prefer to review.

ISDB General Assembly 2005

Dates	11–15 September 2005	
Estimated times	11 September	from 3 pm (registration)
	12–14 September	9.00 am – 5.00 pm
	15 September	9.00 am – 1.00 pm
Host	Therapeutic Guidelines	
Language	English	
Location	Hotel Y, Melbourne, Australia	

For further information about location and venue see<www.visitvictoria.com/> and <www.ywca.net/>.

Reports from members

Boletín AIS-COIME

Benoit Marchand benitom@ibw.com.ni

AIS = Acción Internacional para la Salud (*Health Action International*)
COIME = Coordinadora Interinstitucional de Medicamentos Esenciales (*Interinstitutional Coordination for Access to Essential Medicines)*

Why was Boletín AIS-COIME started?

Under the Sandinist government (1979-1990) there had been strict control of the supply of drugs and drug information. After the change of government in 1990, one of the first actions taken by the new Ministry of Health (MOH) was to 'free' the drug market and allow the importation of drugs without any requirement for registration. As a result of these changes the number of private pharmacies increased, pharmaceutical industry representatives renewed their activities and there was widespread advertising of drugs in newspapers, on television and street posters.

To address some of these problems we started our bulletin. The first two editions were published in 1992 and they denounced the unethical practice of advertising unnecessary, inappropriate or unsafe drugs eg antidiarrhoeal drugs, strychnine and vitamin A-based sexual and brain stimulants.

These articles prompted a national campaign in the mass media and, at a television press conference, the MOH was forced to publicly support the control of drug advertising. Subsequently, offending street posters were withdrawn in the capital. This episode stimulated us to produce an independent source of information for the country.

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

It took us four years to get to the stage of publishing our bulletin on a regular basis of 3 times a year. We were able to achieve this by 1996 once we got financial support to employ a young physician full-time to develop the different activities of our organisation (AIS-Nicaragua) including information, training, advocacy, networking and research.

Working on the bulletin: from left, Carlos Fuentes, Carlos Berrios, Benoit Marchand, Ana Ara, Lester Narvaez

Who receives the bulletin?

Distribution of our bulletin is mainly through the MOH, the two medical and pharmacy faculties and various health nongovernment organisations (NGOs). It is circulated free-of-charge to the majority of more than 3000 physicians working in the country, and also to health managers, pharmacists, and medical and pharmacy students. Our main concern has been to make sure the bulletin reaches all the doctors in the MOH especially those working in remote areas. Better coordination with the MOH has improved distribution.

Over the past few years, the MOH has also been suggesting that activities based on the bulletin (e.g. analysis of articles and completion of tests), be undertaken by municipal committees for rational use of drugs and by primary healthcare doctors, as part of their continuing education.

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

I completed my medical studies in Paris in 1981 and I moved to Nicaragua in 1985. In 1988, I received 6 months training in clinical pharmacology and pharmacoepidemiology at the Catalán Institute of Pharmacology in Spain. I also completed a Master in Community Health in Liverpool.

My role at the bulletin is chief editor. I oversee the whole production process from the selection of topics and review of draft articles, through to layout and illustration.

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

Apart from myself there are 4 other medical practitioners working in AIS, one with a Master of Public Health, and one who is studying pharmacoepidemiology.

Sample copies of the bulletin

We work together in a very small room (20 m²) and have access to facilities such as a fax machine, photocopier, store, library, and a meeting room which we share with another NGO.

The printing costs alone for 9000 copies of our 16-page bulletin costs us US$1500. Most of the bulletins have been funded by European NGOs and some have been funded by the Pan American Health Organization (PAHO) office in Nicaragua.

We are involved in all AIS activities so only part of our time can be devoted to bulletin activities and the production process.

However, we are able to call on a small group of physicians and nurses from different specialties in the MOH, NGOs or private practice to act as reviewers.

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

At a national level we have a good working relationship and collaboration with the MOH Drug Information Centre that provides us with information and reviews as needed and also assists with the distribution of the bulletin. AIS is also an active member of the Interinstitutional Coordination for Access to Essential Drugs and of the National Group for the Promotion of Evidence-Based Medicine. Participants of both networks take part in the article review process.

Internationally and in addition to ISDB, we maintain links with the Health Action International network, AIS-Peru, the Catalán Institute of Pharmacology, the Essential Drugs and Medicines section of the World Health Organization, the Mario Negri Institute in Italy, and *La revue Prescrire* in France.

What kind of material do you cover in your bulletin?

The topics covered in our bulletin include drug policy issues, drug therapy (focusing on problems identified in the field in general practice), reports of research, news about activities to promote rational drug use (mainly at a national level), publications of interest, and critical appraisal of drug advertising and promotion. This latter section is scrutinised by representatives of the pharmaceutical industry who respond by visiting us or sending us letters of demand or asking for clarification. This happened recently after we published a critical appraisal of a Vioxx© advertisement together with a copy of the *Butlletí Groc* article (see p.3).

What are your main challenges for the future?

Our immediate objective is to get sufficient funding to continue our work! Also we need to increase the efficiency of our editorial team, to involve more people in producing and reviewing articles, to increase the frequency of the publication, and to maintain it as a tool for continuing education in the health service.

Physicians using the bulletin during a workshop

ISDB regional workshop (Middle East and West Asia), 19–21 February 2004, Nagarkot, Nepal

Bimal Man Shrestha dda@healthnet.org.np

A 3-day regional workshop took place in February at the Himalayan resort of Nagarkot in Nepal. The theme of the meeting, which was hosted by *Drug Bulletin of Nepal*, was 'Providing drug information to safeguard public health'. T*he Drug Bulletin of Nepal* (which is published by the Department of Drug Administration) had been represented at the ISDB general assemblies in Amsterdam and Dubrovnik, and at the regional meeting in Berlin, but this was the first time Nepal had itself hosted such an event.

In all, there were 36 participants. Of these, 15 were representatives of the 8 ISDB bulletins in the Asia sector of the region: *Drug Bulletin of Nepal*, *Drug and Therapeutics Letter* (Nepal), *Sri Lanka Prescriber* (Sri Lanka), *Rational Drug Bulletin* (India), *Drug & Health* (Bangladesh), *Drugs Bulletin* (India), *The Network's Bulletin* (Pakistan) and *BODHI* (India). Three of the participants are planning to start independent bulletins (in the Tamil Nadu region of India, in Mauritius and in Romania). There were also nonregional representatives from ISDB (3), WHO (1) and United States Pharmacopeia Drug Quality and Information Program (USPDQI) (1) and a delegation of around 18 from the host sponsors (the Department of Drug Administration, Drug Information Network of Nepal [DINoN], and professional organisations). The meeting was a mixture of plenary talks, workshops, breakout groups and brainstorming sessions.

Opening session

The meeting started in the evening of Thursday 19 February. Dr MK Malla, Chief Specialist from the Ministry of Health, was the chairperson of the inaugural session who welcomed participants to Nepal and reminded them of the great value of providing independent advice on medicines. Then Professor Joe Collier, president of ISDB, highlighted the importance of ISDB regional workshops and of the impact on society in general of drug bulletins in promoting the proper use of medicines. Next, Dr HN Acharya (Chief, Public Health Administration, Monitoring and Evaluation; Ministry of Health) spoke of the

Delegates at the workshop in Nepal

enormous potential value of the workshop in contributing to enhancing coordination between drug bulletins published by different countries and also in promoting rational use of drugs within the region. Finally Mr BB Thapa, chief editor of the *Drug Bulletin of Nepal* and Mr Bimal Man Shrestha, member-secretary of the regional workshop organising committee, expressed their hope that the workshop would be an opportunity to build strong relationships between ISDB member bulletins and also to strengthen the activities of promoting rational drug use via publication of bulletins from different sectors.

Presentations, workshops and debates

After a gathering on the roof terrace of the hotel at dawn to witness sunrise over the Himalayas, the second day of the meeting started with a presentation by BB Thapa on 'Nepalese experiences on drug policy, information and IEC (information, education and communication) materials'. Then Joe Collier, spoke on 'Why countries need local, drug bulletins'. These talks were followed by a workshop, which tackled the question 'Who does your bulletin influence—what do you want it to achieve?' It incorporated the issues of engendering trust and ownership among readers, the relationship between bulletins and the media, the role of bulletins in policy-making, communication with patients, politicians and opinion formers, empowerment of patients and knowing if you are successful.

Day 3 was mainly taken up by discussion, although during one session there was an impromptu invited talk by Professor Pijus Sarkar (*BODHI*, India) on 'Experiences of sustaining an independent drug bulletin'. Pijus, who is the founder editor of his bulletin, described his experiences when running an independent bulletin in the region. He stressed the difficulties of starting and sustaining a bulletin. A bulletin should not only be for giving information, but should try to change the prescribing behaviour of prescribers for the betterment of public health. He believed bulletins should, when appropriate, challenge doctors, authorities and pharmaceutical companies. In sustaining an independent bulletin the issues that need to be addressed are payment for contributors, careful attention to the contents, working with article reviewers, keeping to schedules, maintaining production and mailing, and assessing readers' views. Pijus stressed that starting a bulletin was relatively easy: sustaining it over years was the much greater challenge.

A round-table discussion considered editorial independence—whether it is achievable, is it a luxury and why bother about it anyway?

Dr Samir Malhotra of PGI Chandigarh summing up group discussion

Participants expressed independence as ‘not being influenced by financial or extraneous forces’. Independence was also felt to be about maintaining objectivity and impartiality. Some viewed a bulletin’s editorial board as having collective and individual responsibility for editorial independence, with the bulletin’s editor acting as guardian of the editorial board’s independence. There was general agreement that those involved in bulletin work should not have any conflicts of interest. The objective should be to think in such a way that empowered the bulletin to raise issues and be free to campaign. The group argued that for editorial independence to be achieved, editorial processes should be independent of local drug and therapeutics committees or regulatory authorities, and funded independently of the pharmaceutical industry. On the question of whether complete independence is achievable, the group felt that it is probably not achievable fully and in every circumstance, but that bulletins should try to be as independent as possible, and certainly financially independent of drug companies. Editorial independence was not seen as a luxury but a basic goal to strive for.

There was a discussion about the source of data for use in bulletins. Most use local epidemiological data, and primary and secondary evidence from published studies, particularly from sources such as WHO. Access to fully published papers can be difficult, although it is possible to get some papers, 6 months after publication, via the website <www.freemedicaljournals.com>. ISDB could perhaps play a role in helping the regional bulletins to get access to data. For example, via the website, or through a members’ email network, or by arranging a bulk membership access to an online source of primary evidence that could be accessed via password.

Developing the regional network

A particularly important session during the meeting addressed the development of a regional network. The group identified the following goals of common interest in the region:

- reducing irrational prescribing
- tackling the weaknesses of drug registration processes and documentation
- resolving variations across the region in approaches to traditional alternative medicines and complementary and alternative medicines
- dealing with problems related to inadequate access to essential drugs coupled with the provision of medicines at high prices
- exposing and correcting unethical marketing practices
- advising/working with regulatory authorities.

The group also recognised that achieving these goals would be more likely if the bulletins in the region shared their experiences. With this in mind the regional representatives decided to formulate a position paper on regional issues.

Through discussion it emerged that bulletin representatives in the region would like ISDB to help with regional coordination through the website, regional advocacy, and endorsement and support for regional issues. The representatives agreed that communication within the region could be simplified if Gita Fernando, as ISDB regional coordinator, communicated with an identified person in each country, who in turn would communicate with other members in their countries. The people identified were:

Nepal—BB Thapa
Pakistan—Zaeem ul Haq
Bangladesh—Zahed Md Masud
India—Amitava Guha
Sri Lanka—Gita Fernando

The aim would be to disseminate information and coordinate activities in the region and to find potential new members in unrepresented countries (eg Egypt, Bhutan, the Maldives).

Conclusions

In his summary, and based on the discussions at the workshop, Joe Collier noted that:

- Independent bulletins are valued, needed and difficult to produce. The provision of locally produced bulletins is especially important.
- Bulletins will always vary from one another in their terms of reference, ideals, personalities etc.
- Bulletins will also vary in what they do and where they focus their activities (eg advising on prescribing; policing the ‘system’; trying to change and steer thinking).
- Bulletins should aim to be used locally as the local information source.
- There was a common wish that bulletins in the Middle East and West Asia should work together, in the first instance linked by semi-formal mechanisms, and that ISDB would play an important part in helping forge this network.
- It is important for bulletins in the region to define independence, keeping in mind the need to ensure that in their work they do not have conflicts of interest.

Highlights of the ISDB Middle East and West Asia Regional Workshop

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Nepal was the host country for the International Society of Drug Bulletin (ISDB) Middle East and West Asia regional workshop. The beautiful hill resort of Nagarkot provided the backdrop for the meeting held in February 2004.

Professor Joe Collier, ISDB president opened the meeting stressing the importance for independent drug bulletins to adapt published clinical trial data and drug information sources to a local level. He also acknowledged that people who produce drug bulletins share an altruistic outlook and may work in challenging environments with precarious financial resources.

BB Thapa, chief editor of the Drug Bulletin of Nepal, described how Nepal's drug policy and drug administration team produced its drug bulletin. He focused on the balancing act between providing drug information and drug administration.

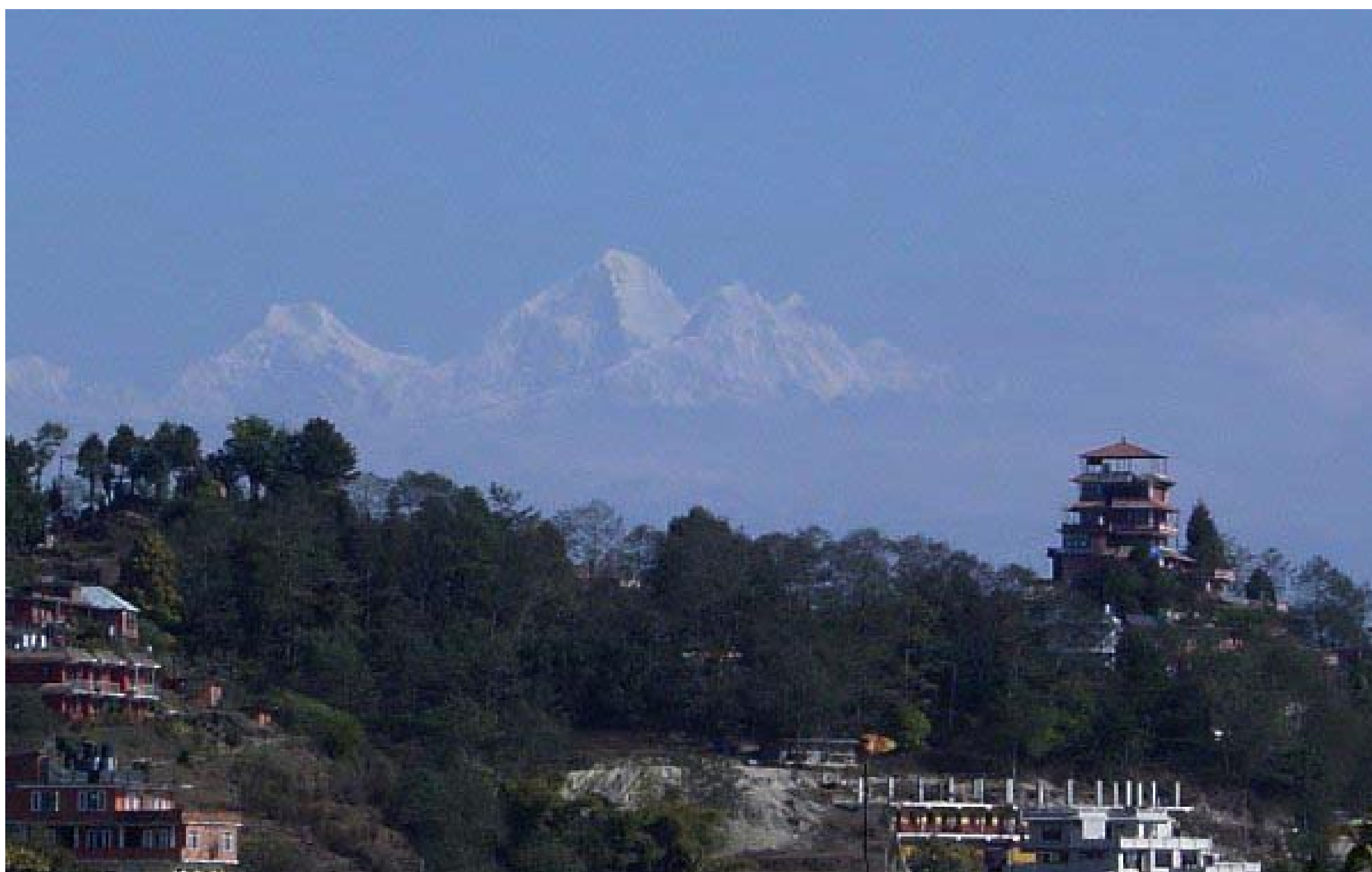
One cannot avoid the arguments that surround receiving, reading and using drug bulletins. Participants were given the opportunity to discuss and debate the merit of and need for a local drug bulletin. In a round-table discussion on creating and maintaining trust and credibility of drug bulletins, the participants were unanimous that bulletins should publish regularly and disclose their sources of information, should have a consistent editorial policy, and should be peer reviewed.

Professor Collier reminded us that editorial independence is most important if a drug bulletin is to be credible. He engagingly discussed; 'Is editorial independence achievable' and 'Is it a luxury'. His presentation, 'Choosing the source of data', was both interesting and informative. Professor Sarkar (*BODHI*, India) addressed the fascinating topic of editorial experience of a drug bulletin. Sarkar provided a guided tour (both friendly and hostile) of his first-hand experience through the history of his bulletin.

It is always interesting to hear about issues experienced at workplaces of individuals. Pranay Mishra and P Subish (Manipal teaching hospital, Nepal), Dr Zaeem (Pakistan) and Dr Shyam (DINoN, Nepal) presented their views on 'hot topics' in the last session of the meeting.

As an ISDB meeting novice, I found the workshop both inspiring and informative. The meeting gave me an international perspective of drug bulletin publication. The experience has left me feeling motivated to provide drug information to the people in my country.

I would like to thank ISDB for financial assistance. I would like to express my gratitude to the Department of Drug Administration (DDA), Nepal and especially to Bimal M Shresta for his encouragement.



View of the Himalayas from the venue of the meeting

Media round-up

Between two cultures

Edwin Gale, Professor of Diabetes and Metabolism, Division of Medicine, University of Bristol, in an article published recently, considers the role he and others like him play at 'the interface between industry, regulation agencies, academia and the health services in which [they] work'.[1] These 'expert clinicians' or 'opinion leaders' stand between the pharmaceutical companies—who, although having good intentions and genuine faith in the product, have a bottom line of making a profit, and are responsible to their shareholders—on one side, and clinicians—who need sufficient accurate information about new drugs to adequately benefit their patients—on the other.

These expert clinicians are often asked to speak at symposia, write reviews, or participate in advisory boards. Sometimes this is in an informal advisory capacity to a drug company; at other times in a formal way such as advising on drug trial design or preparing submission reports. For all these there is usually a remuneration, usually financial.

Gale considers that despite the efforts of many, expensive and potentially useful new drugs often come to the market without the evidence needed to use them effectively. Evidence-based medicine is usually the first thing to disappear in drug development, and is replaced by 'skilled misinformation'. Trials can be set up with specific results in mind. Even randomised controlled trials can be set up to minimise certain results and maximise others. A study might be 'lost' or the details 'missing' and only a positive abstract or summary remains with no supporting data.

Acknowledged experts may be asked early in the process, for advice. More usually they are asked much later to be an advocate for a drug; both senior physicians—with many years experience—and younger clinicians—up and coming, with the latest knowledge. They are needed to present information at national and international meetings and write reviews, and are asked to show a favourable opinion of the new drug.

Gale states many factors induce clinicians to speak at meetings: self-esteem, recognition, money, the chance of a change (eg an international trip, or a business class ticket).

The most valuable expert clinician is the one whose integrity is known and who speaks with conviction. Gale acknowledges that there are many honest people on both sides of the pharmaceutical industry – academic doctor interface. However, he considers that there is a double standard in academic medicine that is insidious and is promoted by secrecy and acceptance. Secrecy and science do not mix and opinion can easily become advocacy. Gale considers that formal guidelines and declarations of interest are inadequate, and those who work in both cultures become less accountable.

Drug company support for education and research are important for clinical medicine. Expert clinicians are the intermediaries between the drug company and the practising doctor. However there are professional and ethical issues involved. Questions always remain:

- How much do financial links influence the opinion and behaviour of expert clinicians?
- How transparent or accurate are the conflict of interest statements?
- If experts are funded by drug companies, how impartial and accurate will their presentations be?

1. Gale EAM. Between two cultures: the expert clinician and the pharmaceutical industry. Clin Med 2003;3(6):538-41.

Deferiprone dilemma

A Canadian haematologist who challenged the efficacy and safety of an oral thalassaemia drug, deferiprone, in a court of law vowed to continue her crusade after she failed in her attempt to have the drug suspended from the European market.

Dr Nancy Olivieri, professor of paediatrics and medicine at the University of Toronto, argued that Apotex, the pharmaceutical company who sponsored a number of deferipone studies including her own, had information regarding deferiprone's reduced effectiveness with long-term use and its ability to cause liver damage in some patients.

Apotex disagreed with her interpretation of the data and attempted, by way of invoking contractual agreements, to prevent her from publishing her findings in an independent journal. Dr Olivieri did however publish these results a few years later.[1] This led to her removal from all deferiprone trials, her sacking from the Hospital for Sick Children in Toronto and a subsequent battle in the European court of justice in Luxembourg to determine the veracity of the claims.

The European court of justice ruled in favour of keeping deferiprone on the market by arguing that Dr Olivieri had no standing to challenge submissions put forward to the drug licensing body of Europe. Dr Olivieri has said, 'this ruling guarantees that only a drug company attempting to sell a drug will control the content of scientific data submitted or not submitted'. Furthermore, she suggested that 'it no long matters whether drug companies tell the truth, the whole truth and nothing but the truth, because it's unchallengeable now'.[2]

However, the case is not clearcut. Subsequent studies have found deferiprone to be safe and effective,[3] and without a progression of hepatic fibrosis with long-term use.[4]

Who is right? Julian Savulescu, Uehiro chair in practical ethics at Oxford University, points out that 15 years after the first deferiprone studies its exact role is still uncertain and this uncertainty is compromising patient welfare. He argues that 'a moral imperative exists to conduct potentially life saving research properly and as quickly as possible' and that drug companies, researchers, governments and ethics committees could have worked harder to resolve this dispute and facilitate the necessary research.[5] He further adds 'anything that delays the delivery of good evidence harms people because during the unnecessary delay some people are denied an effective treatment'.

1. Olivieri NF, Brittenham GM, McLaren CE, Templeton DM, Cameron RG, McClelland RA, et al. Long-term safety and effectiveness of iron-chelation therapy with deferiprone for thalassemia major. N Engl J Med 1998;339:417-23.

2. Dyer C. Whisteblower vows to fight on [news]. BMJ 2004; 328:187.

3. Cohen AR, Galanello R, Piga R, De Sanctis V, Tricta F. Safety and effectiveness of long-term therapy with the iron chelator deferiprone. Blood 2003;102:1583-7.

4. Wanless IR, Sweeney G, Dhillon AP, Guido M, Piga A, Galanello R, et al. Lack of progressive hepatic fibrosis during long-term therapy with deferiprone in subjects with transfusion-dependent beta-thalassemia. Blood 2002;100:1566-9.

5. Savulescu J. Thalassaemia major: the murky story of deferiprone [editorial]. BMJ 2004;328:358-9.