Global Counsel

The policy case for a Trade in Healthcare Agreement

Beyond the IP impasse in global trade and public health at the WTO

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Foreword

In the wake of the COVID-19 pandemic, strengthening global health security has emerged as a core theme of multilateral policymaking. COVID-19 has embedded health security – including our ability to deliver emergency medical countermeasures rapidly on a global scale - firmly in our concept of global security.

As has been widely noted, the experience of COVID-19 demonstrated the way that global supply chains and distribution networks are integral to delivering health security objectives. Throughout the COVID-19 crisis, both pre-existing and new supply chain infrastructure absorbed steep demand-increases to ensure essential therapeutics, vaccines, and diagnostics were developed, manufactured and distributed to patients worldwide. Ultimately, 11.5 billion doses of COVID-19 vaccines were delivered in less than two years. COVID-19 produced numerous examples of local innovation and resilience, but no individual country beat COVID-19: the world did.

Nevertheless, the pandemic exposed some important weaknesses in the global trading system and in the WTO Membership's capacity to convene around practical action. Over the course of the pandemic, many governments imposed restrictions on exports of medical supplies and blocked exports of finished goods. Against the urgency of the crisis, the fact that many critical medical supplies are still subject to tariffs despite the statement of intent represented by the 1994 WTO Pharmaceutical Agreement and still face burdensome customs requirements seem obvious problems to address.

This GC insight paper seeks to draw lessons from the pandemic experience and suggests concrete steps in which WTO Members might use the global trading system to better equip the world to respond to the next health crisis. In doing this it draws on the under-reported deliberations of WTO Members themselves, many of whom have provided thoughtful post-crisis critiques in Geneva of the way the trading system might learn from COVID-19. Yet in the wider public debate this analysis has too often simply been reduced to a debate about intellectual property rights. This paper seeks to amplify that deeper reflection.

The 13th WTO Ministerial Conference (MC13) in early 2024 is an important opportunity to put the WTO at the service of global health security. MC12 failed to produce binding commitments to pandemic response. The next Ministerial should not reproduce this failure. The policy space and opportunity still exist to translate the loose principles that emerged at MC12 - and have been debated since in Geneva - into binding commitments at MC13. Despite the parallel and intense negotiations at the World Health Organization to deliver a Pandemic Accord, there is no similar effort among WTO Members. Using the convening power of February's ministerial to explore the potential for a plurilateral Trade in Healthcare Agreement amongst like-minded Members is an appropriate place to start.

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Executive summary

The debate about the lessons learned for trade and global health security during the COVID-19 pandemic started before the crisis was even over. Despite the overwhelming focus in the media and in much of public debate on changes to intellectual property rules as part of a pandemic response, WTO Members have in fact engaged in a much more wide-ranging reflection about how the WTO system might have worked better during the pandemic. The impasse on IP has in large part acted as a check on taking that wider debate further.

This short paper seeks to amplify and contribute to that debate. It also takes the additional step of connecting its emerging conclusions to a set of practical steps WTO Members might now take to turn those reflections into concrete and practical changes to prepare the international trading system for a future health crisis.

CRISIS PROBLEMS, POLICY SOLUTIONS

CRISIS EXPERIENCE	AGREEMENT PILLAR
Disproportionate or poorly targeted export restrictions	**Export restrictions.** WTO Members should adopt a joint declaration to review and eliminate unnecessary existing restrictions on medical exports; refrain from imposing new export restrictions; and ensure that any restrictive measures deemed necessary are implemented in such a way that is consistent with WTO obligations and principles outlined in Article XI of the GATT.
Weak mechanisms for coordination or sharing best practices	**Regulatory cooperation and capacity building.** WTO Members should adopt a joint declaration to share best practices across borders, adopt the highest standards into domestic regulation and cooperate in international fora. They should also design and implement formal capacity building programmes, ideally as part of their WTO Aid for Trade strategies and widen the use of mutual recognition and equivalence frameworks to support cross-border sourcing and supply.
Tariff costs on imported medicines and inputs	**Tariff liberalisation.** WTO Members should eliminate tariffs on finished medicines and vaccines, as well as the raw materials, chemicals, inputs, and equipment used to make them. This can be achieved through expanding the scope and membership of the WTO Pharmaceutical Agreement and unilaterally reducing MFN tariffs on a non-discriminatory basis.
Administrative import burdens on essential and other goods	**Trade Facilitation.** WTO Members should improve trade facilitation measures at the border based on lessons learned from the COVID-19 pandemic. This should be done by establishing best practices, devising and publishing national trade facilitation plans, and fully implementing the WTO Trade Facilitation Agreement (TFA).
Administrative obstacles to rapid medicines deployment	**Open public procurement.** WTO Members should make clear commitments to non-discrimination between foreign and domestic suppliers in the life sciences sector. This should be done by WTO Government Procurement Agreement (GPA) signatories adopting a joint declaration to this effect and encouraging other countries to join the GPA.

The trade and health agenda after covid-19

The COVID-19 pandemic produced a wide range of views on the role of trade policy in enabling resilient pandemic planning and effective mechanisms to make and distribute vital medicines and vaccines. However, in practice, what began as a broad spectrum of ideas was pared down to the agreement reached at the WTO in 2022 to waive commitments to protect certain IP for COVID-19 vaccines.

This outcome (the TRIPS Decision[1]) dominated MC12 and negotiations continue over the possibility of extending the Decision beyond vaccines, to cover COVID-19-related therapeutic and diagnostic products. But the focus on IP as the central pillar of a WTO response to the pandemic is increasingly difficult to justify. This is because IP-centred proposals have only succeeded in capturing the debate to date by marginalising alternative and viable policy pathways.

By the same token, seeking changes to IP frameworks is a short-sighted political aim because it centres solely on a contentious area and monopolises negotiating bandwidth. These factors have arguably driven suboptimal policy outcomes to date. For example, the TRIPS Decision took 20 months to agree and resulted in a narrow instrument that only clarifies existing flexibilities and came into effect during a period of "vaccine abundance".[2]

At the time of this paper's publication in December 2023, no WTO Member had notified its intent to use the flexibilities in the TRIPS Decision. This fact must raise the question as to the purpose of both the initial Decision and ongoing expansion initiatives and whether resources should have been re-directed to other proposals to improve patient access during the pandemic.

If the core question driving current negotiations is: can multilateral frameworks that address the inequity experienced during the pandemic be implemented whilst preserving the innovation model that delivered solutions? Then the answer is yes. But solutions that command consensus will not be located by focusing on IP, as has been the case to date.

As noted above, throughout the pandemic, the WTO and its Members undertook important work to locate and reduce trade barriers that impeded access to COVID-19 critical products. This included identifying regulatory and production bottlenecks, manufacturing and input constraints, quantitative restrictions, tariff barriers and exposing the logistical complexities associated with vaccine deployment. In this respect, an obvious shortcoming of MC12 must be recognised in its failure to translate this extensive evidence base into tangible solutions and binding commitments.

Instead, political deadlock diminished the ability and appetite of the Membership to address the well-established technical and logistical barriers that contributed to pandemic-related inequity. It is unfortunate that in the process a single issue – the TRIPS Decision – became linked to the institutional credibility of the WTO. Ultimately, this resulted in a missed opportunity to exploit the urgency and momentum the pandemic generated to address other trade-related issues that are integral to the WTO's *raison d'etre*.

Nevertheless, it is possible to locate common ground in this fractious debate. And this is where future efforts should now focus.

This paper does not contest that the pandemic exposed health inequity or that the WTO has struggled to provide solutions to respond to global

1. "Ministerial Decision on the TRIPS Agreement (Adopted June 17, 2022)," World Trade Organization, June 22, 2022.
2. "World Trade Organization General Council, July 2022: UK statements," UK Foreign, Commonwealth & Development Office, August 9, 2022

health emergencies. What it argues is that the key to harnessing momentum lies in addressing the multitude of trade barriers that continue to hamper efforts to improve global health equity. It is in this spirit that this paper proposes a plurilateral Trade in Healthcare Agreement (THA) as a means of partially bridging the gap to consensus that has evaded WTO Members to date and unlock progress in this vital area.

LESSONS TO LEARN

Reviewing the policy response to the crisis in an 'Experience Sharing Session[3]' in September 2022, under the auspices of the WTO Secretariat, WTO Members highlighted a number of lessons learned from the crisis.[4]

These included:

- The need for greater collaboration and transparency in identifying essential goods to limit the application of trade restricting measures and to allow trade-expediting measures to be targeted where they are necessary.[5]
- The value of lowering the costs of importing essential goods, both temporarily in a crisis but also permanently as a way to limit disruptions and facilitate trade in essential goods.[6]
- The value of streamlining or eliminating burdensome customs procedures for essential goods, and the wider adoption of digital tools for supply chain efficiency.[7]
- The value of developing forward-looking strategies for trade in a public health crisis that anticipate and address the pressures a crisis will place on the system.[8]
- The need to reassert the status of export restrictions as a tool of "last resort" that should be necessary, targeted, explicitly temporary and subject to formal review mechanisms.[9]

Recognising that this is not a consensus statement or formal statement of any individual WTO Member state's views, this paper picks up the implicit challenge in translating this assessment into viable policy proposals to take forward. It argues that the experience reflected in this analysis by WTO Members points to a way beyond any impasse on public health policy and trade. Converting these reflections from the crisis into practical policy recommendations demonstrates the potential for a plurilateral WTO Trade in Healthcare Agreement (THA) based on the following five core pillars (Table 1).

Many of these ideas were in fact raised in some form during the pandemic. The Ottawa Group's November 2020 'Trade and Health Initiative' raised the question of restraint in the use of export restrictions.[10] The May 2021 'COVID-19 And Beyond: Trade And Health' communication from 24 WTO Members outlined a series of measures designed to facilitate trade in essential medical goods.[11] The EU's June 2021 communication to the WTO on 'Urgent Trade Policy Responses to the COVID-19 Crisis' focused on trade facilitation, disciplining export restrictions, and facilitating the transfer of technology and know-how through voluntary licensing agreements.[12] The June 2022 Ministerial Declaration on the WTO response to current and future pandemics identified regulatory cooperation and trade facilitation, amongst others, as areas of key focus for future work.[13]

This emphasises the fact that there are a range of avenues for reshaping the global trading framework for medicines beyond the question of IP that would improve its capacity to deliver public health outcomes. Not all would be easy to deliver, but certainly none are less realistic than a further set of changes on global commitments to protect IP. All would be important practical increments for the system. Packaged as a new global Trade in Healthcare Agreement (THA), they would be an important way of channelling the experience of COVID-19 into a positive outcome for global healthcare. These ideas need to be revived, consolidated, and agreed.

3. WTO Secretariat, "Lessons learned from the experience-sharing sessions on trade in COVID-19 related goods (held of November 21, 2022)," World Trade Organization, December 14, 2022

4. Interestingly, this session did not make any reference for the need for further focus on IP rules.

5. Experience Sharing Session: Section 2

6. Experience Sharing Session: Section 4

7. Experience Sharing Session: Section 4

8. Experience Sharing Session: Section 3

9. Experience Sharing Session: Section 4

10. "Ottawa Group proposes a global Trade and Health Initiative," European Commission, November 23, 2020

11. "COVID-19 and Beyond: Trade and Health," World Trade Organization, July 15, 2021

12. European Commission, "Urgent Trade Policy Responses to the COVID-19 Crisis," World Trade Organization, June 4, 2021

13. "Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics," World Trade Organization, June 22, 2022

TABLE 1: CRISIS PROBLEMS, POLICY SOLUTIONS

CRISIS EXPERIENCE	AGREEMENT PILLAR
Disproportionate or poorly targeted export restrictions	**Export restrictions.** WTO Members should adopt a joint declaration to review and eliminate unnecessary existing restrictions on medical exports; refrain from imposing new export restrictions; and ensure that any restrictive measures deemed necessary are implemented in such a way that is consistent with WTO obligations and principles outlined in Article XI of the GATT.
Weak mechanisms for coordination or sharing best practices	**Regulatory cooperation and capacity building.** WTO Members should adopt a joint declaration to share best practices across borders, adopt the highest standards into domestic regulation and cooperate in international fora. They should also design and implement formal capacity building programmes, ideally as part of their WTO Aid for Trade strategies and widen the use of mutual recognition and equivalence frameworks to support cross-border sourcing and supply.
Tariff costs on imported medicines and inputs	**Tariff liberalisation.** WTO Members should eliminate tariffs on finished medicines and vaccines, as well as the raw materials, chemicals, inputs, and equipment used to make them. This can be achieved through expanding the scope and membership of the WTO Pharmaceutical Agreement and unilaterally reducing MFN tariffs on a non-discriminatory basis.
Administrative import burdens on essential and other goods	**Trade Facilitation.** WTO Members should improve trade facilitation measures at the border based on lessons learned from the COVID-19 pandemic. This should be done by establishing best practices, devising and publishing national trade facilitation plans, and fully implementing the WTO Trade Facilitation Agreement (TFA).
Administrative obstacles to rapid medicines deployment	**Open public procurement.** WTO Members should make clear commitments to non-discrimination between foreign and domestic suppliers in the life sciences sector. This should be done by WTO Government Procurement Agreement (GPA) signatories adopting a joint declaration to this effect and encouraging other countries to join the GPA.

Five pillars for a new global healthcare package

PILLAR 1. A NEW DECLARATION ON EXPORT RESTRICTIONS

At the height of the first wave of the COVID-19 pandemic, governments around the world resorted to trade-restricting measures in an attempt to prevent shortages of critical goods. By April 2020, a total of 145 export restrictions had been imposed on medical goods.

While the political instinct behind protecting national supply is clear enough, such restrictions also create mismatches between supply and demand, and disrupt supply chains. They can prevent those countries without manufacturing capacity in medicines from accessing treatments. They can encourage tit-for-tat behaviour that can lead to a cycle of negative reciprocity.

For example, in March 2020, India imposed a ban on the export of paracetamol and a number of other medicines. This led to restrictions on availability for patients and substantial price rises. As a result of the export restriction, UK pharmacy chain Boots imposed a limit of two items per customer on cough and cold medication, pain relief, children's medicines, thermometers, and tissues.

The harm caused by export restrictions is already acknowledged by WTO Members. The GATT establishes the fundamental principle that countries should avoid imposing quantitative restrictions on exports and Article XI imposes a general restriction on their use. While medicines in a time of crisis might be legitimately argued to meet the very narrow exception criteria under this provision, WTO Members must recognise the implications of their generalised use. Far from guaranteeing that states can "prevent or relieve critical shortages", restrictions can cause severe disruption to global supply chains and undermine trust between trading partners.

For these reasons, a new commitment from all WTO Members to **review and promptly eliminate unnecessary existing restrictions on medical exports** must be central to a Trade and Healthcare Agreement. WTO Members should also commit to **refraining from imposing new export restrictions** on medical goods, including vaccines and critical inputs.

While disciplining the use of unnecessary export restrictions must be at the heart of a new agreement, WTO `Members should also agree that any measures deemed necessary to prevent or relieve critical shortages are **implemented in such a way that is consistent with WTO obligations and principles**. This means that new measures must be:

- → implemented in a targeted, transparent, proportionate and temporary manner that is no longer than 90 days;
- → supported by evidence that the restriction will genuinely prevent or relieve the critical shortage, rather than exacerbate the supply problem, and will not create critical supply shortages in another state whose citizens are dependent on manufacturing in the first state;
- → notified to the WTO and published on a domestic website before the measure is in force – not in retrospect – to enable companies to take mitigating actions and adapt their supply chains;
- → extended only in exceptional circumstances that are supported by a strong evidence base and justified in the Member's notification to the WTO; and

- implemented in such a way that does not disrupt the provision of humanitarian shipments of essential medical goods, nor the work of international facilities in distributing vaccines or similar essential medicines.

PILLAR 2. REGULATORY COOPERATION AND CAPACITY BUILDING

Safety and reliability are fundamental to medicines. It is for this reason that medical goods are among the most regulated categories of goods in the world. Pharmaceutical products alone attract the highest number of non-tariff measures (NTMs) in the global trading system. In OECD countries, they must comply with 38 NTMs on average – chiefly in the form of technical barriers to trade (TBT), sanitary and phytosanitary measures (SPS), price-control measures, and import licensing measures.[14] While these standards and regulations ensure medicines are safe and effective, they also translate into compliance costs and controls at the border.

Regulatory complexity is always a challenge for global supply chains. It can impose duplicative requirements for companies that lead to unnecessary costs and delays. It can also impede supply chain flexibility where change to sourcing patterns means securing new regulatory authorisations.

To ensure supply chains remain as open and flexible as possible, both through and beyond times of crisis, WTO Members should commit to deepening regulatory cooperation and sharing best practices across borders. This can be done in three key ways.

First, WTO Members should adopt a joint declaration confirming their commitment to **sharing best practices** to support the regulation of medicines to the highest international standards; encouraging the **adoption of those standards in domestic regulation;** and deepening **cooperation on regulatory standards in international fora.**

Frameworks like the guidelines produced by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), the International Organization for Standardization (ISO), and the Good Manufacturing Practices (GMP) framework overseen by the World Health Organization (WHO) are all notable examples of the way in which both firms and governments have helped create international norms to inform and help converge regulatory practice.

Second, WTO Members should **design and implement formal capacity building programmes** to ensure regulators around the world are armed with the necessary capabilities. This will help to ensure that regulatory processes are as robust and expeditious as possible, regardless of the jurisdiction a company is operating in.

In particular, developed country WTO Members with strong records in GMP design, batch testing certification, clinical trials, and wider pharmaceutical regulation should make available capacity building support for less economically developed countries. This could be conducted through their WTO Aid for Trade strategies, which provide support for less economically developed countries to address trade-related constraints.[15]

Third, WTO Members should seek to **widen the use of mutual recognition or unilateral deference** for batch testing and GMP to support international supply chains and multi-country production models.

This may involve agreeing new Mutual Recognition Agreements (MRAs) between Members following the adoption of best practices into domestic regulation, such as the WHO's GMP framework, and/or a period of capacity building to develop domestic regulatory frameworks and skills. It could also involve opening up existing MRAs in areas like GMP, batch testing, and regulatory data to act as platforms for those meeting the exacting standards required. Such frameworks can also be applied unilaterally, as in the case of the UK and the EU, where London has chosen to extend unilateral measures to recognise batch testing of medicines in the EU, facilitating trade and reducing duplication.[16] In parallel, the UK has created bespoke "regulatory recognition routes" for medical products approved by specified regulators, allowing for an expedited review by the regulator.[17] In both cases the UK authorities retain the power to decide.

In the longer term, they will allow firms to better manage regulatory costs and ease the burden of complying with multiple regulatory regimes when moving goods around the world. This facilitates and expedites patient access to vital medicines. This will also ensure that developing countries can better integrate into global supply chains for medicines, and thereby strengthen the overall diversity and resilience of supply chains.

PILLAR 3. TARIFF LIBERALISATION – ON AN MFN BASIS

Every time a component of the life sciences supply chain crosses a border it is potentially subject to a tariff. These tariffs impose a direct cost on trade in medicines and pharmaceutical ingredients, as well as those conducting research and development (R&D) activities. Efforts to diversify manufacturing capacity and build capabilities across all jurisdictions must go hand in hand with tariff elimination.

14. "Using trade to fight COVID-19: Manufacturing and distributing vaccines," OECD, February 11, 2021
15. WTO, Aid for Trade
16. "MHRA announces new recognition routes to facilitate safe access to new medicines with seven international partners," GOV.UK, May 26, 2023.
17. "International Recognition Procedure," GOV.UK, August 30, 2023

The 1994 WTO Pharmaceutical Agreement eliminates tariffs on all finished medicines and some APIs for signatory countries.[18] However, unlike finished medicines, APIs and intermediates (inclusive of chemicals) that are used in the manufacture of medicines do not automatically qualify for zero tariffs. As this WTO-managed list has not been updated since 2010, many APIs used to produce the newest, most innovative medicines are subject to import tariffs. So too are the specialist transportation, storage, and laboratory equipment imperative for their safe shipping and preservation in transit.

According to the OECD, tariffs on vaccines exist in 22% of countries, with 8% applying duties above 5%.[19] These tariff costs are often hidden by the fact that they apply to raw materials and inputs, not necessarily the finished product. However, the average world tariff on vaccine ingredients such as preservatives, adjuvants, stabilisers, antibiotics range from 2.6% to 9.4%.[20]

To address this issue, WTO Members should commit to **eliminating tariffs on medicines and vaccines, as well as the wide range of raw materials, chemicals, inputs, and equipment** necessary to develop, manufacture and transport the final product. This should be done in two ways.

First, signatories should **expand the scope and Membership of the WTO Pharmaceutical Agreement.** For the agreement to keep pace with the realities of the modern-day biopharmaceutical sector, tariff elimination should be expanded to the following areas:

- → All APIs developed post-2010.
- → Components used in treatment delivery and measurement devices such as needles, demo pens and test medium.
- → All chemical compounds that are used in research and clinical trials listed within sections VI and VII of the Harmonised Tariff Schedule , with particular focus afforded to Chapter 30 (Pharmaceutical Products) as these relate to next generation biologics and cellular therapies.
- → Manufacturing production and R&D equipment, including blinded test kits and placebos used in specific research products.
- → Specialist transportation and storage machinery, including temperature-controlled storage.

Crucially, WTO Members that have not signed up to the agreement – such as China and India – should be encouraged to do so. Some WTO Members are likely to balk at this liberalisation of Chinese trade in particular. But inputs from China – often produced in part by non-Chinese firms in China – are a critical part of the manufacturing ecosystem of producers and lowering their costs would be a global good greater than any perceived advantage from denying Chinese-based exporters tariff liberalisation. China itself also imports more than $40bn in medicines annually, and applies tariffs to many of these imports.

Second, individual WTO Members who have not yet signed up to the agreement should strongly consider a **unilateral reduction or elimination of their MFN tariffs** on the same range of goods. They should pay special attention to existing tariffs on vaccine ingredients and inputs – and eliminate these as a matter of urgent priority.

While there is value in preferential liberalisation via Free Trade Agreements (FTAs), such preferential liberalisation can work against supply chain resilience and diversification, which is why Members should commit to eliminating MFN tariffs. This is especially the case where tariff-free trade is only possible when using narrow channels between the FTA partners determined by strict local content requirements enshrined in rules of origin (ROO) protocols. These create incentives to concentrate supply lines along 'preference channels', potentially creating added tariff costs if manufacturers are forced to switch to suppliers outside the preferential trade area.

Liberalisation is much more powerful when it is done on a unilateral basis, allowing importers to select and switch suppliers amongst the widest possible pool of global exporters without the added risks of additional tariff costs. It is most powerful of all when a large group of importers and exporters agree to implement that liberalisation in a simultaneous, coordinated way.

PILLAR 4. TRADE FACILITATION

As highly regulated products, pharmaceuticals are subject to careful monitoring as they cross borders and are placed on local markets. While such controls are necessary to ensure product safety, overly complex and inefficient border processes can cause additional costs, delays, and even result in loss of product. Streamlined customs procedures reduce such risks, helping to strengthen global supply chains and ensure vital medical goods reach patients without disruption or delay.

Acknowledging that burdensome customs processes can result in unnecessary costs and restrict patient access to medicines, WTO Members should commit to improving trade facilitation measures for medical goods, based on best practices implemented during the pandemic.

As a first step towards this goal, WTO Members should **establish best practices by sharing experiences** of the trade facilitating measures that have been put in place during the pandemic. This activity should be organised and guided by the WTO, including through the Trade

18. Signatory countries includes EU Member States, the US, Canada, Australia, Japan, Norway, and Switzerland.
19. "Using trade to fight COVID-19: Manufacturing and distributing vaccines," OECD, February 11, 2021.
20. "Using trade to fight COVID-19: Manufacturing and distributing vaccines," OECD, February 11, 2021.

Facilitation and TBT Committees, in close collaboration with other international organisations such as the World Customs Organization (WCO) and the WHO .

Based on the above, WTO Members should **devise and publish national trade facilitation plans** to ease the import of specified medical goods and their inputs. While the specific measures are likely to depend on national circumstances, they could potentially include the creation of permanent special lanes for the shipment of medical goods and the introduction of a single trading window to enable companies to provide information required by various official agencies – such as customs declarations, import/export permits, certificates of origin and trading invoices – via a single digital system.

WTO Members should also commit to fully implementing the TFA. Of upmost importance here is the TFA's encouragement of **adopting and maintaining electronic preclearance procedures**, allowing for submission and processing of import documentation and other required information, such as manifests, prior to the arrival of products. The importance of providing enhanced customs flexibility through digitising customs procedures cannot be underestimated, saving time and both financial and human resources.

Taken together, these steps will help to ensure that precious time and resource is not wasted at the border through inefficient or burdensome customs processes. In the context of the ongoing COVID-19 crisis, it will ensure that vaccines are not lost or spoilt at the border, and that doses reach global populations as quickly as possible.

PILLAR 5. PUBLIC PROCUREMENT

Governments are often the largest customer for pharmaceuticals in any economy, procuring on behalf of national health systems. That unique role of buyer will often tempt governments to seek to exercise their power as a lever for supporting 'national' suppliers over foreign ones. They can do this directly through their selection of suppliers, or through the imposition of local content requirements designed to capture part of the value chain for local suppliers.

As with export restrictions, these policy measures can quickly become counterproductive from a resilience standpoint, and even work against wider policy aims. Foreign suppliers may be locally invested, with local employment and investments in research, development, and advanced manufacturing. Even when they are not, constraining policymakers to purchase only locally produced goods and services limits their own options for supply. It imposes arbitrary segmentation on the market for government buyers, incentivising geographical concentration of production and encouraging trading partners to do the same.

To best support trade in healthcare, WTO Members should **commit to non-discrimination between foreign and domestic suppliers** in all areas of pharmaceuticals and related goods and services. For signatories of the WTO Government Procurement Agreement (GPA), Members should adopt a joint declaration, or annex to their schedules, committing them to sustaining an open and internationalist approach to public procurement for life sciences. If required, they should update their GPA schedules to this effect.

WTO Members that have not signed up to the GPA should be encouraged to do so. Expanding the Membership of the GPA will only strengthen its role in ensuring open, fair and transparent conditions of competition in government procurement markets.

TABLE 2: THA PILLAR CONTENT

PILLAR	AGREEMENT CONTENT
Pillar 1: Export restrictions	→ Commitment to review and eliminate all residual export restrictions linked to the pandemic. → New declaration on the application of GATT XI to export restrictions in medicines; stressing their status as a tool of last resort, defining temporary as limited to 90 days and acknowledging that in a pandemic critical shortages need to be understood as a global problem.
Pillar 2: Regulatory cooperation	→ Commitment to a new programme of best practices sharing through enhanced cooperation in the context of the ICH, ISO and WHO contexts. → New funded commitments to capacity building in developing country regulators. → A commitment from Members to step up their work on mutual and unilateral recognition of batch testing and GMP inspections to facilitate trade in medicines.
Pillar 3: Tariff Liberalisation	→ Agreement to expand the scope and Membership of the WTO Pharmaceutical Agreement. → Unilateral reduction of MFN tariffs rates for important medical imports for states unwilling to join a full plurilateral agreement.
Pillar 4: Trade Facilitation	→ Full WTO-led review of best-in-class trade facilitation measures adopted during the pandemic that can be adopted as general protocols. → Commitment by all WTO Members to adopt and publish national trade facilitation plans. → Re-commitment to full implementation of the WTO TFA, especially with respect to electronic pre-clearance procedures.
Pillar 5: Public Procurement	→ New declaration on non-discrimination in public health procurement for GPA signatories, with updated schedules if required.

Wider aims for open trade in healthcare

While the five pillars set out above should be the baseline for a WTO Trade in Healthcare Agreement , there are a number of additional areas that could help ensure that trade in healthcare works for all countries and patients. WTO Members should consider supporting the supply and distribution of essential medical goods in several areas, including but not limited to:

A) FREE MOVEMENT OF DATA AND DIGITAL TRADE

The freedom to move research, clinical trial and patient data between countries helps support valuable research and the regulatory authorisation process for medicines. WTO Members should continue to collaborate on the design of data protection and data use frameworks.

For the healthcare sector, digitalisation and digital solutions play an essential role in enhancing data flows in pharmaceutical manufacturing, pharmacovigilance, medicines development, and clinical trials. They also facilitate the understanding of real-world data and treatment uptake and outcomes, which in turn can contribute to a more efficient, value-based healthcare sector. The pandemic has clearly accelerated how consumers and patients use technology and this should be supported by designing robust frameworks for sharing data, avoiding data localisation requirements and deepening cross-border market access for the specific R&D services that underpin the design and conduct of effective clinical trials. Some of these issues are addressed in the ongoing WTO e-commerce negotiations.

B) MOBILITY OF LIFE SCIENCES PROFESSIONALS AND ACADEMICS

The development of innovative medicines and vaccines starts with skilled and creative people. The life sciences are an international endeavour, drawing on talent and partnerships between the brightest minds across the world. This is why the most effective global companies and research centres facilitate the temporary relocation of scientific professionals and research specialists to their jurisdictions. This should be both a basic feature of migration policy and something that WTO Members actively encourage in others, including through provisions in FTAs that support the posting of specialists between international operations of a life sciences company or research facility.

C) DISPUTE RESOLUTION

Much of the content of a possible WTO THA depends on a willingness of WTO Members to abide by obligations in their core GATT commitments. This is exemplified by their obligations under Article XI on export restrictions. While recognising that any WTO initiative must ultimately be underpinned by a shared sense of goodwill and commitment to the value of open and free trade in medicines, a functioning Dispute Settlement Mechanism (DSM) is an important backstop to any binding commitments made by Members. Restoring the DSM should be a general aim for WTO Members, but is also an important component and context of a Trade in Healthcare Agreement .

Conclusion

The urgent backdrop of the COVID-19 pandemic added both a sense of imperative around trade and medicines, but also at times worked against careful reflection on problem framing and solution design. Throughout the pandemic, medical supply chains faced intense challenges as demand for certain medical goods rose sharply, supply chains faced an array of new challenges. Yet ultimately, the global trading system has deployed billions of doses of vaccines and huge volumes of other medical equipment on timeframes that broadly enabled societies around the world to reopen.

While COVID-19 will leave an enduring mark on our societies, we are now distant enough from the pandemic's most intense phase to draw on the experience to make concrete recommendations for the future of trade and healthcare. Even if we were not at an apparent impasse on the role of IP in this future, to limit the policy question to IP would be to fundamentally fail to address the many ways in which trade policy was found wanting during the crisis.

The WTO rulebook already provides the tools and principles to create a new benchmark for openness, fairness, and cooperation in trade in healthcare. What is required now is the clear and committed application of those principles to some of the challenges emphasised by COVID-19. Ideally, this should be captured in a new plurilateral agreement based around the five pillars set out in this report.

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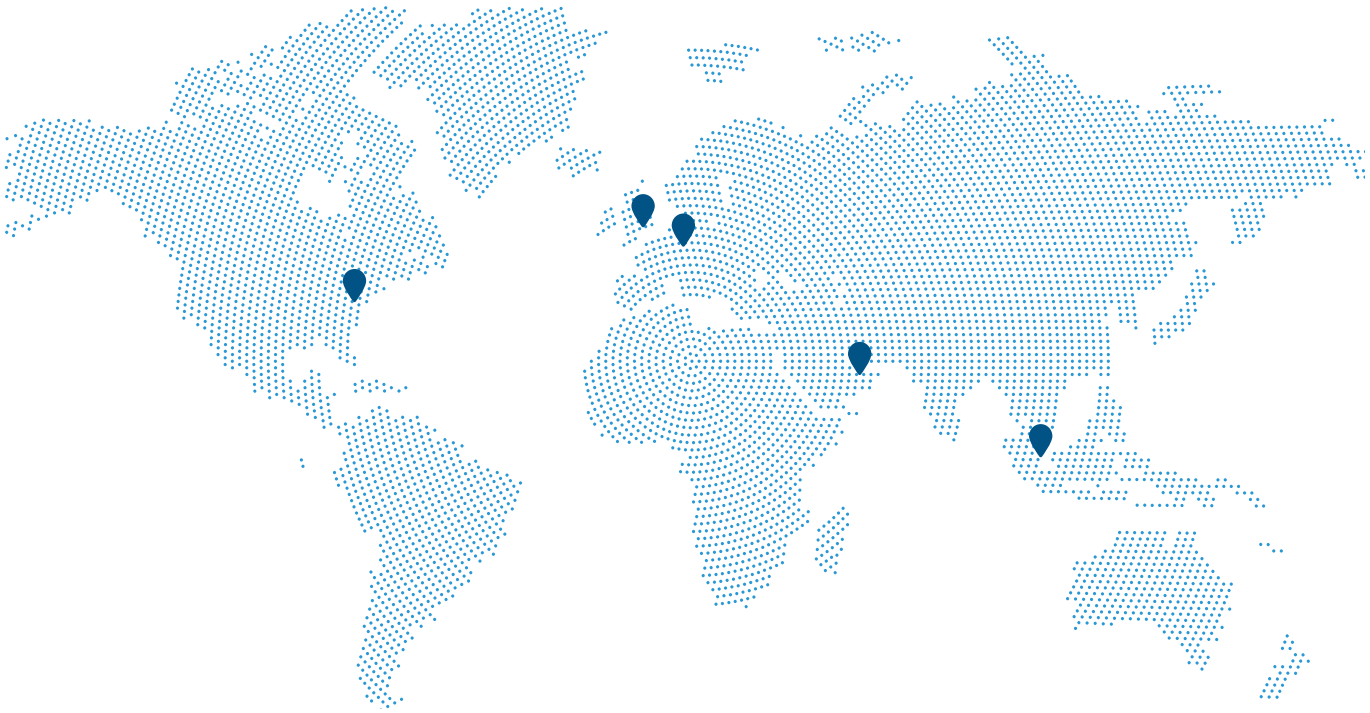

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