STUDY

Trade and Health

Towards Mutually Supportive World Trade and Health Governance Systems

CUTS International

Trade and Health: Towards Mutually Supportive World Trade and Health Governance Systems

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Abbreviations

DSB	Dispute Settlement Body
EU	European Union
FAO	Food and Agriculture Organization
FCTC	Framework Convention on Tobacco Control
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GPA	Government Procurement Agreement
HS	Harmonized System
IMF	International Monetary Fund
ICT	Information and Communications Technology
IP	Intellectual Property
IPPC	International Plant Protection Convention
ITA	Information Technology Agreement
LDCs	Least-developed Countries
LMICs	Low- and middle-income countries
MFN	Most-favoured Nation
MSMEs	Micro, small and medium-sized Enterprises
MTS	Multilateral Trading System
OECD	Organisation for Economic Cooperation and Development
OIE	World Organisation for Animal Health (Organisation mondiale de la santé animale)
PPE	Personal Protective Equipment
R&D	Research and Development

SDG	Sustainable Development Goal
SPS	Sanitary and Phytosanitary Measures
STC	Specific Trade Concern
TBT	Technical Barriers to Trade
TFA	Trade Facilitation Agreement
TFAF	Trade Facilitation Agreement Facility
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UHC	Universal Health Coverage
UK	United Kingdom
US	United States
USTR	United States Trade Representative
WB	World Bank
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Executive Summary

Trade and health interlinkages have been strongly highlighted amidst the COVID-19 pandemic. Not only has trade in medical goods grown substantially between 2019 and 2021, but the deeper relationship between trade and health has also raised many interrogations. Among others, health-related discussions were initiated at the WTO while trade-related measures were put forward by the WHO. This study aims at giving a broad overview of the multiple connections between trade and health. By reviewing the whole WTO framework from an health point of view, the study provides key elements on which the WTO has the competence to enhance health through trade-related policies.

Health being a fundamental human right, it is important to reassess the essential determinants of a well-functioning health system. To fulfill the multiple goals of a health system, the following are needed: i) a transparent governance and good leadership practices, ii) health information systems, iii) health financing, iv) human resources for health, v) service delivery and vi) essential medical products and technologies. While all of them have relationships with trade, the study focusses on the two last points as they can be directly impacted by trade policies.

Indeed, many aspects of the access to medical goods, services and technologies is governed by the WTO agreements. The General Agreement on Tariffs and Trade (GATT) – and several subsidiary agreements to GATT – is applicable trade in medical goods also, among others. Trade in different types of goods can impact health through, for example, trade in foodborne diseases or trade in "health bads". Hence, WTO agreements such as the Sanitary and Phytosanitary (SPS) Agreement as well as the Technical Barriers to Trade (TBT) Agreement help containing circulation of goods that could potentially endanger human health and life. In addition, the Pharmaceutical Agreement relates directly and only to trade in medical goods. On the other hand, the General Agreement on Trade in Services (GATS) of the WTO covers trade in health services. While the liberalisation commitments by WTO Members in health services have been limited so far, there is substantial growth potential in this sector through various modes of supply. Finally, Intellectual Property (IP) protection is a critical part of the debate revolving around access to medical goods and technologies, including vaccines. The WTO TRIPS Agreement aims at protecting innovation, including in the health sector, through IP rights while trying to balance it with the flexibilities required to deal with public health emergencies. It is therefore central to current discussions concerning affordable accessibility of COVID-19 prevention, containment, and treatment goods and technologies around the world.

The Trade and Health Initiative brought to the fore in 2020 at the WTO manifests the crucial need for policy makers to link trade and health matters. Furthermore, the COVID-19 pandemic demonstrated the importance of a strong collaboration between international organisations dealing with trade and health (i.e. the WTO and the WHO) respectively. The continuation and strengthening of such collaboration as well as an improved dialogue between trade and health policy makers have the potential to foster better health in the whole world for the years to come. This potential can be realised through an integrated framework approach to the world trade and health governance systems.

SECTION 1

Introduction

"Health and trade have long been interconnected. The increasing trade of medical products and of health-related services provides many opportunities for improving people's lives worldwide. However, the deepened liberalization of trade has also posed new challenges for national health authorities."

WHO, 2015
Trade and Health: Towards building a national strategy

Covid 19 pandemic seems to have brought to reality one of the worst nightmares of the humanity. As of 3:28pm CET, 8 November 2021, there have been 249,743,428 confirmed cases of COVID-19, including 5,047,652 deaths, reported to WHO.[1] The pandemic has not spared any part of the globe. Nor has it distinguished between developed or developing countries or between rich and poor people though the adverse impacts have been much harder for poor countries and people.

The effects of the pandemic and response measures have been severe, testing the limits of healthcare systems, capacities of governments, and economic and social well-being of people. According to the IMF World Economic Outlook of April 2021, the global economy shrank by 3.3% in 2020.[2] Much more significantly, however, the poverty has worsened, for the first time after two decades of reductions in global poverty. It is estimated that part of the gains of the last two decades in reducing global poverty is going to be reversed with between 119 and 124 million people have been pushed into poverty in 2020 due to Covid.[3] The health crisis has in fact become a global socio-economic crisis of formidable proportions.

International trade has been an important part of both the negative impacts of the pandemic as well as the global efforts towards recovery and long-term resilience. According to WTO estimates, the volume of world merchandise trade fell by 5.3% in 2020. While it is estimated to increase by 8.0% in 2021, the outlook remains marred by regional disparities and continued weakness in services trade, among others. [4] At the same time, international trade can be credited for contributing to the supply of much-needed medical equipment and products for a robust response to Covid, availability of food and other essential items, and responding to some

[1] WHO website (accessed on 9th November 2021). *WHO Coronavirus (COVID-19) Dashboard.* Available at: https://covid19.who.int/

[2] IMF (2021). *World Economic Outlook*. Available at: https://www.imf.org/en/Publications/WEO/Issues/2021/03/23/world-economic-outlook-april-2021

[3] Christoph Lakner et al. (2021). *Updated estimates of the impact of COVID-19 on global poverty: Looking back at 2020 and the outlook for 2021.* World Bank Blogs. Available at: https://blogs.worldbank.org/opendata/updated-estimates-impact-covid-19-global-poverty-looking-back-2020-and-outlook-2021

[4] WTO press release (31 March 2021). *World trade primed for strong but uneven recovery after COVID-19 pandemic shock.* Available at: https://www.wto.org/english/news_e/pres21_e/pr876_e.htm#:~:text=World%20merchandise%20trade%20volume%20is,below%20the%20pre%2Dpandemic%20trend

job losses. The multilateral trading system under the World Trade Organisation (WTO) played an important role in this regard. According to the WTO Director-General Ngozi Okonjo-Iweala, "The strong rebound in global trade since the middle of last year has helped soften the blow of the pandemic for people, businesses, and economies." She further stated that "Keeping international markets open will be essential for economies to recover from this crisis and a rapid, global and equitable vaccine roll-out is a prerequisite for the strong and sustained recovery we all need."[5]It will be no exaggeration to say that the pandemic has brought to fore important linkages between health and trading systems. In fact, the two must work in positive harmony with each other for a quick recovery and, perhaps even more importantly, building longer-term resilience. In that sense, the severe shock induced by Covid has also provided an opportunity to learn useful lessons about the relationship between health and trading systems, and to identify the ways and means for positive synergies between the two, particularly in the context of the United Nations Sustainable Development Goals (SDGs). The present study strives to contribute to that. Its objectives are: i) to provide key information in respect of both health and trade to demonstrate their linkages; and ii) to identify how the synergies between the two can be increased particularly through harnessing the potential of the multilateral trading system and some of the specific agreements under the WTO.

The study does not claim to be either comprehensive or prescriptive. Rather it aims to provide information and analysis to support further work and meaningful dialogue particularly at the WTO in the run-up to its next Ministerial Conference to be held later this month in Geneva, Switzerland.

[5] Ibid

SECTION 2

The determinants of a well-functioning health system

2.1 Health as a fundamental right

Before engaging in the analysis of the healthcare system, it is important to lay down the foundations of how health is defined and which are the parties involved in its scheme. The World Health Organization (WHO) defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".[6] The mention of health's broad aspect, larger than a mere absence of disease, is necessary to understand how wide are its implications and how many are the necessary policies to ensure the fulfilment of the fundamental right to health.

The right to the highest attainable standard of health is one of the fundamental rights since its recognition in the 1966 by the International Covenant on Economic, Social, and Cultural Rights.[7] Contrary to what one may think, the right to health does not rely only on the building of hospitals. The Committee on Economic, Social, and Cultural Rights cites the underlying determinants of health to be [8]:

- Safe drinking water and adequate sanitation
- Safe food
- Adequate nutrition and housing
- Healthy working and environmental conditions
- Health-related education and information
- Gender equality

The attainment of the right to health for every individual, encompassing each of the above-mentioned determinants, is an ambitious objective and requires the cooperation of many organisations and states.

Universal Health Coverage (UHC) is one of the WHO's strategic priorities. It is described by the organisation as "all people having access to the health services they need, when and where they need them, without financial hardship". [9] Currently, at least half of the people in the world do not receive the health

[6] WHO website (accessed the 2nd June 2021). *Who we are. Constitution*. Available at: https://www.who.int/about/who-we-are/constitution

[7] OHCHR (1966). *International Covenant on Economic, Social and Cultural Rights*. Available at: https://www.ohchr.org/Documents/ProfessionalInterest/cescr.pdf

[8] OHCHR and WHO. *The Right to Health. Fact Sheet No 31*. Available at: https://www.ohchr.org/documents/publications/factsheet31.pdf

[9] WHO website (accessed the 2nd June 2021). *Health Topics. Universal Health Coverage.* Available at: https://www.who.int/health-topics/universal-health-coverage#tab=tab_1

services they need.[10] To counter this fate, the WHO brings technical assistance and strategic support in both developed and developing countries. Its implication is aligned with the Sustainable Development Goal (SDG) target 3.8 which focuses on achieving UHC through financial risk protection, access to quality essential healthcare services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all. [11]

2.2 Determinants of a well-functioning health system

Optimising the health system to improve its outcome is a difficult task. First, objectives have to be defined. For the WHO, the following components are the key goals of a well-functioning health system [12]:

- Improving the health status of individuals, families, and communities
- Defending the population against what threatens its health
- Protecting people against the financial consequences of ill-health
- Providing equitable access to people-centred care
- Making it possible for people to participate in decisions affecting their health and health system

These goals aim at responding to people's needs and expectations related to their health in a balanced way. In addition, the WHO recommends the following blocks that need to be built to achieve these objectives.

Leadership and governance

Governance has the potential to shape the development of a country. Even though a country's history often predetermines its governance, good leadership practices can be identified and can frame healthier systems. In the health sector, for example, it is necessary to ensure that health authorities are taking full responsibility for the entire health sector and for dealing with current as well as potential future challenges. The authorities should have a transparent strategy to set a clear direction for fulfilling the needs of its citizens.

Health information systems

However, to determine the needs of individuals and to satisfy them, information on health challenges and their environment are a requirement. Surveys should be conducted at different levels, whether at households' or hospitals', with the aim to identify particular health challenges that need to be resolved. Data collected would also inform about consumption and access to pharmaceutical or health services among others. With time, information will allow to rank health services provided under a national plan and to adjust where needed.

Health financing

Health financing relates directly to the concept of Universal Health Coverage (UHC) aforementioned. Raising funds is a key section of health systems. To improve health coverage and to reduce health inequalities, it is

[10] Ibid
[11] SDGs website (accessed the 2nd June 2021). *Goal 3.* Available at: https://sdgs.un.org/goals/goal3

[12] WHO (2010). *Key components of a well functioning health system*. Available at: https://www.who.int/healthsystems/EN_HSSkeycomponents.pdf

essential to remove financial barriers to access to medical care. In 2020, a WHO and World Bank Group report revealed that about 90 million people are still pushed into extreme poverty due to their health expenditures.[13] This situation is far from achieving universal coverage and should be rectified. The health system has a role to play in it and should raise sufficient funds to provide accessible healthcare. A pooling of financial resources across population groups to share financial risks is an option. Finally, the financing system should be supported by relevant legislation, financial audits, and public expenditure reviews to ensure efficient use of funds.

Human resources for health

A well-performing workforce is a central pillar of an efficient health system. Countries with different stages of development may share common concerns about the functioning of their workforce. Improving recruitment, education, training, distribution, productivity, and performance while still strengthening retention is a difficult exercise. To enhance the potential of a health workforce, the WHO recommends the following procedures.[14] First, to diversify the workforce in terms of numbers and competencies to achieve the right mix. Second, a payment system that produces the right kind of incentives proved to be a critical element for results.[15] Each payment system creates a different set of incentives that may prove effective or not in different contexts. A mix of payment methods and a regular reassessment of its effectiveness is recommended. Establishment of job-related norms and other measures to ensure a safe and secure work environment is also undoubtedly important for a healthy and functioning workforce. Finally, the cooperation of all stakeholders is, as always, essential to guarantee coordination and synergies across the different systems.

Service delivery

The delivery of healthcare services is the crucial ending link of the health system. The provision of primary care should be available in local areas with a back-up of specialized and hospital services. However, reaching remote populations is one of the main struggles in developing countries and first aid is often kilometers away. The WHO recommends standards, norms, and guidance to ensure access and essential dimensions of quality, safety, effectiveness, integration, continuity, and people-centeredness.

Essential medical products, and technologies

Finally, all the above-mentioned components of the health system heavily depend on access to essential and affordable medical products and technologies. Medical products represent the largest component of private health expenditure in low and middle-income countries (LMICs). It is, therefore, necessary to guarantee their access and affordability. The regulatory system for medical products should be supported by relevant legislation and enforcement mechanisms to ensure the

[13] WHO and World Bank Group (2020). *Global monitoring report on financial protection in health 2019*. Available at: https://www.who.int/publications/i/item/9789240003958

[14] WHO (2010). *Key components of a well functioning health system*. Available at: https://www.who.int/healthsystems/EN_HSSkeycomponents.pdf

[15] WHO website (accessed the 2nd June 2021). *Health financing for universal coverage. Provider payment mechanisms.* Available at: https://www.who.int/health_financing/topics/purchasing/payment-mechanisms/en/

quality of the delivery. The government should also draft a national list of essential medical products to guide procurement. It could be based on the WHO list of essential medicines which is updated every two years since 1977.[16] The supply and distribution system should ensure access through public and private channels, with a focus on the poor and disadvantaged. Finally, a national medical products availability and price monitoring system should be established.

2.3 Links between a well-functioning health system and trade

Every element of a well-functioning health system can be related to trade. The table hereinbelow aims to link the components of a well-functioning health system to trade-relative elements in order to determine which synergies come out of the collaboration between the two sectors.

Figure 1: Interlinkages between health systems and trade

Determinants of the health system	Trade-related elements	Outcome of collaboration
Leadership & Governance	Trade-related policymaking and process	Overall coherent leadership and governance to guide both the systems towards inclusive, holistic, and sustainable development
Health information systems	Information-related products and services	Improved availability of needed information
Health financing	i. Better economic opportunities for individuals through trade ii. Larger fiscal revenues for governments from trade iii. Health services liberalisation and regulation	i. More and better-paid jobs make it easier for individuals to spend on healthcare ii. Improved availability of financial resources for public sector investments in the health sector iii. Larger private sector investments in the health sector
Human resources for health	Regulation and liberalisation of education and training services for health workers	Improved availability of the right mix of needed health professional
Service delivery	Regulation and liberalisation of health services	Improved availability of universal health services
Essential medical products and technologies	Support of R&D and innovation through a balanced intellectual property protection system, Transfer of technology	Improved availability of needed medical products and technologies

Source: Authors

[16] WHO website (accessed the 2nd June 2021). *WHO Model Lists of Essential Medicines.* Available at: https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists

To summarise, trade can contribute to a well-functioning healthcare system in three ways: i) by being a part of a coherent leadership and governance for inclusive, holistic, and sustainable development; ii) by providing financial resources to individuals, health enterprises, and governments to increase the spending and investments on health and healthcare systems; and iii) by improving the access to medical goods, services, and technologies.

For the rest of this study, the focus will be made on access to medical goods, services and technologies as those are the most directly linked to trade-related agreements in place at the WTO.

2.4 The determinants of access

Access to medical goods, services, and technologies is a crucial pillar of a well-functioning health system. Besides, it is one element that can be directly impacted by trade decisions. Trade restrictions or facilitations influence the supplied outcome of medical goods and services in a country. Hence, its importance should not be underestimated. For this reason, the focus will be oriented towards the special issue of access to medical care and its relation to trade for the rest of the study.

First and foremost, access is defined by the United Nations Development Group in their document describing indicators of the SDGs as "having drugs continuously available and affordable at public or private health facilities or drug outlets that are within one hour's walk of the population". [17] Access, thus, encompasses both the notions of availability and affordability. Affordability is calculated by the WHO as the number of days' wages of lowest-paid unskilled government worker required to purchase selected courses of treatment for common, acute, and chronic conditions.[18] Price is a critical determinant, especially in developing countries, where the public health sector is weak and a large part of the population has to purchase their treatment on the private market and pay for it with their thin savings. Data is lacking on the matter but, based on 26 surveys conducted in LMICs between 2007 and 2014, patients' prices for lowest-priced generics were on average 2.9 times higher than international reference prices in public-sector facilities. The difference in prices goes up even higher in private-sector facilities and can rise until 4.6 times higher than international reference.[19] As a result, households tend to pay a high percentage of their budget on healthcare. It is estimated that 927 million people worldwide spend more than 10 per cent of their household budget on health medicines and services.[20]

Tariffs and non-tariff measures, among others, have the potential to significantly impact the price of imported medical goods, services, and technologies. They tend to account for as much as distribution costs at the domestic level, including mark-ups and pharmacy

[17] United Nations Development Group (2003). *Indicators for Monitoring the Millennium Development Goals.* Available at: https://millenniumindicators.un.org/unsd/mi/Metadatajn30.pdf

[18] WHO (2008). *Measuring medicine prices, availability, affordability and price components.* Available at: https://apps.who.int/iris/rest/bitstreams/66201/retrieve

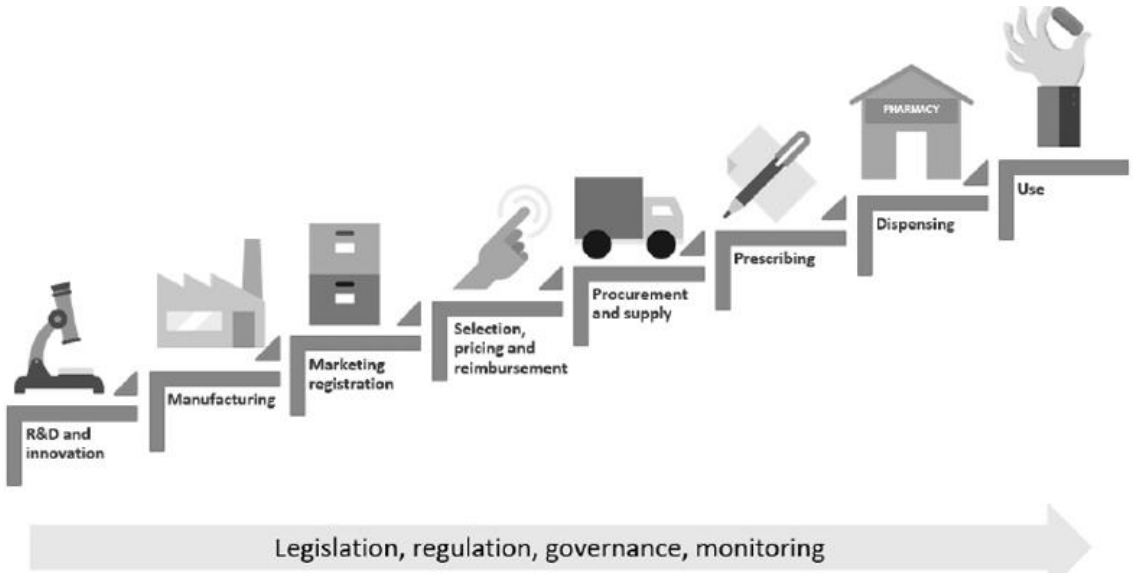
[19] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[20] WHO and World Bank Group (2020). *Global monitoring report on financial protection in health 2019.* Available at: https://www.who.int/publications/i/item/9789240003958

dispensing fees. In addition to tariffs, the availability and price of health-related products also depend on costs and delays related to their importation and exportation. Import licenses, authorizations, sampling, testing, conformity assessment procedures, certification, and inspections all threaten to increase trade costs and cause delays. This issue is especially relevant in least-developed countries (LDCs) where transportation, distribution, and logistical costs tend to be highest.[21]

Ensuring a maintained access throughout the whole value chain is essential to secure the availability and affordability of products. The pharmaceutical value chain is described by the UN as followed.

Figure 2: The Pharmaceutical Value Chain



Source: UN Toolkit on Synthetic Drugs[22]

In research and development (R&D), specific needs of LMICs and vulnerable populations, like children, should be taken into account. About one-third of private providers in developing countries lack the availability of essential medicine.[23] Thereby, increasing the availability of essential medicines at the source is fundamental.

During the manufacturing process, a weak regulatory system may impair initiatives for improving access through, for example, a long approval deadline which would cause additional costs. A strong regulatory system will therefore improve access and quality of provided goods.

As the rational selection of medicines is conducted, precious financial resources should not be wasted on less efficient interventions and should be reserved to guarantee the affordability of the product.

[21] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[22] UN website (accessed the 2nd June 2021). *UN Toolkit on Synthetic Drugs. The Pharmaceutical Value Chain*. Available at: https://syntheticdrugs.unodc.org/syntheticdrugs/en/access/pharmaceutical/index.html

[23] WHO. *Access to affordable essential medicines*. Available at: https://www.who.int/medicines/mdg/MDG08ChapterEMedsEn.pdf

At the level of procurement and distribution, good governance is necessary to avoid issues of corruption, waste, fraud, and abuse which would incur additional costs.

Finally, in the last stage of the value chain, good access to information is essential for a correct prescription and usage of the medicines. Indeed, the WHO estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately.[24]

To sum up, trade has the potential to impact a majority of the value chain's stages. For example, in R&D, trade agreements on Intellectual Property can provide protection for the invention of new medicines which often require high sunk investment costs while ensuring that the benefits of the R&D reach the people at affordable prices. As mentioned above, trade restrictions impair the availability of products at the distribution level.

Nevertheless, access does not only concern access to medical goods, services and technologies but also relies on access to capacity building and sustainable financing. Indeed, sustainable financing of health systems is a prerequisite for a steady supply of medicines and medical technologies. In this area, the WTO also has a role to play through its Aid for Trade and Trade Facilitation Agreement.

[24] WHO website (accessed the 2nd June 2021). *Activities. Promoting rational use of medicines*. Available at: https://www.who.int/activities/promoting-rational-use-of-medicines

SECTION 3

The relationship between health and trade

As mentioned earlier, trade has an impact on health through multiple channels. In the following section, its impact has been divided into four areas: trade in goods, trade in services, trade in intellectual property, and potential externalities of trade. This approach allows for a better understanding as it is based on the well-established categorisation of international trade and trade agreements, including at the WTO.

3.1 Trade in goods

Trade in medical goods

Trade in medical goods obviously has a direct impact on health. As explained before, access to medical products is one of the essential pillars of a well-functioning health system. Access to medicines, vaccines, and other medical technologies is critical to enhance the health status of a country. Therefore, trade has a role to play in liberalizing trade in medical goods to achieve a higher level of healthcare provided to the population.

Significant growth in international trade in health-related products has been observed since 1995. However, more recently, amidst the COVID-19 pandemic, an increase in medical products' trade has also been observed in response to the crisis. Imports and exports of medical goods rose by 16 per cent, reaching US$ 1'139 billion.[25] A quick and effective response to the pandemic was critical. Nevertheless, some governments, perhaps understandably, also took trade-restrictive measures to secure their access to necessities such as personal protective equipment (PPE) or sanitizers. The WTO recorded more than 370 notifications related to COVID-19, most of them concerning trade in medical goods.[26]

It is interesting to notice that developed and developing countries do not have the same relationship with exports of medical goods. Developed countries still account for 66 per cent of all exports of health products.[27] But the share of exports from developing countries is rising nowadays mainly thanks to China which specialised in some categories such as pharmaceutical inputs, chemical inputs, and medical technology equipment.[28] While being insignificant at the world level, exports of medical products from some developing countries account for a significant share of their national exports. This is the case for

[25] WTO Secretariat (2020). *Trade in medical goods in the context of tackling COVID-19: developments in the first half of 2020.* Available at: https://www.wto.org/english/tratop_e/covid19_e/medical_goods_update_e.pdf

[26] WTO website (accessed the 2nd June 2021). *WTO members' notifications on COVID-19.* Available at: https://www.wto.org/english/tratop_e/covid19_e/notifications_e.htm

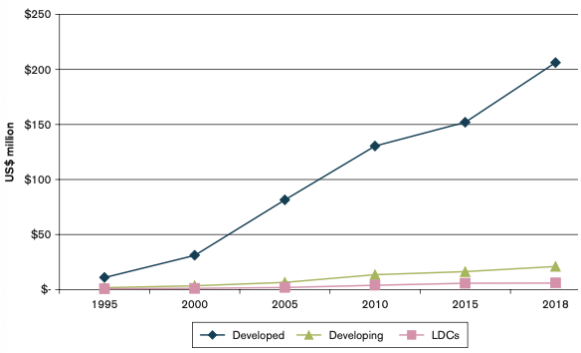
[27] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[28] Ibid

Costa Rica, Panama, and the Dominican Republic among others.[29]

When it comes to imports, developing countries and LDCs are heavily reliant on other countries due to their low capacity to produce medicines. Imports statistics are therefore reasonable indicators of overall consumption of medicines. Sadly, compared to developed countries, the level of importation in developing countries and LDCs remained very low and did not improve much in the last years, despite LDCs having the highest burden of diseases.[30]

Figure 2: Per capita imports of pharmaceutical formulations 1995-2018



Source: Calculations by the WTO Secretariat[31]

For the WHO, countries should "reduce or abolish any import duties on essential drugs".[32] Indeed, some initiatives aiming at reducing tariffs on essential medical goods such as the Malaria Taxes and Tariffs Advocacy Project (see Box 1.1) proved helpful in saving human lives in sub-Saharan Africa. However, it should also be reminded that if tariff rates on imports of medical technology are on average higher in developing countries[33], it could be partially because those countries tend to rely heavily on import taxes and customs duties that still constitute a large part of their fiscal revenues. Therefore, if tariff barriers on trade in medical products were to be abolished, an alternative solution for raising fiscal revenues should be provided to developing countries. Another potential explanation brought for high tariffs in developing countries is the protection of national industries producing medical goods. However, there does not seem to have evidence for this in the data.[34]

[29] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[30] Ibid

[31] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[32] WHO (2001). *How to develop and implement a national drug policy*. Available at: http://apps.who.int/iris/bitstream/handle/10665/42423/924154547X.pdf;jsessionid=59F84FCDF848E4791A1409583234D3A5?sequence=1

[33] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[34] Matthias Helble and Benjamin Shepherd (2017). *Trade in health products: reducing trade barriers for better health.* Asian Development Bank Institute. Available at: https://www.adb.org/sites/default/files/publication/224171/adbi-wp643.pdf

Box 1: The Effect of Tariffs on Anti-Malarial Products

According to the 2020 World Malaria Report, 229 million persons were infected by malaria in 2019.[35] This represents one additional million people compared to 2018.[36] The disease is still spreading and affects primarily the WHO African Region as well as children under 5 years old.[37] Malaria is a preventable, curable but life-threatening disease transmitted to people through mosquitoes.[38]

The Malaria Taxes and Tariffs Advocacy Project aimed at understanding the role of taxes and tariffs on prices and access to anti-malarial commodities.[39] Indeed, there exist multiple products to prevent malaria and one of the cheapest and easiest solutions lies in long-lasting insecticidal nets. However, high tariff rates are levied on those nets in many African countries and this could affect their accessibility. The rationale for tariffs could be multiple. The main reason generally mentioned by developing countries is that tariffs allow to generate fiscal revenues. In the case of long-lasting insecticidal nets, a 2011 ITC study found that the contribution by anti-malarial commodities to total customs revenue was relatively small in most countries.[40] Nevertheless, the reason could also be technical and historical. Mosquito nets were classified under the same HS code as textile products which are important to the African economy. Therefore, high tariff rates were raised to protect domestic textile production. But, since 2017, the Harmonized System has been revised to specify for anti-malarian products. It is aimed at allowing tariffs on such products to be removed in order to improve their accessibility.[41] Indeed, according to a WTO working paper written by Arne Klau, tariffs on mosquito nets in developing countries have reduced demand by approximately 3.1 million bed nets and contributed to some 2.9 million malaria cases between 2011 and 2015.[42] This confirms other surveys conducted as part of the Malaria Taxes and Tariffs Advocacy Project.[43] Overall, empirical evidence demonstrates that lowering tariffs on anti-malarial products could lead to lower propagation of the disease.

[35] WHO (2020). *World malaria report 2020.* Available at: https://www.who.int/publications/i/item/9789240015791
[36] Ibid
[37] WHO (2020). *World malaria report 2020*. Available at: https://www.who.int/publications/i/item/9789240015791
[38] WHO website (accessed on 11th June 2021). *Fact Sheets. Detail. Malaria.* Available at: https://www.who.int/news-room/fact-sheets/detail/malaria#:~:text=In%202019%2C%20there%20were%20an,of%20all%20malaria%20deaths%20worldwide
[39] William Davidson Institute website (accessed on 11th June 2021). *Programs & Projects*. Available at: https://wdi.umich.edu/programs-projects/malaria-taxes-and-tariffs-advocacy-project/
[40] ITC (2011). *Non-tariff measures and the fight against malaria.* Available at: https://www.intracen.org/publications/non-tariff-measures-and-the-fight-against-malaria.pdf
[41] UN (2017). *HS 2017 perspectives.* Available at : https://unstats.un.org/unsd/trade/events/2017/suzhou/presentations/Agenda%20item%2017%20%28a%29%20-%20WCO.pdf
[42] Arne Klau (2017). *When bad trade policy costs human livers: tariffs on mosquito nets.* WTO Working Paper. Available at: https://www.wto.org/english/res_e/reser_e/ersd201714_e.pdf
[43] William Davidson Institute website (accessed on 11th June 2021). *Programs & Projects*. Available at: https://wdi.umich.edu/programs-projects/malaria-taxes-and-tariffs-advocacy-project/

Trade in foodstuffs

Trade in foodstuffs has the potential to impact health in both a positive and a negative way. Although there is little evidence of the direct impact of trade liberalisation in foodstuffs on undernutrition, national availability and prices, which are influenced by trade, concretely influence undernourishment.[44]

Trade liberalisation tends to increase the overall amount of food, feed, and raw materials imported into a country, especially for countries with insufficient domestic food production. [45] An enhanced trade in foodstuffs, therefore, has the potential to improve food security in importing countries. As national food availability rises, inhabitants will likely have the opportunity to improve their diet. Empirical evidence shows that food availability has been associated with a decline in stunting since the 70s.[46]

When it comes to prices, lowering trade barriers tends to, in theory, improve the affordability of agricultural commodities, leading to higher consumption.[47] However, the world market can also be subject to volatility and crises. In 2006-2008, the food price crisis demonstrated that high food prices increased undernutrition, especially in young children.[48]

On the negative side of the impact of increased trade in foodstuffs on health, the threat of new safety hazards can be mentioned. Food-borne diseases are more likely to spread worldwide. [49] Yet, as developing countries are net food importers and imported food is typically of higher sanitary quality than food in domestic markets, it is unlikely that they will be negatively affected by imported food-borne diseases.[50] On the other side, there is also little evidence that LMICs' foodstuff quality has been improved by increased international attention to food safety regulation.[51]

Finally, higher trade in foodstuffs induces a shift in patterns of consumption from high in cereals toward energy-dense diets. [52] Empirical evidence shows that trade agreements and liberalisation correlate strongly with the increased intake of soft drinks and fast foods. And this is not only the case in developed countries, LMICs have observed rapid rates of growth in sales of packaged foods between 1996 and 2002.[53]

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[44] Corinna Hawkes, Delia Grace, Anne Marie Throw (2015). *Trade liberalization, food, nutrition and health. Trade and Health: Towards building a National Strategy.* WHO. Available at: https://www.who.int/phi/documents/trade-and-health/en/

[45] Anne Marie Throw and Corinna Hawkes (2009). *The implications of trade liberalization for diet and health: a case study from Central America.* Globalization and Health 5. Available at: https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-5-5

[46] Lisa Smith, Lawrence Haddad (2014). *Reducing Child Undernutrition: Past Drivers and Priorities for the Post-MDG Era.* Available at: https://onlinelibrary.wiley.com/doi/full/10.1111/j.2040-0209.2014.00441.x

[47] Corinna Hawkes, Delia Grace, Anne Marie Throw (2015). *Trade liberalization, food, nutrition and health. Trade and Health: Towards building a National Strategy.* WHO. Available at: https://www.who.int/phi/documents/trade-and-health/en/

[48] World Bank (2012). *Food Prices, Nutrition, and the Millennium Development Goals*. Global Monitoring Report 2012. Available at: https://openknowledge.worldbank.org/handle/10986/6017

[49] Corinna Hawkes, Delia Grace, Anne Marie Throw (2015). *Trade liberalization, food, nutrition and health. Trade and Health: Towards building a National Strategy.* WHO. Available at: https://www.who.int/phi/documents/trade-and-health/en/

[50] Ibid

[51] Corinna Hawkes, Delia Grace, Anne Marie Throw (2015). *Trade liberalization, food, nutrition and health. Trade and Health: Towards building a National Strategy.* WHO. Available at: https://www.who.int/phi/documents/trade-and-health/en/

[52] WHO (2003). *Diet, nutrition and prevention of chronic diseases*. Available at: http://apps.who.int/iris/bitstream/handle/10665/42665/WHO_TRS_916.pdf?sequence=1

[53] Corinna Hawkes, Delia Grace, Anne Marie Throw (2015). *Trade liberalization, food, nutrition and health. Trade and Health: Towards building a National Strategy.*

Still, to conclude, it is important to reassess the impact of trade liberalisation on other issues than health. Integration in the global market risks driving prices down due to stronger competition and this, in turn, will reduce incentives for domestic production.[54] This is particularly important because of the great amounts of subsidies mainly provided by some developed countries to their agriculture which decreases the prices of their agricultural exports. According to OECD estimates, 54 countries – all OECD and EU countries, plus 12 key emerging economies – provided on average USD 536 billion (EUR 469 billion) per year of direct support to farmers from 2017 to 2019.[55] As agriculture contributes to a major part of employment and GDP in developing countries, these lower prices may have disastrous effects on their farmers who are often small and subsistence-based. Therefore, every decision related to trade facilitation in foodstuffs should be carefully reviewed and potential externalities should not be forgotten.

Trade in health "bads"

Health "bads" are referred to as "products which can result in harm to health when used" according to a WHO report.[56] Included in this category are for example tobacco, weapons, or toxic chemicals. When traded, those products could potentially hurt the well-being of individuals whether intentionally or not. From an exclusive health point of view, health "bads" should not be traded. However, some of these, e.g. tobacco, also contribute to the employment and economies of some developing and least-developed countries, and hence any trade-related action should take that into account to avoid adverse consequences on these countries.

3.2 Trade in services

Health services, while accounting for US$ 50 billion in international trade[57], still remained at low levels in the last years, despite a growing potential.[58] Cheaper travel, enhanced technologies, lower barriers, and better information all point towards an expansion of health services in the future, accelerated by the COVID-19 pandemic.[59] Health services comprise different types of services: hospital services, other human health services, social services, medical and dental services as well as services provided by midwives, nurses, physiotherapists, and paramedical.[60] All of these can be traded through one or more of the four modes of supply, established by the General Agreement on Trade in Services (GATS). Each of the four modes as well as their advantages and disadvantages is discussed below based on a WHO publication.[61]

WHO. Available at: https://www.who.int/phi/documents/trade-and-health/en/

[54] Corinna Hawkes, Delia Grace, Anne Marie Throw (2015). *Trade liberalization, food, nutrition and health. Trade and Health: Towards building a National Strategy.* WHO. Available at: https://www.who.int/phi/documents/trade-and-health/en/

[55] OECD (2020). Agricultural Policy Monitoring and Evaluation 2020. Available at: https://read.oecd-ilibrary.org/agriculture-and-food/agricultural-policy-monitoring-and-evaluation-2020_928181a8-en#page1, accessed on 3 June 2021

[56] David P. Fidler (2015). *Implementing trade commitments with a public health perspective. Trade and Health: Towards building a National Strategy.* WHO. Available at: https://www.who.int/phi/documents/trade-and-health/en/

[57] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[58] Ian Gilson and Karen Muramatsu (2020). *Health Services Trade and the COVID-19 Pandemic. Trade and COVID-19 Guidance Note.* World Bank Group. Available at: https://openknowledge.worldbank.org/bitstream/handle/10986/33716/Health-Services-Trade-and-the-COVID-19-Pandemic.pdf?sequence=1&isAllowed=y

[59] Ibid

[60] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[61] Pierre Sauvé, Chantal Blouin, Aniket Bhushan, Olivier Cattaneo (2015). *Trade in health services. Trade and Health: Towards building a National Strategy.* WHO.

First, the predominant mode of supply is the commercial presence. It accounts for 71 per cent of health services supplied and consists in the establishment of foreign-controlled medical institutions in a country.[62] The main advantage of this mode of supply is that it brings additional foreign investment and allows to upgrade healthcare infrastructures in the receiving country. Implementation of these new institutions creates jobs for the local population, brings innovative knowledge, and provides a broader array of specialised medical services than those previously available. However, there is a risk to increase inequity in access to health care and to divide the healthcare sector into two different categories: one basic healthcare sector provided by the government and one secondary sector where one has to pay to get additional or better-quality services. It is called two-tier healthcare and is often highly differentiated in developing countries.

The second most used mode of supply is consumption abroad, i.e. when people travel to another country to "consume" the health services there. This accounts for 23 per cent of the services supplied.[63] Sometimes called "health tourism", it has the benefit to improve the healthcare system in the exporting country and to alleviate health care budgets in the importing country. Moreover, it creates positive synergies with tourism-related activities. Still, services provided abroad may be of lower quality than those offered in the home country. If the treatment is given incorrectly, it could even increase the cost in the importing country when a corrective treatment becomes necessary. Furthermore, insurances may not be valid abroad and procedures may not be recognised. The equity aspect, as in mode 3, is also an issue as, in general, only the better-off would be able to travel to receive healthcare in another country. Finally, and in the wake of Covid 19 pandemic, travel has become restricted due to stringent measures and requirements put in place by countries.

On the other hand, the use of cross-border supply of health services (mode 3) through telemedicine or advanced robotics, for example, has grown tenfold during the last year. A market research report by Fortune Business Insight recorded a growth of 91.7 per cent in the global market of telemedicine in 2020.[64] Its benefits have been observed during the pandemic when lockdowns and fear of catching the coronavirus disabled many people to conduct basic doctor's appointments. It has also proved to be a powerful complement to physical healthcare systems in helping to address shortages of doctors, especially in developing countries.[65] Moreover, telemedicine allows services to reach remote populations living in inaccessible places. However, cross-border supply of health services also reallocates resources away from rural health care towards an export-oriented strategy. On top of that, those e-health services tend to be specialized health services targeting higher-income population segments.

Available at: https://www.who.int/phi/documents/trade-and-health/en/

[62] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[63] Ibid

[64] Fortune Business Insights (2021). *Market Research Report.* Available at: https://www.fortunebusinessinsights.com/industry-reports/telemedicine-market-101067

[65] Ian Gilson and Karen Muramatsu (2020). *Health Services Trade and the COVID-19 Pandemic. Trade and COVID-19 Guidance Note.* World Bank Group. Available at: https://openknowledge.worldbank.org/bitstream/handle/10986/33716/Health-Services-Trade-and-the-COVID-19-Pandemic.pdf?sequence=1&isAllowed=y

Finally, the smallest part of the health services mode of supply is mode 4, i.e. the temporary presence of health professionals from one country into another to provide health services (1 per cent).[66] Movements of natural persons to provide health services abroad temporarily have the advantage of helping developing countries to exploit their comparative advantage in skilled and semi-skilled labour. Healthcare professionals have, thereby, the opportunity to gain experience and knowledge abroad in order to take it back home afterwards. Nevertheless, such movements may encourage workers to settle down permanently in the new country as a result of better working conditions, for example. This situation is called the brain drain problem. Healthcare professionals are highly needed in developing countries but the latter may be attracted abroad, leaving their country with a limited health workforce.

1.1 Trade in Intellectual Property

The access to medicines can be limited by two crucial factors: a high price of new medicines and a lack of medicines to treat neglected diseases. Both could be the results of the implementation of Intellectual Property (IP) rights. However, the establishment of IP rights could also lead to higher research and development funds for pharmaceutical enterprises and an incentive to create new medicines. Therefore, as IP rights have the potential to influence health in both ways, it is essential to learn more about their functioning.

According to the World Intellectual Property Organization (WIPO), Intellectual Property refers to "creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names, and images used in commerce".[67] IP is protected in the law by patents (for inventions), copyright (for creative works), and trademarks (for enterprises), among others.[68] It enables people to earn recognition or a financial benefit for their invention or creation. The goal of the IP system is to promote a conducive environment for creativity and innovation. IP protection also intends to correct a market failure that would result in an under-provision of innovative activities.[69]

In the specific case of medicines, IP takes the form of patents and since the 2000s, their use has considerably grown.[70] The main goal of patents is to give the inventors an economic advantage and therefore an incentive to innovate. However, this objective may sometimes conflict with the public health goal of more, universal and affordable access to medicines. Therefore, the WHO reckons that the implementation of IP rules in the pharmaceutical sector should be governed by public health principles provided by the Constitution of the WHO in order to ensure the following[71]:

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[66] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation.* Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[67] WIPO website (accessed in June 2021). *About IP. What is Intellectual Property?* Available at: https://www.wipo.int/about-ip/en/

[68] The WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) also includes geographical indications, industrial designs, layout designs of integrated circuits, and undisclosed information that should be protected through appropriate laws etc by the WTO Members. Kindly see https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

[69] WIPO Secretariat (2008). *Report on the International Patent System. Standing Committee on the Law of Patents. Twelfth Session.* Available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev.pdf

[70] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[71] WHO (2005). *Access to Medicines. WHO Drug Information*. Vol 19, No.3. Available at:

- Rapid and effective response to public health needs and crises
- Supply of quality medicines at affordable prices
- Effective competition through a multiplicity of potential suppliers
- Provision of a wide range of pharmaceuticals to meet the basic health needs of the population
- Equality of opportunities for countries in need, irrespective of their membership in the WTO, level of technological capacity, or lack of manufacturing capacity

IP presents one of the most difficult tasks for policy-makers and regulators in public health.[72] On the one hand, patents allow the pharmaceutical industry to develop new medicines and vaccines to counter existing diseases. They also ensure a safe supply and effective medicines.[73] However, on the other side, patents tend to increase the price of new medicines on the market which, intuitively, decreases affordability and thus, access to those essential products. [74] Therefore, the right balance between public health and commercial interests has to be found.

Understandably, a debate on the comparative relevance of patents in determining access to medicines has been ongoing for years now. According to the WHO, it has not been determined that a patent system provides incentives for pharmaceutical innovation. [75] Indeed, empirical studies found evidence of both positive and negative effects of patents on innovation.[76] The WHO also states that "market exclusivity conferred by patents leads to company profits that often out-strip the associated research, development and production costs altogether".[77] Furthermore, that "patent system has not provided sufficient incentive for research and development of new medicines needed for diseases that afflict public health, including neglected diseases or orphan drugs because forecasts deem the market too small or commercially unattractive".[78]

The core of the debate lies mainly in the effect of patents in developing countries. Indeed, developing countries account only for a small fraction of the global pharmaceutical market and therefore, a prevalence of patents can be observed in countries where the technological capacity and substantial market exist. [79] Despite being the most affected by treatable diseases, developing countries suffer from high levels of IP that exacerbate the issue of access to affordable medicines.[80] Finally, IP protection also tends to delay the arrival of generic competition on the market while those are the only proven method of reducing

https://www.who.int/medicines/areas/policy/AccesstoMedicinesIPP.pdf

[72] Frederick Abbott (2015). *Trade in medicines. Trade and Health: Towards building a National Strategy.* WHO. (Frederick Abbott 2015)Available at: https://www.who.int/phi/documents/trade-and-health/en/

[73] Ibid

[74] Frederick Abbott (2015). *Trade in medicines. Trade and Health: Towards building a National Strategy.* WHO. Available at: https://www.who.int/phi/documents/trade-and-health/en/

[75] WHO (2005). *Access to Medicines. WHO Drug Information. Vol 19, No.3.* Available at: https://www.who.int/medicines/areas/policy/AccesstoMedicinesIPP.pdf

[76] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[77] Ibid

[78] WHO (2005). *Access to Medicines. WHO Drug Information*. Vol 19, No.3. Available at: https://www.who.int/medicines/areas/policy/AccesstoMedicinesIPP.pdf

[79] Ibid

[80] Oxfam website (accessed the 3rd June 2021). *Our Work. Trade. Intellectual Property and Access to Medicine.* Available at: https://policy-practice.oxfamamerica.org/work/trade/intellectual-property-and-access-to-medicine/

medicine prices in a sustainable way, according to Oxfam.[81]

3.3 Externalities of Trade

Finally, trade has the potential to influence health through indirect channels. Those externalities, positive or negative, result from synergies created by relationships between trade and other variables.

The WTO stipulates that enhanced trade linkages lead to more wealth thanks to a stimulation of economic growth and a boost in employment. [82] Open economies are described as growing faster and more steadily which catalyst the job market as profitable companies tend to hire more workers. Such beliefs are in place since the dawn of classical economics with the pioneers Adam Smith and Ricardo. However, the WTO recognises the importance to acknowledge that trade, while having broad benefits for a country's development, still is a threat for some consumers and producers. Joseph Schumpeter's "creative destruction" describes this process of innovation that revolutionises the economic structure from within, continuously destroying and creating new frameworks. [83] Inferring causality between trade and income is particularly troublesome due to an endogeneity problem. Nevertheless, the International Monetary Fund (IMF) found a strong positive correlation between trade and income, significant over time. [84] Other studies, conducted by Ondrej Dvoulety and Leibovici, and Crews, tend to point towards those results as well. [85] [86] If trade does indeed lead to higher wealth, it is likely that trade will also lead to better health. In fact, wealth is positively correlated with health as demonstrated by multiple studies. [87] [88] Therefore, trade has the potential to improve the health status of inhabitants through the expansion of the economy and higher incomes.

Better governance is another potential externality of trade. Even though the endogeneity problem is existent in this case as well. A positive link between increased trade and better governance has been found by some studies. First, Wei (1999) demonstrated that more open economies tend to have lower corruption levels and thus, better governance.[89] Islam and Montenegro (2002) showed that trade openness is robustly associated with institutional quality, and contrarily to inequality and ethnic diversity.[90] Finally, the IMF indicated that trade openness

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[81] Ibid

[82] WTO website (accessed the 4th June). *WTO can … stimulate economic growth and employment.* Available at : https://www.wto.org/english/thewto_e/whatis_e/10thi_e/10thi03_e.htm

[83] Joseph Schumpeter (1942). *Capitalism, Socialism and Democracy.* Available at: https://periferiaactiva.files.wordpress.com/2015/08/joseph-schumpeter-capitalism-socialism-and-democracy-2006.pdf

[84] Diego Cerdeiro and Andras Komaromi (2017). *The effect of trade on income and inequality: a cross-sectional approach.* IMF. Available at: https://www.imf.org/~/media/Files/Publications/CR/2017/cr1766-ap-2.ashx

[85] Ondrej Dvoulety (2019). *More Trade, More Wealth? Impact of Trade on the Economic Development of African Developing Countries.* Globalization in Developing Economies: Economic and Socio-Cultural Perspectives from Emerging Markets (pp. 241-255). Available at: https://www.researchgate.net/publication/328282922_More_Trade_More_Wealth_Impact_of_Trade_on_the_Economic_Development_of_African_Developing_Countries

[86] Fernando Leibovici and Joans Crews (2018). *Trade Liberalization and Economic Development*. Economic Synopses. No 13. Available at: https://files.stlouisfed.org/files/htdocs/publications/economic-synopses/2018/04/20/trade-liberalization-and-economic-development.pdf

[87] L. Kawachi, B. Kenney, L. Lochner & D. Prothrow-Stith (1997). *Social capital, income inequality and mortality*. Am J Public Health. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1380975/

[88] R. Wilkinson and K. Pickett (2008). *Income Inequality and Socioeconomic Gradients in Mortality*. Am J Public Health. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2376999/

[89] Shang-Jin Wei (1999). *Corruption in Economic Development: Beneficial Grease, Minor Annoyance, or Major Obstacle?* Policy Research Working Paper. World Bank. Available at: https://documents.worldbank.org/en/publication/documents-reports/documentdetail/175291468765621959/corruption-in-economic-development-beneficial-grease-minor-annoyance-or-major-obstacle

[90] Islam, Roumeen; Montenegro, Claudio E. (2002). *What Determines the Quality of Institutions?* Policy Research Working paper. World Bank. Available at: https://openknowledge.worldbank.org/handle/10986/15725

is positively associated with both institutional transitions and the quality of economic institutions. [91] Concerning developing countries specifically, the Hamburg Institute of International Economics (HWWI) found overall evidence that trade liberalisation can help to improve governance in the latter as well. [92] However, when governance is low, the country has to reach a particular development level before it can benefit from trade openness.

On the negative side, trade, as described in trade in foodstuffs, can induce a change in consumption patterns, leading to a worsening of the diet. But this is not the only bad externality. As observed with the COVID-19 pandemic, globalisation, through trade and travel, fosters the cross-border spread of infectious diseases. [93] Charles Perrings, an Arizona State University professor stated in 2015 that "The more trade grows as a proportion of global production, the more likely it is that diseases will be spread through trade, and the higher the economic cost of resulting trade bans". [94] His paper "Options for Managing the Infectious Animal and Plant Diseases of International Trade" dives deeper into the subject and proposes solutions specific to trade in foodstuffs. [95]

Finally, trade can have adverse consequences on the environment. Whether through trade in chemical hazards, degrading natural resources, or simply increasing pollution, countries, especially developing ones, may suffer from those consequences. [96] Trade in hazardous waste for example is usually targeted at developing countries that do not have the proper capacity to treat them. Therefore, hand pickers may be subject to diseases when having to handle such materials. Also, a study from nature communications showed that, in China, both international export and interprovincial trade exacerbated the health burdens of air pollution and especially in less developed interior provinces. [97] Therefore, it can be inferred that trade, if not properly regulated, can have an adverse impact on the environment and on the health of already the most vulnerable countries.

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[91] IMF (2005). *World Economic Outlook. Chapter III. Building Institutions*. Available at: https://www.imf.org/~/media/Websites/IMF/imported-flagship-issues/external/pubs/ft/weo/2005/02/pdf/_chapter3pdf.ashx

[92] Hamburg Institute of International Economics (2007). *Institutions, Governance and Trade. An Empirical Investigation of the Linkages in View of the Proposed ACP/EU Economic Partnership Agreements.* Available at: https://www.hwwi.org/fileadmin/hwwi/Leistungen/Gutachten/Institutions-Governance-and-Trade.pdf

[93] P. Antras, S. Redding, E. Rossi-Hansberg (2020). *Globalization and Pandemics*. Working Paper 27840. NBER Working Paper Series. Available at: http://www.princeton.edu/~reddings/papers/GP.pdf

[94] Skip Derra (2015). *Infectious disease spread fueled by international trade*. Arizona State University. Available at: https://www.sols.asu.edu/news-events/news/infectious-disease-spread-fueled-international-trade

[95] Charles Perrings (2015). *Options for managing the infectious animal and plant disease risks of international trade.* Food Security. Available at: https://link.springer.com/article/10.1007/s12571-015-0523-0

[96] OECD website (accessed on the 4th June 2021). *Trade and the environment. How are trade and environmental sustainability compatible?* Available at: https://www.oecd.org/trade/topics/trade-and-the-environment/

[97] Wang and al. (2017). *Trade-driven relocation of air pollution and health impacts in China. Nature Communications.* Available at: https://www.nature.com/articles/s41467-017-00918-5.pdf

SECTION 4

The role of the WTO in regulating health-related trade

4.1 The GATT Agreement

The General Agreement on Tariffs and Trade (GATT) was revised in 1994 with the creation of the WTO at the end of the Uruguay Round (1986-1993). It intends to commit members to eliminate or reduce tariff rates and non-tariff measures applicable to trade in goods while adhering to the principle of non-discrimination. The principle of non-discrimination refers to two key elements of the GATT: the Most Favoured Nation (MFN) principle and the principle of National Treatment. Both aim at reducing differences of treatment and discriminatory behaviours within the WTO.

In the case of trade in health-related goods, the GATT makes an exception and explicitly allows governments to take restrictive trade measures to pursue national health policy objectives. This is specified in the GATT's Article XX(b): "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: […] b) necessary to protect human, animal or plant life or health".[98] Thereby, the GATT recognises that the protection of health is an important government function and that it should not be hindered by trade agreements.

In addition, and under the overall umbrella of the GATT, there are a number of WTO agreements that deal with various aspects of trade in goods. Some of these having implications for health are briefly presented and discussed below.

The Sanitary and Phytosanitary Agreement

The Agreement on Sanitary and Phytosanitary Measures (SPS) entered into force with the establishment of the WTO on 1 January 1995. Concerned about food safety and animal and plant health regulations, 124 government representatives, participating in the Uruguay Round, contributed to the negotiations. The SPS Agreement aims to set up basic rules for food safety and animal and plant health standards to protect human, animal, or plant life or health. However, as it allows to raise trade barriers, the SPS had to close a potential loophole where governments could use SPS measures for protectionists purposes. As part of the GATT, the SPS Agreement has to comply with the principle of non-discrimination and, therefore, should not

[98] WTO (1947). *GATT*. Available at: https://www.wto.org/english/docs_e/legal_e/gatt47_02_e.htm#top

arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.

Thus, the SPS Agreement determines two key features. First, it allows countries to set their own standards. But, second, regulations must be based on science. Indeed, the SPS Agreement is the first science-based provision obligation in the GATT. Trade restrictions can be imposed to protect human, animal, or plant life or health but these measures must be based on i) adequate assessments of health risk, ii) scientific principles and sufficient scientific evidence, and iii) recognised international SPS standards. [99] Still, the SPS Agreement provides for members to be able to provisionally adopt sanitary or phytosanitary measures where scientific evidence is not sufficient as long as they will seek additional information within a reasonable period of time (SPS Agreement, Article 5.7). [100] This obligation to base measures on scientific risk assessment has been very successful in diminishing the disingenuous use of sanitary and phytosanitary regulations and in promoting some convergence of measures among countries.[101] In terms of food safety guidelines and recommendations, the text of the SPS Agreement refers to the Joint FAO/WHO Codex Alimentarius Commission, the International Office of Epizootics (OIE), and the relevant international and regional organisations operating within the framework of the International Plant Protection Convention (IPPC), thus fostering cooperation between trade and health institutions.[102]

As discussed in the preceding section, trade in foodstuffs may have multiple negative effects on health if not properly regulated. Food-borne diseases are more likely to spread worldwide and food quality coming from least-developed countries may be lower than national standards. Therefore, despite sometimes decreasing access to food products, such regulations are necessary to ensure the quality, safety, and efficacy of these products.

Finally, the SPS Agreement also provided a forum for negotiations on the reduction of food safety risks. Between 1995 and 2020, WTO Members reported 505 specific trade concerns (STCs) about food safety, plant and animal health regulations. [103] 2020 constituted the year with the highest number of notifications since 1995 with 2'122 notifications being submitted by members for new or changed SPS measures.[104] Due to the COVID-19 pandemic, most notifications referred to human health and food safety as their reason for action. Overall, the increasing number of notifications for SPS measures shows the crucial importance of the SPS Agreement in protecting human, animal, or plant life or health.

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[99] WTO (1994). *Agreement on the Application of Sanitary and Phytosanitary Measures*. Available at: https://www.wto.org/english/docs_e/legal_e/15sps_01_e.htm

[100] Ibid

[101] Tim Josling, Donna Roberts and David Orden (2004). *Food Regulation and Trade: Toward a Safe and Open Global System – An Overview and Synopsis*. Available at: https://ageconsearch.umn.edu/record/20008/files/sp04jo04.pdf

[102] WTO (1994). *Agreement on the Application of Sanitary and Phytosanitary Measures*. Available at: https://www.wto.org/english/docs_e/legal_e/15sps_01_e.htm

[103] WTO Secretariat (2021). *Committee on Sanitary and Phytosanitary Measures. Annual Overview – Implementation of SPS Transparency Provisions and Specific Trade Concerns*. G/SPS/GEN/804/Rev.13. G/SPS/GEN/204/Rev.21. Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/G/SPS/GEN804R13.pdf&Open=True

[104] Ibid

The Technical Barriers to Trade Agreement

The Technical Barriers to Trade (TBT) Agreement covers all technical regulations, voluntary standards and procedures, to ensure that they do not create unnecessary obstacles to trade. Protection of human health or safety is listed in the Agreement as a legitimate objective and the TBT Agreement recognises as well that health protection is a legitimate goal that can be pursued through regulations and standards.[105]

Even though the TBT Agreement was not developed primarily for the purpose of regulating SPS measures, it still covers technical requirements resulting from food safety and animal and plant health measures. Those types of measures include pesticide residue limits, inspection requirements, specific treatment or processing of products, and labelling requirements, for example.[106] Furthermore, technical regulations and standards may include, for example, quality requirements for pharmaceuticals, labelling and packaging requirements for pharmaceuticals and medicines, as well as safety standards for X-ray machines.[107] Those are essential to ensure that health products are safe and can be used properly.

Manufacturing and trading substandard as well as falsified products are, thereby, detected and can be sanctioned adequately. This process is especially necessary for LMICs where 1 in 10 medicines is substandard or falsified.[108] When regulation is effective, as in most developed countries, the incidence of these kinds of medicines is very low and accounts for less than 1 per cent of market value.[109]

In 2020, WTO members submitted more than 3'000 notifications about requirements for traded goods to the TBT Committee.[110] It is the third year in a row that members submitted more than 3'000 notifications and this illustrates the WTO Members' and especially LDCs' commitment to increase transparency about trade in goods.[111] Due to the COVID-19 pandemic, protection of human health or safety was at the heart of almost half (45 per cent) of all notified regulations in 2020.[112] Most measures aimed at easing conformity assessment of Personal Protective Equipment (PPE) and other medical products to accelerate access and increase supply.[113]

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[105] WTO (1994). *Agreement on Technical Barriers to Trade.* Available at: https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

[106] David P. Fidler (2015). *Implementing trade commitments with a public health perspective. Trade and Health: Towards building a National Strategy.* WHO. Available at: https://www.who.int/phi/documents/trade-and-health/en/

[107] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation.* Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[108] WTO, WIPO, WHO (2020*). Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[109] Ibid

[110] WTO (2021). *Technical Barriers to Trade Agreement. 10 Key Results from 2020*. Available at: https://www.wto.org/english/res_e/booksp_e/tbt10keys2021_e.pdf

[111] Ibid

[112] WTO (2021). *Technical Barriers to Trade Agreement. 10 Key Results from 2020.* Available at: https://www.wto.org/english/res_e/booksp_e/tbt10keys2021_e.pdf

[113] WTO Secretariat (2020). *Standards, regulations and COVID-19 – What actions taken by WTO members? Information note.* Available at: https://www.wto.org/english/tratop_e/covid19_e/standards_report_e.pdf

Box 2: Tobacco Products and TBT

The tobacco industry is a complex sector to analyse and regulate. On the one hand, it has been established that all forms of tobacco are harmful and that it damages health through cardiovascular and respiratory diseases as well as different types of cancer.[114] On the other hand, tobacco production occurs primarily in developing countries (around 90 per cent) and contributes to their employment and GDP.[115] Still, according to the WHO, the tobacco industry actively exaggerates the economic importance of the industry by manipulating public opinion, discrediting scientific research, and intimating government through litigation.[116]

On top of its direct impact, tobacco farming has multiple externalities. It causes massive deforestation, air pollution, different types of illnesses, and so on…[117] Moreover, its consumption leads to an economic opportunity cost due to the approximate 10 years of life lost (YLL) for smokers.[118] Therefore, even though the tobacco industry creates jobs and generates revenues in the short term, its long-run contribution to developing countries suffers from social, economic, health, and environmental costs.[119]

The Framework Convention on Tobacco Control (FCTC), implemented in 2005, was the first international public health treaty, negotiated through the WHO, that provides a systematic evidence-based framework of obligations and guidelines for countries to enact comprehensive tobacco control legislation and resist the pressures of the tobacco industry.[120] Since then, many disputes concerning tobacco products were initiated at the WTO. Two of the most recent concluded disputes were the US-Clove Cigarette case and the issue of Packaging Requirements of Tobacco Products in Australia.

The US-Clove Cigarette case commenced with a complaint by Indonesia and a request for consultation with the US concerning a provision of the Family Smoking Prevention Tobacco Control Act of 2009 which banned clove cigarettes.[121] The US law was banning the importation of flavoured cigarettes and Indonesia complained that this violated the national treatment provision of the TBT Agreement as the US continued to permit the sale of domestically manufactured menthol-flavoured cigarettes, whereas the TBT Agreement does not allow members to justify a violation of the national treatment principle. Indonesia also referred to the SPS Agreement in its complaint. The case was resolved in 2014 following a mutually agreed solution between Indonesia and the United States.

Concerning the packaging of tobacco products in Australia, five different complaints have been raised by WTO members between 2012 and 2013, following the implementation of the Tobacco Plain Packaging

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[114] WHO website (accessed on the 15th June 2021). *Tobacco Fact Sheet*. Available at: https://www.who.int/news-room/fact-sheets/detail/tobacco
[115] WHO (2017). *Tobacco and its environmental impact: an overview.* Available at: https://apps.who.int/iris/bitstream/handle/10665/255574/9789241512497-eng.pdf?sequence=1
[116] WHO (2012) *Tobacco industry interference: a global brief.* Available at: https://apps.who.int/iris/handle/10665/70894
[117] Action on Smoking and Health (ASH) website (accessed on the 15th of June 2021). *ASH Fact sheet: Tobacco and the Developing World.* Available at: https://ash.org.uk/wp-content/uploads/2019/10/Tobacco-Developing-World.pdf
[118] Centers for Disease Control and Prevention (CDC) website (accessed on the 15th June 2021). *Smoking & Tobacco Use. Tobacco-Related Mortality.* Available at: https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm
[119] WHO (2008). *The global tobacco crisis. WHO report on the global tobacco epidemic*. Available at: https://www.who.int/tobacco/mpower/mpower_report_tobacco_crisis_2008.pdf
[120] Action on Smoking and Health (ASH) website (accessed on the 15th of June 2021). *ASH Fact sheet: Tobacco and the Developing World.* Available at: https://ash.org.uk/wp-content/uploads/2019/10/Tobacco-Developing-World.pdf
[121] WTO website (accessed on the 15th June 2021). *DS406: United States – Measures Affecting the Production and Sale of Clove Cigarettes.* Available at: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds406_e.htm

Act 2011.[122] Complainants argued that Australia's tobacco plain packaging measures were more trade-restrictive than necessary to achieve its legitimate objective under the TBT Agreement. They also argued that those measures were inconsistent with many provisions of the TRIPS Agreement relating to trademarks. Most of the disputes were ended between 2018 and 2020 as the Dispute Settlement Body (DSB) adopted the Appellate Body reports and the panel reports that did not accept the arguments of the complainants including with regard to the TBT Agreement.[123]

The above cases show that there can be instances of potential conflict between specific national health measures on the one hand and the WTO agreements (e.g. TBT Agreement) on the other. However, the WTO dispute settlement mechanism has been able to address these so far.

The Trade Facilitation Agreement

The Trade Facilitation Agreement (TFA) negotiations were completed in 2013 at the 9th WTO Ministerial Conference held in Bali, Indonesia, and it came into force on 22 February 2017 after two-third of the members ratified it. The aim of the Agreement is to simplify, modernise and harmonise the export and import processes. Moving goods across borders can be quite wholesome and the TFA contains provisions for expediting the movement, release, and clearance of goods. For example, required paperwork can be simplified and customs requirements harmonised. This way, costs and time can be significantly reduced in the export and import of goods.

Diminishing trade costs is particularly important in the case of health-related products. As pointed out in the last section, affordability is one pillar of access to medical goods. The TFA becomes even more relevant when it is shown that trade costs are equivalent to 134 per cent of ad valorem tariffs on products in high-income countries and 219 per cent of tariff equivalent in developing countries.[124] Estimates demonstrate that the full implementation of the TFA could reduce trade costs by 14.3 per cent with its biggest gains being realised in the poorest countries.

Moreover, and for the first time in the history of the multilateral trading system (MTS), the requirements to implement the Agreement are directly linked to the capacity of the country to do so.[125] Furthermore, the WTO Trade Facilitation Agreement Facility (TFAF) was created at the request of developing and LDCs to help ensure that they receive the assistance they need to implement the TFA. Thereby, the TFAF organises workshops, capacity-building events and provides information to countries in need.[126]

Such a capacity to facilitate trade is, undoubtedly, crucial during a crisis like pandemics in order to ensure the movement

[122] WTO website (accessed on the 15th June 2021). *DS434 / DS435 / DS441 / DS458 / DS467 Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging.* Available at: https://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm
[123] Summary "Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging" available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds435_e.htm#bkmk435abr
[124] WTO (2015). *World Trade Report 2015. Speeding up trade: benefits and challenges of implementing the WTO Trade Facilitation Agreement*. Available at: https://www.wto.org/english/res_e/booksp_e/world_trade_report15_e.pdf
[125] WTO website (accessed the 7th June 2021). *Trade Topics. Trade Facilitation.* Available at: https://www.wto.org/english/tratop_e/tradfa_e/tradfa_e.htm
[126] Ibid

of essential medical, food, and IT supplies.[127] The OECD recommended implementing reforms in the WTO TFA and asked governments to apply three processes: i) to ensure that all formalities are transparent and accessible to all traders, especially MSMEs, ii) to expedite standard formalities to leave room for necessary additional COVID-19 related controls, and iii) to digitise all possible processes as much as their infrastructure allow it. The TFA, therefore, has been cited frequently during 2020. However, it should not be forgotten after the pandemic as the TFA has the potential to make a direct contribution to better access to health products.

The Government Procurement Agreement

The Government Procurement Agreement (GPA) is a plurilateral agreement within the framework of the WTO, which means that not all WTO members are parties to the Agreement.[128] At the present date, 48 WTO members are taking part in the GPA. Their goal is to ensure open, fair, and transparent conditions of competition in the public procurement markets as well as liberalising access to them [129], thereby, combining procurement efficiency with commercial interests.

Government agencies are often the ones purchasing goods and services to fulfil their functions. In the case of the health sector, governments are likely to buy pharmaceuticals for their use in national health programmes. However, government procurement is explicitly exempted from the GATT and the GATS, as specified in Article III:8 and XIII:1 respectively. Therefore, preferential treatment for government procurement is permitted as long as it is not done for purposes of commercial resale.[130] When a WTO member is part of the GPA, it may have accepted non-discrimination commitment in this area and it may result in higher competition in the medicines procurement markets.

A well-designed framework for government procurement has a positive impact on the health sector as it ensures that the procurement of medicines is not prone to weak governance. The GPA and its transparent and fair framework help to deliver improved values of money for governments. Altogether its impact can be substantial as the size of government procurement markets in health-related sectors amounts to US$ 49 billion for hospitals and US$ 47 billion for health in general.[131]

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[127] OECD (2020). *Trade Facilitation and the COVID-19 Pandemic*. Available at: https://read.oecd-ilibrary.org/view/?ref=130_130609-v8jn83j1j3&title=Trade-facilitation-and-the-covid-19-pandemic&_ga=2.248184839.1661798787.1623072371-838050883.1622458854

[128] WTO website (accessed 7th June 2021). *Agreement on Government Procurement*. Available at: https://www.wto.org/english/tratop_e/gproc_e/gp_gpa_e.htm

[129] Ibid

[130] David P. Fidler (2015). *Implementing trade commitments with a public health perspective. Trade and Health: Towards building a National Strategy*. WHO. Available at: https://www.who.int/phi/documents/trade-and-health/en/

[131] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation.* Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

Box 3: GPA flexibilities and COVID-19

The GPA Agreement has two types of flexibilities that enable governments to enhance the efficiency of their processes and to speed up their procedures in the case of an emergency situation. Flexibilities on procedural requirements allow entities to directly contact their suppliers without notice of intended procurements and with shorter-than-usual deadlines. On top of that, flexibilities on usual obligations allow members to make any procurement-related measures that are necessary to protect human life or health. In Ukraine, the government put in place exemptions from the Public Procurement Law to prevent the spread of COVID-19 and the establishment of specific, simplified procurement procedures for a list of supplies, works, and services necessary for COVID-19 control. In Europe, some parties used joint government procurement procedures to increase their bargaining power and purchasing options. The European Commission, for example, launched joint procurements of PPE and medical devices which, otherwise, would need to be acquired separately.

Based on WTO Information Note (2020). How WTO members have used trade measures to expedite access to COVID-19 critical medical goods and services.[132]

The Information Technology Agreement

Concluded by 29 participants at the Singapore Ministerial Conference in December 1996, the Information Technology Agreement (ITA) now groups together 82 participants, representing 97 per cent of world trade in IT products.[133] The ITA focus on completely eliminating tariffs on IT products covered by the Agreement to foster technology transfers across countries. At first, the Agreement included high technology products such as computers, telecommunication equipment, semiconductors, or scientific instruments.

But, in 2012, 15 years after the implementation of the ITA, members recognised that new categories of IT products had been developed and that there was a need to include them in the Agreement. The process was initiated and in July 2015, Members agreed on eliminating tariffs on an additional list of 201 products. Annual trade in these products was valued at over 1.3$ trillion per year and accounted for approximately 7 per cent of the global trade.[134] Furthermore, the new accord covered a new generation of technologies including many different sorts of medical equipment such as magnetic resonance imaging products and ultra-sonic scanning apparatus, electrocardiographs, ultrasonic scanners, and pacemakers.[135] As described above with the Trade Facilitation Agreement, a reduction in tariffs for those types of goods has the potential to decrease their prices and therefore, increase access to their availability and use.

On the occasion of the 25th anniversary of the ITA in December this year (2021), a WTO workshop on how trade in ICT products

[132] WTO Information Note (2020). *How WTO members have used trade measures to expedite access to COVID-19 critical medical goods and services*. Available at: https://www.wto.org/english/tratop_e/covid19_e/services_report_16092020_e.pdf

[133] WTO website (accessed the 8th June 2021). *Information Technology Agreement – an explanation.* Available at: https://www.wto.org/english/tratop_e/inftec_e/itaintro_e.htm

[134] Ibid

[135] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

helped countries to combat COVID-19 will be held.[136]

The Pharmaceutical Agreement

In 1994, the WTO Pharmaceutical Agreement, a sectoral initiative, eliminated tariffs on all finished pharmaceutical products as well as on designated active ingredients and manufacturing inputs. [137] Only a subgroup of WTO members, all developed countries, committed to its implementation: Canada, the European Union (EU), Japan, Macao (China), Norway, Switzerland, the United Kingdom (UK), and the United States (US). Since the adoption of the Pharma Agreement, international trade in pharmaceutical products has experienced dynamic growth. Imports of finished pharmaceutical products grew by almost 14 per cent over the last 20 years. [138] Nevertheless, obtaining data on tariff and import statistics for these products is complex. A clear definition of health products does not exist and the Harmonized System (HS) does not differentiate chemical substances used both for pharmaceutical productions and other products. Therefore, it is complicated to disentangle results between those two.

4.2 The GATS Agreement

The General Agreement on Trade in Services (GATS) was negotiated during the Uruguay Round and came into force on 1 January 1995. This was the first time that trade in services was brought under the purview of the multilateral trading system.

As health services account for US$ 50 billion in international trade, health is one important sector covered under the GATS.[139] Similar to the GATT, it is mentioned in the Article XIV of the GATS that Members are authorised to take measures to restrict services and services suppliers for the protection of human, animal, or plant life or health.[140] It is also important to recall that the GATS does not apply to public services. Therefore, many public-sector health services lie outside the scope of the GATS.[141]

Trade in services is classified as being supplied through four modes under the GATS: cross-border supply (mode 1), consumption abroad (mode 2), commercial presence (mode 3), and movement of natural persons (mode 4).[142]

Few WTO members have made commitments to open their health and social services to suppliers from other WTO members, compared to other sectors. As depicted in the figure 3 below, the health sector ranks among the least committed of all major service sectors covered by the GATS, with only 53 WTO members having scheduled

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[136] WTO website (accessed the 8th June 2021). *Workshop on Information Technology Agreement to be held in September 2021.* Available at: https://www.wto.org/english/news_e/news21_e/ita_19apr21_e.htm

[137] WTO website (accessed on the 9th June 2021). *The WTO's Pharma Agreement.* Available at: https://www.wto.org/english/tratop_e/pharma_ag_e/pharma_agreement_e.htm

[138] Ibid

[139] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation.* Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[140] WTO (1994). *General Agreement on Trade in Services*. Available at: https://www.wto.org/english/docs_e/legal_e/26-gats_01_e.htm

[141] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[142] Kindly see Section 3.2 above for more details on these four modes of supply as applied to health services

commitments, the lowest coverage ratio of all sectors.[143]

The main reasons for this lower level of liberalisation commitments for the health services may be twofold. One, given the critical importance of national health services and the structure of the health sector (e.g. public health services remain the main provider in many countries), WTO Members may not be keen to open this sector. Two, most of the liberalisation commitments were undertaken during the Uruguay Round. Doha Round, launched in 2001 and originally scheduled to be completed within three years was expected to broaden and deepen Members' commitments across various services sectors. However, these negotiations have been stalemated for many years and hence the level of commitments by Members has not increased since 1995.

Despite the above-described caveats, the overall level of policy engagement in health services trade and investment has been growing during the last years.[144] This is due to both the supply and the demand side factors. On the demand side, the population is ageing as a result of a demographic change. They require more advanced treatments and therefore, increase the demand for medical services. On the supply side, new technologies, as well as an increasing range of health services, allow to answer more efficiently to the growing needs. The liberalisation of cross-border investment in health-related services in addition to the increased mobility of health care professionals also permitted a wider scope of healthcare supply, even to remote or under favoured populations.

The revival of WTO negotiations on trade in services will also create impetus for more commitments in the health services sector. In fact, the application of the recently concluded negotiations on services domestic regulations among 65 WTO Members may increase the volume of trade in health services.[145]

Therefore, as the level of policy engagement in health services trade is rising, a greater interest in issues related to health services and the GATS may be expected.

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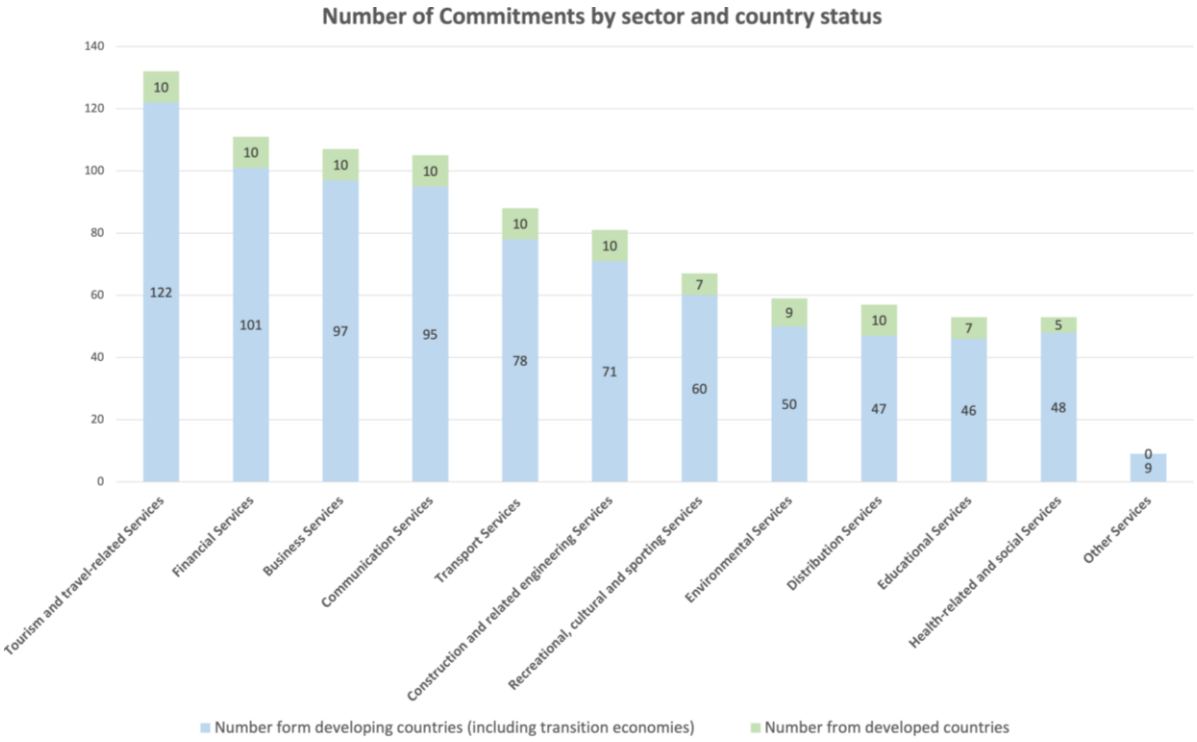
[143] WTO-World Bank I-TIP Services database, accessed the 8th June 2021. Available at: http://i-tip.wto.org/services/ReportResults.aspx

[144] Pierre Sauvé, Chantal Blouin, Aniket Bhushan, Olivier Cattaneo (2015). *Trade in health services. Trade and Health: Towards building a National Strategy.* WHO. Available at: https://www.who.int/phi/documents/trade-and-health/en/

[145] Joint Initiative on Services Domestic Regulations, *Reference Paper on Services Domestic Regulations,* available at https://bit.ly/3nenyDg. The disciplines on Services Domestic Regulation in the Reference Paper elaborate upon the provisions of Article VI.4 of GATS to address the difficulties which may be faced by service suppliers in complying with measures relating to licensing requirements and procedures, qualification requirements and procedures, and technical standards of other Members in the sectors where they have undertaken commitments.

Figure 3: Sectoral distribution of market access commitments under the GATS



Source: WTO-World Bank I-TIP Services database, computation from the authors[146]

4.3 The TRIPS Agreement

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement was also negotiated during the 1986-1994 Uruguay round and introduced intellectual property rules into the multilateral trading system for the first time in history.[147] It was negotiated at a time when some Asian and Latin American countries were entering the market of drug manufacturing during the end of the 1980s and the beginning of the 1990s. The increased competition concerned the main drug manufacturers at the time (e.g. the United States of America (USA), and the European Union (EU) who were worried that that many developing countries held a shorter period of patent protection as well as a narrower definition of protection. [148] This threatened a loss of foreign sales for main producers of pharmaceutical products in particular.[149] Moreover, developing countries' governments tended to be more tolerant concerning the production and sale of cheap imitations. The lack of transparency, legal security, and certainty in the patent-granting process and enforcement frightened

[146] Ibid
[147] WTO website (accessed on the 9th June 2021). *TRIPS – Trade Related Aspects of Intellectual Property Rights.* Available at: https://www.wto.org/english/tratop_e/trips_e/trips_e.htm
[148] Michael Trebilcock, Robert Howse and Antonia Eliason (2013). *The Regulation of International Trade. Routledge.* Available at: https://www.routledge.com/The-Regulation-of-International-Trade/Howse-Eliason/p/book/9780415610902
[149] Ibid

developed economies which asked for a more regulated competitive environment.[150]

This is where the TRIPS Agreements comes into play. The TRIPS is the most comprehensive multilateral agreement on intellectual property (IP).[151] It represents the legal recognition of existing links between IP and trade and the need for a balanced IP system. The TRIPS Agreement covers five areas[152]:

- How general provisions and basic principles of multilateral trading system apply to international IP
- What the minimum standards of protection are for intellectual property rights that members should provide
- Which procedures members should provide for the enforcement of those rights in their own territories
- How to settle disputes on IP between members of the WTO
- Special transitional arrangements for the implementation of TRIPS provisions

The TRIPS Agreement provides patent protection for pharmaceutical products. Eligible inventions, including both products and processes, are be protected for at least 20 years.[153] Patents rights must be enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced, according to Article 27 of the TRIPS Agreement.[154] TRIPS also describes the minimum rights that a patent owner holds and defines the conditions under which exceptions to these rights are permitted. For example, a government can refuse to issue a patent for an invention if its sale needs to be prohibited for reasons of public order or morality. Governments also have the right to issue compulsory licences under certain circumstances which allow competitors to produce the product or use the process under licence without the owner's consent. This clause has been of particular concern and interest in relation to public health and pharmaceutical products.

In the wake of high HIV/AIDS incidence in late 1990s and early 2000s, when many developing countries were struggling to provide anti-retroviral drugs to their populations, many felt that the original provision for compulsory licenses in the TRIPS Agreement needed clarification. This led to the negotiations towards the famous Doha Declaration on the TRIPS Agreement and Public Health which is discussed later in the Section.

South Africa Case: HIV/AIDS Drugs and TRIPS Flexibilities

The tension between the obligations imposed by the TRIPS Agreement on the one hand and public health objectives on the other was first brought to the fore in 1997 when President Nelson Mandela of South Africa signed the Medicines and Related Substances Control Amendment Act.[155] The Act aimed at

[150] Michael Trebilcock, Robert Howse and Antonia Eliason (2013). *The Regulation of International Trade. Routledge.* Available at: https://www.routledge.com/The-Regulation-of-International-Trade/Howse-Eliason/p/book/9780415610902

[151] WTO website (accessed on the 9th June 2021). *TRIPS – Trade Related Aspects of Intellectual Property Rights.* Available at: https://www.wto.org/english/tratop_e/trips_e/trips_e.htm

[152] Ibid

[153] Ibid

[154] WTO (2017). *Agreement on Trade-Related Aspects of Intellectual Property Rights* (as amended on 23 January 2017). Available at: https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm

[155] Republic of South Africa (1997). *Government Gazette. No. 18505*. Available at: https://www.gov.za/sites/default/files/gcis_document/201409/a90-97.pdf

promoting affordable medicines and would allow the South African government to use different measures to reach this goal. For example, the Government would have the right to import patented life-saving medicines from countries where they were sold more cheaply. Parallel importing, as it is called, means that the South African Government was allowed to source the lowest-price patented products on the global market, rather than taking the price determined for the South African market by pharmaceutical companies.[156] The Act would also permit the imports of generic versions of patented medicines through compulsory government-use licenses.

This Medicines Act intended to transform the HIV/AIDS situation in South Africa. At the time, over 4.5 million people were infected and a majority of those persons did not have access to an effective treatment.[157] Nearly all key anti-retrovirals were under patent and their prices could be between four and twelve times the price of their generic equivalents available on the world market.[158]

However, this act was not to everyone's taste, the South African Pharmaceutical Manufacturers Association and forty Multinational Corporations took legal action against the Government of South Africa. They claimed that the act was unconstitutional because it went against the WTO TRIPS patent rules and deprived them of their right to property.[159]

On the other side, many organisations, such as Oxfam, claimed that the South African Government had a higher constitutional duty to improve health care for everyone and that measures permitted by the Act were allowable under the WTO rules. They reiterated their positions that the high cost of patented medicines is a central obstacle to accessibility.

This debate was major and a precursor of the challenges to come. It brought up two key issues in debates revolving around patented medicines. First, the interpretation of flexibilities of TRIPS and their use for public health purposes. Second, the trade pressures of industrialized countries to defend the interest of their multinational industries.[160] The ultimate conclusion of this court case was to determine whether a government's right to protect people's health would take precedence over monopolies on life-saving medicines.[161]

In April 2001, following pressures from international organisations as well as governments, the pharmaceutical companies withdrew their case against the government in the Pretoria High Court. The South African Government reiterated that it will use this section to import only brand-name drugs which are on the foreign market at a lower price than in South Africa and that it will

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[156] Oxfam (2001). *South Africa vs. the Drug Giants: A Challenge to Affordable Medicines*. Available at: https://oxfamilibrary.openrepository.com/bitstream/handle/10546/620381/bn-access-to-medicines-south-africa-010201-en.pdf?sequence=1&isAllowed=y

[157] Ibid

[158] Oxfam (2001). *Oxfam Update on South African Court Case. South Africa vs. the Drug Giants.* Available at: https://oxfamilibrary.openrepository.com/bitstream/handle/10546/620381/bn-update-access-to-medicines-south-africa-110401-en.pdf;jsessionid=2DA8A4AA4A47069C7E916065AB4F5F6A?sequence=2

[159] Oxfam (2001). *South Africa vs. the Drug Giants: A Challenge to Affordable Medicines.* Available at: https://oxfamilibrary.openrepository.com/bitstream/handle/10546/620381/bn-access-to-medicines-south-africa-010201-en.pdf?sequence=1&isAllowed=y

[160] Ellen't Hoen (2002). *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha. Chicago Journal of International Law.* Volume 3. Number 1. Article 6. Available at: https://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=1171&context=cjil

[161] Ibid

comply with its international obligations on the protection of IP rights. This case was a turning point in the history of public health. And it is still relevant today amidst the COVID-19 crisis.[162]

WTO Doha Declaration on the TRIPS Agreement and Public Health

As mentioned earlier in this Section, the WTO Doha Declaration on the TRIPS Agreement and Public Health was negotiated to address the tension between TRIPS obligations and public health objectives which were brought to the fore by the South African case in the context of HIV/AIDS. It aimed to provide the necessary clarity, including with regard to the use of compulsory licenses for pharmaceutical products. and was adopted at the WTO Ministerial Conference held in Doha, Qatar in December 2001. It affirmed that the TRIPS Agreement should not provide an obstacle to the availability of essential medicines at affordable prices at least concerning certain critical diseases.[163] The Declaration identified certain specific options available to governments to address public health needs. It also included "flexibilities" and recognised their importance.

The main flexibility identified in the Doha Declaration on the TRIPS Agreement and Public Health was the right of the governments to grant compulsory licences to make use of a patented invention without the consent of the patent holder. [164] Indeed, confusion had existed about the TRIPS Agreement's provision on the matter, as TRIPS did not specifically list reasons that might be used to justify compulsory licensing. The Doha Declaration on the TRIPS Agreement and Public Health confirms that countries are free to determine the grounds for granting compulsory licenses and to determine what constitutes a national emergency.[165]

Other flexibilities introduced by the Doha Declaration include[166]:

- 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.
- Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted
- Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics can represent a national emergency or other circumstances of extreme urgency
- The effect of the provisions in the TRIPS Agreement that are relevant to the

[162] Joe Nocera (2021). *There's a Precedent for Overriding Patents on Vital Medications*. Bloomberg. Available at: https://www.bloomberg.com/news/articles/2021-05-11/aids-drugs-in-south-africa-shows-precedent-for-overriding-patents-on-medications

[163] Michael Trebilcock, Robert Howse and Antonia Eliason (2013). *The Regulation of International Trade. Routledge.* Available at: https://www.routledge.com/The-Regulation-of-International-Trade/Howse-Eliason/p/book/9780415610902

[164] Ibid

[165] WTO website (accessed on the 9th June 2021). *TRIPS and public health*. Available at: https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

[166] WTO (2001). *Declaration on the TRIPS Agreement and Public Health.* Available at: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

In 2003, the implementation of the Doha Declaration on the TRIPS Agreement and Public Health also offered a solution to the difficulties encountered by WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector related to compulsory licensing.[167] Then, in 2005, the Decision on the Amendment of the TRIPS Agreement replaced the 2003 Decision and removed this difficulty by creating a new additional form of compulsory licence especially tailored for the export of medicines to countries in need. [168] The new article 31bis of the TRIPS Agreement gives full legal effect to this system and allows the production of low-cost generic medicines as well as their exportation under a compulsory licence. However, this provision should exclusively be used for the purpose of serving the needs of countries that cannot manufacture those products themselves.[169]It is also important to note that the new Article 31bis has been used only once, i.e. by Rwanda in 2007 when it issued a compulsory license to a Canadian drug manufacturer for the production and export to Rwanda of some anti-retroviral drugs. [170] It has been argued that the procedural requirements to use Article 31bis are rather onerous and may need to be streamlined.[171]

The above history and succinct details of the WTO Doha Declaration on the TRIPS Agreement and Public Health is important to bear in mind due to its relevance for the current debates in the WTO regarding the response to Covid 19 pandemic through a TRIPS waiver.

Covid-19 Pandemic and TRIPS Flexibilities

Amidst the pandemic, many countries turned to the TRIPS Agreement to facilitate access to existing drugs and to support the creation, manufacture, and dissemination of new drugs and technologies. Several government policy and administrative options allowed under the TRIPS Agreement were used by WTO Members. Out of the 383 notifications submitted until June 2021 at the WTO, 57 were concerning IP rights.[172] The measures concerned primarily the transparency of IP rights information, the government decisions in support of voluntary collaboration, and measures taken by IP offices. Following are some examples:[173]

- The Russian Federation took the decision to accelerate the consideration of applications for inventions and models

[167] WTO (2003). *Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*. Available at: https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

[168] WTO (2005). *Decision on the Amendment of the TRIPS Agreement.* Available at: https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm

[169] WTO website (accessed on the 9th June 2021). *TRIPS and public health.* Available at: https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

[170] WHO. *Country experiences in using TRIPS safeguards: Part I.*

[171] Carlos M. Correa, *Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?* South Centre Policy Brief 57 of January 2019. Available at https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf

[172] WTO website (accessed on the 17th June 2021). *WTO members' notifications on COVID-19.* Available at: https://www.wto.org/english/tratop_e/covid19_e/notifications_e.htm

[173] Based on WTO Information Note (2020). The TRIPS Agreement and COVID-19.

associated with technologies combating viruses and associated diseases without charging an additional fee.

- Australia issued guidance for IP offices where the Trade Mark COVID-19 Helpline supports and assists small to medium businesses that struggle to adapt to COVID-19 regulations.

- Israel's Minister of Health issued a permit to allow the government to import generic antiretroviral medication from India as a means to exploring the possibility of treating COVID-19 patients.

COVID-19 and TRIPS Waiver

Covid-19 pandemic also brought back the issue of TRIPS obligations and flexibilities to deal with public health emergencies at the centre of TRIPS-related debates at the WTO. Some WTO developing country members argued that a waiver on certain TRIPS obligations was necessary during the COVID-19 situation.[174] In October 2020, India and South Africa submitted a proposal for a temporary waiver to address prevention, containment, and treatment of COVID-19.[175] The proposed waiver aimed at avoiding barriers to timely access to affordable medical products as well as scaling up research, development, manufacturing, and supply of essential medical products. The proposal received support from many other developing countries while most developed countries opposed it.

An important development took place on May 5, 2021 when the United States Trade Representative (USTR) released a statement announcing the Biden-Harris Administration's support for waiving intellectual property protections for COVID-19 vaccines.[176]

The proponents of the waiver proposal submitted a revised proposal on May 25, 2021 for negotiations. The revised proposal responded to concerns from some members that saw the waiver as a mean to permanently waive various TRIPS Agreement obligations. It specified the scope as applying to health products and technologies, including diagnostics, therapeutics, vaccines, medical devices, and personal protective equipment needed to tackle COVID-19.[177] Furthermore, the waiver would be in force for a minimum of 3 years and should be reviewed annually. As of late June 2021, more than 60 WTO members supported the proposal including the LDC group.[178]

On June 4, 2021, the EU made its communications to the WTO General Council and the Council on TRIPS on "Urgent Trade Policy Responses to Covid-19 Crisis".[179] The subsequent EU proposal (IP/C/W/681) of July 2021 focusses on Articles 31 and 31 bis of the TRIPS Agreement. It proposes to use as a basis the Doha Declaration on the TRIPS Agreement and Public Health of 2001 (discussed above)

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[174] European Parliament (2021). *World Trade Organization TRIPS waiver to tackle coronavirus.* Available at: https://www.europarl.europa.eu/RegData/etudes/ATAG/2021/690649/EPRS_ATA(2021)690649_EN.pdf

[175] WTO (2020). *Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19.* IP/C/W/669. Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True

[176] Office of the United States Trade Representative. *Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver,* May, 5, 2021. Available at https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver

[177] WTO (2021). *Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19.* IP/C/W/669R1. Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True

[178] WTO website (accessed on the 17th June 2021). *Members approach text-based discussions for an urgent IP response to COVID-19.* Available at: https://www.wto.org/english/news_e/news21_e/trip_09jun21_e.htm

[179] EU Press release. *EU proposes a strong multilateral trade response to the COVID-19 pandemic* 4 June 2021. Brussels. Available at https://ec.europa.eu/commission/presscorner/detail/en/IP_21_2801

and to make use of TRIPS Articles 31b and 31bis. The use will be under 'a national emergency or other circumstances of extreme urgency' to be declared by a national government and for which no authorisation from the title holder is needed. It would apply to both vaccine and medicines. However, there must be an adequate remuneration to the patent holder.

The EU was not convinced that the broad waiver proposed by a number of WTO members would be the best to achieve the widest and timely distribution of COVID-19 vaccines. However, it indicated its readiness to discuss any option that could help end the pandemic as soon as possible.

WTO members have held several meetings and consultations since then without reaching any agreement on any proposal. The issue is likely to be high on the agenda of the forthcoming WTO Ministerial Conference – the highest decision-making body of the organisation – that is scheduled from 30 November till 3 December 2021 in Geneva, Switzerland. The outcome will be critical to deal with Covid-19 pandemic particularly in developing countries where only 2.5 percent of the total population has been vaccinated so far.

4.4 The Trade and Health Initiative

On the 23rd November 2020, Australia, Brazil, Canada, Chile, the EU, Japan, Kenya, Republic of Korea, Mexico, New Zealand, Norway, Singapore, and Switzerland communicated their desire to make international trade a powerful tool to help contain the pandemic and contribute to economic recovery through a Trade and Health Initiative.[180]

Since the beginning of 2020, 88 WTO members have taken trade measures whether of restrictive or facilitating character. By the end of the year, there were still over 70 WTO members with trade measures in place that restricted exports of medicaments, medical supplies, or food. According to the proponents of the Trade and Health Initiative, those trade-restrictive measures go against the goal of providing scarce essential medical goods and vaccines amongst WTO Members, in particular the most vulnerable ones. The objective of their initiative is to enhance the capacity of the trading system to respond to public health emergencies and to support improvements in the resilience of supply chains. To achieve this, proponents of the initiative recommend the actions described in the following table.

[180] WTO (2020). *COVID-19 and beyond : Trade and Health. Communicaton from Australia, Brazil, Canada, Chile, The European Union, Japan, Kenya, Republic of Korea, Mexico, New Zealand, Norway, Singapore and Switzerland.* Available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/GC/223.pdf

Figure 4: Actions recommended by the proponents of the Trade and Health Initiative

Exports restrictions	• Review and promptly eliminate unnecessary existing restrictions on exports of essential medical goods necessary to combat the COVID-19 pandemic • Exercise restraint in the imposition of any new export restrictions, including export taxes on essential medical goods and any prospective vaccine or vaccine materials
Customs services and technical regulations	• Share experience as regards the trade facilitating measures put in place in response to COVID 19 crisis to establish best practices • Cooperate in the exchange and implementation of best practices
Tariffs	• Temporarily remove or reduce tariffs on goods considered essential to fighting the COVID-19 pandemic (see indicative list of COVID-19 related goods established by the WCO and WHO)
Transparency and review	• Respond swiftly to requests for information on trade measures adopted during the present health crisis • Engage fully with the trade monitoring exercises done on a regular or an ad hoc basis in the WTO and pay particular attention to complying with all WTO notification requirements during the COVID-19 crisis
Cooperation of the WTO with other organisations	• Members commend the work of the WTO Secretariat resulting in an extensive database of measures related to COVID-19 and a range of dedicated studies and reports allowing them to have a comprehensive and accessible overview of the situation • The WTO Director-General is strongly encouraged to intensify cooperation with other relevant international organisations such as the WHO, WCO, WIPO, OECD, UN as well as G20 with the aim of improving the analytical capacity of Members to monitor market development

Source: Authors based on the proposal by the proponents

The initiative aimed to adopt a Joint Statement of all WTO members to serve as a confidence-building measure and as a starting point for negotiations on the new WTO commitments for MC12.

Finally, the initiative reminds that the flexibilities provided by the TRIPS Agreement and reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health remain available to protect public health and to promote access to medicines for all.

SECTION 5

The Collaboration between the WTO and the WHO

The WHO and the WTO have been collaborating on different types of cross-cutting issues. As stated earlier in this study, health and trade are intimately interconnected and thus, the two organisations have joined efforts to bring attention to the need for policy coherence between trade and health matters at global, regional, and domestic levels. This collaboration takes place through several means as briefly described below.

5.1 WHO's role at the WTO

The WHO has an observer status in the Committee on SPS Measures and in the Committee on TBT. In addition, it has ad hoc observer status in the Council for TRIPS and in the Council for Trade in Services.

Under both the SPS and the TBT Agreements, protection of health is written as a legitimate policy objective for taking regulatory actions. However, those regulatory actions have to be science-based in order to be applied. Thus, trade measures related to health are usually based on the FAO/WHO Codex Alimentarius which acts as the relevant standard-setting organisation for food safety.[181] This Codex Alimentarium is a collection of international food safety standards that have been adopted by the Codex Alimentarius Commission, based in Rome. Including standards on foods, veterinary drugs, and pesticide residues among others, the Codex has proved to be an important reference point for the dispute settlement mechanism of the WTO.[182] Finally, as part of its observer status in the TBT Committee, the WHO regularly attends its meetings.

WHO's role at the WTO can be further strengthened by granting it permanent observer status at the Council for TRIPS and the Council for Trade in Services, thus allowing it to regularly contribute to the issues at the interface of intellectual property and services on the one hand and public health on the other.

5.2 WTO's role at the WHO

As the WHO has an observer role at the WTO, the WTO Secretariat also has an observer status at the World Health Assembly and other WHO bodies. The WTO contributes to the implementation of the WHO's Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property as well

[181] WTO website (accessed on 10th June 2021). *The WTO and the FAO/WHO Codex Alimentarius*. Available at: https://www.wto.org/english/thewto_e/coher_e/wto_codex_e.htm

[182] Ibid

as collaborating closely in the field of technical cooperation. The WHO's Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property was adopted in 2008, following a two-year negotiation process. It aims at promoting innovation, access to medicines, and health research and development for diseases disproportionately affecting developing countries. [183] Since it involves the transfer of technology, IP, and improving delivery and access to health products and services, the WTO, based on its mandate, can play a role in all these areas.

Finally, the WTO Secretariat also participates in conferences organised by the WHO.

These arrangements should continue and can be further strengthened by regular exchanges between the WTO and WHO secretariats.

5.3 Joint Initiatives: Workshops and Standards and Trade Development Facility

Workshops on trade and public health have been held by the WTO and the WHO jointly since 2014. This year, three courses were carried out in virtual format with a special focus on COVID-19.

The Standards and Trade Development Facility (STDF) is a joint initiative of the WTO, World Bank (WB), FAO, WHO, and World Organization for Animal Health.[184] It aims at facilitating safe trade while contributing to sustainable economic growth, poverty reduction, and food security. More specifically, the STDF assists developing countries in establishing and implementing SPS standards to ensure health protection and facilitate trade expansion. Finally, the STDF also works as a forum for coordination and information sharing on SPS-related technical assistance. Trade, health, and agriculture experts worldwide are brought together to address the SPS challenges and find solutions.

5.4 Recent collaborations and ways forward

Covid 19 pandemic has given greater impetus to the collaboration between WTO and WHO. In 2020, the WHO, WTO, and WIPO published a revised version of a joint paper on the intersection between public health, intellectual property, and trade. [185] The publication seeks to determine how innovation and access to medical technologies, such as medicines, vaccines, and medical devices are affected by the interplay between health, trade, and IP.

In June 2021, the IMF, the WB, the WHO, and the WTO issued an extraordinary call to government leaders for financing actions to accelerate the end of the COVID-19 pandemic. [186] US$ 50 billion investment

[183] WHO (2011). *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*. Available at: https://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf

[184] Standards and Trade Development Facility website (accessed on the 10th June 2021). Available at: https://www.standardsfacility.org/

[185] WTO, WIPO, WHO (2020). *Promoting Access to Medical Technologies and Innovation*. Second Edition. Available at: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

[186] WHO website (accessed on the 10th June 2021). *New US$50 billion health, trade and finance roadmap to end the pandemic and secure a global recovery.* Available at: https://www.who.int/news/item/01-06-2021-new-50-billion-health-trade-and-finance-roadmap-to-end-the-pandemic-and-secure-a-global-recovery

would be needed to boost manufacturing capacity, trade flows, and equitable distribution of diagnostics. It would allow to generate US$ 9 trillion in global economic returns by 2025.

These organisations have joined forces to accelerate access to COVID-19 vaccines, therapeutics and diagnostics through creating a Multilateral Leaders Task Force on Covid-19 Vaccines, Therapeutics, and Diagnostics. The Task Force works has partners in governments, regional development banks, members of the Access to COVID-19 Tools (ACT) Accelerator and its COVAX Facility, the Africa Vaccine Acquisition Task Force, pharmaceutical firms, and others in the private sector to leverage multilateral finance and trade solutions, particularly for low- and middle-income countries.[187]

The 2nd High-Level Consultations of the Heads of WTO, WHO, IMF and the World Bank with the CEOs of leading COVID-19 vaccine manufacturing companies were held on 9 November. The objective of the meeting was to identify how to ensure more equitable distribution of vaccines to achieve the targets of vaccinating 40% of people in all countries by end 2021, and 70% of the populations of all countries by the middle of 2022.[188]

The above brief account shows both the longer term as well as more recent collaboration between WTO and WHO. This has been both bilateral (e.g.l through the grant of observer status to each other) as well as in the context of initiatives involving other international organisations (e.g. STDF). Covid-19 has rightly increased this collaboration.

The existing collaboration arrangements between the WTO and WHO should be the basis for regular and robust collaboration in the future also which will be important to effectively deal with the issues at the interface of trade and public health. For this purpose, the two organisations should: i) grant permanent observer status to each other at all relevant bodies; ii) establish a mechanism for regular and structured exchanges between the two secretariats; and, iii) undertake joint initiatives on specific issues - in collaboration with other international organisations where needed.

[187] Covid-19 Task Force website https://www.covid19taskforce.com/en/programs/task-force-on-covid-19-vaccines (accessed on 10 November 2021)

[188] WTO website https://www.wto.org/english/news_e/news21_e/igo_09nov21_e.htm (accessed on 10 November 2021)

SECTION 4

Conclusion

Health is a fundamental human right. It is an important part of the Sustainable Development Goals (SDGs). SDG3 in particular mandates to "Ensure healthy lives and promote well-being for all at all ages". Trade is a critical means to achieve the Goal and its various targets: by promoting development of new and better drugs and technologies; by increasing universal and affordable access to health goods, services and technologies; and by providing economic opportunities and financial resources to individuals, health enterprises, and governments to increase the spending and investments on health and healthcare systems. Conceptually, this contribution can be maximised by a well-functioning international trading system that disciplines protectionism and creates a stable and predictable environment for the smooth flow of goods, services and technologies on fair terms across borders. The WTO agreements can be viewed as serving this purpose.

At the same time, there can be tensions between the needs of the health systems and the obligations under the WTO agreements. These tensions are often due to the aspects that protect commercial interests and well-designed "monopoly rights", e.g. through obligations on intellectual property. Admittedly, protection of commercial interests and IP rights is not bad *per se* as it contributes to increased investments and economic returns including in the health sector. However, there has to be a balance between these and the affordable access to medical goods, services and technologies by all. Experience has shown that such a balance is not automatic. In fact, the lack of this balance becomes apparent during times of public health crisis, necessitating dialogue among WTO members to address the imbalance. This happened in late 1990s and early 2000s in the context of HIV/AIDS that led to the negotiations of the WTO Doha Declaration on the TRIPS Agreement and Public Health. And this has happened in the wake of on-going Covid-19 pandemic where the universal, timely and affordable access to medical goods and technologies for the prevention, containment, and treatment of COVID-19 has been at the centre stage of the WTO for more than a year without reaching any agreement among all members.

Another important element in trade-public health relationship is the collaboration between the international organisations mandated to deal with the two issues, i.e. the WTO and the WHO. The two organisations have been collaborating with each other, e.g, by granting observer status to each other, exchanges between the two secretariats, and as partners in initiatives that also include other international organisations, etc. Understandably, this collaboration becomes deeper and stronger during public health crisis as has been since the onset of Covid-19.

The above raises two key questions: should the efforts to "balance" the international trading and health consideration wait for the onset of a public health crisis?; and, should the WTO and WHO enhance their collaboration only in times of emergencies? A thoughtful answer to both the questions should be in the negative. Covid-19 crisis, therefore, should be viewed as an opportunity to not only balance and collaborate to face this

crisis, but also to find better balance and collaboration for longer term. This requires a holistic approach.

Five key elements of a holistic approach towards mutually supportive world trade and health governance system can be identified:

- High level commitment by all countries to maintain and facilitate the flow of medical goods, services and technologies across borders
- Regular and robust collaboration between the WTO and the WHO under the framework of SDG 3
- Identification of specific provisions in all WTO agreements that are relevant for the well-functioning health systems and regular monitoring of their implementation and impact
- Adopting trade-related strategies for the research and development of goods and technologies for the prevention and treatment of diseases prevalent in developing countries
- Establishing a standing high-level body on Trade and Health with representation from the WTO, WHO, the World Bank, IMF, UNCTAD, the relevant private sector and Civil Society Organisations (CSOs) that meets at least twice every year to discuss pertinent issues at the interface of trade and health and to make suitable recommendations

Implementation of this holistic approach will ensure that the world is much better prepared to face the next public health crisis. More importantly, this will lead to mutually supportive world trade and health governance systems towards achieving SDG3.

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