

UN SECRETARY GENERAL'S HIGH LEVEL PANEL ON ACCESS TO MEDICINES

BUILDING MOMENTUM FOR THE COHERENCE AGENDA ON GLOBAL HEALTH

Background note prepared by the Secretariat of the World Trade Organization (WTO)¹

Key points

- Coherence for public health is an imperative at several levels, ranging from the international legal framework to concrete practical initiatives; encouraging coherence entails addressing each level, as well as promoting positive feedback loops between these distinct levels.
- The Doha Declaration on the TRIPS Agreement and Public Health serves as a blueprint for coherence. It has catalysed coherence in the work of the WTO itself but also in its work with diverse partners. Recently, this has borne fruit in the form of a Trilateral Study and wide-ranging series of policy symposia in partnership with the WHO and WIPO, steps taken consciously towards greater coherence in policy discussions, technical cooperation and capacity building.
- Building national capacity for informed and coherent policymaking is a central concern, given that in practice it is often the domestic environment – law, policy, practice, infrastructure and human capital – that ultimately determines the effectiveness of initiatives for access and innovation in terms of concrete public health outcomes; it is also where the effects of incoherence can be most pronounced. Cooperation for inclusive, broad-based national capacity building is therefore not an adjunct but a direct contribution to coherence.
- WTO Secretariat experience with such technical cooperation in partnership with other agencies underscores the benefits of building domestic capacity for coordinated, informed domestic policymaking, including horizontal learning between government officials confronting similar challenges, drawing on the growing body of practical experience at the domestic level, as is illustrated by the diverse policy and regulatory choices made by WTO Members within the framework of the TRIPS Agreement. Coherence with the wider trade policy framework also contributes to sustainable outcomes from access and innovation policies
- The challenge of developing and implementing effective and equitable policy measures for innovation and access to meet public health goals is dynamic by its very nature, evolving with the disease burden, progress in technology and diversification of innovation systems: adaptive solutions will be needed to address changing and more diverse needs. Whatever specific measures the Panel considers, sustained benefits would flow from encouraging an inclusive, cross-cutting policy dialogue across the multilateral system, to enable mutual learning, cooperation and coordination to meet the challenges lying ahead.
- Equally, in an environment for access and innovation that is dynamic and complex, policy coherence will be supported a stronger empirical foundation, through greater transparency and accessibility of data and efforts to enable policy responses to be based on integrated health, trade and IP data.

¹ This note is prepared only as a background resource to support the work of the High Level Panel, based on the practical experience of the WTO Secretariat in capacity building and policy dialogue relating to public health matters. It does not present an official view for attribution to the WTO as such nor its Members or Secretariat; the Secretariat cannot and does not seek to give any legal interpretation of WTO agreements or any other legal instruments.

Introduction

The UN Secretary General has convened a High Level Panel on Access to Medicines ('the Panel') to address "innovation and access to health technologies," with an overall scope "to review and assess proposals and recommend solutions to remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies that is impeding access and the right to health for millions."² The WTO Secretariat is appreciative of the invitation to participate in the Expert Advisory Group supporting the Panel and to provide this background note.

The WTO has worked extensively on the challenge of coherence in public health and cognate policy fields: it responds to this challenge in a wide range of activities, including technical assistance and capacity building, often conducted through cooperative partnerships within the multilateral system, in policy dialogue, and in the settlement of disputes. Health has a strong voice throughout these activities, and ensuring scope and policy space for pro-health policies and practical measures is integral to the design and structure of WTO legal instruments. There have been important advances towards policy coherence within the multilateral system in recent years, so that hard-won lessons of the past can be applied to future challenges. While there are undoubtedly incoherencies in our respective policy areas that need to be tackled, these efforts will be all the more effective if guided by an understanding of the positive steps towards progressively greater coherence in recent years.

This note draws on this practical experience to illuminate pathways towards ever greater coherence between the legal and policy domains that the Panel is addressing. For the WTO, the coherence agenda for public health reaches well beyond the question of innovation and access to health technologies;³ however, given the specific scope of the HLP's work, this note concentrates only on that specific dimension.

The Sustainable Development Goals and coherence

Policy coherence in furtherance of the twin goals of access to medicines and necessary medical innovation is essential for effective, sustainable and equitable progress towards universal health coverage and improved health outcomes for all. The recent adoption of the Sustainable Development Goals (SDGs) both demonstrates a remarkable degree of consensus about shared goals and targets for 2030, and creates an enabling framework for progress towards policy coherence, with direct bearing on access and innovation. Most directly, this includes, under SDG3, the targets for 2030 of supporting "the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries" and providing "access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in [TRIPS] regarding flexibilities to protect public health, and, in particular, provide access to medicines for all." The SDGs also illustrate the broader dimensions of coherence for public health, including targets on nutrition and food security (SDG 2) and poverty eradication (SDG 1), and setting the trade dimension of development within the context of strengthening the means of implementation and revitalizing the global partnership for sustainable development and addressing "policy and institutional coherence"⁴ (SDG 17) – recalling that, at the broadest level of coherence, trade, development, and improved health go hand in hand. Shortly after the SDGs were concluded, WTO Members, at ministerial level, adopted the Nairobi Declaration⁵ which recognized the role the WTO can play in working towards the achievement of the SDGs.

The TRIPS dimension: the Doha Declaration as a blueprint for coherence

The Panel's mandate refers in general to trade agreements, but from a multilateral perspective at least, it is the WTO TRIPS Agreement that has attracted the most attention. The TRIPS Agreement was consciously crafted and carefully negotiated to safeguard policy space, particularly in the vital area of public health;

² UNDP, UNAIDS, The United Nations Secretary-General's High-Level Panel on Access to Medicines: Terms of Reference, 2015.

³ A general survey is provided in WTO Agreements and Public Health, A joint study by the WHO and the WTO Secretariat, available at https://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf

⁴ UN DESA, Partnerships for the SDGs: A legacy review towards realizing the 2030 Agenda, 2015

⁵ WT/MIN(15)/DEC

accounts from those involved underscore this dimension of the negotiations.⁶ For the first time in a multilateral treaty, it expressly articulated the role of the IP system as a policy tool intended to advance broader public policy objectives: it stated that the IP system should promote both technological innovation *and* the transfer and dissemination of technology, and that this should work for the *mutual advantage* of producers and users of technological knowledge as well as promoting social and economic welfare and a balance of rights and obligations.

Analysis and public debate, and the reported practical experience of WTO Members implementing the Agreement, have since borne out the breadth of the scope for public health policies that the TRIPS Agreement supports, both for diverse forms of innovation and for measures to leverage access, as well as safeguards against abuse of IP rights. The full extent of the scope for public health policies was not, however, widely understood in the early years of TRIPS implementation. It became necessary to map out more clearly the interplay between TRIPS and public health, and to articulate a number of specific options or flexibilities. For the WTO, therefore, a major step towards policy coherence for public health was the adoption of the Doha Declaration on the TRIPS Agreement and Public Health of December 2001 ('the Doha Declaration').

As an exemplar of coherence – in the legal, policy and practical senses – the Doha Declaration situated a multilateral trade agreement squarely within a public health context, and dealt directly with the interplay between public health policies and the IP system. Stating that the TRIPS Agreement had to be part of wider national and international action to address public health problems was a clarion call for coherence, and has progressively catalysed greater coherence in practice. As outlined below, the Declaration supported coherence at several level, for instance affirming that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public, and expressing certain rights and entitlements of governments that are integral to the TRIPS Agreement text but on which some uncertainty had arisen: notably the right to grant compulsory licences and the freedom to determine their grounds, and the freedom to establish an IPR exhaustion regime without challenge. And it led to an amendment to the TRIPS Agreement that dealt directly with a potential legal obstacle for the use of compulsory licences by countries most dependent on imports to meet their need for medicines.

A WHO paper at the time remarked that the Declaration "marked a watershed in international trade demonstrating that a rules-based trading system should be compatible with public health interests" and that it "enshrines the principle WHO has publicly advocated and advanced ... namely the reaffirmation of the right of WTO Members to make full use of the safeguard provisions of the TRIPS Agreement to protect public health and enhance access to medicines."⁷ Human rights guidance on the right to health calls for the letter and spirit of the Doha Declaration to be respected as recognizing "a State's right to protect public health and promote access to medicines for all."⁸ Highlighting the need for the TRIPS Agreement to be implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all, the Doha Declaration provides an impetus for governments to respond to the call earlier in 2001 by the Sub-Commission on the Promotion and Protection of Human Rights⁹ for ensuring that the "implementation of the TRIPS Agreement does not negatively impact on the enjoyment of human rights." In practice, therefore, implementation proves to be of major importance, comparable to the significance of the legal instruments themselves.

The Doha Declaration, while hardly acting in isolation, was one of several factors lending considerable momentum to greater coherence at the multilateral and domestic levels. Since that landmark outcome, coherence has been the watchword of the WTO's work in the area of IP, trade and public health, with growing practical impact on technical assistance, building capacity for informed domestic policymaking, and support for policy dialogue. The 2013 WIPO-WHO-WTO study, *Promoting Access to Medical Technologies*

⁶ Watal, J and Taubman, A, 'The Making of TRIPS,' WTO, 2015.

⁷ World Health Organization, Implications of the Doha Declaration on the Trips Agreement and Public Health - Health Economics and Drugs Series No. 012, 2002

⁸ Report to the General Assembly of the UN Special Rapporteur on the right to the highest attainable standard of health (UN document: A/63/263, 11 August 2008).

⁹ Intellectual property and human rights, Sub-Commission on the Promotion and Protection of Human Rights, Resolution 2001/21.

and Innovation: Intersections between public health, intellectual property and trade ('the Trilateral Study') expressed its role in these terms:

The Doha Declaration has served as a catalyst for developing coherence at the international level. In conjunction with its role of making public health issues a central focus of work carried out by the WTO on IP and international trade, the Doha Declaration has been taken up in a series of World Health Assembly (WHA) resolutions on ensuring accessibility to essential medicines and public health, innovation and IP. Notably, the Doha Declaration was a point of reference in the negotiations on the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI). The WIPO Development Agenda deals extensively with flexibilities in international IP law, including the health-related flexibilities specifically identified in the Doha Declaration.

The coherence agenda in practice

Exemplifying this approach, an active program of coordinated technical assistance and policy dialogue, led at Director General level and centred on public health imperatives, has unfolded in the form of a trilateral initiative with WHO and WIPO. Reaching well beyond the three specialised agencies, this program has drawn widely on diverse policy perspectives and practical experiences, to build a solid foundation of policy insights and empirical data so as to illuminate the pathway to more coherent outcomes. WTO technical assistance and policy dialogue dealing with public health has long been consciously planned and implemented to include a wide spectrum of voices from civil society, the not for profit and philanthropic sector, diverse industry players, competition authorities, and experts from the United Nations system including UNCTAD, UNAIDS and UNDP.

This approach has been manifest in – but not confined to - a series of five trilateral public policy symposia convened with the WHO and WIPO on crosscutting access and innovation issues, enabling broadbased and inclusive dialogues that have explored many of the issues and proposals akin to those submitted to the HLP for consideration, including a review of twenty years of working with TRIPS on innovation and access to medicines issues, the particular innovation and access challenges for middle-income countries, new innovation models, the role of improved patent transparency in enabling access to medicines and freedom to operate, and the impact of pricing and procurement policies on access to medicines.¹⁰ A recurrent theme has been how to make most effective use of data on health, trade and IP to provide a workable, transparent information base for policymakers.

The challenge of developing and implementing effective and equitable policy measures for innovation and access to meet public health goals is, by its very nature, a dynamic one, evolving with the disease burden, progress in technology and diversification of innovation systems. The Panel may wish to consider recommendations for sustaining an inclusive, cross-cutting policy dialogue across the multilateral system on the issues under its mandate, to enable mutual learning, cooperation and coordination to meet the practical challenges lying ahead. In an environment for access and innovation that is dynamic and complex, a key consideration is how to improve the empirical foundation of efforts for policy convergence, how to ensure greater transparency and accessibility of vital data, and how to build integrated information platforms that draw together health, trade and IP data and thus enable more informed and effective policy responses.

Navigating the policy landscape: the trilateral study

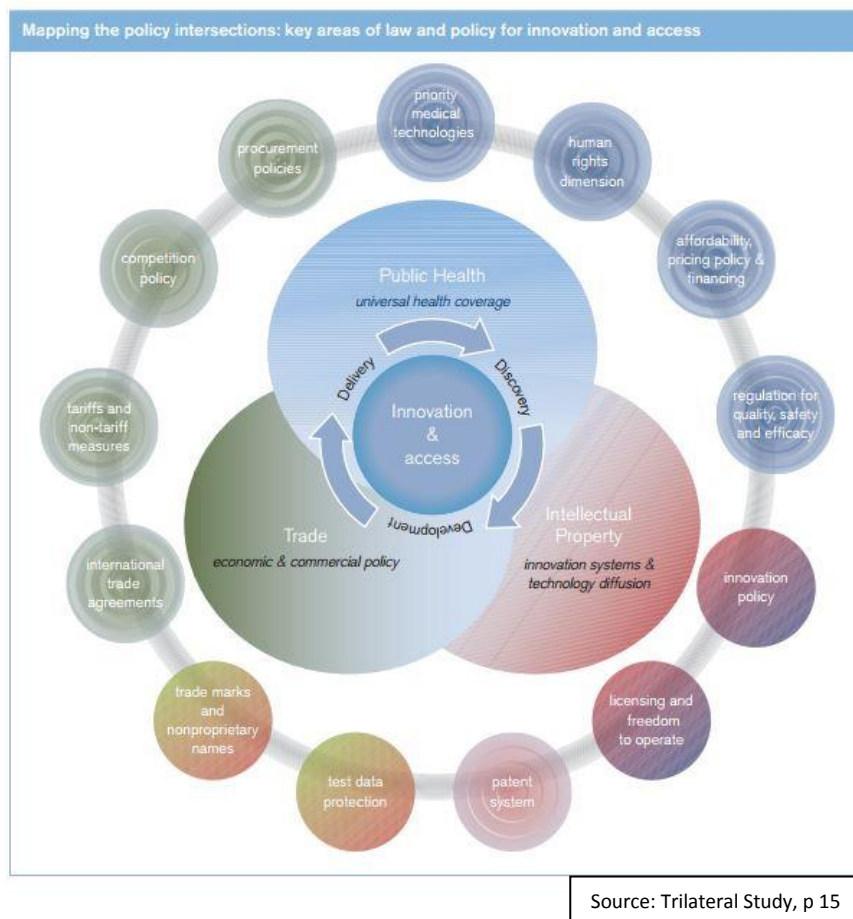
The imperative for coherence also impelled and shaped the 2013 WIPO-WHO-WTO production of the Trilateral Study, which had as its central theme the quest for greater coherence: in their joint Foreword to the study, the three Directors General refer to the “active dialogue, coordination and partnership” that have led “to more effective and tailored capacity-building activities”, with the objective “to create as much policy coherence as possible between the three organizations.” They also underscored the “greater policy

¹⁰ See details of symposia at https://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm

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 MDGs.”

In mapping out an inevitably complex and comprehensive policy framework, the Trilateral Study situates access and innovation at the centre of its considerations, and then consciously and systematically sets IP and trade policy settings in the wider context of public health policy and the right to health. The Study sets public health policy and universal health coverage alongside the right to health, as central considerations, affirming that the “human rights dimension has provided an important legal and policy vantage point for consideration of public health and pharmaceutical issues.” In setting the policy context for access and innovation, it outlines the human rights law with particular bearing on access to essential medicines, the need for non-discriminatory access to essential medicines, and the ‘social function’ of IP. The Study recalls human rights resolutions calling for promotion of access to medicines for all, including through the full use of the TRIPS Agreement and the flexibilities it provides. It observes that “access to essential medicines is a vital component of fulfilling the right to health” and that a “lack of equity in the supply of essential medicines, high prices, informal payments and out-of-pocket payments for the medication required exclude the poor and vulnerable, and do not facilitate the realization of the right to health.”

The three cooperating organizations therefore framed an approach to access and innovation in terms of human rights and equity, recognizing these factors as central to coherence. The study then elaborates across a wide spectrum practical choices for how IP and trade policy tools can be deployed coherently to achieve this end – including a number of the specific ideas under review by the Panel. This publication ensures transparency, inclusiveness and coherence in our many technical assistance and capacity building programs that deal directly with the application of TRIPS flexibilities in crafting access and innovation policies. Indeed, the study planned to provide an objective, inclusive and broadbased platform to support exactly the kind of policy discussion that the Panel is currently undertaking: a foundation to underpin and inform continuing policy exploration and analysis, rather than in itself prescribing predetermined solutions for a complex, diverse and evolving set of challenges.



Forms of coherence

In practice, convergence on shared public health targets requires coherent and effective application of many diverse policy tools and practical initiatives: as the Trilateral Study elaborates, these means include a wide spread of domestic health policies, alongside tailored IP and trade policy settings. Coherence is not, of course, an end in itself, but a prerequisite for more effective deployment of policy options and practical initiatives, removing obstacles to innovation and access, and enabling the more productive use of resources towards public health outcomes. The trade law system and the IP system are themselves tools to be deployed for wider public policy goals, of which public health is an exceptionally compelling instance. The experience of the WTO Secretariat in policy dialogue and capacity-building on public health matters has therefore shown the importance of coherence at several dimensions. One key outcome from our collaborative capacity building work with multilateral partners is the greater dialogue and cooperation it has fostered between different ministries and agencies at the domestic level within national governments – like charity, to some extent, coherence begins at home. This is not to understate the compelling need for coherence at the multilateral level, but rather to point to the powerful synergies for coherence that can occur between the international and national levels – the catalytic demonstration effect that coherence between multilateral agencies can have on domestic policymaking, and the critical need for multilateral agencies to work together to build capacity at the national level to assess and implement policy options tailored to domestic needs and priorities in a coherent and broad-based manner.

The Doha Declaration on the TRIPS Agreement and Public Health itself concretely illustrates how different forms of coherence can serve to advance public health outcomes (discussed further in the Annex below):

Coherence in international law, with reference to WTO Members' right to protect public health and, in particular, to promote access to medicines for all;

Coherence at the political level, as a an authoritative statement by trade ministers confirming public health as a fundamental policy objective, sending a political signal for greater coherence for the WTO, for its work with multilateral partners, and for domestic policymakers;

Coherence in values, recognizing the gravity of the public health problems afflicting many developing and least developed countries, and making those problems a focus of collective effort

Coherence in the implementation of international law, underscoring that both the interpretation of the Agreement, its implementation by WTO Members should be such as to support the right to promote public health and to provide access to medicines for all.

Legal coherence, such as through the Doha Declaration's clarifications concerning the existing law;

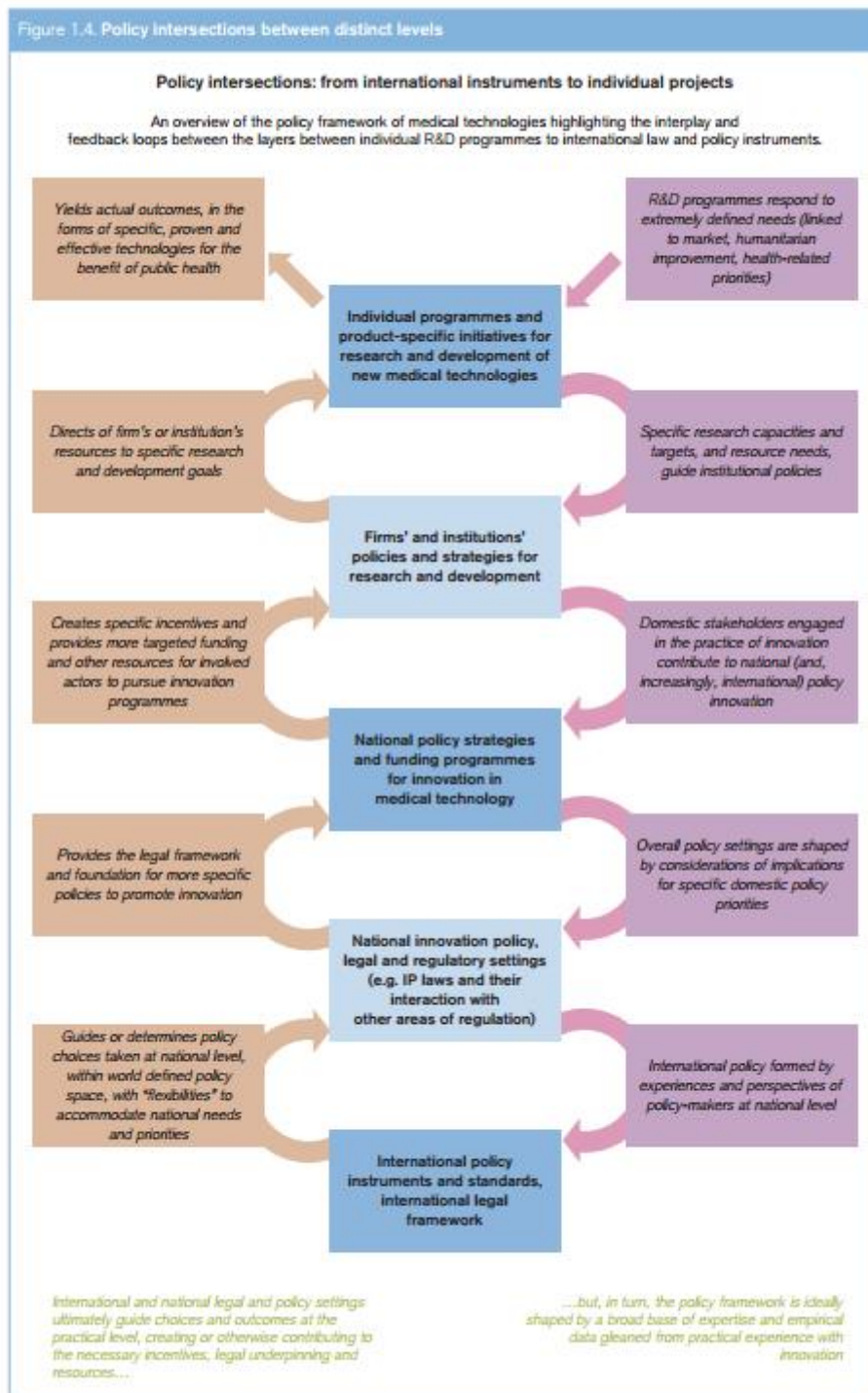
Institutional coherence, both at the level of governance of organizations, and through practical cooperation and collaborative program delivery by agencies and programmes within the multilateral system.

A recent example of institutional coherence is the decision by WTO Member governments to extend to 2033 for LDCs of complete exemption from patenting and data protection, with possibility of further extensions: this affords LDCs maximum flexibility in line with the SDG target on TRIPS flexibilities, running beyond the SDG target date of 2030. Institutional coherence is also vitally important at the operational level, in the planning and delivery of programme activities. For the WTO Secretariat, the Doha Declaration has had far reaching influence on our operations, on the scope and inclusiveness of technical assistance, outreach and support for policy dialogue, and on the range of stakeholders and government officials we work with, in dealing with issues on the intersections of IP, trade and public health.

The promotion of greater coherence should therefore address each of these levels, recognizing that coherence can be advanced through inclusive and broadbased program activities and practical collaboration, as well as through more formal means at the level of governance. The following graphic, extracted from the Trilateral Study, illustrates how each layer of policy and practical implementation influences and is influenced by other layers. Because national policy settings and programmes are so

critical in ensuring innovation and access, a key consideration is ensuring coherent, effective and informed policymaking and implementation at the national level, supported by the international framework, but equally international efforts can be informed by the lessons from national programmes and experiences.

The Panel may wish to address the distinct considerations for promoting coherence at each level of policy and practice, ranging across a spectrum from the formal structures and legal instruments that catalyse greater coherence, to immediate avenues for practical dialogue, technical cooperation and collaboration, and consider available avenues for encouraging sustained coherence at each level of interaction as well as ensuring that practical experience at the national and programme level informs the policy coherence agenda.



Coherence in trade policy settings as a tool for access

For the WTO, too, the coherence agenda for public health, even when focused on access and innovation in medical technologies, has led to a wider focus than the IP/TRIPS framework, enabling greater understanding of how coherence in IP and trade and economic policy settings promotes public health. This is neither to turn away from nor to diminish the IP system/TRIPS issues before the Panel, which have been identified as its central focus. However, a judicious look at trade and economic policy settings will help ensure that solutions found, policy directions adopted, and flexibilities exercised do have greater practical effect.

An obvious instance is competition policy. As discussed below, the TRIPS Agreement expressly refers to competition policy safeguards, as a ground for compulsory licensing of patents and as a means of dealing with abusive licensing practices. A sound competition policy framework can therefore complement the IP system and help ensure that IP protection does produce the positive sum social benefits expected of it. More concretely, while pharmaceutical pricing policies have been applied in countries, other countries rely on generic competition to bring prices of medicines down to more affordable levels. Even greater transparency on prices and on patent coverage can be seen as concrete and effective pro-competition measures, facilitating affordable access, but specific legislative and administrative action may be needed for full policy coherence in practice.

Carefully tailored trade policies also form part of a more coherent approach to access. By definition, any strategy to promote access that does not aim at complete national autonomy of production will have to make use of crossborder trade to source either ingredients or finished medicines. Even 'local production' programmes – for which some advocates have proposed tariff barriers to protect local production – may be adversely affected by tariffs and non-tariff barriers on imported ingredients; and from an access perspective, it would be desirable for more dispersed production capacity in the developing world to be geared to serve regional needs beyond the immediate territory in which they are established. The public health amendment to the TRIPS Agreement foresees both efforts to build local production capacity as one means of overcoming constraints on access,¹¹ as well as regional supply programs,¹² recognizing that economies of scale may be created by gearing access to a region rather than a single jurisdiction.

Pooled procurement and distribution strategies, or group purchasing, for medicines increase bargaining power, lower transaction costs and enable better services and lower prices, but these benefits are limited when there are trade barriers between participating countries:¹³ these strategies have been particularly effective when founded on regional trade groups, such as the Gulf Cooperation Council (GCC) Group Purchasing Programme and the Organisation of Eastern Caribbean States Pharmaceutical Procurement Service.¹⁴

The promotion of local production capacity – an objective recognized in the public health amendment of TRIPS, and one pursued by a number of practical programmes within the UN system¹⁵ – raises IP policy and management questions,¹⁶ but is equally dependant on a wider range of trade policy settings: for instance, the WTO Agreement on Technical Barriers to Trade (TBT) recognizes the contribution of standards to transfer of technology to developing countries.

Accordingly, even access strategies that centre on IP issues, to be coherent and effective, would need to consider other trade-related constraints. Three concrete considerations are discussed here:

Trade costs and delays. Administrative costs and border delays translate directly into higher prices and delayed or interrupted access to medicines, systematically impairing access. Recent estimates illustrate how the level of costs and delays correlate with the level of countries' reliance on affordable access to

¹¹ Annex to the TRIPS Agreement, paragraph 6.

¹² TRIPS Agreement, Article 31*bis*, paragraph 3.

¹³ Trilateral Study, pp 162-3

¹⁴ WHO, Regional Workshop on Strengthening Quantification and Procurement of Essential Medicines, New Delhi, 2014.

¹⁵ Trilateral Study, pp 163-5

¹⁶ See footnote 22 below

medicines via trade. For instance, as a region, Africa faces the highest trade costs, estimated at an equivalent *ad valorem* tariff of over 260%. For landlocked African countries and LDCs, the figure rises to fully 300%.¹⁷ The regressive effect of these costs are demonstrated by statistics¹⁸ showing average import costs for sub-Saharan African countries to be USD 994.3 and the average delay 282.6 hours, rising to national maxima of USD 2964 and 804 hours, compared with high income countries' average costs of USD147.6 and delays of 13.2 hours, with many wealthy countries reporting costs and delays close to zero. Estimated import costs for a single shipment exceed annual per capita GDP in 23 African countries. These trade-related costs and delays in access may not only constrain the access gains available from the policy proposals and access initiatives under consideration by the Panel, but may also have impact on intermediate products, ingredients and production technologies required for domestic production initiatives. Trade facilitation, including implementation of the recently concluded WTO Trade Facilitation Agreement and related technical assistance, may be part of a coherent access strategy.

Tariffs and non-tariff trade barriers. Equally, unless such measures are consciously maintained as a means of building domestic production capacity, higher tariffs and non-tariff barriers have the effect not only of reducing competition and diminishing the sustainability of access to medicines, but also of feeding directly into the cost of medicines at an early stage in the distribution chain, with the consequence that final product prices can be considerably magnified. Similarly, tariffs on diagnostic equipment can run at high levels. The general trend has been towards reductions in tariffs that are actually applied to medicines and pharmaceutical ingredients. Under the WTO Pharmaceutical Agreement, a number of countries agreed to eliminate tariffs on pharmaceutical products and chemical intermediates used for their production (the "zero-for-zero initiative"), including all active ingredients with a WHO International Nonproprietary Name (INN), and agreed to periodically review and expand the list of items covered. The recent conclusion of an expanded WTO Information Technology Agreement (ITA) will lead to zero tariffs in participating countries – including a number of developing countries - on medical equipment, such as magnetic resonance imaging products and ultra-sonic scanning apparatus.¹⁹ Despite the general trend towards lower applied tariffs, the data do show inconsistencies relating to tariffs on medicines and their ingredients: either high import tariffs in countries dependant on imports for essential medicines, or high tariffs on ingredients in countries seeking to establish sustainable local production capacity.²⁰

Regulatory convergence. Effective and appropriate regulation of medical technologies is an essential component of a coherent access and innovation strategy. The Trilateral Study observed that regulation for quality, safety and efficacy of medicines and safety, effectiveness and performance of medical devices "plays an important role in determining access to new products." Yet it noted that "unjustified regulatory measures, coupled with lack of transparency in the regulatory process and slow procedures, can become an obstacle to access".²¹ Diversity of approaches and duplicative testing, inspection, or certification, can significantly increase trade costs and delays. Equally, regulatory systems have a decisive impact on innovation. The questions of incentives for private funding of clinical trials, and of access to clinical trial data, intersect directly with IP policy settings and trade agreement provisions as well. Regulatory convergence around international standards, without easing the rigour and quality of regulation in the public interest, and the reduction of delays and procedural barriers to product approval can certainly play a part in a coherent access and innovation strategy.

Within the WTO system, the TBT Agreement recognises WTO Members' "right to regulate" for policy objectives such as the protection of human health and safety, while strongly encouraging members to base their measures on international standards – however, recognizing also that they may depart from international standards if they consider that their application would be ineffective or inappropriate for the

¹⁷ World Trade Report 2015, p 76

¹⁸ Compiled from World Bank 'trading across borders' statistics compiled in June 2015, at <http://www.doingbusiness.org/data/exploretopics/trading-across-borders>

¹⁹ WTO Briefing note: The Expansion of Trade in Information Technology Products (ITA Expansion), December 16, 2015

²⁰ Helble, M. (2012), "More Trade for Better Health? International Trade and Tariffs on Health Products", WTO Staff Working Paper ERSD-2012-17.

²¹ Trilateral Study, p 47

fulfilment of legitimate objectives. The TBT therefore provides a multilateral framework for appropriate regulatory convergence without reducing the public policy role of effective regulation. Addressing conformity assessment procedures could improve access to medicines and medical equipment and minimize delays. The TBT Agreement provides a legal framework to ensure a balance between what the importing Member requires to obtain positive assurance of conformity with its regulations or standards, and ensuring that procedures do not become unnecessary or discriminatory trade barriers. The WTO TBT Committee in turn offers WTO Members a forum to improve understanding of each other's measures, facilitates an exchange of best practices, and gives opportunity to flag issues of concern.

The Panel may wish to consider the role of coherence in trade policy and regulatory settings as a further means of leveraging improved outcomes from initiatives for enhanced innovation and access, and how these policies can be tailored coherently in different contexts, such as for countries mostly dependent on trade for access, for local or regional production initiatives, for pooled procurement arrangements, or for technology transfer for building production capacity.

Coherence and the TRIPS framework

The legal and policy framework defined by the TRIPS Agreement has understandably come under close attention during the Panel process. Many proposals before the Panel demonstrate that coherence is just as much a practical task as a matter of addressing reconciliation at the highest normative and institutional levels. It is important to understand and to probe the current extent and boundaries of the policy space defined by current legal instruments, but it is equally important to understand and learn from the countless ways in which an ever more diverse array of policy options, legal flexibilities and practical initiatives operate. Similarly, many existing options and flexibilities have not been implemented or used to their full potential, despite having been carefully negotiated and included in the TRIPS Agreement as a balancing factor, and it is timely to promote an enabling dialogue to understand why this is the case, as well as bringing forward case studies of actual usage so as to ground the discussion in practical experience.²²

Policy choices within the TRIPS Agreement framework

The policy options and flexibilities within the TRIPS framework most discussed relating to patents and public health include the shaping of patentability standards, exceptions and limitations, with a particular focus on the scope of patentable subject matter and compulsory licensing. These remain fundamentally important areas of policy choice. With one key exception, the black-letter law of the TRIPS Agreement has not altered in these areas for over two decades, yet numerous national legal systems across the globe have applied and adapted TRIPS standards in many diverse ways: the wealth of experience gained over the past 20 years provides an invaluable information base for mutual learning about achieving coherence at a practical level. This empirical focus has increasingly informed the technical cooperation activities of the WTO, which enable practitioners in developing countries to share diverse perspectives and to explore options based on practical experience, with a view to bolstering self-sustaining capacity to assess and implement policies tailored to national circumstances, in place of a 'top-down' focus exclusively on expounding the international framework. The available documentation of implemented policy options (including notifications under TRIPS²³ and surveys of use of policy options under TRIPS²⁴) and literature on these options are abundant,²⁵ underscoring the need for capacity building programs that provide information on these options in a practical, objective and accessible form.

²² A recent example is the set of case studies published by the WHO, discussing approaches to local production of pharmaceuticals, including within a TRIPS framework: WHO, 'The role of intellectual property in local production in developing countries: Opportunities and challenges,' Geneva, 2016; see also UNCTAD, 'Using intellectual property rights to stimulate pharmaceutical production in developing countries: a reference guide,' 2011.

²³ https://www.wto.org/english/tratop_e/trips_e/trips_toolkit_e.htm

²⁴ <http://www.wipo.int/ip-development/en/agenda/flexibilities/search.jsp>

²⁵ A distinctive contribution has been made by a range of emerging scholars from across the developing world, who have published papers analysing the implementation of public health and IP legal and policy options in the journal WIPO-WTO Colloquium Papers, available at https://www.wto.org/english/tratop_e/trips_e/colloquium_publication_e.htm

Where policymakers identify prospects for greater use of regulatory diversity, policy choices and flexibilities within the TRIPS framework, the Panel may wish to encourage and reinforce current progress towards stronger programmes of mutual learning, pooling of practical experience and building capacity for coherent, informed and tailored domestic policymaking, drawing together public health, IP and trade policymakers, and demonstrating the practice of coherent and inclusive policymaking in these areas.

Many of the proposals before the Panel deal with matters of policy, law and practice which have no bearing on TRIPS standards, and which can therefore be seen as diverse means of working within the broad policy space defined by TRIPS – these include alternative financing models, innovative collaborative research structures such as public-private ventures, non-patent incentives for R&D, voluntary licensing schemes including humanitarian licensing, and a wide spectrum of approaches to managing publicly funded and philanthropic R&D. These examples may assist the Panel in distinguishing essential points of incoherence between international legal instruments, and the wide range of policy options and practical initiatives that ensure greater coherence in practice.

Other proposals before the Panel can be seen as helping to achieve a stronger enabling environment for judicious use of policy options under TRIPS – an example is more effective patent transparency concerning patent coverage, which is a vital prerequisite for planning and implementing access strategies and procurement initiatives, including the use of TRIPS flexibilities to leverage affordable access.

A number of distinct legal measures and policy options provided for under TRIPS have received less attention within the TRIPS framework (both the specific review and technical assistance activities under TRIPS, and more broadly). This background note addresses several that merit closer attention.

Enforcement measures and practical coherence

A systemic policy concern, and a matter of essential fairness and equity, is that enforcement of IP rights should not deter or interfere with legitimate activities. This concern arises in a number of practical contexts concerning access to medicines, both within the borders of national jurisdictions, and when goods are traded across borders. Some TRIPS provisions not only permit action to curb these negative effects, but positively require it. A foundational concern for the TRIPS Agreement was to ensure that enforcement measures should not create a barrier to legitimate trade. Hence it is a positive obligation under TRIPS that enforcement procedures “shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.”²⁶ Alongside general rules providing for transparency, procedural fairness and equity as firm obligations,²⁷ TRIPS contains specific safeguards against such negative impacts of enforcement, such as an obligation to indemnify the defendant in the event of abuse of enforcement, in the form of compensation for the injury suffered by a party wrongfully enjoined or restrained, as well as payment of expenses and legal fees;²⁸ more specific safeguards²⁹ for abusive enforcement are required in the case of provisional measures and border measures. Provisions on border enforcement specifically require assurances to be available to protect the defendant and to prevent abuse, strict time limits for suspension of goods, and compensation for any injury caused by the wrongful detention of goods or detention of goods when substantive proceedings are not commenced.

TRIPS enforcement provisions were raised in complaints filed before the WTO Dispute Settlement Body concerning treatment of generic medicines in transit.³⁰ While these disputes have not proceeded to the panel stage, and no assessment of legal issues is offered here, the issues raised underscore the significance attached by some WTO Members to enforcement measures in the context of access to medicines.

²⁶ TRIPS Agreement, Article 41.1 (emphasis added)

²⁷ Articles 41, 42 and 43 in particular

²⁸ TRIPS Article 44; subsequent jurisprudence has clarified that such measures are positively required to be available for the judiciary to apply at their discretion (Panel Report, India — Patents (EC), para. 7.66)

²⁹ Notably, TRIPS Articles 50 and 56

³⁰ *European Union and a Member State - Seizure of Generic Drugs in Transit - Request for Consultations by India* G/L/921 ; IP/D/28 ; WT/DS408/1; and *European Union and a Member State - Seizure of Generic Drugs in Transit - Request for Consultations by Brazil*, G/L/922 ; IP/D/29 ; WT/DS409/1

Competition policy within the TRIPS framework

Several proposals to the HLP highlight the need to make more effective or systematic use of competition policy to leverage access.³¹ The effective application of competition policy is clearly foreseen in the TRIPS Agreement as a balancing mechanism to assist in ensuring that the IP system is effective in delivering the expected social benefits. There are two specific areas set out in the TRIPS Agreement:

- Removing certain procedural requirements and limitations of scope for a compulsory licence on a patent issued “to remedy a practice determined after judicial or administrative process to be anti-competitive.”³²
- Under the heading ‘Control of Anti-Competitive Practices in Contractual Licences,’ recognition that some IPR “licensing practices or conditions ... which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology,” followed by express recognition of the policy space for specifying remedies against “licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market”, and an obligation on Members to assist, upon request, other Members in specific ways in the enforcement of such remedies.

Technical cooperation on balancing IP rights

Such provisions recall that protection against abuse of IP rights is part of the design of the TRIPS Agreement, and in principle they form part of any greater coherence framework. Competition policy and its links with access to medicines is a regular part of WTO technical assistance for developing country Members. Further, under TRIPS, developed country Members are obliged to provide “on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members.” Alongside measures for protection and enforcement of IPRs, this provision also covers the prevention of their abuse, providing a basis for building capacity in this area should developing country authorities see this as a priority.

On the basis that much of the effect of more coherent legal and policy measures is ultimately determined by effective national measures, in considering the interplay between IP law and policy measures and the public health policy, the Panel may wish to consider how the international system can encourage informed and integrated policy coherence at the practical domestic level.

International trade and compulsory licences

Compulsory licensing of patents has been the most widely discussed and intensively debated health-related flexibility under TRIPS. This was a key point of clarification of the Doha Declaration, which affirmed that WTO Members have both the right to issue compulsory licences, and the freedom to determine the grounds. It also led to the first amendment agreed by WTO Members to the entire package of WTO law, through the amendment of the TRIPS Agreement to create of a new form of compulsory licence, expressly for export, in recognition of the then difficulties of WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector “in making effective use of compulsory licensing under the TRIPS Agreement.” Since this has been a central issue in the work of the WTO since the Doha Declaration, and the focus of a specific treaty amendment, this section focuses on the practical context of compulsory licences, especially in a trade setting.

It follows from the Doha Declaration and the subsequent amendment to TRIPS that the essential questions do not concern the basic legal entitlement as such, which is expressly confirmed, but (i) the policy considerations to be weighed in using this tool (i.e. when and what circumstances it becomes a desirable

³¹ See also UNCTAD Secretariat, 'The role of competition in the pharmaceutical sector and its benefits for consumers,' TD/RBP/CONF.8/3, 2015, Frederick Abbott, Sean Flynn, Carlos Correa, Jonathan Berger and Natasha Nyak, 'Using Competition Law to Promote Access to Health Technologies: A guidebook for low- and middle-income countries,' UNDP, New York, 2014, and WHO, WIPO and WTO Trilateral Study.

³² TRIPS Article 31 (k)

policy choice); (ii) the legal scope under TRIPS; and (iii) the practicality of making use of this means of access. A number of submissions to the Panel discuss these considerations; some query why its use has been relatively limited, including policy, political and legal considerations. This note does not enter into this extensive debate, beyond the observation that – to the extent that compulsory licences are intended to lower prices – there is some evidence that even the realistic availability of compulsory licences has been one factor, among others, in bringing down the prices of medicines over the past 15 years,³³ and so the effect of this policy instrument, and the signal given by the Doha Declaration, may have a broader scope than can be measured solely in terms of actual compulsory licences issued. However, the optimal scope for compulsory licences as a policy tool has been a matter of ongoing debate and no position is advanced here.

Reported experience with compulsory licensing to date has mostly concerned access to medicines within the country of production, which still remains relatively rare in practice. However, the Doha Declaration, in its paragraph 6, put on the practical agenda a distinctive context – the use of compulsory licensing specifically for production in one country and export to another country – what might be termed ‘trade-related’ compulsory licences, or the use of compulsory licences to serve more than the domestic market.

There are several scenarios under which medicines produced under a compulsory licence may be exported:

- Medicines produced under a conventional, domestic-oriented compulsory licence can be exported provided the predominant part of the production is to supply the domestic market;³⁴ this could be the case, for example, if a share of the production mainly for a large population were to be exported to meet the needs one or more significantly smaller countries. This scenario is not dissimilar to common situation in which production of regular generic medicines to serve large domestic populations also supplies smaller export markets.
- There is no requirement to limit exports of medicines produced under a compulsory licence issued to remedy a practice determined after judicial or administrative process to be anti-competitive.³⁵
- The scenario in which production under compulsory licence is undertaken specifically for export and consumption outside the domestic market, and is not mainly to meet domestic need (the scenario addressed by paragraph 6 of the Doha Declaration).

As a legal tool, compulsory licences, whether issued predominantly for domestic need, to remedy anti-competitive practices, or for export to countries in need, create an additional legal pathway but do not assure viability of supply. Broadly, it is self-evident that the presence or absence of a patent, and the presence or absence of a compulsory licence, can shape the legal options for production and distribution, but do not in themselves ensure the economic and technical feasibility of production. Other factors include technological and production capacity, regulatory questions, economies of scale (including consistency of demand over time), and procurement policies.

On production capacity, the amendment of TRIPS recognizes “the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector” and encourages the use of the system of export-oriented compulsory licensing to promote this objective. This legal text therefore recognizes the interplay between the use of compulsory licensing and the building of domestic production capacity. Since the conclusion of this text, considerable experience has been garnered in the development of local production capacity, including using TRIPS flexibilities, and through south-south technology partnerships.³⁶

The decision of the WTO to extend the exemption of LDCs from obligations relating to pharmaceuticals to 2033, well beyond the SDG target date of 2030 (and leaving open the option of further extensions) in

³³ Trilateral Study, pp 175-6

³⁴ TRIPS Agreement 31(f)

³⁵ TRIPS Agreement, Article 31(k)

³⁶ e.g. CIPLA Quality Chemical Industries Limited, producing anti-retrovirals and artemisinin-based combination therapies, <http://www.ciplaqcil.co.ug>; see also Trilateral Study, p.163

principle entitles LDCs to make use of this maximum level of flexibility under TRIPS for all current medicines, all new medicines in the development pipeline, and indeed those that may be invented over the next 17 years and potentially longer, thus extending effectively to all medicines likely to be put on the market until the late 2030s at the earliest (taking account of the lead time between discovery and market entry). To the extent that patents on pharmaceuticals are maintained in some LDCs, some major firms have declared non-assertion or open licensing policies for patents in LDCs and other low income countries. Both circumstances would facilitate both the use of compulsory licences to export to these markets, and the development of production capacity in those jurisdictions, with the potential also to service markets in their region.

Regulation for safety, quality and efficacy – potentially in the country of production and in the country of destination – is a major factor in determining not only the timing but also potentially the economic feasibility of access for exported medicines, just as disparate regulatory approaches can inhibit regional procurement and distribution efforts. This consideration applies to medicines produced with or without applicable patents, or produced under voluntary or compulsory licences. Regulatory coherence or convergence, in particular on a regional basis, could help ease barriers to access if production is intended for more than one jurisdiction.

Economies of scale are necessary to sustain production of medicines at the most affordable prices. Particularly for smaller countries, or relatively rare disease burdens, it may be necessary for demand to be aggregated from a number of domestic markets, and for commitments to purchase over a sufficiently long period, to create a sufficient rationale for the costs sunk into developing production capacity, securing necessary regulatory approval and complying with any procurement policies.

Procurement policies, whether applied by international agencies, philanthropic programmes, or national public procurement, will also be a factor in facilitating optimal outcomes in access and distribution of medicines. Generally, this would entail transparent and open procedures to ensure the best value for public health resources invested in medicines procurement. In addition, coordinated or pooled procurement can serve as an effective means of aggregating demand to ensure economies of scale and bargaining power sufficient to achieve lower prices and sustained supplies of medicines.

Hence, setting aside the broader policy debate, compulsory licensing cannot function as a practical stand-alone tool for medicines procurement in the absence of these factors. This is important background to reviewing the role and function of this tool, whether in the forms proposed in submissions to the Panel, or the specific mechanism for export compulsory licences set out in the amendment to the TRIPS Agreement. Reviewing this question, the Trilateral Study observed

The special export licence [under the TRIPS amendment] is one legal pathway that can be followed when it represents the optimal route to effective procurement, but, as for any compulsory licence, it does not in itself make the production of a medicine economically viable. Sufficient scale and predictability of demand are prerequisites for making it practically and commercially viable for companies to undertake the regulatory, industrial and commercial steps required to produce and export a medicine under such a licence. Regional approaches to procurement and joint notifications by countries with similar needs for accessible medicines may offer pathways to aggregating demand under the System, thus enabling an effective response to the needs identified.

Access through compulsory licences especially for export

As noted, in line with the Doha Declaration, a new form of compulsory licence was devised to enable countries with no or limited production capacity to make effective use of compulsory licences, implemented initially in the form of a waiver and then in the form of a formal amendment to the TRIPS Agreement. This system of compulsory licences specially for export has been widely discussed in the literature and in the WTO TRIPS Council itself (in a series of annual reviews); the following informal reflections, building on discussion in the Trilateral Study, may help situate this novel mechanism within current discussions on tools for enhancing access to medicines:

- The use of compulsory licences specifically for export to meet demand in one or more foreign countries is a new policy tool, creating a legal pathway that corresponds with a very specific procurement scenario: for it to be the optimal choice in practice, the lowest cost medicines at a suitable standard would only be available from a foreign producer who must produce the product under a specific compulsory licence in their country (i.e. affordable generics are not available from any other source, including countries where no patent is in force; neither low cost supplies nor a voluntary licence is available from the patent holder; and the producer is not already produced under a compulsory licence predominantly for the domestic market, with capacity to export the residual production). The extent to which this scenario arises is, ultimately, an empirical question, and can only be assessed with reference to data on patent coverage in potential producer countries as well as data on prices, and existing production and production capacity.
- In the first years of the availability of the system, generic products were widely available to meet many of the needs of the most vulnerable countries. For instance, generic versions of front line HIV-AIDS treatments brought the cost of treatment down dramatically in the early 2000s. When the system was used for the first time for shipments from Canada to Rwanda, it transpired that four alternative generic suppliers were available and able to offer combination therapy produced off-patent at a cheaper price, until the price under the compulsory licence was lowered further. This situation is likely to change for newer treatments, given the greater likelihood of patent coverage in the countries that have been traditional low cost suppliers of medicines. Hence the practical scope for application of the system may increase in coming years.
- Anecdotal evidence suggests that national medicines procurement programmes do not build this mechanism into their routine procurement procedures. Indeed no developing country has yet taken the preliminary step of signalling intent to use the system even in principle. More systematic, practical use of the system would entail potential users signalling their procurement needs at an early stage, as soon as future requirements had been forecast and as part of preparation for procurement by all available means. This does not oblige a country actually to use the system if it transpires that the optimal procurement choice lies elsewhere, but it would open it up its use as a practical option (as well as having other benefits, discussed below).
- The system is straightforward for potential beneficiaries to use: one or at most two communications are needed to the WTO Secretariat (in practice, one or two brief emails from official representatives), one to trigger intent to use the system in general (not required of LDCs), and one to indicate the names and expected quantities of products needed.³⁷
- The system itself recognizes the need to harness economies of scale, including through coordinated supply within a region. Coordinated notifications to the TRIPS Council of expected needs from a number of countries – such as from countries in the same region with similar needs and consistent regulatory requirements - would signal a stronger level of demand that is more feasible for potential suppliers to meet. Given the broader benefits from pooled procurement on a regional or subregional basis, and momentum towards such an approach, coordinated notifications of expected needs would be a useful complement to more effective procurement efforts. Provided similar needs had been identified among a group of countries, the administrative requirements would be remarkably simple – again, one or two emails from each country to the WTO Secretariat.
- The more significant steps to make use of the system must be taken in the exporting country. Recent developments have transformed practical possibilities for use of the system, with a wide range of enabling legislation being passed in potential exporters; research shows that these new provisions are in place in countries responsible for fully 80% of current pharmaceutical exports.³⁸ The number of firms

³⁷ This would also require stating an intent to issue a compulsory licence in the beneficiary country, if this is needed; however, to the extent that demand comes from countries in which no patent is in force, this information is plainly not needed.

³⁸ Kampf, R., 'Special Compulsory Licences for Export of Medicines: Key Features of WTO Members' Implementing Legislation,' WTO Staff Working Paper ERSD-2015-07, 31 July 2015

that could respond to demand signalled under the system has greatly expanded accordingly. In opening up this new legal pathway, the 51 Members concerned have applied it in different ways that have bearing on practical use of the system by exporters, for instance on the reasonable time for seeking a voluntary licence; on whether, and if so what, regulatory clearances are required; on duration of licences; and on scope of licensed production. Hence the legal architecture is now in place for much more widespread use of the system by exporters, if demand is more routinely communicated. These recent developments in potential exporters' domestic systems may go some considerable way to responding to the call by WHO, UNAIDS and UNDP, for countries with manufacturing capacity to "consider implementing [this] mechanism in an administratively efficient and effective manner in order to facilitate the export of generic medicines."³⁹

- The one shipment made under the system so far has been analysed in the Trilateral Study⁴⁰ and in an extensive discussion in the TRIPS Council⁴¹ (as well as by many commentators and analysts). Some practical observations to emerge: the time taken to complete the process was not due to the issuance of a compulsory licence, which took two weeks; considerable time was spent identifying potential demand for an already-identified product, undertaking regulatory approvals, amending the scope of domestic regulation, and a full procurement process in the recipient country. The procurement process reportedly revealed that four generic suppliers could produce the product off-patent without the need for compulsory licences and, through this competition, halved the no-profit price originally proposed, thus doubling coverage for resources expended. This experience highlights the benefits of expected demand being signalled early and for the system to be integrated early in procurement processes, the gains that open competitive tendering can deliver, and the need for regulatory status to be taken into account. Other potential exporting countries have since introduced diverse approaches to the granting of such licences, and this would open up further practical opportunities.
- In policy discussions, some concerns have been expressed that political or trade pressure may deter the use of compulsory licensing. This particular system of compulsory licensing for export has achieved political consensus across the WTO Membership and formal acceptance from the full spectrum of WTO Members; its use in practice was not merely tolerated but has been positively welcomed again by the full spectrum of Members; and there have been calls for timely implementation of the system, for instance by the UN General Assembly⁴² and by ECOSOC.⁴³

The Panel may wish to consider how to facilitate greater practical focus on the potential use of compulsory licences for export as a means of improving access for countries with no or limited pharmaceutical production capacity, in line with the Doha Declaration and the resultant system established within the TRIPS framework.

³⁹ UNAIDS, WHO, UNDP, Policy Brief: Using TRIPS flexibilities to improve access to HIV treatment, 2011

⁴⁰ Trilateral Study, 2013, p 178.

⁴¹ Minutes, Meeting of the Council for TRIPS on 26-27 October, 2010, document IP/C/M/64 from p.21

⁴² UN General Assembly, Political Declaration on HIV and AIDS, A/RES/65/277 (8 July 2011)

⁴³ ECOSOC, Ministerial Declaration – 2009 High-Level Segment, 'Implementing the internationally agreed goals and commitments in regard to global public health.'

ANNEX:

DIMENSIONS OF COHERENCE ILLUSTRATED BY THE DOHA DECLARATION

Coherence at the level of international law, particularly as contained in legal instruments and in their interpretation. The period immediately preceding the Doha Declaration saw considerable debate and analysis, particularly in the human rights community, about the consistency of TRIPS with international human rights norms,⁴⁴ leading to a specific call by the High Commissioner for the WTO Doha Ministerial to “consider establishing closer links between the promotion and protection of human rights and the TRIPS Agreement.” In Doha, trade ministers affirmed that the TRIPS Agreement “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.” With bearing on the interpretation of the treaty text, the Doha Declaration recalled that, in “applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles,” which in turn articulate the attainment of public policy goals coherent with human rights such as the right to health.

Coherence at the political level - As an authoritative statement by trade ministers confirming public health as a fundamental policy objective, and effectively setting the IP system in the context of finding solutions to public health problems, the Doha Declaration sent a political signal not only to one institution but also to many other partners across the multilateral system. It also sent a signal to domestic policymakers – one still resonating today as governments see the benefits of taking an increasingly coordinated approach to dealing with health, trade and IP matters in a more integrated way, certainly an objective of technical cooperation and capacity building programs undertaken in the implementation of the Doha Declaration. This aspect recalls that it is the very same governments that participate in trade negotiations, that legislate for and administer domestic IP systems, and engage in human rights processes, and commit their nations to international standards in each of these areas: coherence or incoherence makes its effects felt at the domestic level, even at the level of specific programmes and institutions.

Coherence in values - Underpinning political and legal coherence are essential values: in this instance, the Doha Declaration made clear that public health is a fundamental concern for the international community, and a focus of collective effort, in particular recognizing the gravity of the public health problems afflicting many developing and least developed countries, and setting TRIPS in the context of finding solutions at the national and international levels. While coherence in values may be considered as ‘soft’ in legal terms, it helps create an enabling platform for practical steps towards achievement of commitments and policy goals identified.

Coherence in the implementation of international law - This dimension concerns not the normative content of the treaty as such, but rather how the standards are reflected in domestic law. The TRIPS Agreement stipulates that “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.” The Doha Declaration stressed that both interpretation *and* implementation of TRIPS should be such as to support the right to promote public health and to provide access to medicines for all. In preparations for the Doha Declaration, a number of developing country WTO Members pointed out that the public policy framing of the IP system in TRIPS Article 7 “stems from a recognition by Members that the mere existence and the exercise of IPRs, such as patents, do not necessarily result in the fulfilment of the objectives of the Agreement” and that concerning health policies, “patent rights should be exercised coherently with the objectives of mutual advantage of patent holders and the users of patented medicines, in a manner conducive to social and economic welfare and to a balance of rights and obligations”.⁴⁵ Notifications of laws under the TRIPS

⁴⁴ UN Sub-Commission for the Protection and Promotion of Human Rights, Resolution on "Intellectual Property Rights and Human Rights", E/CN.4/Sub.2/2000/L.20 on 17 August, 2000, and UN High Commissioner for Human Rights, The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights (E/CN.4/Sub.2/2001/13), 27 June 2001

⁴⁵ IP/C/W/296, TRIPS and Public Health Submission by the Africa Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela.

Agreement,⁴⁶ and surveys of use of policy options under TRIPS (such as the WIPO database on the use of flexibilities in national IP laws⁴⁷) demonstrate the diversity of approaches taken to the implementation of TRIPS standards, which provides invaluable information on how governments have addressed the challenges of coherence at the domestic level.

Legal coherence – The importance of coherence in legal understanding was exemplified by the Doha Declaration’s clarifications concerning the existing law, articulating what was already implicit in the legal text and explaining its positive linkages with measures to protect public health and promote access to medicines, including specific guidance on treaty interpretation. In invoking the objectives and principles of the TRIPS Agreement, this guidance draws attention to the public policy role of IP protection and the need for an equitable, positive-sum coherence between innovation and access.

Institutional coherence – In practice, coherence entails more active information sharing, cooperation and collaboration between distinct agencies and programmes within the multilateral system. Such institutional coherence is enabled, at the level of governance, by the guidance and support of member governments – a recent example is the decision by WTO Member governments to extend to 2033 for LDCs of complete exemption from patenting and data protection, with possibility of further extensions: this affords LDCs maximum flexibility in line with the SDG target on flexibilities beyond the SDG target date of 2030. Institutional coherence is also vitally important at the operational level, in the planning and delivery of programme activities. For the WTO, the Doha Declaration and similar catalysts for multilateral coherence has had far reaching influence on our operations, on the scope and inclusiveness of technical assistance, outreach and support for policy dialogue, and on the range of stakeholders and government officials we work with, in dealing with issues on the intersections of IP, trade and public health.

⁴⁶ https://www.wto.org/english/tratop_e/trips_e/trips_toolkit_e.htm

⁴⁷ <http://www.wipo.int/ip-development/en/agenda/flexibilities/search.jsp>