PROMOTING ACCESS AND MEDICAL INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE

Joint study by the WHO, WIPO and WTO Secretariats

Outline and overview

The WHO, WIPO and the WTO have consolidated their technical cooperation activities on the intersections between public health, intellectual property (IP) and trade in the form of a joint trilateral study which will be released in 2012. The study draws together policy information and empirical data on access to medical technologies and medical innovation, to provide a practical resource for those seeking to navigate through this complex policy territory. This outline sketches the background and contents of the study, and notes some of its key observations.

Structure of the study

- Introduction - rationale of and background to the study
- An overview of international policy instruments and issues with bearing on access and innovation
- A review of the access dimension
- A review of the innovation dimension
- Annex giving details of major players in international policy debates
- Annex providing models for using the 'paragraph 6' access to medicines mechanism under the WTO TRIPS Agreement

An evolving policy context

The study reviews key developments over the last decade:

- An emphasis on public private initiatives with the coming of age of partnerships to develop medical technologies
- Significantly increased funding for vaccine development and immunization
- Maturing of the pharmaceutical industry, and strengthening of medical innovation, in a range of developing countries
- Renewed attention to the strengthening of national health systems
- Growing global awareness of the impact of non-communicable diseases, especially in developing countries
- Insights into the intersections between public health, the IP system, trade and competition rules, and measures to promote innovation and access to medical technologies
- Innovative approaches to medical research, and for financing research and development, particularly for neglected diseases
- Improved coverage and accessibility of data, enhancing the empirical base for informed policy discussions
- Greater policy coherence and practical cooperation on the intersection of health policy, trade and IP issues, within the broader perspectives established by the human rights dimension of health and the UN Millennium Development Goals

At core, a global challenge, and shared responsibility...

Public health has long rightly occupied front rank among priorities for global cooperation and action by the international community. The right to health is an universal human right, just as the burden of disease is shared by all humanity. The WHO Constitution underscores that any one state's achievement in public health benefits the international community at large. This creates a compelling rationale for effective international cooperation for public health, and is an essential foundation for sustainable development: health issues are central to the achievement of the United Nations Millennium Development Goals. The very foundational objective of the WHO is the attainment by all peoples of the highest possible level of health. Moreover, WIPO and the WTO, in line with the mandates given to them by their Member governments and their respective areas of expertise, have increasingly stepped up their efforts to support global efforts towards this end.

... promoting innovation and access to medical technologies…

International cooperation on public health assumes many dimensions, but recent years have seen an intensified focus on the role of medical technologies - the innovation processes that produce new technologies and deliver them to the public; the way in which health solutions are disseminated to those most in need; and the shortfalls between innovation and access and the evolving global disease burden. Access to essential medicines, identified by the human rights community as an element of the right to health, has been an active concern especially over the last 15 years. The policy focus has since broadened to consider the improvement of health systems, how to promote necessary innovation, how to address neglected health needs, and to ensure access to other vital medical technologies, such as diagnostic tools and modern vaccines. Innovation and access are inevitably intertwined - the evolving state of the global disease burden creates a constant demand for new and adapted technologies and their widespread dissemination.

…responding to a rapidly evolving policy environment and diversity of country needs

Against this background, it is both a natural consequence of their mandated responsibilities, and increasingly a practical necessity, for the WHO, WIPO and WTO Secretariats to coordinate and cooperate ever more closely on such questions as patterns of innovation and access, legal and policy factors affecting the production and dissemination of medical technologies, and the interplay between international trade rules and the intellectual property system. These issues are not new: the 2001 Doha Declaration on the TRIPS Agreement and Public Health confirmed that they were already critical concerns for a wider policy community. In 2002, the WHO and the WTO collaborated on a study, *WTO Agreements & Public Health,* which remains a valuable standard reference.

However, important developments have taken place since then, both within and beyond the three organizations, that have significantly transformed the policy context for innovation and access for medical technologies. These include greater availability and more systematic use of empirical data that enables clearer illumination between access to medicines, IP coverage, and trade and competition settings.

Policymakers, too, seek to understand the complex interplay between established fields of study, at a time when improved analytical tools and data open up new possibilities for this work - such opportunities include using economic methods to analyse the contribution of IP to innovation, and strengthening understanding of the human rights dimension of access and innovation issues.

Diverse initiatives have been launched to explore new strategies for product development, yielded a valuable vein of practical experience, and a rich debate has opened up about improving and diversifying innovation structures to address unmet health needs. The role of public research and academic institutions, notably in developing countries, has come under the spotlight. Industry continues to diversify and evolve, with a trend towards integrative and collaborative innovation systems, and the fading of traditional boundaries between research based and generic firms, and between developing and industrialized countries. New and adapted approaches to procurement, particularly for

essential medicines, are bearing fruit and offer considerable insights for wider efforts to obtain needed treatments in an affordable and sustainable way.

…through strengthened partnerships and closer co-operation

Tracking and responding to this fast changing policy environment, and making effective use of this richer, more diverse and inclusive base of empirical data and practical experience to guide technical cooperation, is a challenge for each of the three organizations, as they address specific mandates and work programmes in this area. The technical cooperation they offer, responding to growing and diversifying demand by their Member governments, has been characterized by active dialogue, coordination and partnership, leading to more effective and tailored capacity building activities. One aim of this cooperation has been to strengthen policy coherence between these three World organizations as possible - sometimes in the past assumed to occupy or define different 'worlds', they need to work within and to serve the one world.

This cooperation has also taken concrete shape in the form of a technical symposium series, jointly convened by the three Secretariats, aimed at pooling practical experiences and available sources of data, so as to broaden and strengthen the base of understanding that underpins ongoing programmes and technical assistance. The first symposium, in July 2010, undertook a broad review of issues and factors affecting pricing and procurement of medicines; the second, in February 2011, highlighted the prospects for using patent information to assist more informed choices on access to medicines. The feedback from these events, and many other technical cooperation activities undertaken by the Secretariats, underscored the benefits of capturing these insights in more concrete, accessible and systematic form, distilled as a joint trilateral study.

…and distilling insights from practical experience and technical cooperation, and a wider range of voices

The tenth anniversary of the Doha Declaration provides a timely opportunity to review the experience gained in improving access and promoting medical innovation, and to draw together data on innovation and public health, including data on pricing, access to medicines and patent coverage. The trilateral study aims to harvest the fruits of strengthened trilateral cooperation, capturing a broad range of experience in dealing with the interplay between IP, trade rules and the dynamics of access to and innovation of medical technologies. It draws together the Secretariats' respective areas of expertise regarding the overall framework concerning access and innovation in the field of medical technologies, and provides a platform for sharing practical experiences and updated data, so as to support and help illuminate ongoing technical cooperation and policy discussions. It is also guided by the approach to cooperation on public health catalysed by the WTO Doha Declaration on the TRIPS Agreement and Public Health, the WIPO Development Agenda, and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, and contributions to policymaking such as the landmark 2006 report on *Public health, innovation and intellectual property rights*, prepared by the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH).

The policy debate has, rightly, engaged many and more diverse voices; much is to be gained from the engagement of an ever wider base of actors and practical perspectives. The Secretariats' role is to support and objectively inform policy discussions. The study therefore aims to provide an objective base for these crucially important debates, through a strengthened empirical perspective and a richer base of practical understanding.

The study aims to serve as a background reference for policy makers in the widest sense, including lawmakers, government officials, delegates to international organizations, administrators and NGOs. It does not advance comprehensive new research nor does it provide ready-made answers to the questions of the day. Yet it is essentially forward looking - a baseline of integrated understanding and evidence, to stimulate and inform future co-operation and dialogue.

PROMOTING ACCESS & INNOVATION: A HOLISTIC VIEW

Medical technologies are an essential ingredient for an effective response to many current public health threats. Many factors - legal, policy, infrastructure, financial, cultural, social, and administrative - have to come together to create an en-

abling environment for improved, and more equitable, public health outcomes. The current situation is very far from adequate, as both access to needed medical technologies, and the focus of the innovation are characterized by critical gaps. Health outcomes do not automatically flow from a simple technological fix, as the current work on sustainable financing and health systems, and preventative interventions, clearly illustrates.

Technology is an essential component of public health: medicines, ranging from antibiotics to antiretrovirals, have helped achieve dramatically improved public health outcomes; vaccines have all but eliminated the threat of certain diseases; and other technologies, such as medical imaging, have led to a transformation in diagnosis and treatment. Such technologies are the product of extensive research and development activities.

Development of these technologies is a complex, often risky and uncertain, process, drawing on diverse inputs, originating from both public and private sectors, and often requiring scrupulous testing and regulatory oversight. Innovation of medicines is among the most unpredictable and expensive forms of technology development, creating the need for distinct innovation structures, close regulatory and ethical attention, an appropriately high standard for safety and efficacy, and specific or targeted incentives.

As the disease burden shifts and evolves, so does the demand for new, adapted and more effective medical technologies. A characteristic aspect of access is the distinct need to incentivise research to address hitherto unmet needs - what are termed neglected diseases. Access to necessary medical technologies is not, therefore, a static equation. Integral to appropriate access strategies must be a recognition of the value of targeted and appropriate innovation, both for major new breakthroughs and adaptations and improvements of existing technologies.

Similarly, innovation does not take place in isolation from concerns about equitable access to medicines and other medical technologies. The social value of medical innovation can be measured in part by the extent to which it is effectively and sustainably available to the populations in need. The widespread and equitable health impact of new technologies cannot be achieved without ensuring appropriate means of access to finished products. Hence, an overall policy on medical innovation must also consider the access dimension as an integral factor.

OUTLINE OF THE STUDY

Chapter I: Introduction: context of the study

- Imperatives for international co-operation
- Overview of key actors

The study opens with a review of the context of international cooperation and the general policy background to the study. It introduces the key stakeholders: the WHO, WIPO and WTO and a multitude of players from different sectors that share their expertise in current policy debates and contribute from their respective angles to improving health outcomes through innovation and access to medical technologies.

Chapter II: The policy context for access and innovation

- Defining the need: global disease burden
- Responding to the need
- Main policy instruments
- Economics of innovation and access

Chapter II provides a broad overview of the relationship between public health, IP, trade and innovation with bearing on access and innovation. To clarify the scale and nature of the public health challenge, and to set access and innovation initiatives in context, it describes the concept of global disease burden, and how it is measured. The current global disease burden is outlined, as are likely future trends over the coming decades. An introduction to the policy, economic and legal features of IP and innovation systems concentrates on the key aspects that have bearing on medical technologies and pharmaceuticals in particular. The description of the IP system focuses on aspects of patents, trademarks and copyright, and IP enforcement, that are most widely considered in policy debates on access and innovation of medical technologies. The Chapter also describes pharmaceutical regulation, competition and relevant trade policy measures such as import tariffs, rules on trade in services, government procurement, and regional and bilateral free trade agreements. The chapter outlines the human rights dimension of access to medicines.

Key observations: policy overview

- Multiplicity of international legal and policy elements that help define the general context for access and innovation
- Dynamic interplay of trade and competition settings, procurement policies, the regulatory environment and IP rules that impact on access and innovation

- Growing impact of trade and IP agreements outside established multilateral forums, and in new areas such as competition policy, government procurement and linkages between patents and drug regulation
- Emergence of broader, multidisciplinary policy perspectives, including guidance from human rights law, a richer empirical base, and insights from economic analysis, backed by a wider range of policy actors and more diverse experience from private, public and philanthropic sectors

Chapter III:
Medical technologies - the access dimension

- Key determinants and strategies for access
- Data on access to medicines
- Implications for access of trade, regulation and IP mechanisms, in the multilateral system and free trade agreements
- Traditional medical knowledge

The third chapter concentrates in more detail on the access dimension: it considers how the policy framework specifically applies to access to medical technologies. It explains how access to medicines can be defined and measured, and it presents available data on access to medicines and the related question of prices of medicines. It describes key determinants for access, such as efficient procurement mechanisms, the role of the private sector and other initiatives, trade settings in relation to tariffs, services and procurement, the role of competition policy, the use of TRIPS flexibilities, and local production initiatives.

Recent data on tariffs enables analysis of how procurement and competition policy can support access to medical technologies through enhanced affordability. The linkages with the regulatory system and the impact of mark-ups and taxes on prices are also considered. The study focuses on several key features of the IP system with bearing on access, including the scope of patent and test data protection and IP enforcement mechanisms. It outlines the nature of IP provisions in recent free trade agreements with bearing on access to medicines. This chapter also describes the role of the Doha Declaration and the 30 August 2003 Decision to create the 'paragraph 6' mechanism as an additional pathway for access to medicines. The role of traditional medicines and the protection of traditional knowledge are addressed as an aspect of access to appropriate medicines and health care.

Key observations: access dimension

- Access is a complex equation, and policy-makers actively seek to understand key drivers, which include selection and rational use, price, health systems and sustainable financing
- The Doha Declaration has facilitated awareness and judicious use of TRIPS flexibilities to leverage access, and recent surveys illustrate diverse choices taken by countries to make use of IP policy options
- Effective procurement strategies are key, with a number of procurement initiatives illustrating the effect of accumulated demand, a capacity to negotiate, and full information on such factors as drug regulation and patent coverage
- Competition and lower tariffs can promote access, both through price reductions and in terms of sustainability of supply through diversification of sources
- Evidence of a significant trend over the past decade towards bilateral and regional agreements with specific bearing on those aspects of IP that concern access to medicines, but also related areas such as competition and public procurement
- The factors involved in strengthening local production of medicines and vaccines, particularly in the developing world, are currently the focus of both policy interest and practical initiatives

Chapter IV:
Medical technologies - innovation dimension

- Dynamics of innovation, and the challenge of neglected diseases
- Public and private sector roles, and new partnerships
- Patents and data protection in the innovation cycle - freedom to operate and licensing issues
- Patent information and medical innovation

The last chapter considers how the policy framework specifically applies to innovation of medical technologies. It reviews changing drivers of pharmaceutical innovation, considers reported costs of medical research and development, and identifies changing models in medical research and development, as well as new forms of open and collaborative innovation, distinctions between precompetitive research and data, and more competitive processes towards the end of the product development pipeline.

There is a focus on research related to diseases disproportionately affecting developing countries. The study considers the evolving role of pharmaceutical companies and public private partnerships in product innovation, including research institutions from developing countries and considers different innovation models, the role of patents in medical innovation and the range of options within the patent system from the public interest perspective.

The importance of test data obtained during clinical trials in pharmaceutical product development, freedom to operate issues, and data available from the patent system are also covered. The use of patent data to track innovation patterns and to support innovation processes is described and illustrated with detailed reports on recent WIPO patent landscaping exercises in the public health field.

Key observations: innovation dimension

- Traditional assumptions about innovation models - public vs private, exclusive vs collaborative - are giving way to a more nuanced and dynamic set of innovation patterns
- Policy concern centers on the need to address public health burdens that an essentially commercial approach has so far neglected.
- Major firms are not necessarily confined to exclusive silos of research and development activities, but can act as technology integrators from diverse sources - product innovation as integration of technologies
- Researchers in emerging economies may change the global pattern of research and development as the traditional R&D landscape is progressively transformed and diversified
- Policy focus has broadened from considering how the grant of patents supports medical innovation, to examine the key drivers of innovation and the effectiveness of various incentive models such as prize funds, the concept of delinking prices of medicines from the funding, and incentivization of product research and development
- Important innovation policy issues surround public research organization and university research patenting and IP management in the field of public health, given the central role of these players especially in upstream development of technologies and key inputs such as research tools

BACKGROUND TO THE PROJECT

Given the interrelated nature of the challenge, WHO, WIPO and WTO Secretariats coordinate and cooperate closely on the interplay between global health, international trade and the IP system. The enhanced dialogue over the past ten years among the three Organizations has led to more effective capacity building activities, better tailored to the diverse needs of developing countries. This work has supported policy makers and senior government officials to explore the full range of options available, so that they can choose the right mix which best respond to their domestic needs. The trilateral study is a further milestone towards stronger cooperation.

The study provides a holistic presentation of the full set of issues, including institutional and legal concepts. It draws together working materials used in technical cooperation and addresses emerging needs for information in an accessible, systematic format, to support ongoing collaborative efforts.

It gives an update on IP developments and trade measures that relate to innovation of and access to medical products. It seeks to progress the integration of data sources and mutual learning among those with diverse policy perspectives and practical experiences. It aims to distil this experience into one accessible and comprehensive resource, covering all the main policy instruments. The study is prepared with a view to serving the needs of policymakers who seek a holistic presentation of the full set of issues, including institutions and legal concepts.

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