WHO/WIPO/WTO: health innovation and access to medicines

For the first time, the three global intergovernmental bodies dealing with health, intellectual property and trade have pooled their expertise on a study of policies needed to advance medical and health technologies and to ensure they reach the people who need them.

Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade was launched by the World Health Organization (WHO), World Intellectual Property Organization (WIPO) and World Trade Organization (WTO).

Public health remains a clear imperative for the international community, and promoting both medical innovation and access to the fruits of that innovation is indispensable for progress towards improved and more equitable health outcomes. But to achieve this result demands greater practical cooperation and dialogue within the international system.

The book covers a broad range of complex, yet linked issues relating to public health and innovation in medical technologies, with the ultimate goal of accessibility — making medical advances available globally to all who are sick. It provides solid information for anyone concerned with these issues.

Its target audiences are policymakers, legislators, government officials, delegates to international organizations, nongovernmental organizations, and researchers. The study reflects the debate about health that has evolved over the years, with increasing attention given to medical technologies and their invention and dissemination. Public health and innovation policies, and the rules of trade, competition and procurement, all play a part.

The policy-making focus has broadened from the basic questions of ensuring access to essential medicines, and developing treatments for neglected diseases that are available and affordable for those who are primarily affected — the poor. This is part of the right to health.

More recently, attention has turned to other aspects of how to meet this right: including the measures that are needed to provide incentives for medical innovation — such as medicines, vaccines and medical devices — and how to ensure equitable access to all of these vital medical technologies.

Part of the picture is the international patent system and how governments implement it domestically according to the needs of their countries. The patent system is designed to support innovation, and offers a mechanism to ensure that these innovations are accessible to society.

The research and development pharmaceutical industry therefore relies heavily on exclusive patent rights in order to recoup the investment made in research and development, as shown by the high number of applications for patents on medical technologies under WIPO’s Patent Cooperation Treaty.

The secretariats of the three organizations have drawn on their experience and the data available to them to produce
this study and to support discussions on policy options and legal issues.

The book looks at the need for international cooperation, who is involved, and how to address the challenges that the sector is facing. It examines in detail the range of policy issues from health and human rights and national, regional and global regulation policies, to intellectual property, trade and tariffs, procurement, free trade agreements and other aspects of policy.

It studies a range of issues, such as patents in the pharmaceutical sector; traditional medical knowledge, the importance of knowing what is patented and where, and how easy it is to find out, and questions of affordability and availability of medicines and market failure.

It looks at the development of medical technologies, modern research and development, ways of providing incentives for innovation, and ways of dealing with market failures, in particular with new products for treating neglected diseases. It also includes comprehensive sections on trade and intellectual property rules and the flexibilities they contain for governments to meet various public health objectives.

Reference: World Health Organization (WHO), World Intellectual Property Organization (WIPO) and World Trade Organization (WTO). Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade. Available from WHO Press at bookorders@who.int

EPN study: availability and pricing of children’s medicines in Ghana

The continuous availability of affordable medicines for children is necessary for countries to reduce infant mortality, in keeping with Millennium Development Goal (MDG) 4. In recognition of the importance of availability of medicines for children to the success of MDG 4, the World Health Assembly passed Resolution WHA60.20 in 2007, to include essential children’s medicines in national medicine lists, procurement and reimbursement schemes.

In January 2011, the Ecumenical Pharmaceutical Network (EPN) conducted a study to determine the availability and pricing of selected essential medicines for children in church health facilities in Ghana. The EPN study followed up on a 2007 World Health Organization (WHO) survey of children’s medicines availability in 14 African capitals, which had revealed poor availability of medicines for children in both public and private facilities.

This study was the first significant attempt to collect data on the availability of children’s medicines in health facilities in Ghana. Previous studies have focused on the availability of medicines in general, or on all health facilities, with no focus on either children’s medicines or faith-based health facilities. A similar study was carried out by EPN in Chad, Kenya and Uganda.

Results of the study show that zinc sulphate, chlorpheniramine syrup and vitamin A had the lowest availabilities and over 40% of the facilities surveyed were not stocking zinc sulphate dispersible tablets, vitamin A capsules and chlorpheniramine syrup at all. Unavailability of these crucial medicines could largely compromise the quality of healthcare offered to children.


IOM report on substandard and falsified medicines

The US Institute of Medicine (part of the American Academies of Science) has published a report on Countering the pro-
blem of falsified and substandard drugs. The very careful development and review process of IOM reports is comparable to that of WHO Expert Committee reports.

The report identifies, in particular, the distinction between substandard, falsified and counterfeit medicines. This is a very helpful approach to enabling a meaningful discussion. The report then focuses on the public health impact of substandard and falsified medicines while the term counterfeit medicines is reserved for trade-mark infringements, which are considered outside the scope of the report. Chapter three of the report contains a comprehensive overview of the extent of the problem of substandard and falsified medicines.

The report also makes a number of recommendations for the Food and Drug Administration (FDA), who commissioned the report, and for national authorities, covering various ways and means to strengthen regulatory oversight and to promote supply chain security. For example, a three-step approach is recommended, starting with registration/licensing of all medicine importers in a country, followed by registration/licensing of all national institutions that buy/sell medicines (secondary wholesalers, pharmacies, etc.) and ultimately the use of unique identifiers of individual packages as a final step. This approach is in line with recent EU directives coming into force.

The report also proposes the development of an international code of practice. This type of non-binding international rule would identify and promote regulatory and other governance measures that have proven to be effective in containing substandard and falsified medicines, and could serve as an action guide.


HIFA: Information for healthcare providers

Access to reliable, unbiased information on medicines is fundamental to healthcare. Prescribers and users often lack such information, especially in low-resource settings. Some have no information at all, or the information that they do have is commercially biased. As a result, countless people suffer harm, and sometimes death, as a result of prescribing errors such as the wrong medicine, or the wrong dose. Furthermore, irrational prescribing promotes the emergence of drug resistance. Countless people are already dying from multidrug-resistant tuberculosis and other drug-resistant strains that have emerged largely because of irrational prescribing. There is a real and growing threat to the human species from new microbes that are resistant to all known treatments.

Each year, Healthcare Information for All (HIFA) includes a focus on a specific group of healthcare providers. The HIFA Steering Group has announced the focus of the HIFA 2013–15 challenge to be Meeting the information needs of prescribers and users of medicines. A new page on the HIFA website has been created for this purpose at http://www.hifa2015.org/2013-15-challenge-prescribers-and-users-of-medicines/

The HIFA vision is that every prescriber and user of medicines will have access to the information and knowledge they need to use medicines effectively. HIFA is bringing together a working-group of volunteers to take this forward. The group will:

- Promote discussion on HIFA2015 on relevant issues, including drivers and barriers to the availability and use of reliable information on medicines.
- Promote discussion on issues that are particularly relevant to different groups of prescribers and users.
• Harness insights and perspectives from HIFA members and incorporate these into the HIFA Knowledge Base (currently under development).

Reference: Communication from the HIFA Steering Group at http://www.hifa2015.org/about/administration/

New pregnancy registry protocol
A new protocol has been published in BMC Pregnancy and Childbirth for collecting data on the risks of birth defects due to medicines for diseases such as HIV and malaria. The major components of first-line treatments for these diseases are not recommended during the first trimester, yet many women may take these medications before they are aware that they are pregnant. Sixty-eight percent of the world’s HIV population reside in sub-Saharan Africa and approximately 25 million pregnant women are at risk of malaria.

The protocol is neither disease nor drug-specific. The power of the approach lies in its broad application to a variety of settings in which women may have more than one infectious disease or condition during the course of pregnancy and may also have been exposed to many drugs. Its methods, case record forms and training materials (including a DVD showing how to conduct a surface examination of a newborn) have been tested for feasibility in five countries (four in Africa and one in South America), and further refined and used in the WHO Pregnancy Registry. The approach is integrated within the reproductive health system of the countries, specifically antenatal clinics and labour/delivery facilities.

There are three important features of the pregnancy registry protocol which stand out from most other registries. The first is the simplicity of including women agreeing to take part at their first facility visit for care during their pregnancy. This not only represents the population of pregnant women coming for care but also enables later comparison of birth defects among women who have been exposed to a medicine with those who have not. The second feature is the generic applicability of the approach irrespective of drug or disease, and the third is the improvement of staff capacity to manage and monitor pregnancies and newborns. These qualities add to the practicality and cost-effectiveness of the protocol.

The materials developed are available to any country wishing to join the WHO Pregnancy Registry, on condition that there is a commitment to train the staff to use the materials, to obtain reliable data on drug exposure and to conduct a systematic surface examination of the newborn. The Registry builds capacity within the health system to improve maternal and neonatal care as well as to serve as a sentinel surveillance system for the safety of medicines used in pregnant women.

The specific objectives of the WHO Pregnancy Registry are to:

• Build capacity to obtain reliable information on obstetric, medical, and drug history during pregnancy and diagnose, assess, monitor and manage pregnancy and the outcomes of pregnancy including congenital malformations, stillbirths and prematurity.

• Quantify the baseline risk of major congenital malformations in the absence of drug exposure during the course of pregnancy.

• Quantify the risk of major congenital malformations associated with exposure to medicines during the course of pregnancy.

• Identify other obstetric, therapeutic and clinical factors that may contribute to the risk of major congenital anomalies and other adverse birth outcomes in pregnant women.
• Support a culture of drug safety awareness among women and their providers in participating countries and avoid preventable adverse drug-related pregnancy outcomes.

• Develop an ongoing surveillance system of maternal and newborn health that strengthens the health system to improve maternal and neonatal outcomes.


### Malaria: rapid diagnostic testing

*Malaria rapid diagnostic test performance* is the fourth report in a series of laboratory-based evaluations of rapid diagnostic tests (RDTs) for malaria. It provides a comparative measure of their performance in a standardized way to distinguish between well and poorly performing tests. This information can be used by malaria control programmes and to guide UN procurement policy for these diagnostic tools.

In Round 4, 48 products were evaluated. Overall, the majority of resubmitted products either maintained or improved their performance in Round 4, indicating product improvement by the manufacturers. Also included in the report is an algorithm to assist in the RDT selection process, a field tool to assess RDT packaging, safety and ease-of-use, and a pictorial guide to common anomalies seen in production lots.

The evaluation programme is co-sponsored by the Foundation for Innovative New Diagnostics (FIND), the Special Programme for Research and Training in Tropical Diseases (TDR) and the WHO Global Malaria Programme (GMP). Testing is performed at the US Centers for Disease Control and Prevention (CDC).


### Paediatric ACTs for the treatment of uncomplicated malaria

The Medicines for Malaria Venture (MMV) has announced the release of a new independent study focused on assessing critical barriers to the acceptance and uptake of quality antimalarial medicines for children.

The study examines six francophone countries in Central and West Africa, and draws on a WHO-endorsed framework for evaluating barriers to access to essential medicines. It suggests interventions that could enhance acceptance and uptake of WHO-recommended medicines for children.


### International course on dengue

The 13th International Course on Dengue will be held 12–23 August 2013 in Havana, Cuba. Through theoretical and practical sessions, the main aspects related to dengue will be covered: dengue epidemiology, clinical management, diagnosis, virology and immunology, vector control, environmental risk factors and community participation.

Important aspects to be discussed are trends of dengue at global level, impact of climate change, new dengue clinical classification, opportunities for diagnosis, impact of virus diversity, immunogenetics, complexity of dengue immunity and pathogenesis, dengue vaccines, integrated surveillance and control, difficulties, options, challenges, economic burden, new options for control, and insecticide resistance, among others.
The new global initiatives for dengue and the experiences of several countries and geographical regions will also be updated and general lectures as well as round tables and symposia are scheduled. Two mini-courses on GIS and dengue and modeling of transmission and prediction of dengue as well as other activities and meetings will be also organized.

The course is provided by the PAHO/WHO Collaborating Centre for the Study of Dengue and its Vector, Pedro Kourí Tropical Medicine Institute, Havana, Cuba, in collaboration with the Cuban Ministry of Public Health, the Cuban Society of Microbiology and Parasitology and the Pan American Health Organization (PAHO).