# Trade, Public Health, and the 2030 Agenda for Sustainable Development

Xavier Seuba

ICTSD
International Centre for Trade and Sustainable Development

Think Piece

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This think piece is one of a series of papers developed by ICTSD that explore the contribution that trade and trade policy could make to key objectives of the 2030 Agenda for Sustainable Development adopted by members of the United Nations in September 2015. The series is designed to help policymakers, in particular, to think through the role of trade policy in the implementation of this ambitious global agenda.

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## CONTENTS

## LIST OF ABBREVIATIONS

| | |
|---|---|
| ASCM | WTO Agreement on Subsidies and Countervailing Measures |
| GATS | WTO General Agreement on Trade in Services |
| GATT | WTO General Agreement on Tariffs and Trade |
| GPA | Government Procurement Agreement |
| ICH | International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use |
| MDG | Millennium Development Goal |
| PTA | preferential trade agreement |
| R&D | research and development |
| SDG | Sustainable Development Goal |
| TBT | WTO Agreement on Technical Barriers to Trade |
| TRIPS | WTO Agreement on Trade-Related Aspects of Intellectual Property Rights |
| UN | United Nations |
| UNCTAD | United Nations Conference on Trade and Development |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organization |
| WTO | World Trade Organization |

## FOREWORD

The United Nations 2030 Agenda for Sustainable Development adopted in September 2015 builds on many of the public health priorities set out in the Millennium Development Goals of 2000. The new agenda sets out ambitious targets under Sustainable Development Goal (SDG) 3 on healthy lives and well-being. Some of these targets reflect long-standing global public health challenges, like ending epidemics of communicable diseases like AIDS and tuberculosis, while others focus on emerging public health challenges, like reducing by a third premature deaths from non-communicable diseases. SDG 3 also makes specific reference to trade policy as a "means of implementation" for the achievement of these targets. Target 3.a focuses on improving access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health.

This think piece, written by Xavier Seuba, a Senior Lecturer at the University of Strasbourg's Centre for International Intellectual Property Studies, explores how trade rules, in particular those established at the multilateral level, could support progress towards the 2030 Agenda's objectives related to public health. It forms part of a series that analyses the contribution trade and trade policy could make to achieving key development objectives of the 2030 Agenda. The series is designed to help policymakers and other stakeholders to think through the role of trade policy in the implementation of this new framework of global commitments.

The author, an intellectual property expert, focuses in this think piece on the role of trade policy and trade rules in delivering on two key policy challenges in global public health: improving innovation in the healthcare industry and securing access to the goods and services required to deliver on the 2030 Agenda's ambitious health objectives. The paper reviews the role of a range of trade policy tools, including intellectual property rules, subsidies and tariffs, in the achievement of each of these challenges and articulates options policymakers could consider as they assess how to shape trade policy to support the 2030 Agenda. Many of these options relate to the reform of multilateral trade agreements under the World Trade Organization. These ideas could provide useful inspiration for the multilateral trade system as it seeks to redefine its relevance in the face of rising scepticism about international trade agreements.

The 2030 Agenda should spur policymakers to think about how trade policy can support the global framework's clear and ambitious objectives on climate change and clean energy. We hope that this paper proves useful to this work.

Ricardo Meléndez-Ortiz
Chief Executive, ICTSD

## EXECUTIVE SUMMARY

The United Nations General Assembly adopted in September 2015 the 2030 Agenda for Sustainable Development, a "plan of action for people, planet and prosperity" with the objective of "transforming our world." Health is central in the 2030 Agenda for Sustainable Development. The Agenda announces that it aims at ensuring universal health coverage and access to quality health care, and acknowledges that major challenges remain in terms of reducing maternal and child mortality, improving nutrition, fighting infectious diseases and addressing non-communicable diseases.

This think piece focuses on two broad public health objectives that would benefit from action in the area of trade policy and trade rules; if they were met, they would significantly contribute to satisfying the health-related targets of the 2030 Agenda. These two objectives are health innovation and access to health products of assured quality. The paper outlines how action and reform of relevant World Trade Organization (WTO) agreements could contribute to enhancing innovation and access.

Regarding innovation, short-, mid- and long-term measures are proposed with respect to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Agreement on Subsidies and Countervailing Measures (ASCM) and the General Agreement on Trade in Services (GATS). As far as intellectual property is concerned, four actions are proposed: empiric assessment; adoption of an integrated approach; intensive use of the TRIPS flexibilities; and agreeing on the meaning of pharmaceutical innovation. With respect to services, it is proposed that GATS be clarified in order to avoid the legal challenges that it allows against subsidies granted by states to health research. The GATS could also be positively used to foster innovation, essentially to promote greater international mobility for scientists.

Short-, mid- and long-term measures can also be adopted to improve access. The TRIPS Agreement, the General Agreement on Tariffs and Trade (GATT), the Agreement on Technical Barriers to Trade (TBT Agreement), the Agreement on Public Procurement (GPA) and the bilateral and plurilateral agreements touching upon the same subjects are key targets. The reduction or elimination of tariffs applied to pharmaceutical products should be further promoted so as to lower the prices of medicines. A more intensive use of TRIPS flexibilities and the adoption of an open stance towards the development and implementation of flexibilities are also recommended. It is also proposed that an independent review body be set up comprised of health, human rights and intellectual property specialists to make adjustments to the technical cooperation activities of multilateral organisations. Likewise, provisions that go beyond TRIPS should be assessed against their impact on access to health. Regarding technical standards, more plural, participative and transparent standard-setting forums and processes should be promoted. As far as public procurement is concerned, the diversity of views regarding the desirable level of liberalisation of pharmaceutical public procurement practices suggests that more debate is needed.

# 1. SETTING THE SCENE

## 1.1 The 2030 Agenda, Trade and Health

The United Nations 2030 Agenda for Sustainable Development recognises that international trade is an engine for inclusive economic growth and contributes to the promotion of sustainable development.[1] Likewise, the Sustainable Development Goals (SDGs) it enumerates and the Addis Ababa Action Agenda on financing for development underscore the role of trade in promoting sustainable development[2] and achieving numerous social and economic goals.[3] In that context, United Nations members pledge to promote a "universal, rules-based, open, transparent, predictable, inclusive, non-discriminatory and equitable multilateral trading system under the World Trade Organization, as well as meaningful trade liberalization" (UN General Assembly 2015, para. 68).

International trade agreements are relevant to a policy analysis of health determinants in the trade sector since they influence state action regarding health. The relationship between international trade law and health protection and promotion brings up, among others, questions relating to trade in goods, trade in services, intellectual property, competition, subsidies for research and development, technical standards and public procurement.[4] Hence, both "proximal" and "distal" determinants of health may be positively and negatively conditioned by trade agreements impacting on a wide range of health-related topics, an interface that has become a central subject of academic and public policy consideration in the last 15 years.

Health is "centrally positioned" in the 2030 Agenda for Sustainable Development (WHO 2016, v, 1). Direct references to health abound therein.[5] The health-specific SDG 3 and its 13 associated targets aim to "ensure healthy lives and promote well-being for all at all ages." Other goals also contribute indirectly to health improvement. In this respect, the 2030 Agenda not only refers to the classic health-care components and major diseases, but also mentions health determinants such as healthy environments—like adequate sanitation under SDG 6—global health threats, specific health situations, public health indicators and fundamental rights closely related to health, including the right to enjoy a basic standard of living, in line with SDG 1. Progress towards the Agenda's health-related objectives will also contribute to other SDG objectives: improving maternal health, for instance, would contribute directly to greater gender equality.

1 WHO (2016, v, 1); Annex A of the report includes summaries setting out what is needed to achieve the 2030 targets and indicating what is currently known about the key aspects of equity and the extent of data gaps for each target (see p. 43 of the report).

2 Trade-related targets are included in 12 of the SDGs. See Tipping and Wolfe (2016) in this ICTSD publication series.

3 According to the Addis Ababa Action Agenda, "with appropriate supporting policies, infrastructure and an educated work force, trade can also help to promote productive employment and decent work, women's empowerment and food security, as well as a reduction in inequality, and contribute to achieving the sustainable development goals" (Addis Ababa Action Agenda 2015, para. 79).

4 While this paper focuses on health and trade, it is becoming almost artificial to refer to trade without mentioning the link with investment at the same time. In the UNCTAD investment dispute settlement navigator, out of a total of over 700 arbitration cases under investment agreements, some 500 related to the "tertiary sector" (of these, three to health services). This is another indication of the relative "bite" of investment agreements compared to the WTO/GATS regime, under which fewer than 10 disputes were referred to panels over about the same period. See UNCTAD's Investment Policy Hub at http://investmentpolicyhub.unctad.org/ISDS.

5 This was already the case with the Millennium Development Goals (MDGs). While the impact on health could be traced in all of them, three out of eight MDGs included specific health-related objectives: MDG4 (reducing child mortality), MDG5 (improving maternal health), and MDG6 (combating HIV/AIDS, malaria and other diseases). Target E of MDG8 (Global Partnership for Development) underlined access to essential drugs in the context of a call for an enhanced global partnership for development issues.

The 2030 Agenda contains an overarching paragraph exclusively devoted to health (UN General Assembly 2015, para. 26), which must be read in conjunction with the SDGs. In this paragraph, states pledge to achieve universal health coverage and access to quality health care so as to promote physical and mental health and well-being, and to extend life expectancy. They also make a commitment to end all preventable newborn, child and maternal mortality before 2030, and ensure universal access to sexual and reproductive health-care services. States also commit to accelerating the pace of progress made in fighting malaria, HIV/AIDS, tuberculosis, hepatitis, Ebola and other communicable diseases and epidemics, including by addressing anti-microbial resistance and unattended diseases affecting developing countries. In the same paragraph, they also commit to the prevention and treatment of non-communicable diseases, including behavioural, developmental and neurological disorders.

These goals are in line with the needs identified by the World Health Organization (WHO). According to available data,

> in spite of the major progress during the Millennium Development Goal (MDG) era, major challenges remain in terms of reducing maternal and child mortality, improving nutrition, and achieving further progress in the battle against infectious diseases such as HIV/AIDS, tuberculosis, malaria, neglected tropical diseases and hepatitis. The situation analysis also provides evidence of the importance of addressing noncommunicable diseases and their risk factors. (WHO 2016, v, 1)

Currently, while in high-income countries people live long lives and usually die of chronic diseases, in low-income countries people predominantly die much younger and of infectious diseases. While large declines in mortality from communicable, maternal, perinatal and nutritional causes are projected for 2030, it is expected that the ageing of populations will result in more deaths due to non-communicable diseases. In this respect, innovation systems will need to adjust to these changes in the global disease burden, while the focus on access to medicines will need to broaden so as to encompass medicines for both communicable and non-communicable diseases (WHO, WIPO and WTO 2013, 10).

Almost all the objectives announced in SDG 3 are related in one way or another to trade and trade policy. Some of the objectives have a direct relationship with trade and trade rules.[6] This is clear in the reference made to the implementation of the WHO Framework Convention on Tobacco Control, and the relationship it bears to restrictions on the trade in tobacco products.[7] The direct relationship with trade is also clear in the reference made in SDG 3 to the provision of access to affordable essential medicines and vaccines, and the mention of the Doha Declaration on the TRIPS Agreement and Public Health.

Other targets announced in different SDGs, in particular those relating to innovation promotion, climate change, and strengthening the means of implementation, are also related to health and trade. For instance, in the latter case, among the "means of implementation" listed in the 2030 Agenda, it is important to the achievement of health-related objectives to set up a Technology Facilitation Mechanism to "promote coordination, coherence and cooperation within the United Nations system on science, technology and innovation-related matters, enhancing synergy and efficiency."

### 1.2 The Interface between Health and Trade Policy

This policy paper focuses on two broad public health policy challenges: strengthening health

6 As noted above, even though this paper focuses on health, it is becoming more and more difficult to dissociate health from investment law, as evidenced, for instance, by the complaints lodged by tobacco companies against plain packaging regulation under various bilateral investment treaties.

7 See opposite views on how to address those conflicts in Layton and Lowe (2014) and Lester (2015).

innovation and improving access to health services and health products of assured quality. Efforts to meet these objectives would benefit from action in the area of trade policy and trade rules. Meeting these goals would significantly contribute to the health-related objectives of the 2030 Agenda for Sustainable Development. Indeed, in order to "ensure healthy lives and promote well-being," as SDG 3 proposes, important changes both in terms of access and innovation are necessary. Some SDG 3 targets in fact explicitly allude to "research and development of vaccines and medicines" and "access to health services and medicines," and a large number of other targets under SDG 3 and other goals also depend on improving innovation and access.

The determinants of innovation and access are many and most of them go beyond trade policy and trade rules. A large number are of a socio-economic nature or have to do with organisational aspects of health systems. Poverty or cultural determinants, and factors or policy choices relating to the design and implementation of health systems, are also crucial. Similarly, a good number of measures that can be undertaken to promote innovation and access also go beyond trade policy, for instance cost-containment measures such as pricing policy controls on medical devices and pharmaceutical products, setting up reimbursement limits or taxes, measures relating to the selection and rational use of health-related products or, also, measures in the area of health financing.

While this paper does not address all the determinants of innovation and access, its scope is still broad. The examination of the trade-related aspects of health innovation and access relevant to the 2030 Agenda requires a combination of analysis and proposals touching upon a range of areas of trade policy and trade rules, in particular WTO agreements including the GATT, TBT Agreement, ASCM, GATS, TRIPS Agreement and GPA. Likewise, new bilateral and plurilateral trade agreements deeply influence health regulation and the provision of health products.

The wide variety of trade-related policies conditioning health includes, for instance, the procurement-related mechanisms for the provision of health products, the training of health service providers and the impact that regulatory measures relating to the quality of health products have on both competition and human health. Similar links and impacts on innovation and access can be established with respect to other trade-related areas, such as technology transfer and intellectual property.

While legally and functionally innovation and access are interwoven,[8] many trade-related norms influencing them are distinct. In this regard, the next two sections describe how a number of areas of trade policy and trade rules, in particular those contained in WTO agreements, impact on innovation and on access. The same trade agreement may, indeed, have provisions impacting on both innovation and access. For instance, while measures allowed in the TRIPS Agreement such as the research exception clearly relate to innovation, other measures essentially target access, this being the case for compulsory licences, for instance.[9] On other occasions the same legal requirements may affect both innovation and access, this being notably the case of patentability standards.

8 From a practical point of view, "innovation cannot take place in isolation from concerns about access, and access has to be seen in the broader context of the need for innovation and effective regulation" (WHO, WIPO and WTO 2013, 30).

9 The research exception allows the use of patented technologies for research purposes, while compulsory licences allow the use of the patented technology without the right holder's permission.

# 2. STRENGTHENING INNOVATION IN THE HEALTH SECTOR

## 2.1 Innovation as a Multifaceted Process

Unmet needs of large segments of population, expected changes in the global burden of disease, and crucial phenomena such as the ageing of populations have given rise to new priorities and needs in terms of the medical technologies necessary to respond to these changes.[10] Achieving the public health objectives of the 2030 Agenda in the light of this changing context will require adjustments to existing institutional structures, such as a focus on old-age care in many countries, and will depend on rapid and widespread innovation, particularly in creating new medical technologies.

As technological and social changes take place in a rapidly evolving global society, existing innovation policies, processes and structures will need to be updated. The old linear innovation model—that is, innovation starting with basic research, followed by applied research and development, and then production and diffusion as the end of the process (Godin 2005)—has been replaced by a more complex framework, where many actors intervene at several different stages of the innovation chain,[11] and in a different way depending on the type of innovation.[12] Scientific and technological advances, pressing social needs, increased competition and the ever-evolving role of the state, among other factors such as changing markets and regulatory processes, have prompted the emergence of innovation models pulling together the competences and talents of very diverse stakeholders. More than ever, innovation is highly cumulative and frequently requires collaboration in open, inclusive and enabling networks.[13] In this way, innovation reaches unprecedented levels of sophistication and pursues both private and public policy goals.

Reflections on the strengths and weaknesses of the innovation system as applied to health products have been enriched enormously in the last 20 years. The same can be said of the tools that enable health innovation. More is known about the complexity of innovation and the need to carefully combine policy, legal and scientific instruments in order to produce it. The so-called "innovation elements" encompass varied inputs, processes, legal instruments, financial and economic drivers, policy choices and cultural approaches. Presently, networks of innovators, often of a global nature (Maskus and Saggi 2013), have recourse to a wide range of legal and managerial tools from a rapidly evolving innovation toolbox, which must also be observed against a background of specific policy, economic, legal and cultural settings.

Numerous tools have been deployed to promote pharmaceutical innovation, mention commonly being made of patents, trade secrets, public funding, regulatory processes, availability of venture capital, ownership of innovation "platforms" and "infrastructure," science and engineering education, technology transfer, competition, prizes, "open" strategies and liability rules (Benjamin and Rai 2008). While, in principle, states can regulate intellectual property, technical standards, regulatory systems, investment, services and subsidies as they

10 Wording in this section is partially based on Seuba (2016c).

11 In the 1980s it was already clear that the linear innovation model could not respond to the complexities of innovation processes; see Kline and Rosenberg (1986).

12 Different types of innovation can be distinguished, including cumulative innovation (follow-on innovation), horizontal innovation (expansion in the variety of goods) and vertical innovation (improvements in the quality of goods).

13 Multinational enterprises, high-technology start-ups, universities and public research laboratories, venture capitalists, specialised technology brokers, standard-setting organisations and government agencies are among the actors in innovation networks; Maskus and Saggi (2013, 6).

think best, innovation is often factually and legally determined by international elements, including international trade treaties.[14]

### 2.2 Intellectual Property Rights

The fundamental tenet justifying intellectual property protection is the promotion of innovation.[15] It follows that the multilateral trade framework most closely related to innovation by means of intellectual property protection is the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights. While in the late 1990s many commentators argued that the TRIPS Agreement was a fundamental component of the quid pro quo bargain between developed and developing countries during the Uruguay Round,[16] the view that has ultimately prevailed is that the TRIPS Agreement is a fairly balanced treaty. This view assumes, therefore, that intellectual property promotes innovation.

Economists, principally, but also legal scholars have challenged that view, holding that there is no evidence, or not enough empirical evidence, of the link between innovation and intellectual property protection.[17] However, the prevailing view is still the opposite, that is, that intellectual property and innovation are interlinked and the former positively influences the latter, while social norms and government intervention are also vital enabling tools (WIPO 2015).

The disagreement between the two sides of the argument cannot be overlooked, since the key element in the trade-off between access and intellectual property protection is the promotion of innovation. Clarifying and quantifying to what extent intellectual property contributes to innovation would provide guidance for the design and management of the intellectual property system, in order to promote innovation while reducing the anti-competitive effects of intellectual property protection. In that context, an evaluation of the role of the TRIPS Agreement in promoting innovation has been proposed (Mercurio 2014, 1). In the context of the SDGs, developing and emerging economies would be particularly relevant to this evaluation. While that proposal seems to assume a negative correlation, the outcome of the evaluation could be different.[18] In any case, this is not a new proposal. Both classic[19] and contemporary[20] authors have reflected on it, while clear answers are still missing.[21]

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14 See section 1.1 above and reference to Bettcher, Yach and Guindon (2000).

15 See Article 7 of the TRIPS Agreement ("The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation") and, more broadly, Drahos (2001, 204–13).

16 The views and perceptions concerning the origin and justification of TRIPS were very varied. See in particular Taubman (2015, 42–4); also Sell and May (2005).

17 Mercurio (2014) has summarised that debate.

18 This evaluation would indeed not be simple. The TRIPS Agreement does not exist in isolation and any evaluation should take into consideration the broader WTO context and its impact on the innovation output.

19 In the late 1950s Fritz Machlup made an affirmation which, for many economists, still applies. According to Machlup: "No economist, on the basis of present knowledge, could possibly state with certainty that the patent system, as it now operates, confers a net benefit or a net loss upon society. The best he can do is to state assumptions and make guesses about the extent to which reality corresponds to these assumptions. … If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one" (Machlup 1958, 79–80).

20 As Professor Abbot has noted, if we knew precisely how adjustments to patent laws would impact the trajectory of innovation, we would have gone a long way to determining what the optimal patent policy would be; see Abbott (2005).

21 Mercurio (2014) captures a good amount of economics literature that demystifies the contribution of patents to innovation. However, a similar number of authors can be found holding the contrary position. Then the real question, as Professor Abbott suggests, is to what extent our possibilities for getting a concrete result have improved since Machlup's times.

In addition to the proposed evaluation, in order to achieve the sustainable development goals, intellectual property rights must be properly contextualised as part of a much broader legal order, where other rights and legal interests also deserve protection. In this regard, the interaction between intellectual property rights and other legal and social interests, such as development, environment and public health, has been thoroughly addressed in international fora and in the academic literature in the last decade (see Seuba 2016a). However, there is still lot to do to translate into practice these interfaces, whether in the form of new policies, normative reforms or judicial decisions.

Fulfilling the instrumental purpose of the intellectual property system depends on its actual design and management. The implementation and use of the so-called TRIPS flexibilities—that is, measures that allow intellectual property protection to be adjusted to achieve a proper balance between competition, intellectual property protection and social concerns—is of relevance in that context.[22] The 2030 Agenda recognises this in the commitments to the provision of essential medicines in accordance with the Doha Declaration on the TRIPS Agreement and Public Health (see SDG target 3.b). For the purposes of this paper, the most important conclusion resulting from the discussions and clarification of the TRIPS flexibilities is the consolidation of the right to interpret the TRIPS Agreement in a manner supportive of public health.

As the 2001 WTO Doha Declaration clarifies, and the 2030 Agenda for Sustainable Development endorses, countries have great discretion to tailor their intellectual property regimes to meet the principles and objectives announced in Articles 7 and 8 of the TRIPS Agreement. These provisions frame intellectual property protection in the broader context of the promotion of social and economic welfare, and include explicit references to, among other social goods, the protection of public health (see Yu 2009). The TRIPS flexibilities are of fundamental importance in this broader context. In the case of innovation, some flexibilities deserve specific attention.[23] In particular, and in addition to post-grant measures such as the research exception discussed above, patentability standards stand out.[24]

The legal framework set out in the TRIPS Agreement allows governments to develop guidelines for patent examiners on how to properly implement patentability criteria.[25] National practices diverge in this respect, since countries have adjusted their national patentability standards in light of different priorities and criteria. The relationship is complex and depends on a range of factors, but very generally, flexible standards of patentability lead to a larger number of patented products. This in turn may lead to a lower level of competition, impact on prices, reduce access to patented products and ultimately affect progress towards the objectives mentioned in the 2030 Agenda, such as universal health coverage. Similarly, if patentability guidelines set up a higher standard of patentability, follow-on innovation may be affected or become more expensive. In light of these considerations, and given that innovation is both product and country

22 In the last 20 years, TRIPS flexibilities have been described in great detail. In addition to the classic UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (2005), recent interpretations of the policy space afforded in TRIPS can be found in Max Planck Institute (2014).

23 See the database of the World Intellectual Property Organization (WIPO) on flexibilities in the intellectual property system, www.wipo.int/ip-development/en/agenda/flexibilities/search.jsp.

24 According to TRIPS (Article 27.1), patents should be available when inventions are new, involve an inventive step and are capable of industrial application. TRIPS does not elaborate on these three broad criteria.

25 WHO (2006, para. 46). Along the same lines, some countries have amended national legislation or adopted guidelines for patent examiners concerning patentability criteria. Section 3(d) of India's Patent Act 1970 and Section 22 of the Philippines Intellectual Property Code have set up strict standards of inventiveness, in line with the Argentinean guidelines for examining patent applications for pharmaceuticals.

contextual, the existing room to manoeuvre in TRIPS should be preserved.

In that same context, agreeing on a definition of pharmaceutical innovation would be helpful. Currently, patents granted in the pharmaceutical domain do not necessarily recognise products that contribute to health in a significant manner. Developing a definition of pharmaceutical innovation could be helpful when examining the requirement of inventive step or when granting a patent for an increase in the efficacy of an existing product. While an official definition of pharmaceutical innovation does not exist, it could be arrived at relatively simply. For instance, it could be stated that pharmaceutical innovation refers to the introduction of new products and processes that create value for health.[26] Consistent with that definition, it would seem reasonable to have a much more active role for health and competition authorities in patent-related discussions, for instance to decide whether incremental innovation that meets the criteria for patentability really entails therapeutic benefits or deters competition.[27] Again, while arriving at a compromise over the definition of pharmaceutical innovation may be difficult, mainly for economic reasons, the 2030 Development Agenda sets ambitious objectives that require similarly bold compromises.

### 2.3 Subsidies

Direct subsidisation is the most effective policy response to inadequate incentives for innovation and to high costs of adapting technologies to local requirements (Maskus 2015, 6). It is thus a crucial part of ensuring that health innovation responds to different countries' unique challenges under the 2030 Agenda. Many alternative or complementary proposals to the current intellectual property-based innovation system are, in fact, largely based on some sort of subsidisation. This is the case with prizes and government grants, which are by no means new. In fact, health research already benefits from large amounts of public expenditure directed to academic institutions and public research organisations (WHO, WIPO and WTO 2013, 105), as well as to private firms conducting publicly funded research thanks to subsidies, soft loans, and tax credits. In this context, the Agreement on Subsidies and Countervailing Measures becomes relevant. More precisely, the question that must be posed is whether the research and development subsidies needed, among others, to address the 2030 Agenda health objectives are compatible with the ASCM.

In the ASCM, the WTO members agreed that subsidies fulfil several legitimate policy options. At the same time, it was also agreed that subsidies may also have distorting effects on trade and competition, and may become a tool to achieve protectionist goals.[28] In order to address these conflicting features, the ACSM identified categories of prohibited subsidies, actionable (challengeable) subsidies and non-actionable subsidies, and set forth two basic criteria—benefit and specificity—to decide whether action against a subsidy is legitimate. Research and development subsidies have been challengeable since 2000, when the article under which they were declared non-actionable expired.[29] This means that, where they consist of a financial contribution made by a public body to the benefit of its recipient, and this contribution is awarded to an enterprise, group of enterprises or industries, and provided that harm is caused to other WTO members, they are actionable.

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26 The OECD, in contrast, proposes a broader definition of innovation, merely requiring novelty: implementation of a new or significantly improved product, or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations; OECD-Statistical Office of the European Communities (2005).

27 This is the case with the so-called "Prévia Anuência" in Brazil, whereby by virtue of Article 229-C of Law 2.979/96 the Ministry of Health intervenes by means of the National Health Surveillance Agency (ANVISA) in the award of pharmaceutical patents.

28 See, in greater detail, Sykes (2015).

29 See Article 8 of the ASCM.

This legal framework could be adjusted to avoid potential friction with current practices and policies to promote health research. For instance, would a government grant to a national pharmaceutical company to develop a means of administration of a drug that facilitated its consumption in some specific circumstances be challengeable? It seems so, at least if a WTO member argued that the successful development of that drug could harm national companies currently exporting the same drug under different forms to the country providing the subsidy or to other countries where the benefiting company may also export the successful product. The examples could be numerous, in particular because of the loose regime set out in the ASCM. Two different lines of reasoning can be followed here.

First, it can be argued that the current legal uncertainty provides governments with a degree of policy flexibility, but does not help them to strike a good balance between their health objectives and the efficiency benefits of international competition. In this regard, governments may not be subsidising the health sector enough to meet local health policy needs, for fear of challenge, or may be over-subsidising the sector and in fact distorting trade to the detriment of more efficient producers and the global market overall.

A second line of reasoning would hold that, despite the fact that research and development subsidies have rarely been challenged in the WTO,[30] it is worthwhile reaching an agreement that clarifies further the WTO discipline on subsidies, so as to provide legal certainty. Some of the features and recommended content of such a clarification have been elucidated in the literature (Horlick and Clarke 2015; Maskus 2015). The most relevant options for a health-oriented reform of the WTO disciplines are set out here.

The first and most straightforward option would be the adoption of an explicit and narrowly defined agreement declaring that any subsidy intended to develop a product that satisfies the prevalent health needs of a population, and particularly subsidies relating to any disease and health situations mentioned in the 2030 Agenda, could be made non-actionable. This proposal follows others previously made arguing in favour of a narrowly defined category of non-actionable subsidies with clear boundaries.[31]

A second option would have a more ample scope and introduce a degree of flexibility by focusing on the concept of specificity. While some have argued in favour of a wide and therefore strict definition, which includes all fiscal support, research grants and subsidies to particular groups (Maskus 2015, 9), a more flexible approach, where the conditions are attached to subsidy measures and their intended objective, can be favoured. Thus, even if subsidies are provided specifically to an enterprise or industry or group of enterprises or industries, they could still be deemed non-specific in light of their features and public policy objectives. Among the latter, the fulfilment of the innovation objectives linked to the 2030 Agenda would qualify. As a condition, governments providing subsidies could be required to demonstrate that the subsidy is intended to mitigate a market failure "or [establish] long-lasting research and technical capabilities, rather than propping up inefficient production in the short term" (Maskus 2015, 9).

Other proposals in this same context have been the strengthening of the role of a neutral decision-maker to monitor and resolve disputes

30 The potential explanations of why only three subsidies-related disputes have been launched at the WTO include the difficulty of showing, as the ASCM requires, that a subsidy has caused injury to a complainant's domestic industry, respect for national policy space and the understanding that R&D subsidies are a legitimate domestic policy intervention (Maskus 2015, 1).

31 This proposal would fit within the "subsidies that target R&D activities beneficial to society at large in which private commercial incentives may be insufficient" (Horlick and Clarke 2015).

concerning the various types of subsidies, obtaining better data and measuring impact of subsidies (Horlick and Clarke 2015, 10), and regulating clearly and in a non-discriminatory manner the conditions for accessing publicly funded research or tax advantages under domestic law. Overall, these proposals should enable governments to support R&D for public health without unreasonably distorting trade.

### 2.4 Trade in Services

Greater international mobility for scientists would facilitate dissemination of knowledge and transfer of technology (Barton 2002, 6). Such mobility is instrumental to the promotion of health innovation, although it might need to be balanced with measures to ensure it does not end up reducing access to health in scientists' countries of origin.

International mobility of scientists would benefit from adjustments to international trade treaties. An agreement facilitating the acquisition of experience by scientists and the transfer of knowledge thanks to scientists' mobility would benefit from expanded Mode 4 commitments in the GATS, and potentially an expanded definition of the scope of Mode 4. The commitments made under Mode 4, which touches upon the presence of natural persons, refer almost solely to higher-level personnel, especially to transferees from one facility to another of the same company. Expanding this definition, either in the context of a plurilateral agreement discussed below or in the GATS itself, could help to increase the temporary but relatively long-lasting circulation of technically skilled workers (Maskus and Saggi 2013, 4).

Maskus and Saggi have proposed promoting the adoption of a plurilateral agreement under the auspices of GATS "for significantly liberalized skilled labor flows under the guise of an 'innovation zone' work visa." Such an agreement would address the certification of professional skills acquired in different countries, "though a strong tilt toward mutual recognition seems appropriate." Moreover, countries could exclude sensitive professions or enact safeguards, for example, "to ensure that security-sensitive positions in public agencies or research labs are ineligible" (Maskus and Saggi 2013, 4).

The proposal put forward is certainly ambitious, in particular in light of the paralysis of negotiations at the WTO. At the same time, it needs to be carefully balanced with measures intended to avoid a brain drain, a phenomenon particularly critical in the area of access to health and whose repetition must be avoided in the area of innovation. The difficulties, however, are not insurmountable. Safeguards could be included, for instance, to ensure that skilled professionals from developing countries would only be eligible if they had spent a certain proportion of their careers working in their home country, or that they would return to their countries of origin once a number of years had elapsed.

# 3. ACCESS TO HEALTH PRODUCTS AND SERVICES OF ASSURED QUALITY

The World Health Organization identifies four factors conditioning access to medicines. They are the selection and rational use of medicines; sustainable financing of pharmaceuticals; reliable distribution; and accessible prices. Access must, naturally, be to products of assured quality. The latter depends in turn on the fulfilment of technical standards touching upon a myriad of issues falling within three broad areas: quality, safety and efficacy. These factors closely relate to several trade topics, from procurement practices that permit responses to selection and distribution concerns, to intellectual property protection and tariffs, both impacting on price.

### 3.1. Tariffs and Non-tariff Barriers

The WTO and its predecessor, the GATT, have always manifested a preference for tariffs and customs duties on imported goods rather than quantitative restrictions. They have, moreover, contributed to lowering tariffs to unprecedented levels. However, tariffs on the importation of health products still exist.

National practice with respect to tariffs applied to health products varies. Many countries have completely suppressed tariffs for health products. In fact, in the case of pharmaceutical products, an international agreement even exists for that purpose. Other countries have significantly lowered the tariffs—over the past decade developing countries have lowered their tariffs on medicines from 6.7 percent to 4.2 percent on average, while in the case of least developed countries the applied rates range from 4.5 percent to 2 percent on average (WHO, WIPO and WTO 2013, 78–9)—while other countries maintain tariffs to meet budgetary and industrial purposes (WHO, WIPO and WTO 2013, 78–9).[32]

Given that all countries rely on international trade to satisfy the needs of their domestic markets for health products, particularly in the case of developing countries with little or no production capacity, tariffs are relevant when addressing access to medicines. Tariffs add an extra cost to health products, and therefore impact on availability and access. Given that other costs and mark-ups are added to the price of products once they make their way into a national market,[33] the imposition of tariffs at an early stage of the marketing circle has exponential effects on the final price of products.

Preferential trade agreements (PTAs) have positively impacted this area. Many trade agreements include commitments relating to tariff liberalisation in the area of pharmaceuticals, and contribute to lowering the prices of medicines, a feature of trade agreements that could be promoted and further exploited.[34] Therefore, a clear policy recommendation to continue that trend can be made. Having said that, in pursuing that objective a distinction should be drawn between tariffs on imported finished products and tariffs on intermediate products. Certainly, in some cases, tariffs on intermediate products such as active pharmaceutical ingredients may be justified, for instance during periods of transition to local production.

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32 The agreement is limited in terms of governments subscribing to it and derives from a communication made in the context of the GATT as reflecting records of discussion held. See the Pharmaceutical Tariff Elimination Agreement, 1994, concluded in the context of the Uruguay Round, at www.wto.org/gatt_docs/English/SULPDF/91770009.pdf.

33 Distribution margins for pharmaceutical products, which make up on average 5 to 10 percent of the base price, can, in some countries, amount to up to 29 percent of the base costs, including tariffs. See, in relation to distribution costs, OECD (2008).

34 WHO (2001). More skeptical views about the positive effects of the reduction of tariffs can be found in Mackintosh et al., who say: "A further example has been international donor pressure, including WHO policy advice, on African countries to remove all tariffs on imported formulations, despite a lack of evidence to date on tariff incidence" (2016, 3).

### 3.2 Intellectual Property Rights

Access to medicines could also be supported by governments taking advantage of the built-in flexibilities in the TRIPS Agreement. These flexibilities have been extensively described in the literature[35] and in documents adopted by public bodies.[36] They have also received official endorsement by the member states of several international organisations, including the World Health Organization,[37] the World Intellectual Property Organization[38] and the World Trade Organization.[39] Their relevance has, moreover, been underlined in the context of the 2030 Agenda for Sustainable Development and the Addis Ababa Action Agenda.[40]

TRIPS flexibilities contribute to competitive dynamism in the pharmaceutical market. Their use is widespread and has been beneficial for access to medicines. For instance, many countries have incorporated into their national legislation measures such as the Bolar provision, which allows domestic producers to use patented versions of pharmaceutical products to conduct all necessary tests for regulatory purposes before the expiry of the product's patent. Similarly, the granting of non-voluntary licences to authorise the production and commercialisation of patented products without the patent owner's consent has had a decisive impact on the lowering of the price of patented medicines. Likewise, parallel importation of medicines legally introduced in third markets is a key mechanism for taking advantage of the price differences existing worldwide.

While the use of flexibilities has become common practice in many countries, other countries could consider a more intense or wider use of them (Musungu and Oh 2005). Moreover, some flexibilities remain unexplored and a fertile field to achieve the objectives of the SDGs. For example, a patent exception allowing manufacture for exportation to countries where there is no patent protection is a matter that deserves further consideration (Seuba, Genovesi and Roffe 2017), as well as a regime for automatic non-voluntary licensing of patents relating to essential medicines ('t Hoen et al. 2016), or an automatic licence system to be framed within the exceptions provided for in Article 30 of the TRIPS (Genovesi 2016). In fact, many contributions made in 2015 and 2016 to the United Nations Secretary-General's High-Level Panel on Access to Medicines described new or enhanced ways to implement TRIPS flexibilities.[41]

In light of the new proposals put forward and the current use of TRIPS flexibilities, a recommendation to be considered in the context of the 2030 Agenda for Sustainable Development is a more widespread and extensive use of well-known TRIPS flexibilities and the adoption of an open stance towards the development and implementation of new ones. For this purpose, there is no need to adopt new wording or amend TRIPS, but rather a need to interpret it in a flexible, health-oriented manner. The manufacturing for export exception, mentioned above, is a case in point. An intensified use of TRIPS flexibilities would not run against the development of new ones

35 One among many references in the academic literature, containing numerous references to other works, is Mercurio (2013).

36 Probably the most influential, even today, was WHO (2006).

37 See, in particular, WHA (2006; 2007; 2009).

38 Recommendations 13, 14, 17, 22 and 25 of the WIPO Development Agenda explicitly allude to the TRIPS flexibilities, see WIPO (2007).

39 Doha Declaration on the TRIPS Agreement and Public Health (Doha WTO Ministerial 2001).

40 Where its signatories "reaffirm the right of WTO members in taking advantage of the flexibilities in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and reaffirm that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health"; see Addis Ababa Action Agenda (2015, para. 86); and also SDG target 3.b.

41 See them all at http://www.unsgaccessmeds.org/list-of-contribution/.

which target different situations but pursue the same pro-access objectives.

Even more important, however, is the adoption of an integrated approach to intellectual property regulation and management. The last 20 years have seen a consolidation of the understanding of international intellectual property law as part of the broader international legal framework. This understanding facilitates an integrated approach to health policy. Such an approach takes into account obligations that belong to different international regimes and touch upon aspects such as development, environment or human rights. This is probably what WIPO, WTO and WHO have in mind when they underline the "interaction between the legal and policy principles in different domains, so that law and policy instruments can be interpreted and applied in practice to promote public health" (2013, 30; see also Chan, Gurry and Lamy 2013, 7).

A specific policy proposal that builds on this integrated view is the idea that national pharmaceutical policies could integrate both intellectual property and human rights aspects, using in particular the right to health as a basis. Such an integrated policy could help to define a clear space and role for trade-related policy instruments, like tariffs on imported goods or the use of TRIPS flexibilities, in the service of broader public health objectives and the implementation of the 2030 Agenda. This requires a relatively protracted process of consensus-building to clarify the specific terms and content of that integration, but the adoption and implementation of these policies would be commensurate with the ambitious objectives set forth in the 2030 Agenda.

A second specific proposal touching upon the integration of intellectual property and human rights in the particular context of health is to review and modify as necessary technical cooperation activities conducted by multilateral organisations (in particular WHO, UNCTAD, WIPO and WTO) in light of that integration. In this case, the implementation of such a review would be possible in the short term and would go beyond the proposal by the Directors-General of WIPO, WHO and WTO to use the "richer, more diverse and more inclusive body of empirical data and practical experience available to guide technical cooperation" (Chan, Gurry and Lamy 2013). An independent body comprised of health, human rights and intellectual property specialists could be set up for that purpose. Along similar lines, the report of the United Nations Secretary-General's High-Level Panel has proposed setting up "an inter-agency taskforce on health technology innovation and access. This taskforce, operating for the duration of the SDGs, should work toward increasing coherence among United Nations entities and relevant multilateral organisations like the WTO" (UN High-Level Panel 2016, 10).

In a number of cases the relationship between intellectual property and access to health would benefit from the clarification of existing legal provisions. The list of potential clarifications is long, and each topic within it would require individual treatment. At a minimum, the list includes the relationship between Article 5(A) of the Paris Convention and Article 31 of the TRIPS Agreement, to provide certainty regarding the grant of compulsory licences for the non-local working of patents; clarifying the conditions under which counterfeit products can be stopped in the country of transit; clarifying the relationship between trademark protection and international non-proprietary names, in particular for biotechnology products; and clarifying that the use of information appearing in brochures for approved medicines is not an infringement of copyright. Each of these topics represents an entire area of discussion and is independent of the others. However, a common characteristic they share is that the adoption of one interpretation or another influences competition and therefore has an effect on access. From this point of view, choosing the interpretation that favours access may help in meeting the access objectives of the 2030 Agenda.

In other cases, it may be the content of the norm that is difficult to reconcile with the protection of public health. Intellectual

property provisions that have gone beyond TRIPS, agreed in the context of preferential trade agreements, are a case in point. The trade agreements signed by the United States, and more recently those by the European Union, establish contradictory goals. On the one hand, these treaties generally include a supportive reference to the Doha Declaration on the TRIPS Agreement and Public Health. On the other hand, their intellectual property provisions, taken together, enhance the position of the right holder to the detriment of competition in the pharmaceutical market of the parties to the PTA. In this last respect, as the World Health Organization has stated, when concluding trade agreements WHO members should take into account the TRIPS flexibilities and the impact on public health of more extensive intellectual property protection.[42]

While a number of obligations set forth in PTAs have an impact on innovation, the majority of TRIPS plus and extra provisions found in PTAs impact on access. Table 1 sets out the new and strengthened standards regarding intellectual property protection going beyond TRIPS that are frequently adopted in PTAs and describes their impact on innovation and access.

**Table 1: TRIPS plus and extra provisions found in recent PTAs**

| Areas of regulation | New and strengthened standards |
|---|---|
| Patent term | Extension given for delays caused by regulatory and patent approval processes. |
| Second-use patents | Obligation to provide patents for new uses of known products. |
| Patenting of life forms | Obligation to provide patent protection for plants and animals. |
| Compulsory licences | Compulsory licences limited to national emergencies, antitrust remedies, and for public non-commercial use. |
| Linkage between patent and marketing authorisation | Patent owner must be notified when marketing approval is sought during the patent term. Marketing approval is forbidden during the patent term. |
| Test data for medicines | Patent owner has exclusive use of test data for five years. Additional three years of data exclusivity triggered by "new clinical information." |
| Parallel imports | Patent holders may limit parallel imports through licensing contracts. |
| Enforcement | Expansion of minimum standards, making compulsory enforcement standards which are optional pursuant to TRIPS.<br>Expanded border enforcement, involving the jurisdiction of the country of transit.<br>Expansion of criminal enforcement. |

### 3.3 Technical Standards

A range of activities are conducted at the international level to guarantee the safety, quality and efficacy of medicines.[43] International harmonisation of information concerning these activities fulfils an important public health objective since it avoids the repetition of tests already carried out, or tests very similar to others already carried out. It therefore reduces risks to human health and unnecessary expense, thus facilitating access to products of ensured quality. Although harmonisation can be helpful, the content of internationally harmonised standards does not necessarily reflect a wide variety of interests and values.

42 WHA (2009); see, in particular, Elements 5.2 (a), (b) and (c).

43 This section is based on Seuba 2016b.

Both international standards of reference and the WTO Agreement on Technical Barriers to Trade are of relevance in this context, since they guide national standards on the quality, safety and efficacy of pharmaceutical products. Particularly important are the standards adopted by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The ICH is presently the most productive and influential source of international pharmaceutical standards, with over 90 guidelines adopted in its 20 years of existence. ICH guidelines enjoy a high level of implementation and influence beyond ICH member states.

The potential impact of technical standards as restrictions to international trade is a matter of concern with respect to access to medical technologies. Adopting a specific standard may impede the entrance of products into the national market or make those products more expensive, and therefore may not only impact access but also be used as a protectionist measure.

The objective of the TBT Agreement is to ensure that national regulations do not become unnecessary barriers to trade. In order to do so, it establishes that national regulations—by definition, mandatory—cannot be more trade-restrictive than the levels established in international standards of reference. The latter are not identified in the TBT Agreement, and nor are the international standard-setting organisations. On the contrary, the agreement only sets forth some basic criteria. Fundamentally, it establishes that national regulations must satisfy the "necessity test," that is, they cannot be more trade-restrictive than necessary to fulfil a legitimate objective. Pursuant to the TBT Agreement, whenever a technical regulation is adopted to achieve one of the legitimate objectives identified, including the protection of human health, and the national regulation matches relevant international standards, it shall be rebuttably presumed not to create an unnecessary obstacle to international trade.

In this regard, with respect to the international standards of reference, the increasing importance of the ICH, the declared objective of expanding ICH guidelines to non-ICH states (and the fact that some non-ICH states actually adopt them), the consensus that characterises the adoption of these guidelines, and the fact that the WHO also endorses ICH guidelines may result in the perception that ICH guidelines are, in effect, the international standards of reference.[44] Whether this is a good policy from the public health point of view is a different matter.

A challenge in this context is that participation in the ICH is restricted to a select group of states and actors. Until October 2015 only innovative industry associations of the United States, Japan and the European Union, together with their respective regulatory authorities, were full members of the ICH. Recent changes have impacted on the nature of the ICH as an organisation, its membership, the name of the managing bodies, and the norm-setting process. However, the rules on the acceptance of new members still make it extremely difficult for emerging and developing economies to integrate into the ICH, and for generic companies to participate in the debates. Inclusiveness, thus, is a matter of concern, and therefore the institutional design of the ICH and the process of international norm-setting in the area of pharmaceutical standards should be reviewed. Emerging and developing countries, as well as generic industries, would benefit from a more plural, participative and transparent standard-setting forum and processes.

44 The practical consequences may seem evident, but it is still worth clarifying them: (1) medicines necessary for the achievement of the 2030 Agenda goals must be of ensured quality, so standards matter; (2) those medicines must also be accessible, therefore standards that are excessively demanding make products more expensive; (3) medicines must be available, therefore they must reach domestic markets and not be stopped by trade barriers.

### 3.4 Government Procurement

Most countries have a degree of public involvement in the health sector, although how much and how this is structured varies considerably. Public procurement in the area of health products may have an important impact on prices and availability, and hence on access to health products. While as a matter of principle transparent policies are beneficial to everyone, the level of liberalisation and competition endorsed in procurement practices is more controversial. This is an area closely related to national pharmaceutical policies, which, for a number of public health reasons, are still a matter left to the discretion of states. Certainly, procurement practices such as centralised public purchasing systems may lower the prices of medicines, since they promote economies of scale and improve purchasing power. There are, however, numerous procurement mechanisms and different methods of implementing them.

The WTO's plurilateral Government Procurement Agreement provides an optional international framework of rules, with the goal of promoting efficiency and good governance in the public procurement of goods. Essentially, it is intended to enhance transparency and competition in government procurement, therefore improving "value for public expenditure" (WHO, WIPO and WTO 2013, 14). The large majority of states, however, have decided against becoming members of the GPA and to maintain the policy space to decide on the details of their pharmaceutical procurement practices.[45]

The advice in this area is somewhat contradictory, since some international organisations suggest liberalised schemes for the procurement of medicines (WHO, WIPO and WTO 2013; also 2010), while others promote polices that in one way or another limit that liberalisation. The latter approach is common when governments also prioritise promoting the autonomy of national pharmaceutical markets. Such a prioritisation usually includes the stimulus of local production of pharmaceutical products, which is frequently accompanied by specific procurement practices.

In light of this scenario and the diversity of national views regarding the desirable level of liberalisation of pharmaceutical public procurement practices, there is clearly no single policy direction to recommend. However, when assessing the relationship between international norms and national practices concerning government procurement, public health principles and objectives, including those stated in the 2030 Agenda, should take centre-stage. Promoting principles such as transparency in procurement practices could improve competition and the prices and quality of products procured without necessarily resulting in full levels of liberalisation.

### 3.5 Services

Access to health services is also an important part of the 2030 Agenda.[46] For instance, medical samples being tested in another country involve cross-border supply of services (GATS Mode 1), while medical tourism is consumption of health services abroad and trade (GATS Mode 2). There is also a degree of foreign investment in health services provision (Mode 3). To the extent that trade makes a greater variety of health services available, it may increase access to health services. However, it could also result in reduced access for domestic consumers if domestic health providers focus on international rather than local consumers (see Pocock and Phua 2011).

As noted in the joint study conducted by WHO, WIPO and WTO,

> it is almost impossible to measure the impact of GATS commitments on health services—and any other sector—because of limited data and the difficulty of distinguishing the effects of trade policy bindings from those of other policy and regulatory measures. However,

45 Governments could join the GPA but choose not to schedule commitments for pharmaceutical procurement.

46 This section builds on comments made by R. Adlung and A. Tipping.

> studies suggest that the effects of GATS commitments—where such commitments exist—on trade patterns probably have been insignificant. GATS commitments do not entail additional liberalization, but (at best) they bind existing levels of market access. (2013, 79–80)

However, in the current context, what ultimately matters is not the existence and impact of GATS commitments, but the scope of actual policies affecting services trade as covered by the GATS. In any case, international trade in health services is certainly taking place.[47]

Therefore, while it appears that a large part of trade in health services takes place independently of formal frameworks of trade rules, a relevant question is whether trade policy could be used more actively to harness the potential benefits of trade to increase access to health services. While this is a sensitive topic deserving a thorough evaluation, in the context of the 2030 Agenda governments it could be re-examined whether and how careful liberalisation of aspects of trade in health services—for instance combined with requirements that service providers deliver a certain level of service to poorer sections of the domestic population—could contribute to increasing access to health services.

Mobility of service providers may heavily impact on medical personnel, who may abandon low income countries in search of better economic and living conditions. In an effort to limit brain drain, some public service obligations on the professionals concerned and promotion of their repatriation after a period of stay abroad can be imposesd. Professor Adlung also notes that the GATS might also be used to guarantee liberal conditions of access to foreign hospital investors insofar as the country provides for private participation in the sector. A case in pont is India, where the current GATS schedule of commitments allows for foreign market access under Mode 3 in hospital services subject to a foreign equity ceiling of 51 percent. At the same time, the country reportedly requires all private hospitals, regardless of their ownership status, to treat poor patients on a pro-bono basis as 20 percent of their caseload. Since this regulation is of a non-discriminatory nature, it can even be maintained in the event of full commitments under GATS.

47 See on medical tourism, Lunt et al. (2011); and on trade in health services in ASEAN, Arunanondchai and Fink (2016).

## 4. CONCLUSION

The provision of public goods generally spans several legal regimes. This is the case with health, which involves norms belonging to international health law, human rights law and international economic law. The 2030 Development Agenda identifies ambitious goals relating to health, many of them requiring action in the area of international trade norms and policies.

This paper has focused on actions of relevance to health innovation and access to health products. Many of the measures identified need careful assessment and discussion, which go beyond this rather navigational exercise. The annex attached to this paper classifies both the actions previously identified and other actions not mentioned in the body of the text. The classification is made depending on whether the actions can be adopted in the short (within three years), mid (four to eight years) or long (nine to fourteen years) term. The temporal limits are more complex, however: many actions could be adopted earlier than specified, while others may require a longer time-frame.

The contribution of trade and trade policy to the health-related objectives of the 2030 Agenda could be monitored and reviewed by trade policy institutions like the WTO, based on inputs from governments, civil society and international organisations. Tipping and Wolfe (2016, vii) propose states to conduct self-assessment by themselves and at the global level in multilateral agencies and the High-Level Political Forum. While some of the measures proposed in this paper may go beyond the competence of the relevant WTO committees and councils, the reports produced by bodies such as the TRIPS Council and the WTO Committee on Government Procurement would be of relevance. The information provided therein could be compiled by an inter-agency task force in charge of the aggregation of all the trade-related reports (Tipping and Wolfe 2016, 3).

In a nutshell, the options set out in this paper point to a number of key aspects of trade rules which could be reformed to help make sure that international trade policy contributes to ensuring healthy lives for all people in the years to 2030.

As far as the TRIPS Agreement is concerned, four actions are recommended. The first is an empiric assessment of the impact of the TRIPS Agreement on innovation, in particular on innovation of relevance for developing and emerging economies. Second, the adoption is also recommended of an integrated approach between public health, intellectual property and human rights, which should be realised in the development of integrated national policies and a new approach to international negotiations and regulations. Third, the intensive use of the TRIPS flexibilities, in particular of the flexibility existing with respect to patentability criteria, is also underlined. Finally, it is held that reaching an agreement on the meaning of pharmaceutical innovation would also be helpful in enhancing significant innovation.

With respect to services, it is proposed that GATS be clarified so as to avoid the legal challenges it allows against subsidies that states may grant to health research. In this sense, the adoption is recommended of a declaration stating that all subsidies intended to develop a product or intervention that satisfies the prevalent health needs of a population will be non-actionable. An alternative and more open option is the adoption of a flexible understanding of the concept of specificity, where the conditions of the measures and the objective intended by these measures become central.

The GATS could also be positively used to foster innovation, essentially to promote greater international mobility for scientists. In order to achieve that goal, the commitments made under the Mode 4 of the GATS could be expanded to increase the temporary but relatively long-lasting circulation of technically skilled workers, ideally by creating an “innovation zone” work visa. This has to be carefully combined with measures intended

to avoid “brain drain” and the need to ensure the scientists return at a later stage to their country of origin.

Four factors condition access to medicines: selection and rational use; sustainable financing; reliable distribution; and accessible price. The quality of medicines depends in turn on the fulfilment of technical standards touching upon numerous aspects falling within three broad areas, namely quality, safety and efficacy. These factors closely relate to several trade topics, from procurement practices that permit a response to selection and distribution concerns, to intellectual property protection and tariffs, both impacting on the price of medicines. Short-, mid- and long-term measures can be adopted to improve access in the context of the TRIPS Agreement, the General Agreement on Tariffs and Trade, the Agreement on Technical Barriers to Trade and the Agreement on Public Procurement. Bilateral and plurilateral agreements touching upon the same subjects also shape health determinants and could be studied when addressing the trade and health interface.

In the context of TRIPS, a more intensive use of well-known TRIPS flexibilities and the adoption of an open stance towards the development and implementation of new ones are recommended. In parallel, an integrated approach to intellectual property regulation and management is also proposed. Such an approach requires taking into consideration obligations that belong to different international regimes and that touch upon aspects such as development, environment and human rights, something that already happens at the national level when judges have to enforce rules belonging to different realms. Also in the context of the TRIPS Agreement, it is proposed that an independent review body be set up comprised of health, human rights and intellectual property specialists with the aim of adjusting technical cooperation activities conducted by multilateral organisations. The paper also identifies a number of provisions found in TRIPS and other legal situations that would benefit from some clarification. Finally, those provisions that go beyond TRIPS and strengthen intellectual property protection could be assessed against their impact on access to health. When the projection is that the impact is uncertain or not clearly positive, and the negotiations are exhausted, governments should take appropiate measures in their national systems to support a positive outcome and final result.

The use of technical standards to restrict international trade is a matter of concern with respect to access to medical technologies. Emerging and developing countries, as well as generic industries, would benefit from more plural, participative and transparent standard-setting forums and processes. Either the reform of the International Council for Harmonisation so as to open it to other relevant stakeholders or the reinforcement of the relevant WHO committees is necessary to promote high-quality transparent standards that enable competitive pharmaceutical markets of products meeting the right standards on quality, safety and efficacy.

As far as public procurement is concerned, in light of the diversity of national views regarding the desirable level of liberalisation of pharmaceutical public procurement practices, more debate is needed. In particular, when assessing the relationship between international norms and national practices concerning government procurement, public health principles and objectives, including those stated in the 2030 Agenda, could take centre-stage. This may promote principles such as transparency in procurement practices, without however resulting in specific levels of liberalisation.

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## ANNEX

**Action to Be Taken in the Area of Trade and Health in Light of the 2030 Development Agenda Innovation**

| | Intellectual Property Rights | Subsidies | Trade in Services |
|---|---|---|---|
| Short term | • Empirical research on the relationship between patents and innovation, particularly on the impact of the TRIPS Agreement on meaningful innovation for low- and mid-income countries.<br>• Contextualise legal tools for innovation in the broader legal order, where other rights and legal interests deserve protection.<br>• Review as needed technical cooperation activities conducted by multilateral organisations in light of the interface between intellectual property and fundamental rights of relevance to health.<br>• Coordination of the Secretariats of WIPO, WHO, WTO and UNCTAD on issues touching upon innovation and access. Inclusion of all relevant stakeholders, including non-governmental organisations and generic and innovator industries, in the discussions.<br>• Ensure policy coherence at the national and international levels with respect to the intersection of health policy, trade and intellectual property issues. Possibility of setting up inter-ministerial intellectual property committees.<br>• Contribute to and support the process set up by the High-Level Panel on Access to Medicines. | • Study the feasibility, negotiate the content and decide legal status of a text declaring that any subsidy intended to develop a product, service or intervention that satisfies the prevalent health needs of population is non-actionable.<br>• Adopt a flexible approach either by legal interpretation or reform to the concept of specificity, where the conditions and objective of the measures are relevant.<br>• Strengthen the role of a neutral decision-maker to monitor and resolve disputes for the various types of subsidies, obtaining better data and measuring impact of subsidies.<br>• Regulate in a clear and non-discriminatory manner the conditions for accessing publicly funded research or tax advantages. | • Promote technology transfer and acquisition of experience by facilitating greater international mobility for scientists, in particular by expanding Mode 4 commitments. |

| | Intellectual Property Rights | Subsidies | Trade in Services |
|---|---|---|---|
| Short term | • Maintain room for manoeuvre allocated in TRIPS with respect to patentability standards: leave patentability standards undefined at the international level.<br>• Implementation and use of TRIPS flexibilities of special relevance to innovation, in particular research exception, patent opposition procedures, non-voluntary licences in cases of patent dependency, patentability standards adjusted to local priorities regarding innovation.<br>• Adopt a definition of pharmaceutical innovation that focuses on the introduction of new products and processes that create value for health. | | |
| Mid term | • Draw conclusions and proposals from the research conducted on the impact of the TRIPS Agreement on R&D meaningful to low- and mid-income countries. Implement them.<br>• Monitor the contextualisation of legal tools for innovation in the much broader legal order where other rights and legal interests deserve protection.<br>• Ensure policy coherence at the national and international levels with respect to the intersection of health policy, trade and intellectual property issues.<br>• Follow up and contribute further to the process initiated by the High-Level Panel on Access to Medicines. | • Implementation, monitoring and assessment of the agreement declaring that any subsidy intended to develop a product, service or intervention that satisfies the prevalent health needs of population is non-actionable.<br>• Ensure the implementation of a flexible approach to the concept of specificity, where the conditions and objective of the measures are relevant.<br>• Follow-up of the strengthened role of a neutral decision-maker to monitor and resolve disputes for the various types of subsidies, obtaining better data and measuring impact of subsidies. | • Implementation and monitoring of expanded Mode 4 commitments. |

| | Intellectual Property Rights | Subsidies | Trade in Services |
|---|---|---|---|
| Long term | • Monitor the implementation of proposals for action resulting from the research conducted on the impact of TRIPS on R&D meaningful to low- and mid-income countries.<br>• Ensure policy coherence on the intersection of health policy, trade and intellectual property issues at the national level.<br>• Consolidate the policy and normative changes arising from the process initiated by the High-Level Panel on Access to Medicines. | • Monitoring of the agreement on the exclusion of subsidies intended to develop products, services or interventions that satisfy the prevalent health needs of population.<br>• Monitoring and eventual revision of the flexible approach to the concept of specificity. | |

**Access to goods and services of ensured quality**

| | Intellectual property | Technical standards | Tariffs | Procurement |
|---|---|---|---|---|
| Short term | • Monitor the relationship between patents and access, as well as prompt reaction and opportune use of TRIPS flexibilities.<br>• Intensive use of well-known TRIPS flexibilities and an open stance towards the development and implementation of new TRIPS flexibilities.<br>• Clarification of currently controversial options to foster competition.<br>• Review and modify as needed technical cooperation activities conducted by multilateral organisations in light of the interface between intellectual property rights and fundamental rights of relevance to health. | • Monitor the impact of technical standards in the area of pharmaceutical products as a tool to restrict international trade.<br>• Assess the international institutional framework for standard-setting in the area of pharmaceuticals.<br>• Proposals for a more transparent and open process for standard-setting in the area of pharmaceuticals. | • Study the impact that tariffs cuts have on local production of health products.<br>• Continue lowering to a final suppression of tariffs applied to health products. | • Adopt transparent government procurement norms and practices.<br>• Address the interface between competition, access and government procurement, as well as its impact on local manufacturing capacities. |

| | Intellectual property | Technical standards | Tariffs | Procurement |
|---|---|---|---|---|
| | • Use richer, more diverse and more inclusive body of empirical data and practical experience available to guide technical cooperation of multilateral organisations.<br>• Coordination of the Secretariats of WIPO, WHO, WTO and UNCTAD on issues touching upon innovation and access. Inclusion of all relevant stakeholders, including non-governmental organisations and generic and innovator industries.<br>• Ensure policy coherence on the intersection of health policy, trade and intellectual property issues.<br>• Contribute to and support the process set up by the High-Level Panel on Access to Medicines.<br>• Address the practical implications of the adoption of an integrated approach merging intellectual property and human rights. Set up an independent body, comprised of health, human rights and intellectual property specialists, for that specific purpose.<br>• Independent assessment of the TRIPS plus and TRIPS extra provisions impacting on access to health. | | | |

| | Intellectual property | Technical standards | Tariffs | Procurement |
|---|---|---|---|---|
| Mid term | • Study the legality of TRIPS flexibilities not implemented so far, for instance the exception for exportation purposes.<br>• Monitor the use of TRIPS flexibilities.<br>• Implement the policy options which currently have a dubious legality, once they have been clarified.<br>• Ensure policy coherence on the intersection of health policy, trade and intellectual property issues. Implement and follow up the recommendations of the High-Level Panel on Access to Medicines.<br>• Implement an integrated approach which takes into consideration obligations belonging to different international regimes and which touch upon human rights. | • Set up an open, participative and transparent standard-setting international framework, integrating the experience of the ICH and the WHO in that context. Decide whether this new framework is within WHO, consists of an amendment of ICH or is an entirely new structure.<br>• Include all types of industries and countries at all levels of development in the new framework for the standard-setting in the area of pharmaceuticals. | • Monitor the relationship between non-tariff barriers and access to health products. | • Adopt compromises regarding liberalisation of public procurement and health products in light of the assessment conducted. |
| Long term | • Ensure policy coherence on the intersection of health policy, trade and intellectual property issues. Follow up the recommendations of the High-Level Panel on Access to Medicines. | • Monitor the open, participative and transparent standard-setting international framework. | Adopt a total ban on tariffs for health products. | |

ICTSD has developed a series of papers that explore the contribution that trade and trade policy could make to key objectives of the 2030 Agenda for Sustainable Development.

- Trade in *Transforming Our World*: Options for Follow-up and Review of the Trade-related Elements of the 2030 Agenda for Sustainable Development. By Alice Tipping & Robert Wolfe, 2016.
- The 2030 Agenda and the Potential Contribution of Trade to Gender Equality. By Jeni Klugman, 2016.
- Trade, Food Security, and the 2030 Agenda. By Eugenio Díaz-Bonilla & Jonathan Hepburn, 2016.
- Priority Trade Policy Actions to Support the 2030 Agenda and Transform African Livelihoods. By Lily Sommer & David Luke, 2016.
- Climate Change and Sustainable Energy in the 2030 Agenda: What Role for the Trade System? By Kasturi Das & Kaushik Ranjan Bandyopadhyay, 2016.

**About ICTSD**

The International Centre for Trade and Sustainable Development (ICTSD) is an independent think-and-do-tank, engaged in the provision of information, research and analysis, and policy and multistakeholder dialogue, as a not-for-profit organisation based in Geneva, Switzerland. Established in 1996, ICTSD's mission is to ensure that trade and investment policy and frameworks advance sustainable development in the global economy.