INNOVATION COUNCIL

Bio-Pharmaceutical Manufacturing and R&D:

The Impact of Policy Coherence in Trade Policy

CONTENT

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INTRODUCTION

The COVID-19 pandemic has illustrated the importance of coherent policy approaches to health security, trade in health products, and investment in health-related R&D and supply capacity. Indeed, the events of the past year have placed in stark relief the fact that no country can rely exclusively on domestic resources to satisfy demand in equipment, diagnostics, and treatments. With the backdrop of the COVID-19 crisis – and the shortcomings of the global response – in mind, it is important to look more broadly at the issue of global capacity in the manufacture and R&D of bio-pharmaceuticals, in order to discern the ways in which its adjustment can improve countries' ability to respond to health crises.

At the start of the COVID-19 pandemic, the Director-General of the World Trade Organization (WTO) and Director-General of the World Health Organization (WHO) issued a joint statement: "Protecting lives is our top priority, and these efforts can be impeded by unnecessary disruptions to global trade and supply chains … keeping trade in health technologies as open and predictable as possible is therefore of vital interest. This will help countries to respond to this crisis, to recover from it and to build the health systems that will foster greater resilience in the future."1 G20 Leaders in March 2020 echoed this concern about disruption of global pharmaceutical supply chains, calling for commitments to "expand manufacturing capacity to meet the increasing needs for medical supplies and ensure these are made widely available, at an affordable price, on an equitable basis, where they are most needed and as quickly as possible."2

One year on, it is clear that this concern was warranted. Scarcity of medical supplies has been one of the defining features of the pandemic, and has affected the availability not only of relatively simple products, such as personal protective equipment,3 but also of advanced technology, such as pharmaceuticals.4 Problems with supply chains have been a major contributing factor to these shortages.5 Indeed, COVID-19 has underlined the vulnerability of global pharmaceutical production chains that rely on a small number of producers of final products or certain essential ingredients.

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1 Joint statement by WTO Director-General Roberto Azevêdo and WHO Director-General Tedros Adhanom Ghebreyesus (20 April 2020), available at: https://www.wto.org/english/news_e/news20_e/igo_14apr20_e.htm

2 G20, G20 Leaders' Statement on COVID-19, available at: https://g20.org/en/media/Documents/G20_Extraordinary%20G20%20Leaders%E2%80%99%20Summit_Statement_EN%20(3).pdf

3 Cohen and Rogers, "Contributing Factors to Personal Protective Equipment Shortages during the Covid-19 Pandemic," December 2020, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7531934/.

4 Sara Berg, "COVID-19 Exacerbates Drug Shortages. AMA Details next Steps," 17 November 2020, available at: https://www.ama-assn.org/delivering-care/public-health/covid-19-exacerbates-drug-shortages-ama-details-next-steps.

5 Hannah Balfour (European Pharmaceutical Review), "Pharma Supply Chain Still Highly Vulnerable to COVID-19, Says Research," 19 November 2020, available at: https://www.europeanpharmaceuticalreview.com/news/133953/pharma-supply-chain-still-highly-vulnerable-to-covid-19-pandemic-says-research/. ; Lianna Matt McLernon, "Report Details COVID-19 Drug Shortages—and Solutions," 21 October 2020, available at: https://www.cidrap.umn.edu/news-perspective/2020/10/report-details-covid-19-drug-shortages-and-solutions.

This working paper argues that investment in diversified sources of R&D and production, distributed geographically, can enhance manufacturing capacity and strengthen health security, complementing existing pharmaceutical production chains and making them less vulnerable to future shocks to the supply chain. As the experience of the COVID-19 pandemic would suggest, distributed manufacturing and R&D capacity will be particularly useful in the area of bio-pharmaceuticals, such as vaccines and diagnostics.

To successfully support bio-manufacturing and R&D activities, governments must ensure coherent policies in the inter-related areas of health, trade, and investment. "Policy coherence" refers to the alignment of policies endorsed by different national Ministries (e.g. health, trade, finance) and, where relevant, the alignment of policies among government partners within the context of regional cooperation.

The COVID-19 crisis has provided a valuable—and tragic—case study in the vulnerability of global supply chains as they are currently constructed. With this lived experience in mind, this working paper is intended to start a more general conversation about the importance of policy coherence for efforts to build resilience into global value chains for health technologies. The analysis rests on the premise that globally distributed bio-manufacturing and R&D activities can improve healthcare delivery and aid countries in responding to health crises beyond COVID-19. The paper focuses on trade and health policies as an illustrative example, and it introduces original research regarding tariffs on products specific to bio-pharmaceuticals manufacturing and R&D.

OVERVIEW

Bio-pharmaceuticals are increasingly central to healthcare delivery in high and low-income countries alike. There are myriad so-called biologics on the market to treat non-communicable diseases (NCDs) such as arthritis, cancer, and diabetes. A well-known example of these large molecule-based treatments are vaccines. Biologics production and R&D require know-how and equipment that differ from those used in the production of chemical pharmaceuticals, which are referred to as small molecules. The establishment of regional or domestic bio-infrastructure is rapidly becoming a strategic necessity for countries wishing to improve their health security.

This paper does not argue that all countries should aim for the establishment of a domestic bio-pharmaceutical industry. Rather, it suggests that expanded global capacity for the manufacture and R&D of bio-pharmaceuticals – including enhanced capacity in Low- and Middle-income Countries (LMICs) – could improve healthcare delivery and health security worldwide, and enable a more effective response to health crises including global pandemics. It is addressed to those governments that have made a policy decision to advance local or regional bio-manufacturing and that wish to design an enabling policy framework for sustainable production.

Establishment of bio-production can contribute to public health as well as industrial development objectives. The distribution of R&D and bio-manufacturing activities has the potential to enhance healthcare delivery and access to healthcare technologies in LMICs, contributing to the achievement of Universal Health Coverage (UHC). And it can enable countries to rapidly address pandemics and other health crises. In the short- to medium-term, building up domestic bio-infrastructure, for instance fill and finish technologies, could enable countries to contribute to the swift production of large volumes of bio-pharmaceuticals. In the longer term, developing countries can be expected to steadily grow their production and R&D capacity, enabling them to address specific local needs and contribute to global R&D, for instance through outsourced R&D tasks in the global pharmaceutical value chain.

Enabling policies and policy coherence will be essential to the success of such projects, with the right health, procurement, investment, and trade policies forming one important element of an enabling policy environment. In relation to trade policies, many LMICs have focused on reducing or eliminating tariffs on finished healthcare products, aware of the negative effect these can have on price and availability. An important next step will be to eliminate tariffs also on bio-manufacturing and R&D inputs. Such tariffs can set back local production, by driving up costs for local producers that are already facing challenges such as achieving economies of scale, lack of local technical and scientific capacity, and increasing uncertainty due to exchange rate fluctuations.

International organizations – such as the World Health Organization (WHO) and the United Nations Conference on Trade and Development (UNCTAD) – have long identified local production of health products as a critical contributor to UHC and the achievement of the Sustainable Development Goals. WHO implemented the Local Production Programme, based on the mandate provided under Resolution WHA61.21, to support Member States (e.g. Ethiopia, Indonesia, Nigeria, South Africa, and Tanzania) in strengthening local production, technology transfer, and R&D while promoting policy coherence. Policy coherence is an important enabler of local production, particularly of biologics, which have an increasingly central role in healthcare systems.

THE HEALTHCARE IMPETUS FOR LOCAL BIOLOGICS PRODUCTION AND R&D

Half the world's population lives on less than USD 5.5 per day, according to the World Bank.[6] Poverty is an obstacle to access health technologies, including medicines and vaccines. Moreover, health budgets everywhere are under increasing pressure. Governments face

6 World Bank, "Piecing Together the Poverty Puzzle," 2018, available at: https://openknowledge.worldbank.org/bitstream/handle/10986/30418/9781464813306.pdf.

many challenges to ensuring access to healthcare and to appropriate healthcare technologies. Local production is one approach that can potentially improve sustainable availability of health technologies including biologics. It can also confer important economic benefits, contributing to social and economic growth in LMICs by stimulating the establishment and growth of local businesses, developing existing and new markets, and strengthening local scientific and innovative capacity.

While local production can improve affordability, it is important to note that it does not necessarily result in lower prices compared to imported generics in the short term. Recent evidence from Kenya indicates that local medicines production may under certain circumstances generate lower prices than imported generic medicines.[7]

Building local R&D and production capacity is best viewed as a mid- or long-term economic and healthcare objective.[8] Beyond pricing, local R&D and manufacturing can address the relatively smaller investments in R&D for diseases that most affect people in developing countries, and it can help to reduce dependence on international supply chains which carries the risk of interruptions and stock-outs. And evidence suggests that locally manufactured medicines may improve availability by relying on existing local distribution networks.[9]

Local production of health technologies has long been on the global health agenda. Following decades of discussion at the World Health Assembly, Resolution WHA 61.21 on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) highlighted the value of local production, along with technology diffusion, as a key strategy to promote innovation, build domestic capacity, and improve access to quality-assured medical products. At the World Health Assembly in 2018, Member States underlined the importance of local production in the context of addressing the global shortage of, and access to, medicines and vaccines. In 2019, the first Inter-Agency Statement on promoting Local Production, endorsed by WHO, UNAIDS, UNIDO, UNICEF, UNCTAD and the Global Fund, confirmed growing interest among LMICs in expanding their capacity to make quality-assured medicines and other health technologies.[10] These agencies are working with governments to advance local production, with the expectation this will improve access to health technologies and contribute to achievement of UHC. Resolution WHA72.8 on Improving the transparency of markets for medicines, vaccines, and other health products calls for national capacities for local production to be improved.[11] At the WHO Executive

7 Health Action International, "Prices and Availability of Locally Produced and Imported Medicines in Kenya," 8 August 2018, available at: https://haiweb.org/media-resouce/prices-and-availability-of-locally-produced-and-imported-medicines-in-kenya/.

8 Case studies by the WHO, together with a range of other publications and tools, are available at: https://www.who.int/phi/implementation/tech_transfer/en/.

9 UNCTAD, "Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries: A series of case studies by the UNCTAD Secretariat," United Nations, 2011, 121, 124, available at: https://unctad.org/en/PublicationsLibrary/diaepcb2011d7_en.pdf.

10 WHO, Inter-Agency Statement on promoting local production of medicines and other health technologies, 24 May 2019, available at: https://www.who.int/phi/implementation/tech_transfer/Interagency-statement-on-promoting-local-production.pdf?ua=1.

11 World Health Assembly, Resolution WHA72.8 "Improving the transparency of markets for medicines, vaccines, and other health products," 28 May 2019, available at: https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf.

Board meeting in February 2020, the representatives of several Member States underlined the importance of local production.[12]

BOX 1: LOCAL PRODUCTION OF VACCINES

Vaccines provide an example of an area where private-public partnerships to establish local bio-manufacturing may be warranted. A recognized cost-effective health intervention, vaccines improve individuals' and communities' well-being and productivity. GAVI (the Global Alliance for Vaccines and Immunization) provides co-financing, with certain conditions imposed, for the procurement of vaccines. This often represents a significant part of vaccines-related spending in beneficiary countries. Certain countries have already had to transition away from GAVI co-financing, and others are in the process of doing so. At the same time, studies reveal that the cost of vaccination is rising. For instance, a 2015 Médecins Sans Frontières (MSF) Report found that the cost of vaccines recommended in the WHO childhood immunization schedule had gone up by 68 per cent between 2001 and 2014. Rising costs hit countries especially hard at a time when they are transitioning out of GAVI co-financing. More widespread local manufacturing could improve the sustained availability of vaccines, through public-private collaboration aimed not only at improving healthcare but also at improving efficiency of production and delivery. In the case of pandemics, it could also contribute to overall global production capacity in large volumes at affordable prices and, hence, increase access.

LMICs face significant challenges in developing pharmaceutical and bio-pharmaceutical production capacity. By way of example, they may face difficulties in relation to: human resource capacity constraints; limited access to foreign financial markets and commercial bank credits needed to invest in quality upgrading; difficulties in raw material procurement; infrastructure challenges and lack of technological capacity; achieving good manufacturing practice (GMP) compliance; and achieving economic feasibility. The economic feasibility of local R&D and manufacturing activities depends, in part, on access to the required tools and other inputs. Unfortunately, in many places, such access is hampered by counterproductive government policies including, for instance, the imposition of tariffs.

12 A recording of Member States' interventions is available at: https://www.who.int/about/governance/executive-board/executive-board-146th-session.

POLICY COHERENCE: INVESTMENT, TECHNOLOGY PARTNERSHIPS AND ADVANCEMENT ALONG THE BIO-PHARMACEUTICAL VALUE CHAIN

Strengthening local production and R&D activities related to bio-pharmaceuticals is a cross-cutting project requiring engagement with many types of stakeholders. Government officials are well-positioned to evaluate their countries' healthcare needs – including in relation to healthcare technologies – and to prioritize national budgets to meet them. However, in many countries, governments may lack the expertise needed to successfully build and operate the facilities required for local production, particularly of bio-pharmaceuticals, or to successfully support local companies to do so. Collaboration and technology transfer, often requiring private sector partners, can be crucial to success. Such ventures, whether North-South or South-South, can improve local technical capacity and the domestic manufacturing base over time. They can also contribute to better availability, certainty of supply, and pricing, all of which are important factors in health technologies uptake.

Once established, facilities can be operated by either public or private sector actors. In addition to commissioning the establishment of such facilities within the public sector, governments can consider using incentives to establish bio-infrastructure, such as tax credits or procurement agreements. They can also work to improve policy coherence and legal certainty. A "Tool Box" developed by UNCTAD provides governments with valuable guidance in this respect.13

In the past, high start-up costs and lack of local expertise were serious impediments for local bio-manufacturing. To some degree, they still are. At the same time, there are new turnkey solutions on the marketplace that mean local production facilities can be set up in a fraction of the time, and at much lower cost, than it would take to build from the ground up. New, flexible bio-processing solutions on the market can be used to make multiple products, unlike traditional facilities which were geared towards producing a limited product range.

Depending on the investment policy of countries, investors may be exempted, on a case by case basis, from paying the applicable tariffs on capital goods required to establish bio-manufacturing and R&D activities.14 This approach, however, seems less beneficial for local producers than a general elimination of relevant import tariffs under a country's trade policy.

13 UNCTAD, "Tool Box for Policy Coherence in Access to Medicines and Local Pharmaceutical Production," 2017, available at: https://unctad.org/en/pages/PublicationWebflyer.aspx?publicationid=1921.

14 An example is the Ethiopian Investment Incentives and Investment Areas Reserved for Domestic Investors, Regulation No. 270/2012, which provides for tariff-free imports of capital goods for investment.

National investment policies often allow the tariff-free importation of goods required for local bio-manufacturing and R&D – but this is usually limited to new investment projects and capital goods required at an initial stage of investment. In other words, tariff-free importation may not extend to all capital goods, spare parts, and consumable inputs that are required thereafter. Moreover, investment regulations may limit the transfer of capital goods that have been imported tariff-free, unless the recipient is either another eligible investor or willing to pay the original tariffs.

Beyond tariff exemptions, national investment policies can support local production through a variety of measures aimed at facilitating effective technology partnerships. Investment policies should acknowledge the essential role played by foreign investors in transferring pharmaceutical technology and related know how. As a technologically intensive sector, investment in the pharmaceutical sector may involve, inter alia, the transfer of formulation technology and know-how, and the assignment and licensing of intellectual property.

Beyond tariff exemptions, national investment policies can support local production through a variety of measures aimed at facilitating effective technology partnerships.

Contracts to set up local bio-production facilities are generally accompanied by ongoing technology transfer and consulting services. This is of critical importance to developing countries, because it helps to ensure that local producers have access to know-how, the facility is efficient, and the products are of assured quality and can achieve full regulatory compliance. The process leads to better scientific and technical capacity over time, with the ability to target local health challenges that may not capture the attention of global R&D operations.

A national investment regime can promote technology partnerships for example by:

- Enabling deeper liberalisation of the sector across the value chain, including laboratory and training services, in addition to the manufacturing segment of the sector; as well as by removing barriers, such as requirements related to minimum capital, joint-venture, etc.;
- Expanding the investment incentives beyond the initial stages of investment, including providing incentives for local producers to invest in upgrading facilities to comply with current good manufacturing practices; introduce state of the art equipment and R&D input, and training of personnel;
- Providing incentives for investment across the value chain, including for firms that undertake research, clinical trials, or provide services in engineering, training and skills development and laboratory;
- Facilitating in-kind contributions and intellectual property licensing; and
- Allowing and facilitating movement of skilled labor.

Evidence shows that, at all levels, national production activities rely on imported inputs ranging from equipment to consumable inputs, from packaging materials to chemicals. This drives home the importance of appropriate trade policies alongside other government action, such as support for scientific research and improvements in the regulatory system.

Table 1 below, derived from UNCTAD's Tool Box, illustrates how domestic companies can move up the bio-pharmaceutical value chain over time, often in collaboration with foreign technology partners. WHO and UNCTAD have published case studies illustrating how in the real economy this process unfolds in countries across regions.[15] Evidence shows that, at all levels, national production activities rely on imported inputs ranging from equipment to consumable inputs, from packaging materials to chemicals. This drives home the importance of appropriate trade policies alongside other government action, such as support for scientific research and improvements in the regulatory system.

Table 1: Progressing from Level 1 to Level 5 along the Pharma Value Chain

Level 1: Import
• Distribution of imported finished pharmaceutical products • Produced under national or international GMP standards in country of manufacture
Level 2: Packaging and Labelling
• Packaging and labelling of imported bulk finished pharmaceutical products • Following national or international GMP standards
Level 3: Product Manufacturing
• Formulation of finished products from imported active pharmaceutical ingredient (API) and excipients
Level 4: API Manufacturing
• Production of active pharmaceutical ingredients and excipients • Following national or international GMP standards
Level 5 Research & development (R&D)
• Research and development for new formulations, processes and new chemical entities • Following national or international GLP/GCP and ethical standards

Source: UNCTAD Tool Box for Policy Coherence in Access to Medicines and Local Pharmaceutical Production

15 See references above, footnotes 6 and 7.

Ultimately, beyond supplying the domestic market, producers in emerging countries become competitive to the point they can contest regional and global markets. This is already the case for producers of bio-pharmaceuticals in a range of emerging countries – and there is significant growth potential, as well as public health needs. Developing countries, least developed countries (LDCs), and transition economies are home to 85 per cent of the world population and yet they only account for 20 per cent of exports of health technologies.[16]

POLICY COHERENCE: TARIFFS AND TRADE POLICIES

Many factors contribute to an enabling policy environment for biologics R&D and production. This section argues that, all things equal, the imposition of tariffs on production inputs can set back efforts to cultivate a domestic bio-manufacturing sector. This is because they raise costs for fledgling producers.

UNCTAD recommends that countries support public-private partnerships that advance local manufacturing by taking the following types of measures: (1) maintain effective national regulatory authorities to support quality control; (2) ensure predictable procurement, and thus improve market certainty; (3) support technology providers in identifying local partners; (4) ensure policy coherence and an appropriate enabling policy environment for local production; (5) invest in needed physical infrastructure.[17]

> Appropriate policy enabling environments are critical to the success of projects to localize R&D and production.

One important aspect of policy coherence is the identification and removal of border measures that could unnecessarily drive up production costs for local manufacturers. This makes sense from an industrial policy as well as fiscal perspective. A recent study found that the "sum of tariff-induced premiums on final prices for pharmaceuticals paid for by governments tends to exceed the tariff revenues initially collected by these governments' customs authorities."[18] This is because the final price of the pharmaceuticals includes mark-ups for importers, wholesalers, and retailers, calculated from the factory price, and the

16 WTO, WIPO and WHO, "Promoting Access to Medical Technologies and Innovation", 2013, available at: https://www.wipo.int/policy/en/global_health/trilateral_cooperation.html.

17 See UNCTAD, "Tool Box."

18 Bauer, Matthias, "The compounding effect of tariffs on medicines: Estimating the real cost of emerging markets' protectionism," European Centre for International Political Economy (ECIPE), ECIPE Policy Brief No. 1/2017, September 2017, available at: https://ecipe.org/publications/the-compounding-effect-of-tariffs-on-medicines-estimating-the-real-cost-of-emerging-markets-protectionism/.

added costs of tariffs increase the price along the distribution channels.[19] In addition, customs procedures and documentations entail administrative costs.

We note that WHO Member States have already identified tariffs and trade policies in the Global Strategy and Plan of Action (GSPOA) as an area requiring further attention, in order to support local manufacturing activities aimed at improving availability of treatment and other healthcare technologies.

BOX 2: WHO GLOBAL STRATEGY AND PLAN OF ACTION

"Several factors contribute to the price of health products and medical devices, and public policies should address these factors to increase their affordability and accessibility. Among others, competition and reduction or elimination of import tariffs on these products and devices can contribute to the reduction of prices. Countries should monitor carefully supply and distribution chains and procurement practices to minimize costs that could adversely influence the price of these products and devices."

Source: WHO Global Strategy and Plan of Action on Public health, Innovation, and Intellectual Property[20]

The following section provides some indication of the scale of tariffs imposed on certain inputs, processing and packaging materials for bio-manufacturing, by countries worldwide with significant potential for local production. These inputs represent consumables used for bio- manufacturing and R&D, as opposed to equipment imported to set up a facility (which, as noted above, is often tariff-free depending on the country's investment regime). In some cases, no tariffs are imposed.

An important facilitator of bio-manufacturing, tariff elimination should be considered across the board for bio-manufacturing inputs, including those used also by other industries. Many countries analyzed for this working paper have expressed an intention to expand the local production of health technologies. While it may be difficult politically to eliminate tariffs, because they provide a revenue stream, economic and health considerations arguably warrant moves in this direction.

19 According to the International Finance Corporation (IFC) of the World Bank Group, the average price mark-ups for medicines in emerging markets are at least 25 per cent for importers, wholesalers, sub-wholesalers and finally for retailers. See IFC, "Private Sector Pharmaceutical Distribution and Retailing in Emerging Markets: Making the Case for Investment," 2017, 11 (Figure 5), available at: https://www.ifc.org/wps/wcm/connect/d723b362-7ba7-4019-8652-c7b37cb5a803/Pharma+Distribution+%26+Retailing_FINAL.pdf?MOD=AJPERES&CVID=lFI9Mea.

20 WHO, "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property," 2011, available at: https://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf?ua=1.

TARIFFS ON BIO-MANUFACTURING AND R&D INPUTS

Many countries are seeking to establish and expand their bio-manufacturing capacity, in line with health and health security, economic development, and other objectives. At the same time, the reality is that most countries still import significantly more bio-pharmaceutical products than they export.

Complicating the establishment of pharmaceutical and bio-manufacturing infrastructure is the fact that imports are often subject to tariffs and other border measures (e.g. licenses, distribution and regulatory charges). In the real economy, the development and production of final and intermediate pharmaceutical products is organized into regional and global value chains. Thus, border measures can have a substantial impact on the cost structure for producers and on the cost of final goods, to the detriment of healthcare systems and, ultimately, patients.

Below we provide a snapshot of the tariffs affecting local bio-manufacturing, drawing on input by the private sector as well as certain products listed as pharmaceutical products used in the World Trade Organization (WTO) "Zero-for-Zero" initiative.[21] The analysis addresses tariffs on inputs for the manufacture of bio-pharmaceuticals and on final products (see Annex).[22]

International trade in products for bio-pharmaceutical production is highly concentrated, with a few countries responsible for a large share in global trade. Based on a dataset of WTO notifications and information by the UN Statistical Division, we observe that global trade of bio-pharmaceutical products reached more than USD 400 billion in 2019.[23] Over the last 20 years, overall trade in these products has shown compound annual growth rates of more than 10 per cent, and even higher growth rates when only considering the imports of developing countries.

Analysis of trade flows of products that are essential for the production of bio-pharmaceuticals shows that exports are very concentrated among a few countries, with 43 per cent of global exports originating in Asian countries, including China, Japan, Korea, India.[24] This global share of exports is followed by exports of the European Union and Switzerland, exporting around 33 per cent. Europe is followed by Northern America, including

21 This initiative was launched in 1994 by the European Communities, Canada, Japan, Norway, Macao (China), Switzerland and the United States of America.

22 Tariff and non-tariff measures affecting trade of pharmaceutical products are very diverse and many of the same inputs are used for the development and manufacture of biologics as for pharmaceuticals. Many intermediate products that are traded are inputs to the production of higher value-added treatments. And many products and chemical ingredients used in the pharmaceutical (including biologics) industry are also used elsewhere in sectors that are related to healthcare technologies production. There is some complexity, therefore, in quantifying trade in pharmaceutical products and identifying the most problematic tariffs on inputs. Despite this, we were able to identify a list of inputs that we can point to as relevant to bio-manufacturing.

23 UNSD Comtrade, http://comtrade.un.org, 2019 or latest available year, EU intra-trade excluded. See Table 2.

24 Ibid.

the United States, Canada, and Mexico, and reaching a global export share of more than 19 per cent.[25]

Regarding imports, Asia accounts for 39 per cent of global trade of bio-pharmaceutical products, followed by North America which account for about 25 per cent and Europe for about 22 per cent of global trade of such products. South and Central America and the Caribbean account for 5 per cent, and Africa 3 per cent.[26]

Despite the increasing trade in bio-pharmaceutical products, including biologics, in many countries customs duties are still an important trade barrier, affecting both the domestic manufacturing and the domestic availability of final products.

We analyzed tariffs imposed on products specific to biologics manufacturing and R&D activities. The following table presents our findings for a number of economies, providing their corresponding average WTO Most Favored Nation (MFN) applied tariff and the highest tariff for a product found within the categories we analyzed (Annex).

25 Ibid.

26 Ibid.

Table 2: Trade in products for bio-pharmaceutical production, 2019

WTO Most Favored Nations (MFN) average and maximum tariffs ranked by region and import value

Region	Country/territory	Average MFN duty	Maximum MFN duty	Trade in $US million		Global import rank
				Imports	Exports	
World total				424,661	404,080	
Africa	South Africa	1.1	20	2,432	2,473	26
Africa	Egypt	2.7	20	2,241	120	27
Africa	Morocco	4	25	1,327	115	35
Africa	Nigeria	5.7	35	696	16	40
Africa	Tunisia	1.2	20	629	288	42
Africa	Zambia	4.8	25	402	37	51
Africa	Kenya	2.1	25	399	28	52
Africa	Angola	1.7	50	267	15	57
Africa	Uganda	2.1	25	245	9	59
Africa	Ghana	5.7	35	236	7	61
Asia	China	5.2	15	52,475	68,143	3
Asia	Japan	1.3	5.1	20,509	27,191	4
Asia	Korea, Republic of	4.7	50	15,962	19,414	6
Asia	India	9.5	30	14,583	7,311	8
Asia	Singapore	0	0	9,823	14,637	10
Asia	Hong Kong, China	0	0	9,017	8,808	12
Asia	Viet Nam	1.1	17	7,435	3,173	14
Asia	Australia	1.3	5	7,030	1,911	15
Asia	Thailand	1.1	10	6,517	4,210	16
Asia	Chinese Taipei	2.8	8	6,515	9,049	17
Asia	Malaysia	1.3	20	5,084	7,765	19
Asia	Indonesia	4.5	20	4,169	1,017	20
Asia	Philippines	2.3	15	2,569	745	24
Asia	Cambodia	7.6	35	196	9	66
Com. of Independent States (CIS)	Russian Federation	3.1	6.5	7,479	2,183	13
Com. of Independent States (CIS)	Ukraine	2.2	10	1,820	191	30
Com. of Independent States (CIS)	Kazakhstan	3	6.5	845	32	38
Europe	EU	3.7	6.5	71,873	113,189	2
Europe	Switzerland	0.4	4.4	15,260	20,867	7
Europe	Turkey	4	7	5,811	1,245	18
Europe	Norway	0	0	2,468	2,204	25
Middle East	Saudi Arabia, Kingdom of	4.2	20	3,369	1,283	21
Middle East	United Arab Emirates	3.8	5	2,888	1,780	22
Middle East	Israel	0.7	12	2,017	1,635	28
North America	United States of America	2.2	6.5	78,545	65,089	1
North America	Mexico	1.9	15	16,047	6,624	5
North America	Canada	2.1	270	11,568	6,633	9
South/Central America, Caribbean	Brazil	6.8	18	9,348	1,305	11
South/Central America, Caribbean	Argentina	6.8	25	2,672	185	23
South/Central America, Caribbean	Colombia	1.4	15	1,543	130	31
South/Central America, Caribbean	Chile	6	6	1,419	103	33
South/Central America, Caribbean	Peru	0.3	6	917	31	36
South/Central America, Caribbean	Dominican Republic	1.2	20	628	102	43
South/Central America, Caribbean	Ecuador	2.5	20	525	15	46
South/Central America, Caribbean	Costa Rica	0.5	14	493	123	48

Sources: Tariff data: WTO Data Portal, ***http://data.wto.org***, including non-ad-valorem equivalents (AVEs), 2020 or latest available year

Trade data: UNSD Comtrade, ***http://comtrade.un.org***, 2019 or latest available year, EU intra-trade excluded.

Despite a general trend of decreasing tariffs on finished products and inputs for the bio-pharmaceutical industry, some countries still show substantial average customs duties across all products relevant for the development and production of bio-pharmaceuticals. Average tariffs in South and Central America and the Caribbean reached 3.6 per cent, in Asia 4.3 per cent, and in African countries 4.9 per cent. Despite relatively low average customs duties on bio-pharmaceutical products across regions, some products are subject to customs duties of 25 per cent or more in countries such as Angola, Ghana, and Nigeria in Africa, the Republic of Korea, Cambodia and India in Asia, or Argentina in Southern, Central and Northern America.[27] Those high tariffs, imposed on individual bio-pharmaceutical products and the inputs for their manufacture and R&D, can have a direct trade impact by increasing the local cost of production – and thus prices – accordingly.

At all levels, customs duties can discourage domestic production and integration into regional and global value chains, reducing local competitiveness and potentially causing local prices to rise. Given the potential of bio-manufacturing and R&D to improve health security and delivery of healthcare in the coming years, this is a topic of relevance to health officials, as well as trade and industry officials. The experience to date of the current pandemic simply drives home this point.

FINAL THOUGHTS

Broader investments in bio-manufacturing and R&D activities globally – and the establishment of appropriate enabling policies to support such activities – have the potential to greatly enhance healthcare delivery and outcomes across the globe. Needless to say, the COVID-19 pandemic has underscored the general need for such improvements. Recent developments in technology make it possible to build bio-infrastructure more quickly and cheaply than ever before, and it is crucial that the global community take full advantage of this potential, in order to better manage future health crises. The establishment of bio-pharmaceuticals production and R&D capacity in a broader range of countries could enhance supply chain resilience, thus improving healthcare delivery and health security.

This paper highlights the potential for more bio-manufacturing and R&D activities in LMICs, in light of the rising value of bio-pharmaceuticals in global trade and given that most countries are currently importing them. It focuses on policy coherence as an important enabler of efforts to broaden bio-infrastructure globally, looking specifically at trade policies as an illustrative example. It provides evidence about tariffs on inputs for the development and production of bio-pharmaceuticals, and sets forth the observation that the imposition of tariffs may be at odds with aspirations among LMICs to establish bio-infrastructure and scale capacity in this area over time.

27 The maximum MFN duty for Canada refers is applied to "milk protein substances" (tariff line 350400) with a corresponding out-quota duty of "270% but not less than $3.15/kg."

"The medical need for biopharmaceuticals is growing – and so are the barriers to entry to develop and manufacture them. Action is urgently needed to address prohibitive costs for manufacturers and innovators in LMICs, to ensure we can contribute to global preparedness for the next pandemic."
-Biovac, South Africa

ANNEX: BIO-PHARMACEUTICAL PRODUCTS AND THEIR MANUFACTURING INPUTS INCLUDED IN THE ANALYSIS

HS 2017	Product description
282739	Chlorides (excl. ammonium, calcium, magnesium, aluminium, nickel and mercury chloride)
283699	Carbonates and peroxocarbonates "percarbonates"; commercial ammonium carbonate containing ammonium carbamate (excl. disodium carbonate, sodium hydrogencarbonate "sodium bicarbonate", potassium carbonates, calcium carbonate, barium carbonate, lithium carbo
284590	Non-radioactive isotopes; inorganic or organic compounds of such isotopes, whether or not chemically defined (excl. heavy water "deuterium oxide")
285000	Hydrides, nitrides, azides, silicides and borides, whether or not chemically defined (excl. compounds which are also carbides of heading 2849, and inorganic or organic compounds of mercury whether or not chemically defined)
290110	Saturated acyclic hydrocarbons
290129	Hydrocarbons, acyclic, unsaturated (excl. ethylene, propene "propylene", butene "butylene" and isomers thereof and Buta-1,3-diene and isoprene)
290290	Cyclic hydrocarbons (excl. cyclanes, cyclenes, benzene, toluene, xylenes, styrene, ethylbenzene and cumene)
290559	Halogenated, sulphonated, nitrated or nitrosated derivatives or acyclic alcohols (excl. ethchlorvynol "INN")
290613	Sterols and inositols
290719	Monophenols (excl. phenol "hydroxybenzene" and its salts, cresols and their salts, octylphenol, nonylphenol and their isomers and salts thereof and naphthols and their salts)
290729	Polyphenols and phenol-alcohols (excl. resorcinol and hydroquinone "quinol" and their salts, and 4,4'-isopropylidenediphenol "bisphenol A, diphenylolpropane" and its salts)

291531	Ethyl acetate
291560	Butanoic acids, pentanoic acids, their salts and esters
291590	Saturated acyclic monocarboxylic acids, their anhydrides, halides, peroxides and peroxyacids; their halogenated, sulphonated, nitrated or nitrosated derivatives (excl. formic acid and acetic acid, mono-, di- or trichloroacetic acids, propionic acid, butan
291614	Esters of methacrylic acid
291711	Oxalic acid, its salts and esters (excl. inorganic or organic compounds of mercury)
291739	Aromatic polycarboxylic acids, their anhydrides, halides, peroxides, peroxyacids and their halogenated, sulphonated, nitrated or nitrosated derivatives (excl. esters of orthophthalic acid, phthalic anhydride, terephthalic acid and its salts and dimethyl t
291821	Salicylic acid and its salts (excl. inorganic or organic compounds of mercury)
292090	Esters of inorganic acids of non-metals and their salts; their halogenated, sulphonated, nitrated or nitrosated derivatives (excl. esters of hydrogen halides, phosphoric esters, phosphite esters, and thiophosphoric esters "phosphorothioates", their salts
292119	Acyclic monoamines and their derivatives; salts thereof (excl. methylamine, dimethylamine, trimethylamine, and their salts)
292129	Acyclic polyamines and their derivatives; salts thereof (excl. ethylenediamine and hexamethylenediamine, and their salts)
292142	Aniline derivatives and their salts
292159	Aromatic polyamines and their derivatives; salts thereof (excl. o-phenylenediamine, m-phenylenediamine, p-phenylenediamine or diaminotoluenes and their derivatives, and salts thereof)
292229	Amino-naphthols and other amino-phenols, their ethers and esters; salts thereof (excl. those containing > one kind of oxygen function; aminohydroxynaphthalenesulphonic acids and their salts)
292250	Amino-alcohol-phenols, amino-acid-phenols and other amino-compounds with oxygen function (excl. amino-alcohols, amino-naphthols and other amino-phenols, their ethers and esters and salts thereof, amino-aldehydes, amino-ketones and amino-quinones, and salt

HS 2017	Product description
292390	Quaternary ammonium salts and hydroxides (excl. choline and its salts, tetraethylammonium perfluorooctane sulphonate and didecyldimethylammonium perfluorooctane sulphonate)
292419	Acyclic amides, incl. acyclic carbamates, and their derivatives, and salts thereof (excl. meprobamate [INN], fluoroacetamide [ISO], monocrotophos [ISO] and phosphamidon [ISO])
292429	Cyclic amides, incl. cyclic carbamates, and their derivatives; salts thereof (excl. ureines and their derivatives, salts thereof, 2-acetamidobenzoic acid "N-acetylanthranilic acid" and its salts, ethinamate "INN" and alachlor "ISO")
292529	Imines and their derivatives; salts thereof (excl. chlordimeform [ISO])
292690	Nitrile-function compounds (excl. acrylonitrile, 1-cyanoguanidine "dicyandiamide", fenproporex "INN" and its salts, methadone "INN"-intermediate "4-cyano-2-dimethylamino-4,4-diphenylbutane" and alpha-Phenylacetoacetonitrile)
293090	Organo-sulphur compounds (excl. thiocarbamates and dithiocarbamates, thiuram mono-, di- or tetrasulphides, methionine, 2-(N,N-Diethylamino)ethanethiol, Bis(2-hydroxyethyl)sulfide (thiodiglycol (INN)), aldicarb [ISO], captafol [ISO] and methamidophos [ISO]
293139	Separate chemically defined organo-phosphorous derivatives, n.e.s.
293190	Separate chemically defined organo-inorganic compounds (excl. organo-sulphur, mercury, tetramethyl lead, tetraethyl lead and tributyltin compounds, and organo-phosphorous derivatives)
293220	Lactones
293299	Heterocyclic compounds with oxygen hetero-atom[s] only (excl. compounds containing unfused furan ring, whether or not hydrogenated, in the structure, and lactones, isosafrole, 1-[1,3-benzodioxol-5-yl]propan-2-one, piperonal, safrole, tetrahydrocannabinols
293329	Heterocyclic compounds with nitrogen hetero-atom[s] only, containing an unfused imidazole ring, whether or not hydrogenated, in the structure (excl. hydantoin and its derivatives, and products of subheading 3002 10)
293359	Heterocyclic compounds with nitrogen hetero-atom[s] only, containing a pyrimidine ring, whether or not hydrogenated, or piperazine ring in the structure

	(excl. malonylurea "barbituric acid" and its derivatives, allobarbital "INN", amobarbital "INN", barbi
293379	Lactams (excl. 6-hexanelactam "epsilon-caprolactam", clobazam "INN", methyprylon "INN", and inorganic or organic compounds of mercury)
293399	Heterocyclic compounds with nitrogen hetero-atom[s] only (excl. those containing an unfused pyrazole, imidazole, pyridine or triazine ring, whether or not hydrogenated, a quinoline or isoquinoline ring-system, not further fused, whether or not hydrogenate
293410	Heterocyclic compounds containing an unfused thiazole ring, whether or not hydrogenated, in the structure
293499	Nucleic acids and their salts, whether or not chemically defined; heterocyclic compounds (excl. with oxygen only or with nitrogen hetero-atom[s] only, compounds containing in the structure an unfused thiazole ring or a benzothiazole or phenothiazine ring-
300212	Antisera and other blood fractions
300220	Vaccines for human medicine
300230	Vaccines for veterinary medicine
340213	Non-ionic organic surface-active agents, whether or not put up for retail sale (excl. soap)
350400	Peptones and their derivatives; other protein substances and their derivatives, n.e.s.; hide powder, whether or not chromed (excl. organic or inorganic compounds of mercury whether or not chemically defined)
350790	Enzymes and prepared enzymes, n.e.s. (excl. rennet and concentrates thereof)
380210	Activated carbon (excl. medicaments or deodorant products for fridges, vehicles etc., put up for retail sale)
382100	Prepared culture media for the development or maintenance of micro-organisms "incl. viruses and the like" or of plant, human or animal cells

HS 2017	Product description
382200	Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, and certified reference materials (excl. compound diagnostic reagents designed to be administered to the patient, blood-grouping reagents
390390	Polymers of styrene, in primary forms (excl. polystyrene, styrene-acrylonitrile copolymers "SAN" and acrylonitrile-butadiene-styrene "ABS")
390599	Polymers of vinyl esters and other vinyl polymers, in primary forms (excl. those of vinyl chloride or other halogenated olefins, poly"vinyl acetate", vinyl acetate copolymers and poly"vinyl alcohol", whether or not containing unhydrolised acetate groups)
390720	Polyethers, in primary forms (excl. polyacetals and goods of 3002 10)
391400	Ion-exchangers based on polymers of heading 3901 to 3913, in primary forms
391733	Flexible tubes, pipes and hoses of plastics, not reinforced or otherwise combined with other materials, with fittings, seals or connectors
391740	Fittings, e.g. joints, elbows, flanges, of plastics, for tubes, pipes and hoses
392119	Plates, sheets, film, foil and strip, of cellular plastic, unworked or merely surface-worked or merely cut into squares or rectangles (excl.those of polymers of styrene, vinyl chloride, polyurethanes and regenerated cellulose, self-adhesive products, floo
392690	Articles of plastics and articles of other materials of heading 3901 to 3914, n.e.s (excl. goods of 9619)
842129	Machinery and apparatus for filtering or purifying liquids (excl. such machinery and apparatus for water and other beverages, oil or petrol-filters for internal combustion engines and artificial kidneys)
842139	Machinery and apparatus for filtering or purifying gases (excl. isotope separators and intake air filters for internal combustion engines)
842191	Parts of centrifuges, incl. centrifugal dryers, n.e.s.
842199	Parts of machinery and apparatus for filtering or purifying liquids or gases, n.e.s.
847982	Mixing, kneading, crushing, grinding, screening, sifting, homogenising, emulsifying or stirring machines, n.e.s. (excl. industrial robots)

847989	Machines and mechanical appliances, n.e.s.
847990	Parts of machines and mechanical appliances, n.e.s.
854140	Photosensitive semiconductor devices, incl. photovoltaic cells whether or not assembled in modules or made up into panels; light emitting diodes (excl. photovoltaic generators)
901110	Stereoscopic optical microscopes
901180	Optical microscopes (excl. for photomicrography, cinephotomicrography or microprojection, stereoscopic microscopes, binocular microscopes for ophthalmology and instruments, appliances and machines of heading 9031)
901210	Electron microscopes, proton microscopes and diffraction apparatus
902750	Instruments and apparatus for physical or chemical analysis, using UV, visible or IR optical radiations (excl. spectrometers, spectrophotometers, spectrographs, and gas or smoke analysis apparatus)
902780	Instruments and apparatus for physical or chemical analysis, or for measuring or checking viscosity, porosity, expansion, surface tension or the like, or for measuring or checking quantities of heat, sound or light, n.e.s.
902790	Microtomes; parts and accessories of instruments and apparatus for physical or chemical analysis, instruments and apparatus for measuring or checking viscosity, porosity, expansion, surface tension or the like, instruments and apparatus for measuring

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