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COUNCIL FOR INTERNATIONAL  
ORGANIZATIONS  
OF MEDICAL SCIENCES  
ESTABLISHED UNDER THE AUSPICES OF THE  
WORLD HEALTH ORGANIZATION AND UNESCO

CIOMS

CONSEIL DES ORGANISATIONS  
INTERNATIONALES  
DES SCIENCES MÉDICALES  
FONDÉ SOUS LES AUSPICES DE L'ORGANISATION  
MONDIALE DE LA SANTÉ ET DE L'UNESCO



Pharmacovigilance and Related Ethical Issues

16-17 December 1999  
Geneva

Preliminary Programme

Thursday, 16 December 1999

9:30 OPENING OF CONFERENCE

J.H. Bryant, President of CIOMS

Welcome Addresses: G.H. Brundtland, Director-General, WHO  
F. Mayor, Director-General, UNESCO

10:30 Coffee Break

11:00 Session I

REPORTING ADVERSE DRUG REACTIONS - DEFINITIONS  
OF TERMS AND BASIC REQUIREMENTS FOR THEIR USE

Chair: J. Venulet  
R. Mann

- Introduction J. Venulet
- Importance for Users:  
Drug Regulators G. Kreutz  
M.M. Lumpkin  
W. Aellig
- Pharmaceutical Industry W. Aellig
- Clinicians R.D. Mann
- World Health Organization J.E. Idänpään-Heikkilä

12:30 Lunch

14:00 Session I continuation

- The final outcome  
Cumulative volume/CD-ROM

G. Kremer

Panel Discussion

15:30 Tea Break

16:00 Session II

CIOMS – THE FIRST 50 YEARS

Chair: J.H. Bryant

S. Gorovitz

- Birth and Development

F. Gutteridge  
S.S. Fluss

- Recent Activities

A. Gellhorn

Panel Discussion: Looking Forward – the Next 50 Years

18:00 Reception

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Friday, 17 December 1999

9:00 Session III

ADR MONITORING AND CIOMS WORKING GROUPS I-V

Chair: W.M. Castle

M.M. Lumpkin

Introduction/Overview

W.M. Castle

- CIOMS Working Groups I (IA)
- CIOMS Working Group II
- CIOMS Working Group III
- CIOMS Working Group IV

C. Bénichou  
S. Roden  
G. Kreutz  
B. Rowsell

10:30 Coffee Break

Panel Discussion

- ° CIOMS V and other Parallel Groups I.R. Edwards
- ° Overall Achievements M.M. Lumpkin
- ° Overview of Lessons Learned M. ten Ham

12:30 Lunch

14:00 Session IV

ETHICAL ISSUES IN DRUG DEVELOPMENT AND USE

Chair: J.H. Bryant  
S. Gorovitz

- ° Highlights of the CIOMS Guidelines Revision R.J. Levine

Panel Discussion

- ° European Perspective R. Gillon
- ° Chinese Perspective Qiu Renzong
- ° Japanese Perspective R. Kimura

(15:30 Coffee Break)

- ° Eastern Mediterranean Perspective M. Abdussalam
- ° African/Sub-Saharan Perspective E. Mbidde
- ° Latin American Perspective F. Lolas
- ° North American Perspective A.M. Capron

(The above perspectives should include the perspective of academia, consumers, regulatory agencies and the industry)

Concluding Address on Future Prospects

17:30 CLOSING OF CONFERENCE

PROGRAMME AND ORGANIZING COMMITTEE

ABDUSSALAM, M. Former Chairman, WHO Advisory Committee for Health Research for the Eastern Mediterranean; CIOMS Ethics Committee, Geneva, Switzerland

BANKOWSKI, Z. Secretary-General, Council for International Organizations of Medical Sciences (CIOMS), Geneva, Switzerland

BRYANT, J.H. Chairman, President, Council for International Organizations of Medical Sciences (CIOMS), Moscow, Vermont, U.S.A.

FLUSS, S.S. Consultant, Council for International Organizations of Medical Sciences (CIOMS), Geneva, Switzerland

GALLAGHER, J. Consultant, Council for International Organizations of Medical Sciences (CIOMS), Geneva, Switzerland

IDANPAAN-HEIKKILA, J.E. Former Director, Drug Management and Policies, World Health Organization, Helsinki, Finland

VENULET, J. Co-Chairman, Senior Advisor, Council for International Organizations of Medical Sciences (CIOMS), Geneva, Switzerland

Background note on the  
CIOMS Conference on Pharmacovigilance and  
Related Ethical Issues  
(Geneva, 16-17 December 1999)

The existence of a nongovernmental organization for fifty years is a good indication that it is fulfilling a real need. This year marks not only the end of a century (and of a millennium) but also the 50<sup>th</sup> anniversary of the NGO now known as the Council for International Organizations of Medical Sciences, created jointly by UNESCO and WHO and still working in close harmony with these specialized agencies of the United Nations system.

To mark the occasion it has been decided to hold a Conference -- devoted primarily to past achievements (particularly in the pharmacovigilance sphere) but also to related ethical issues, from a cross-cultural and multidisciplinary perspective. It will begin with a commemorative session devoted to the first 50 years of CIOMS, including presentations on its origins and development and on some of its recent activities. The first of the sessions on pharmacovigilance will focus on definitions and basic requirements for the use of adverse drug reaction (ADR) terminology, with presentations by representatives of drug regulatory agencies, the pharmaceutical industry, practitioners of clinical medicine, and WHO, as well as an address describing the two final products of this project. The second session on pharmacovigilance will focus on the contributions of CIOMS Working Groups I-V. Finally, ethical issues in drug development and use will be addressed in a fourth session, with presenters from many parts of the world describing the perspectives on these issues of academia, consumers, regulatory agencies, and the pharmaceutical industry. An account will also be given of the current status and scope of the draft revision of the 1993 CIOMS Guidelines. To maximize audience participation, a panel discussion will follow each session.

The Conference, which will close with an address on future prospects for CIOMS, will, it is hoped, attract a wide range of participants from each of the sectors of civil society whose concerns are on the agenda and which have a common interest in the maximum possible level of drug safety.

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REGISTRATION FORM

Pharmacovigilance and Related Ethical Issues

16-17 December 1999  
Geneva

Family Name \_\_\_\_\_ First Name \_\_\_\_\_

Title / Position \_\_\_\_\_

Organization represented \_\_\_\_\_

Mailing Address \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Telephone \_\_\_\_\_

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This form should be filled in and returned, at your earliest convenience, to the CIOMS Secretariat, c/oWorld Health Organization, avenue Appia, CH-1211 Geneva 27, Switzerland; Telefax: (41-22) 791-0746

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(Signature)

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(Place, date)