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INTERNATIONAL ROUND TABLE

"Biomedical Research in Developing Countries: The Promotion of Ethics, Human Rights and Justice"

15-16 DECEMBER 2008

FAO, Iran Room, V.le delle Terme di Caracalla, Rome

Provisional Programme

Monday, 15 December

h. 8.00 ***Registration of Participants***

h. 9.00 Welcome message by the Italian National Authorities

Introduction to the meeting, Guido Rasi, Chief Executive, Italian Medicines Agency, AIFA

Presentation of the Round Table, Sandro Calvani, Director, UNICRI

h. 9.30 ***I Session: The International Legislation and Guidelines Protecting the Research Participants***

Chairpersons: To be confirmed

Henk ten Have, Director, Division of Ethics of Sciences and Technology, UNESCO: "*The Universal Declaration on Bioethics and Human Rights and the UNESCO work in building capacity for ethical review*"

Eva Bagenholm, Chair, WMA Committee on Medical Ethics, President of the Swedish Medical Association, and Julia Seyer, WMA Medical Ethics: "*WMA Declaration of Helsinki, Ethical Principles for Medical Research Involving Humans Subjects*"

Maurizio Salvi, Head of Secretariat, European Group on Ethics in Science and New Technologies – EGE, Policy Adviser at the Bureau of European Policy Advisers to the President of the European Commission: "*The role and functions of the European Commission in protecting human participants in biomedical research*" (Provisional title)

Marie-Charlotte Bouesseau, Team Leader, Ethics and Health, Department of Ethics, Equity, Trade and Human Rights, WHO Geneva: "*The WHO activities: strengthening ethics review of research involving human participants"*

h. 10.30 Discussion

h. 11.00 ***Focus on Africa: National and Regional Initiatives on Ethics in Biomedical Research***

Chairpersons: To be confirmed

Wenceslaus L. Kilama, Managing Trustee, Tanzania Commission for Science and Technology: "*AMANET Activities in Strengthening Ethical Review Capacity Across Africa*"

Chris Zielinski, Technical Coordinator, Research for Health, WHO/AFRO: *"Status of ethical review of biomedical research in the WHO African Region"*

h. 11.30 Coffee Break

h. 12.00 Alice Paola Brizi, Alessandra O'Neil, Justice Protection and Ethics Unit, UNICRI, Umberto Filibeck, Director, GCP Promotion Unit, GCP and Pharmacovigilance Inspectorate, Italian Medicines Agency: "*Survey on national legislation and ethical review capacity in Africa" (Provisional title)*

Clement Adebamowo Chairman, National Health Research Ethics Committee of Nigeria (NHREC): "*The challenges and opportunities in establishing research ethics regulatory infrastructure in Nigeria*"

h. 12.30 Discussion

h. 13.00 Lunch

h. 14.00 ***II Session: Ethics, Human Rights and Health Protection***

Chairpersons: To be confirmed

Charles Mgone, Executive Director, European and Developing Countries Clinical Trials Partnership – EDCTP: "*Capacity strengthening of the health research ethics review mechanism in sub-Saharan Africa through the EDCTP programme*"

Jan Helge Solbakk, Chair of Medical Ethics and Head of Section, Section for Medical Ethics, Faculty of Medicine, University of Oslo, Norway: "*Goodness and ethics in biomedical research conducted in developing countries*" (Provisional title)

Valeria Piccone, Judge, Human Rights Expert, Ministry of Justice, Italy*: "The Judiciary in the protection of human rights"* (Provisional title)

Jerome A. Singh, Professor at the Harvard School of Law, Head of the Centre for the AIDS Programme of Research in South Africa – CAPRISA, Bioethics Programme, Nelson R. Mandela School of Medicine, University of Kwala-Zulu Natal, South Africa: "*How human rights and the law can enhance protection of human participants in biomedical research*" (Provisional title)

h. 15.00 Discussion

h. 15.30 ***Focus on Africa: National and Regional Initiatives on Ethics in Biomedical Research***

Chairpersons: To be confirmed

Godfrey B. Tangwa, Associate Professor of Philosophy and Head of Department at the University of Yaoundé, Cameroon "*Ethical review of research in Cameroon"* (Provisional title)

Aissatou Toure, National Ethics Committee of Senegal, Institute Pasteur, Dakar, Senegal: "*The experience of Senegal in conducting ethical research*" (Provisional title)

Aceme Nyika, Ethics Coordinator, African Malaria Network Trust (AMANET): "*AMANET Needs Assessment Survey of Ethical Review Committees in Africa: Overview of Findings*"

h. 16.15 Discussion

h. 16.30 Coffee Break

h.16.45 ***III Session: The National Organizations in Support of Ethical Review of Biomedical Research***

Chairpersons: To be confirmed

Melody Lin, Deputy Director and Director of International Activities Program, Office for Human Research Protection, Department of Health and Human Services, United States of America: "*OHRP's international activities in support of ethics teaching and GCP application*" (Provisional title)

Umberto Filibeck, Director, GCP Promotion Unit, GCP and Pharmacovigilance Inspectorate, Italian Medicines Agency: "*The Italian legislation and the work of the Italian Medicine Agency in the field of ethics of clinical trials*" (Provisional Title)

h. 17.15 Discussion

Tuesday, 16 December

h. 9.00 ***IV Session: Status of Health Research and Ethical Review Capacity in Developing Settings***

Chairpersons: To be confirmed

Carel Ijsselmuiden, Director, Council on Health Research and Development COHRED, Edlyn Jimenez-Santos, Fellow, Global Forum on Bioethics in Research: "*Health research priorities in developing countries*" (Provisional title)

Juntra Karbwang, Clinical coordinator, UNICEF, UNDP, World Bank, WHO Special Programme for Research and Training in Tropical Diseases (TDR): "*The Strategic Initiative for Developing Capacity in Ethical Review 'SIDCER: The Asia experience"*"

Volnei Garrafa, Chairman, Post-Graduate Programme in Bioethics, University of Brasilia, Brazil: "*Biomedical research and research ethics in Latin America*" (Provisional title)

Abdul Ghaffar, Research Policy and Cooperation, WHO Regional Office for the Eastern Mediterranean: "*Policy and practice challenges for research ethics in the Muslim World*"

h.10.00 Discussion

h.10.30 Coffee Break

h.10.45 ***V Session: The Process of Regulation of Medicines***

Chairpersons: To be confirmed

Hans-Georg Eichler, Senior Medical Officer, European Medicines Agency: "*Clinical trials in developing countries submitted to EMEA for regulatory purposes"* (Provisional title*)*

Melba Gomes, Scientist, Evidence for Antimalarial Policy and Access, UNICEF, UNDP, World Bank, WHO Special Programme for Research and Training in Tropical Diseases (TDR): "*Ethical issues in a clinical trial of artesunate for malaria treatment*" (Provisional title)

Roma Chilengi, Clinical Coordinator, AMANET: "*Challenges of ethical and regulatory review for malaria vaccine trials in Africa*"

Liliana Chocarro, Quality, Safety and Standard, Department of Immunization, Vaccines and Biologicals, WHO Geneva "*Status of regulatory oversight of clinical trials in Africa*"

h. 11.45 Discussion

h. 12.15 Conclusion and Recommendations