Agenzia Italiana del Farmaco
AIFA
Italian Medicines Agency
GCP Promotion Unit, GCP and
Pharmacovigilance Inspectorate

International Round Table AIFA-UNICRI

Biomedical research in Developing Countries: the Promotion of Ethics, Human Rights and Justice

Rome, 15-16 Dicembre 2008

Final Conclusions

Considering that the respect of the GCP principles in clinical trials of medicines, guarantees the ethics of trial as well as the protection of rights of the involved participants, this could be achieved by:

a) Legislation authorizing Clinical Trials only if the protocol is in compliance with GCP principles, following the evaluation of Ethical Committees

b) Legislation authorizing the marketing of medicines only if their efficacy and safety is based on CTs performed in the respect of GCP principles

c) Implementation of CTs in compliance with GCP principles

d) GCP Inspectorates which verify the respect of GCP principles before, during and after CTs conduction

AIFA INVITES

1) International and regional organizations, NGOs and Regulatory Authorities participating in the Round Table and operating in this field, **to collaborate** with each others according to their mandate, for setting up the necessary measures for the implementation of the points a), b), c), d) in Developing Countries.

2) In order to implement the collaboration mentioned in point 1), AIFA invites these organizations to identify, propose and share among each others the needed measures to start a joint mechanism of information so as to implement the necessary actions in a integrated, complementary and harmonized way, in the respect of the autonomy of each institution.