

International Society of Drug Bulletins' (ISDB) program for promoting independent information

Introduction

The International Society of Drug Bulletins (ISDB) promotes the production of good quality independent information about drugs and therapeutics for health professionals and the public in all countries.

Its formation in 1986 was prompted by growing concern about problems arising from commercial influences in the production of information about pharmaceuticals, and the recognition that the problems were not just occasional breaches of methodological and ethical principles.

To ensure the relevance and currency of the Society's policies and activities, factors thought to influence the independence of information are discussed regularly. Following a discussion at a meeting of the ISDB Committee in Verona (24-25 November 2006) it was decided to document the issues surrounding competing interests in the production of information about pharmaceuticals and to develop a program of activities for ISDB to address these issues over the next few years.

Issues

1. Independence, as defined in Figure §, characterises the daily activities of all members of ISDB working in different contexts around the world.

Figure §

Independent information consists of data, and interpretation of that data, produced with the highest possible degree of objectivity. The bodies developing independent information must have no commercial (or other) interest in the promotion of any particular treatment. Their only aim must be to optimise treatment in the interest of patients and society.

2. Independence is threatened by structural problems involving the entire health care system. Within health care systems, the quality of drug information is an important indicator of the balance of power between vested interests and the needs of patients and populations.
3. ISDB's unique experience and knowledge makes it a key player in the development of independent information within health care systems. ISDB not only monitors institutional transparency and ability to meet scientific standards, but also suggests policies for improvement. Independence is not brought about just through good intentions; it requires continuous and objective monitoring, and a commitment to defend and promote the interests of populations and patients.
4. ISDB has two complementary international strategies:
 - a) to promote an understanding of the importance of addressing the issue of independence as a global priority;

- b) to promote an understanding that it is possible and necessary to work towards independence in different ways depending on the context in individual countries.
5. This statement relates to, and integrates, previous statements on some of the most sensitive drug information issues:
- * *Uppsala Declaration on Transparency and Accountability in Drug Regulation (1996)*
This is a joint statement on the need for transparency and greater access to drug information from regulatory agencies.
 - * *Paris Declaration on Therapeutic Advance in the Use of Medicines (2001)*
This is an ISDB statement that defines and discusses the concept of ‘therapeutic innovation’.
 - * *Berlin Declaration on Pharmacovigilance (2005)*
This is an ISDB statement on how to achieve more effective pharmacovigilance and a safer use of drugs.
 - * *Relevant Health Information for Empowered Citizens (2006)*
This is a joint declaration from HAI Europe, ISDB, AIM, BEUC and the Medicines in Europe Forum to counter a proposal from the European Commission to allow drug companies to provide ‘information’ to the general public.

Action program

The ISDB Committee has developed a five-point program and has identified this program as a priority for ISDB at regional, national and global levels. ISDB as a whole is committed to implementing this program. Individual members are encouraged to support the program but are not committed to do so.

1. The Role of Government Agencies

ISDB activities, by definition, relate to some of the most controversial actions and roles of government agencies responsible for health in general and pharmaceuticals in particular. Currently there is concern that these agencies have not yet met satisfactory standards of transparency and public accountability.

- 1.1 ISDB calls for full transparency by government agencies responsible for pharmaceuticals. They should make all relevant information publicly available without delay. One way to encourage full transparency is to monitor and report on current levels of transparency. Actions are needed both in less-developed countries (that are often dependent on the international market and registrations), and at a regional level (e.g. the implementation of the transparency provisions in the EU Directives 2004/27/EC).
- 1.2 ISDB calls on WHO and regulatory agencies to assure full transparency on conflicts of interest, especially for external experts who contribute to the formulation of guidelines, and for any partner engaged in the definition of drug policy and information (e.g. patient groups, umbrella organisations). Even though disclosure of conflicts of interest does not solve the problem of bias it is an essential preliminary step.
- 1.3 ISDB will campaign for its members to have complete and timely access to data held at the WHO Uppsala Centre, so ISDB members are able to provide optimal coverage of adverse reactions.
- 1.4 ISDB will campaign for WHO to take a more active role in the area of clinical trials registries.

2. Non-Profit Research and Independent Continuous Medical Education

The evidence base for most medical practice is dominated by clinical trials sponsored by pharmaceutical companies. The public health implications of this are serious and have been well documented. As a result, many in the scientific community and in health authorities are becoming aware it is not sufficient to just monitor and criticize misleading trial reports. The role of independent non-profit trials and clinical research must be strengthened and promoted using cultural, legislative and economic resources.

- 2.1 ISDB will identify priority areas where independent research is urgently needed. ISDB will also contribute to lobbying for the development of funding sources for research and development other than drug companies. ISDB will also support the streamlining of procedures to make more independent research and development easier and more efficient. The recently implemented policy of the Italian drug agency (AIFA) is a promising example of this.
- 2.2 ISDB will seek stronger relationships with health professionals' organisations, and consumer associations, to promote projects capable of producing independent information (e.g. through pragmatic trials and outcomes research etc) for controversial therapeutic and preventive problems. ISDB will give priority to developing relationships with general practitioners' organisations because general practitioners are the main audience for most ISDB members' bulletins. The experience in 2006 of ISDB participation in a meeting on the European branch of the World Organization of Family Doctors (WONCA) was a step in this direction
- 2.3 Efforts will be made to test and to promote the use of ISDB bulletins as a preferred tool for continuing medical education programs. ISDB will also support the development of education about drug promotion. The experiences of Prescire and Healthy Skepticism, among others, are notable in this area.

3. Surveillance of Guidelines

Evidence-based treatment guidelines are considered a good tool to implement evidence-based medicine. However, the development of guidelines is often influenced, or even directly sponsored, by the pharmaceutical industry and recommendations can be biased towards excessive medicalization. This has led to the suspicion that guidelines are sometimes misused for 'disease mongering'.

It is important to make health professionals, organizations and ISDB members aware of this problem and to promote more judicious use of treatment guidelines.

ISDB will prepare and circulate a background document on methodology for assessing the independence and reliability of treatment guidelines. This document will provide a basis for the following actions:

- 3.1 ISDB and its members commit themselves to the active monitoring and critical appraisal of guidelines produced by scientific societies, as well as by national and international agencies in areas important both epidemiologically and clinically (e.g. the management of asthma, chronic obstructive pulmonary disease, depressive disorders, cardiovascular risk in elderly populations), to promote more targeted and responsible prescribing.
- 3.2 Efforts should be made to increase the participation of consumers in the development and implementation of guidelines especially for conditions where lifestyles and behaviours may be just as, or more than, important as drugs.

- 3.3 The direct participation of ISDB (and of individual bulletins at national level) in the development of treatment guidelines should be considered. ISDB and its members can assist with assessment of evidence and with putting industry-oriented information into context.

4. Relationship with Major Journals

Major journals are an authoritative source of primary information and ISDB bulletins are intensive users of them. Because of its independence and competence, ISDB should always be considered by major journals as a valuable information resource. However, few major journals have paid an appropriate level of attention to the special expertise of ISDB members so far. This is especially problematic when recommendations made in major journals conflict with those of bulletins.

A more systematic, equal and open interchange of primary and secondary sources of information could provide important opportunities for the promotion of more rigorous prescribing practices.

ISDB is therefore committed to developing a direct and collaborative relationship with major journals.

- 4.1 ISDB will submit articles for publication in major journals to increase the profile of ISDB and its members and to highlight the value of independent information to readers of major journals.
- 4.2 ISDB will seek publication of articles on controversial issues and the widespread relevance of appropriately qualified information to prescribers in routine care, both in high and low income countries.

5. Closer Alliances with Consumers

Although primarily focused on prescribers, ISDB has also begun to collaborate with consumer organizations on campaigns to advance the interests of consumers.

The importance of this area has been underlined in a recent document (the joint Declaration from October 2006 'Relevant Health Information for Empowered Citizens'). The direct delivery of industry-generated information to consumers is likely to be an important area of debate in the coming years.

- 5.1 ISDB confirms its commitment to give priority and support to countering policies and legislation that would allow drug companies to target the general public with advertising including advertising disguised as 'information'.
- 5.2 ISDB recommends that bulletins allocate more space for reports of the experiences and proposals of consumer groups. ISDB and its members will also comment on positions promoted by consumer groups where independence and reliability of information appears not to have been assured.
- 5.3 All ISDB bulletins are invited and will be supported in their efforts to translate their 'technical' content into language that is easy for the general public to understand. The aim is to improve interaction between patients and prescribers leading to better use of drugs, and thus better health and economic outcomes.