WHO HIS (SDS and EMP) Commentary

The consensus framework for ethical collaboration between patients’ organizations, health care professionals and the pharmaceutical industry

To be delivered by Ed Kelley, Director, a.i., Service Delivery and Safety, Health Systems and Innovation Cluster, WHO (on behalf of ADG HIS)

• First let me thank the organizers of today’s event – International Alliance of Patients Organizations (IAPO), International Council of Nurses (ICN), International Federation of Pharmaceutical Manufacturers Association (IFPMA), International Pharmacists Federation (FIP), World Medication Association (WMA) - for investing their time and resources in the very important topic of ethical collaboration between patients’ organizations, health care professionals and the pharmaceutical industry. As we all here know, the history of this collaboration between pharmaceutical industry and what should have been its partners in health care and its partners in patients, has not always been perfect. But today’s event shows how far we have come.

• WHO congratulates IAPO, CEO, IFPMA, FIP, WMA for taking the initiative of developing a consensus framework for ethical collaboration between patients’ organizations, health care professionals and the pharmaceutical industry. This document is an heritage of a long tradition but also addresses new concerns of many stakeholders with regard to ethics in health research and health care. It is in line with a number of WHO commitments and on-going projects aiming to promote ethics and good governance principles in global health.

• One of the main principles of this framework is to “put patients first”, recognizing their active role in healthcare and R&D, in the global debate on health priorities and equitable access to safe treatments, in promoting ethical conduct of research for health. Ethics means questioning our practices and improving our behaviours. This framework reflects a cultural change in the interaction between stakeholders, for the benefit of the community, that is for “high quality patient care”. The same principle inspires the WHO strategy on person centred care and the network of “Patients for patient safety”.

• WHO itself helped lead the world in the first global effort to involve patients and their families in improving patient safety when it launched the World Alliance for Patient Safety a decade ago. One of the pillars of that innovative effort to improve safety of healthcare globally was a programme entitled Patients for Patient Safety. PFPS is still a strong network today with over 300 champions around the world. Our partners here in the room, IAPO, have worked hand in hand with us for the past years to expand that network and to ensure that patients and their families have the right information and the right support to understand their care, to work with providers to improve their health care and to be engaged in the design and delivery of care generally.

• Our collective history in this area is a full one with examples of strong collaboration. An example of joint efforts to promote transparency in the field of clinical trials is the WHO initiative on clinical trial registration: following a resolution adopted by the WHA in 2006, the
International Clinical Trial Registry Platform (ICTRP) was created to facilitate public access to information about ongoing research; it now includes data related to more than 250,000 clinical trials. This effort could be complemented, adding information about the results of research. This year the research community is celebrating the 50th anniversary of the Declaration of Helsinki; in this context we have to acknowledge the close collaboration between WMA, WHO, and many others, and the progress made in building a global consensus on ethics of research, for example to ensure that the benefits of research are adequately shared.

- Another initiative is the Medicines Transparency Alliance, which aims to improve access to medicines through better transparency. The initiative is carried out in countries by a multi-stakeholder group involving the public and private sectors, and civil society. WHO provides technical support and cooperates in the global management of the initiative. In the pilot phase of the project, which ran from 2008-2010, the multi-stakeholder group collected and disseminated data on the pharmaceutical sector. The current phase will run until 2015 and will focus on data collection, analysis and dissemination and evidence-based policy dialogue.

- "An important area of work within the WHO access to medicines and health products agenda is the implementation of the WHO Ethical Criteria for Medicinal Drug Promotion that have been adopted by the World Health Assembly in 1988. These criteria support the provision of independent information to health professionals and the public, sets out a range of principles that Member States can use in regulating promotional practices, and promote the development of professional codes of conduct based on strong ethical values. WHO appeals to the pharmaceutical industry, patients’ organizations, and health care professionals to join forces in order to ensure that these ethical criteria are used in their spheres of activity and responsibility and that their use is monitored."

- The document being launched today describes the main ethical principles that should guide the interaction of the private sector with patients and professionals; transparency is one of the most important ones. It has very concrete implications in providing access to reliable information, which is the basis of community empowerment and managing potential conflicts of interests to maintain the public trust.

- We at WHO would encourage us all to look at what comes after the launch of this document. It is clearly a good first step. But we must go beyond our current discussions – difficult as they may be – about how compliance with this framework could and should be monitored. A framework of principles provides a basis for common understanding. In the improvement world, though, we are fond of saying “whatever is not measured, cannot be managed.”

- WHO and its Member States are working towards Universal Health Coverage; in this perspective, an important ethical consideration for all stakeholders active in the field of public health is to provide equitable access to safe medication and optimal care. The duty to
provide “optimal care for all” echoes the WHO Constitution and it is extremely encouraging to confirm the commonality of our fundamental principles. Inefficient public and private markets and poorly functioning supply chains restrict the access of the poor to affordable, quality and appropriate medicines. Lack of information and information asymmetries (e.g. between manufacturers, wholesalers, retailers and consumers) fuel inefficiencies, distort competition, allow corrupt practice, hinder effective management and encourage irrational use of medicines. The World Health Report (2010) notes that medicines account for 3 of the 9 most common causes of inefficiency.

- As part of WHO’s leadership on the issue of Universal Health Coverage, it has “reenergized” the area of Health Systems Strengthening with the HIS Cluster. Health systems strengthening is about the “how” - tools we use to improve health systems – through improving quality and safety, through expanding access to essential medicines, through strengthening financing systems and risk pooling mechanisms, through improved health information systems and statistics. Universal health coverage, however, is “the what” – the goal that countries are moving toward. It is an evolution and a journey that can only be undertaken with all partners on board – patients, providers, policymakers... and the private sector.

- Two initiatives that will be launched to help support this type of collaborative, transformative work in the 2014-15 biennium will be the WHO Strategy on Integrated, People Centered Health Services and the 3rd WHO Global Patient Safety Challenge on Medication Safety. We look forward to discussing these further with the partners here today in the room.

- WHO shares the principles established in this framework and is engaged with Member States to ensure their implementation and to monitor progresses. We believe that, as a living document, this framework will inspire a number of other initiatives, especially at country level. An Ethical Framework is only as good as is the full alignment of actions of all stakeholders with its principles. WHO encourages you all to “walk your talk”

- My thanks again to the organizers of today’s event and let us look ahead to our next challenges of ensuring that this framework helps us all to accomplish our common goal – of greater transparency in research and development, of better interventions and medicines for our patients and of improved health for all peoples globally. Thank you.

WHO documents
- Standards and operational guidance for ethics review of health-related research with human participants http://www.who.int/ethics/publications/research_standards_9789241502948/en/index.html
- Research ethics committees: basic concepts for capacity-building http://www.who.int/ethics/Ethics_basic_concepts_ENG.pdf