

WHAT IS CIOMS?

The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental, non-profit organization established jointly by WHO and UNESCO in 1949. In 2009 it is celebrating the 60th anniversary of its creation.

Through its membership, CIOMS is representative of a substantial proportion of the biomedical scientific community. The membership of CIOMS in 2009 includes over 60 international, national and associate member organizations, representing many of the biomedical disciplines, national academies of sciences and medical research councils. The main objectives of CIOMS are:

- To facilitate and promote international activities in the field of biomedical sciences, especially when the participation of several international associations and national institutions is deemed necessary;
- To maintain collaborative relations with the United Nations and its specialized agencies, in particular with WHO and UNESCO;
- To serve the scientific interests of the international biomedical community in general.

To achieve its objectives, CIOMS has initiated and coordinates the following main long-term programmes:

- Bioethics
- Health Policy, Ethics and Human Values - An International Dialogue
- Drug Development and Use
- International Nomenclature of Diseases

BIOETHICS

The remarkable progress of biomedical sciences and biotechnology, and its applications in medical practice, are confronting our societies with new ethical dilemmas, extending from traditional medical ethics to the many emerging areas of bioethics.

The particular contribution of CIOMS in this field has been the issuance of international guidelines for the application of ethical principles in various key areas. Specific reference should be made to the International Ethical

Guidelines for Biomedical Research Involving Human Subjects (developed in conjunction with WHO), which superseded Proposed Ethical Guidelines (1982) and were published in 1993. They have been very widely utilized, particularly in low-resource countries. In 1999-2002 the Guidelines were revised and updated. CIOMS published in 2002 the new text of the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* which are available on the CIOMS website. Moreover, translations of the Guidelines have been made into French, Spanish, Portuguese, Chinese, Japanese, Korean and Vietnamese.

A chapter by Professor Juhana E. Idänpään-Heikkilä and Mr Sev Fluss, CIOMS, describing the 2002 Guidelines has been included in *The Oxford Textbook of Clinical Research Ethics*.

In 1991 CIOMS issued the *International Guidelines for Ethical Review of Epidemiological Studies*. In 2003 CIOMS initiated the revision of these Guidelines by establishing a multidisciplinary Core Group which has collected comments on the draft revision of the guidelines from various institutions, organizations and individual experts involved in ethics and epidemiological research. Provisional text - pending printed version was posted on the CIOMS website in February, 2008.

Specific reference should also be made to the "Principles of Medical Ethics Relevant to the Protection of Prisoners Against Torture", prepared by CIOMS at the invitation of WHO and adopted by the United Nations General Assembly in March 1983.

HEALTH POLICY, ETHICS AND HUMAN VALUES - AN INTERNATIONAL DIALOGUE

This major programme originated at an international conference organized by CIOMS in cooperation with WHO, held in Athens in 1984. This programme has brought together health policy-makers, ethicists and philosophers from many of the world's major cultural and religious groups, as well as "secularists". The topics covered have included equity, social justice, community participation, and the dignity of individuals in sickness and health in the context of health policy-making.

DRUG DEVELOPMENT AND USE

Safety requirements for the use of drugs

This programme was initiated in the early 1980s in the light of the benefits that society as a whole derives from modern drugs and vaccines. At the same time, society must be prepared to accept the possibility of remote risks to the individual as the corollary of modern medical care and further

therapeutic progress; without this realization, the basis of contemporary drug development will ultimately founder. Moreover, society must be assured that a responsible and committed effort is undertaken to minimize drug-induced injury, and that the risks of such injury compare favourably to those accepted in other aspects of daily life.

Assessment and monitoring of adverse drug reactions and pharmacogenetics

The following CIOMS working groups are currently preparing their reports or have published their recommendations:

CIOMS I. (1990) International Reporting of Adverse Drug Reactions

The most valuable outcome of the working group of CIOMS I was the introduction of the "[*CIOMS I reporting form*](#)" for standardized international reporting of individual cases of serious, unexpected adverse drug reactions.

CIOMS II. (1992) International Reporting of Periodic Drug-Safety Update Summaries

This working group proposed a standard for periodic safety update reports, which has been adopted extensively since the publication of the report in 1992. It also served as a basis for the development of the official ICH guideline for such reports.

CIOMS III. (1999) Guidelines for Preparing Core Clinical-Safety Information on Drugs - Including New Proposals for Investigator's Brochures (second edition).

This Working Group Report developed proposals for international harmonization of the practical aspects of defining, creating and modifying the sections of data sheets or package inserts that contain safety information. It elaborated the concept introduced under CIOMS II of a manufacturer's Core Data Sheet for a product and the Core Safety Information (CSI) it contains.

CIOMS IV. (1998) Benefit-Risk Balance for Marketed Drugs: Evaluating Safety Signals

CIOMS IV was to some extent an extension of CIOMS II and III. It examined the theoretical and practical aspects of how to determine whether a potentially major, new safety signal signifies a shift, calling for significant action, in the established relationship between benefits and risks; it also provides guidance for deciding what options for action should be considered and on the process of decision-making should such action be required.

CIOMS V.(2001) Current Challenges in Pharmacovigilance: Pragmatic Approaches

CIOMS Working Group V commenced work in 1997 to revise and put together the most important elements that need to be taken into consideration in dealing with drug safety of post-marketed drugs. The final report was published in 2001; for further information, see the Publications section of this website.

CIOMS Working Group on Pharmacogenetics (2005)

In 2001, senior scientists from ten drug regulatory authorities, with senior scientists from ten pharmaceutical companies, plus experts from WHO and academia, formed a CIOMS Working Group to consider drug development and regulatory, ethical, educational and economic issues related to pharmacogenetics. Issues related to genetic testing, genetic data, genetic information, human genome projects and databases for clinical trials using pharmacogenetics were also considered.

The final report entitled “*Pharmacogenetics – Towards Improving Treatment with Medicines*”, was published in 2005.

CIOMS Working Group on Standardised MedDRA Queries (SMQs)

Since 2003, the CIOMS Working Group has developed search queries for some 95 selected adverse reactions based on MedDRA in order to use the terminology in a rational way and to allow comparisons of drug safety findings between databases. The Working Group has as members senior scientists from drug regulatory authorities and pharmaceutical companies, the MedDRA Maintenance and Support Service Organisation (MSSO) and WHO. The Working Group operates in close collaboration with the ICH MedDRA Management Board and the ICH Secretariat. By October, 2008 it had published 67 SMQs and it will finalise 19 additional SMQs in 2009.

In 2004, the Working Group published a report entitled “*SMQs – Development and Rational Use of Standardised MedDRA Queries (SMQs)*”

As of September 2008, the Working Group has been replaced by a Core Group for the maintenance of SMQs.

CIOMS VI.(2005) Management of Safety Information from Clinical Trials

The Working Group was established in 2001 to consider issues related to

the surveillance, assessment and reporting of drug safety data from clinical trials. It was composed of 12 senior scientists from drug regulatory authorities (including representation from South America, Africa and Asia) and the final report “*Management of Safety Information from Clinical Trials*” was published in 2005.

CIOMS VII.(2006) Development Safety Update Report (DSUR)

The Working Group considered the rational, format and content of a periodic development safety update report to inform drug regulatory authorities on safety findings of new medicines during their developmental research. The report, “*The Development Safety Update Report (DSUR): Harmonizing the Format and Content for Periodic Safety Reporting During Clinical Trials*” was published in 2006.

Joint CIOMS-WHO Working Group on Drug Development Research and Pharmacovigilance in Resource-Poor Countries.(2006)

Many endemic diseases appear only in developing countries and the development of safe and effective treatments require clinical trials to be conducted in these countries. Many obstacles and barriers to clinical trials and creation of an efficient collection and assessment of drug safety data from clinical trials need special consideration and appropriate solutions in resource-poor countries.

The recommendations of the Working Group were posted in 2006 on the CIOMS website for comments.

CIOMS/WHO Working Group on Vaccine Pharmacovigilance

The Working Group was created in 2005 at the request of WHO to:

- develop general definitions strictly focused on vaccine pharmacovigilance;
- contribute to the development, review, evaluation and approval of definitions on adverse events following immunization as developed by the Brighton Collaboration process and to their dissemination; and
- collaborate with other CIOMS Working Groups

The Working Group is composed of 23 members from the pharmaceutical industry, regulatory authorities, governmental institutions and academia, from both industrialized and developing countries.

The *definition on Vaccine Pharmacovigilance* was adopted by the Working Group in 2007 and is published on the CIOMS website.

CIOMS VIII. CIOMS Working Group on Signal Detection (Points to consider in application of signal detection in pharmacovigilance)
(2006).

This CIOMS Working Group was established in 2006 based on requests from drug regulatory authorities and pharmaceutical companies. The Working Group is currently developing a consensus report on "Points to consider in the development and application of quantitative methods for signal detection using pharmacovigilance databases" The report will be published in 2009.

The progress made in the various CIOMS Working Groups can be seen in the section "Current Programme and Planned Activities."

Reporting and Terminology of Adverse Drug Reactions

The use and interpretation of certain ADR terms differ considerably in different countries. This can lead to misinterpretation of data or delay their proper evaluation by drug regulatory authorities. The need to establish minimum requirements for the proper diagnosis of a suspected ADR, and thus to describe it with the correct term in reports, represents the most important type of information for raising suspicions about drug safety, generating signals and, frequently, even taking action. Single case reports are transmitted by a reporting physician to a collecting centre at either a drug regulatory agency or a pharmaceutical company, and quite often between these organizations as well.

The magnitude of the project is reflected in the fact that over 180 terms were defined, more than 120 experts were involved, and 16 working meetings were held. The end product of the project was the publication in 1999 of a cumulative volume entitled *Definitions and Basic Requirements for the Use of Terms for Reporting Adverse Drug Reactions* and a corresponding CD-ROM.