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The Erice Declaration

REFERENCE PAPER
Currently Discussed

1. ISDB members in Asia & Pacific region are planning a regional meeting to be held in Sri Lanka in October 2000. For more information please contact Krisantha Weerasuriya (e-mail: **kw_twcp@slt.lk**) and Margaret Ewen (e-mail: **margaret_ewen@moh.govt.nz**)
2. Drug and Therapeutics Bulletin is planning a training course for editors in 200. More details will be given in the next newsletter.
3. The French bulletin la revue Prescrire would be glad to organise a meeting of editors in Paris in summer 2000. The main objective would be to exchange editorial exchange editorial experiences among ISDB bulletin editors.

Anyone interested in attending and contributing to such a meeting is invited to get in touch with Christophe Kopp (e-mail: **christophe.kopp@wanadoo.fr**)

THE ERICE DECLARATION
On Communitcatingnformation Drug Safety I

The Erice Declaration on communications in pharmacovigilance was published in 1997 following the International Conference on Developing Effective Communication in Pharmacovigilance. The meeting was organised by: the Uppsala Monitoring Centre, the Clinical Pharmacology Unit, Institute of Pharmacology of Verona University, with the support of IUPHAR's Division of Clinical Pharmacology, the Ettore Majorana Centre for Scientific Culture, International School of Pharmacology, the World Health Organisation, and supported by EQUUS Communications, London. This Declaration is still relevant today and deserves a second round.

The following declaration was drawn up at the International Conference on Developing Effective Communications in Pharmacovigilance, Erice, Sicily, 24-27 September 1997. It was attended by health professionals, researchers, academics, media writers, representatives of the pharmaceutical industry, drug regulators, patients, lawyers, consumers and international health organisations.
Monitoring, evaluating and communicating drug safety is a public-health activity with profound implications that depend on the integrity and collective responsibility of all parties – consumers, health professionals, researches, academia, media, pharmaceutical industry, drug regulators, governments and international organisations – working together. High scientific, ethical and professional standards and a moral code should govern this activity. The inherent uncertainty of the risks and benefits of drugs needs to be acknowledged and explained. Decisions and actions that based on this uncertainty should be informed by scientific and clinical considerations and should take into account social realities and circumstances.
Flaws in drug safety communication at all levels of safety can lead mistrust, misinformation and misguided actions resulting in harm and the creation of a climate where drug safety data may be hidden, withheld, or ignored.
Fact should be distinguished from speculation and hypothesis, and actions taken should reflect the needs of those affected and the care they require. These actions call for systems and legislations, nationally and internationally, that ensure full and open exchange of information, and standards of evaluation. These standards will ensure that risks and benefits can be assessed explained and acted upon openly and spirit that promotes general confidence and trust. The following statements set forth the basic requirements for this to happen, and were agreed upon by all participants from 34 countries at Erice:

1. Drug safety information must serve the health of the public. Such information should be ethically and effectively communicated in terms of both content and method. Facts, hypotheses and conclusions should be distinguished, uncertainty acknowledged, and information provided in ways that meet both general and individual needs.
2. Education in the appropriate use of drugs, including interpretation of safety information, is essential for the public at large, as well as for patients health-care providers. Such education requires special commitment and resources. Drug information directed to the public in whatever form should be balanced with respect to risks and benefits.
3. All the evidence needed to assess and understand risks and benefits must be openly available. Constraints, on communication parties, which hinder their ability to meet this goal must be recognised and overcome.
4. Every country needs a system with independent expertise to ensure that safety information on all available drugs is adequately collected, impartially evaluated, and made accessible to all. Adequate non-partisan financing must be available to support the system. Exchange of data and evaluations among countries must be encouraged and supported.
5. A strong basis for drug safety monitoring has laid over a long period, although sometimes in response to disasters. Innovation in this field now needs to ensure that emergent problems are promptly recognised and efficiently dealt with, and that information and solutions are effectively communicated.

These ideals are achievable and the participants at the conference dedicate/commit themselves accordingly. Details of what might be done to give effect to this declaration have been considered at the conference and form the substance of the conference report.

Erice, September 27, 1997

**Motion agreed on by a General Assembly of the ISDB,
Amsterdam September 1999**

EUSURING THAT DRUG REGULATORY AUTHORIETIES SERVE PUBLIC HEALTH FIRST AND FOREMOST

The ISDB adopt the aim engaging in actions that ensure that drug regulatory authorities place public health considerations above the commercial interests of the drug industry.
To this end ISDB will undertake actions aimed at ensuring that drug bulletins obtain full data on the indications, efficacy and risks of drugs from the drug regulatory authorities.

FUNDING OF MEDICINES AGENCIES
This paper was published in the December issue of la revue Prescrire.

More and more countries are creating medicines agencies responsible for licensing new drugs and for postmarketing surveillance, tasks previously confided to health ministry departments. European Union member states have the European Medicines Evaluation Agency (EMEA), which, for some categories of drugs, supplants national bodies.
These new agencies are public bodies under state control, but have a certain degree of autonomy. While the budget of health ministry departments responsible for drug evaluation was included in that of the ministries concerned (i.e. drawn from the public coffer), the new agencies manage their own expenditures and funding. The latter consists largely of fees paid by drug manufacturers on submission of marketing authorisation requests (a).
The yearly reports released by some agencies give an approximate idea of their funding sources. They can therefore be used to compare the parts represented by public and private funding (the latter consisting mainly of fees paid by drug companies).
We examined the latest reports released by the French medicines agency (which, in 1999, was renamed the French Acency for Health Product Safety1 and by the European Medicines Evaluation Agency (EMEA)2, i.e. the two agencies via which drugs on the French market. We also examined the latest financial report from the United States Food and Drug Administration (FDA), one of the oldest such bodies (b)3.
The contributions made by the public and private sectors vary according to the agency but, in all three cases, the part represented by drug manufacturers' fees is large and growing. Thus, it represented 36% of the FDA budget (for human drug assessment) in 1997, and 40% in 1998 3; for the French agency, manufactures' dues represented 68% of receipts in 1997 and 1998, while public funding fell from 27% to 24% (c)1; finally, for the European agency (EMEA), drug companies fees represented 39% of receipts in 1996, 48% in 1997 and 53% in 19982.
This trend towards increasing funding by the industry (in the form of fees), and the corresponding reduction in public funding is confirmed by the EMEA Management Board, which anticipates that industry will account for 69% of funding and the European Union only 28% in the year 20004.
Fees paid by manufacturers are increasingly high, and are thus gradually becoming the main funding source for medicines evaluation agencies.
Is this logical, when these agencies work not on behalf of drug manufacturers but also have a public health mission? And is it reasonable in a context where pharmaceutical companies are becoming increasingly concentrated (by merging) and powerful, and, pressed by international competition, more and more in a hurry to obtain market authorisation for their new products?
Likewise, the race between the larger medicines agencies (American, European and Japanese) to offer manufactures the shortest interval between file submission and marketing authorisation carries a risk of premature drug marketing. This is one of the inevitable consequences of "independent" medicines evaluation agencies getting much or most of their running costs directly from industry.

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a- Manufactures also pay fees for other services, but those paid for
marketing applications are highest. In 1999, marketing application fees for new drugs were 7.500 to 22.500 Euros in France, 140.000 to 200.000 Euros for the EMEA, and equivalent of 189.500 Euros for the FDA.
b- More precisely, it is the financial report involving the section of the FDA responsible for drug assessment.
c- Note that the part of income corresponding to services and goods rose from 3% to 6% during the same period.
d- The data given in the French medicines agency reports for 1997 and 1998 correspond to estimated budgets.

1- French medicines Agency "Rapport 1997": 270 pages.
2- The European Agency for the Evaluation of Medicinal Products "Fourth General Report" 1998: 83 pages.
3- Food and Drug Administration "FY 1998 PDUFA Financial Report" 1998: 26 pages.
4- The European Agency for the Evaluation of Medicinal Products – Press release "Twenty-first meeting of the management board" 10 February 1999: 1 page.