WHO-WIPO-WTO TECHNICAL SYMPOSIUM

INNOVATION AND ACESS TO MEDICAL TECHNOLOGIES – CHALLENGES AND OPPORTUNITIES FOR MIDDLE-INCOME COUNTRIES

WEDNESDAY, 5 NOVEMBER

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DDG OPENING REMARKS

INTRODUCTION

Let me wish you all a very warm welcome to the World Trade Organization. I am also delighted to welcome my colleagues, Marie-Paule Kieny, Assistant Director General of the World Health Organization, and Johannes Christian Wichard, Deputy Director General of the World Intellectual Property Organization, two of our most valued partners in the multilateral system. They will be sharing the opening session with me.

The strong personal commitment by the Director Generals of the three collaborating agencies, Dr Margaret Chan from the WHO, Francis Gurry from WIPO and Roberto Azevêdo from the WTO, to building a relationship of dialogue and cooperation is borne out by the fact that this is the fourth in the series of trilateral policy symposia; the four years of trilateral cooperation have also seen the production of a pathbreaking trilateral study as a shared foundation for our continuing work together and for our outreach to many other partners.

The indispensable importance of continued collaboration within the international system on public health issues is underscored yet again today as we witness the emergence of the *Ebola* crisis, an international challenge that our WHO colleagues are addressing with remarkable dedication and commitment. It is a reminder, yet again, that a public health crisis in one part of the world is inherently a concern for us all, one that imposes a firm obligation on the international community to work together towards sustained and effective solutions.

But it is also the latest developments in this international health crisis that made it impossible at the very last minute to hold the personal dialogue between the Directors General of WHO, WIPO and the WTO today; in particular, Dr Chan has been unavoidably called away from Geneva in the context of the WHO's response to the crisis. This dialogue between the three Directors General will therefore have to be rescheduled to take place at the next trilateral event, tentatively foreseen for mid-2015. In the meantime, today's symposium will nonetheless take place as scheduled, in order to maintain the momentum of trilateral cooperation.

Turning to the topic of today's symposium, we are continuing the underlying motif that has sustained this series of policy symposia – the need to learn practical lessons about how policy choices made at the international, national and institutional level can contribute to public health outcomes, with a particular focus on innovation and access to medical technologies. This time, we turn to the experience of the middle income countries. Why? It is the remarkable dynamism and yet the diversity of these countries in the public health field that make them such an important focus for policymakers today. They stand at a critical juncture – increasingly significant in the production and innovation of medical technologies, middle income countries are an important and growing source of medicines and other technologies for other countries, particularly developing countries, thanks to a rising trend in exports of finished products and of technologies. Yet many such countries continue to confront challenges for access for significant portions of their own populations. They are contending in diverse ways with the policy balance of promoting innovation and the implementation of new technologies, while facilitating access on the part of those most in need.

The symposium therefore aims to review developments in these countries, and to learn from their diverse experiences. It is a timely opportunity to review trends in innovation in those countries, to understand various strategies and challenges for access to medical technologies, and to consider

how to work together to inform our continuing programs of technical assistance so as to strengthen the capacity of Member governments to develop and apply needed policies in the critical areas of intersection between public health, intellectual property and trade.

INNOVATION AND ACCESS TO MEDICINE – WTO'S CONTRIBUTION

These issues have been fundamentally important to the WTO and its Member governments. An early landmark for the WTO was the Doha Declaration on the TRIPS Agreement and Public Health: this provided a blueprint for a coherent way of addressing public health objectives within the framework of the multilateral trade system. The world's trade ministers voiced a common concern about the global burden of diseases, and the need for the TRIPS to be part of the wider national and international action to address health problems.

In identifying ways in which TRIPS rules can support public health outcomes, the Doha Declaration also reinforced the basis for multilateral cooperation on issues on the intersection of public health, trade, and intellectual property. It became abundantly clear that the goals of the Doha Declaration couldn't be achieved in isolation but required an integrated, cross disciplinary approach, combining the expertise and experience of all sectors concerned. This is why the WTO has built a partnership with other agencies into the core of its work on trade, IP and public health issues.

Doha was also a clear reminder that adherence with WTO rules is not and should not be a constraint on effective public policy choices, including and indeed especially in the critical area of public health. It led to the first agreement among Members on an amendment to the whole body of WTO trade law, and this purely to open up work on a new pathway for access to medicines by the most vulnerable countries. It also helped to clarify that Members can pursue a wide range of policy options and flexibilities enabling them to tailor an IP laws and policies that are responsive to their particular domestic policy objectives. One clear example is the regulatory review exception under patent law, confirmed by WTO dispute settlement and now present in some form in a wide cross section of WTO Members' laws, as a specific tool for reconciling appropriate patent protection with the smooth operation of necessary drug regulation and the policy goal of encouraging effective generic competition after a patent expires.

Our work has also highlighted many other areas where the right kind of trade policy settings have a positive impact on public health. Above all, no country is or can hope to be entirely self sufficient in medicines and medical technologies. The trading system creates a broader base for access, and facilitates the kind of competition that drives innovation and cuts prices.

Import tariffs on finished pharmaceuticals are imposed at a relatively early stage in the distribution of a product, and later markups and taxes therefore magnify their effect on the ultimate price and thus affordability of a medicine. And tariffs on ingredients and inputs to medicines push up costs for domestic producers and thus affect their sustainability. A number of WTO Members agreed, in the context of the Uruguay Round, on a Pharmaceutical Tariff Elimination Agreement (so-called 'Zero for Zero') on certain pharmaceutical products, including active ingredients and intermediate products. Currently, the trend in other countries is towards lower tariffs in this domain. This is a reminder that what is ostensibly a trade policy goal has broader systemic impact. Another example is the area of trade facilitation. I will not dwell on the procedural question we are confronted with on this matter. It is nonetheless worth bearing in mind that the significance of trade facilitation for an improved flow of trade, a reduction of costs, needless paperwork and delays at the border, and thus its impact on access to medicines traded across borders.

A significant proportion of our work in other areas, too, such as on health-related measures under the TBT and SPS Agreements, concern establishing an effective, positive sum linkage between trade policy and the kind of measures that are vital for ensuring public health. Access to medicines and other medical technologies is also, in large part, an exercise in government procurement, where transparent and competitive procurement strategies – in line with the WTO Agreement on Government Procurement – can deliver greater impact for scarce public monies in this area. The GPA – in the past seen as largely a developed country agreement – is now attracting increasing interest among a number of middle income countries; it generally covers a wide scope of medical procurement by the public sector.

MIDDLE INCOME COUNTRIES – IP STRATEGIES AND CHALLENGES

In exploring the significant role of middle-income countries, we should avoid getting tied up in definitions and boundaries. The key point is that there is a growing number of countries with the resources, the capacity and the knowhow to make a major impact in the innovation and dissemination of much needed medical technologies. Their growing domestic markets support growth in the medical technology sector, a ramping up of capacity and a diversification of supply that has important spillovers for access to these technologies in foreign markets as well.

I hesitate to refer to patent statistics in front of my considerably better qualified colleague from WIPO. However, even for a lay person, it is instructive to track the rise in innovative capacity that is illustrated by the rise in patenting activity in the medical technology field emerging from middle income countries. Under the WIPO PCT system, the rate of middle income applicants filing patent applications in the pharmaceutical and medical technology fields rose sevenfold between 1995 and 2012; this tripled their global share of activity in this area from 9% to 27% - an incomplete, but nonetheless telling indicator of the shifting centre of gravity of innovative endeavour.

This growing patent portfolio in the middle income countries – shared between the public and private sectors in different proportions – underlines the growing significance paid to the strategies regarding IP rights and business models pursued by the pharmaceutical sector in these countries, as well as policies relating to public sector patents. This is a key issue that will be explored today – one question is who is taking out patents in this area, but another, perhaps more interesting but more challenging question concerns how they are managing and exercising those patents, with a view to promoting the introduction to the public of new medical technologies.

The statistics also offer insights into the growing significance of middle income countries when it comes to exports of pharmaceuticals. Taking three middle income countries alone, Brazil, China and India – admittedly among the most significant in this sector - their reported pharmaceutical exports rose almost twentyfold in the life of the WTO, from around USD 1 billion in 1994 to 19.5 billion last year. Last year, these three countries exported medicines respectively to 145, 194 and 202 separate trading partners.

Given their increasing status as producers, adaptors and innovators of medical technologies, middle income countries are also playing an important role not only as suppliers of affordable products but as a source of appropriate production technologies transferred to LDCs. Thus, Director General Azevêdo, during a recent visit to Uganda, visited a production facility for triple therapy antiretroviral drugs, much needed to combat HIV AIDS in the East African region. Its production technology is transferred from a leading Indian producer. Another example is a Brazilian initiative to build ARV packaging and production capacity in Mozambique.

Trade, and the framework the international trading system provides for the flow of products and the transfer and dissemination of technology, form one part of the overall system of policy, legal and regulatory settings that governments need to deploy to put medical technologies to work in the service of public health. This is a clear message of the trilateral study, and the central theme of our trilateral cooperation: appropriate trade and balanced IP settings are an essential prerequisite, but not sufficient in themselves, to facilitate a measured and sustainable response to the challenges of innovation and dissemination of medical technologies for improved public health outcomes. Cooperation with our multilateral partners and Member governments are vital, and learning from their areas of competence and experience is essential. Within this collaborative framework, I believe that the WTO can make a distinctive and valuable contribution, and certainly we wish to bolster this work in dialogue with our partners. Our contributions include:

- More tailored, better coordinated capacity building: we have made considerable efforts to develop and tailor our technical cooperation programs in this area to respond to the emerging needs of WTO Members. This includes taking a more holistic approach, looking at individual components of the policy mix within their full practical context. Next month we convene the WTO's annual Geneva workshop on public health – over the years this has evolved from a relatively technical focus, to a much broader review of the IP and trade policy. The trilateral initiative itself stems from our technical assistance work, and now provides a sure basis for a comprehensive, holistic approach that is better tailored to the practical needs of policymakers. This work also involves exploring emerging issues – for instance, we find growing demand for technical cooperation dealing with competition policy questions.

- Putting statistics to work, to provide a stronger empirical foundation for policy discussions: the WHO is used to working with a range of trade and trade policy information that is part of understanding the international framework for medical innovation and access. Combining this information in an accessible, systematic way with date on health and on the IP system managed by our trilateral partners offers remarkable possibilities for deep insights into the environment for innovation and access.
- Transparency is a core principle of the WTO: the notifications made by WTO members provide a unique, wideranging overview of the legislative and regulatory measures adopted by WTO Members, many with considerable significance for public health policy. We are finding new ways of accessing and analysing this body of information, and again this will help illuminate the complex environment of public health policy.
- Policy debate: the WTO provides a forum for a thorough, searching exchange of views among Members regarding their legislative and policy choices
- And of course in the event that a matter does end up as a dispute between trading partners, we offer a unique forum for resolving disputes – the experience to date has demonstrated a clear and appropriate scope for public health measures

CONCLUSION

The essential ingredient for the successful program of trilateral cooperation is above all a spirit of mutual respect and collegiality – the three organizations contribute their respective areas of knowledge and competence in a mutually supportive way. We hope very much that this example will find resonance elsewhere, both in the international system and at the national level – since attaining public health outcomes ultimately requires the effective collaboration between government agencies responsible for health, trade and intellectual property

We remain committed to joint policy dialogue and capacity building with the aim of providing the factual and technical information that is needed by policymakers to take well-informed decisions, and at building dialogue between specialists and policymakers from different fields of expertise and responsibility. I trust that today's symposium will provide a major step forward in this direction. We are delighted that you have joined us here at the WTO to resume one of Geneva's most important conversations – and I wish you a productive and stimulating day of discussion and mutual learning.

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