

Proposals for trade related measures to support the fight against the Covid-19 pandemic

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The Covid 19 outbreak was declared a Public Health Emergency of International Concern on 30 January 2020 by the World Health Organisation. The global nature of a pandemic suggests the possibility of successive waves of infections. It has led to both an admirable world-wide collaboration of the scientific community, and a ruthless competition between States to acquire goods to fight the illness, protect their health care workers and their population. Some companies are also trying to benefit from the crisis by raising their prices and limiting collaboration. National and European leaders must look beyond their own borders and use all instruments to allow all countries, rich and poor to overcome the pandemic.

Trade measures can both support and hamper the fight against Covid-19. Complex goods like pharmaceuticals or respirators include multiple elements, which need to cross several borders before becoming final products. Their production is limited to a few companies in a few countries, while most others were blindly relying on international trade to secure their supplies.

The global race to produce and procure needed protection equipment, pharmaceuticals, tests and complex medical devices has brought this fragile system to its knees, with borders closing, exports being restricted, and the richest actors outbidding all others and leading to shortages in some of the most affected countries and a global explosion of prices for life-saving equipment.

Beyond the short-term absolute urgency of procuring the needed materials to protect workers, test for the virus, and maintain patients alive, exit strategies require the discovery, production and distribution of a vaccine and a cure. Both the research and the deployment of effective therapies will require governments to use all flexibilities related to Intellectual Property Rights, and their trade aspects. Patents, data exclusivity and trade secrets can all lead to higher prices and make research collaboration more difficult, costing lives. The WTO, which is responsible for the administration of the controversial TRIPs (Trade-Related aspects of Intellectual Property Rights) agreement has remained silent of the possibility to relax international Intellectual Property rules to protect the Human Right to Health.

Finally, there is an acute need to scale up production independently from existing supply chains. In countries that can afford it, it requires massive State support, and the voluntary or mandatory sharing of designs and certification processes between producers. While such actions could in normal times be prohibited by WTO and free trade agreements, the current emergency situation should enable all States to do what needs to be done without fearing trade retaliation from other WTO members. For countries which cannot afford to scale up their own production and still rely on imports, international solidarity will be key.

Concrete proposals for trade related actions by the EU and EU member States :

Using all flexibilities and emergency measures related to Intellectual Property Rights and their trade aspects. Future vaccines, therapeutic drugs, tests and needed medical devices must be produced and sold throughout the world at the lowest possible cost, and with the least amount of bureaucratic hurdles or disputes over patent rights. Data exclusivity rules and trade secrets must also be circumvented to ensure global collaboration. Already, some [investment banks have been urging pharmaceutical companies to raise their prices](#) and to create a business opportunity out of live-saving medical products under development. Valuable time cannot be wasted in engaging in protracted negotiations with intellectual property rights holders or campaigns to persuade them to co-operate. The EU and Member States¹ should:

- Reaffirm and push other WTO members to reaffirm that the **Human Right to Health takes precedence over TRIPs rules**. All countries, especially developing countries, should be able to use all flexibilities in their broadest interpretation without fear of retaliation.
- Support the suggestion of the government of Costa Rica, calling for a **voluntary pool of coronavirus related intellectual property rights** (including patents, regulatory test data, know-how, copyrights and design rights) managed by the WTO. The call has been endorsed by the WHO Secretary-General.
- **Call intellectual property right holders to offer cheap licenses or waive them** via international patent pools, on a voluntary basis and for all Covid-19 related rights. This will be especially relevant for a newly developed vaccine, or an approved treatment. If rights holders do not act, the Commission must call on Member States to **issue compulsory or government licenses** - suspending the monopoly effect of patents and allowing others than the patent holder to produce and supply protected products.
- Review past decisions limiting the **import of medicines produced abroad under compulsory licenses**, and call on the WTO Secretariat to issue a note to WTO Members to relax these requirements. The TRIPS agreement states that compulsory licenses must be used "predominantly" for local markets, a requirement that complicates the ability of countries to import drugs manufactured abroad. The EU and many Member States have compromised their own ability to make swift and effective use of compulsory licensing by opting-out of the system established under the August 30th 2003 Decision of the WTO². It enables imports of medicines made under compulsory licensing in other countries, especially those with larger production capacities.
- **If needed, circumvent existing legislation on trade secret via requisition powers or new emergency laws**, and mandate the publication of critical research data related to Covid-19. The best way to identify candidate drugs to treat Covid-19 patients is to crunch huge

¹ Respective competences of EU and Member States: pricing and reimbursement of medicinal products are Member State competences and are regulated at national level; the EU provides legislation on intellectual property, clinical trials, marketing authorisation, transparency in pricing, pharmacovigilance and competition.

² Amendment to the TRIPS Agreement since 2017

quantities of data on existing medicines to find the ones that might work. Existing medicines have already been tested and declared safe, saving a lot of time in clinical trials. However, many pharmaceutical companies do not share their data, on the grounds that it is commercially confidential. There are currently no existing compulsory licenses or government-use exceptions for trade secrets, if relevant companies refuse to voluntarily share.

- **Allow waivers to data and market exclusivity**, when a compulsory or government use license has been issued. EU regulation of **clinical test data protection**, and the granting of **market exclusivity** interfere with the effective use of compulsory licensing. Data exclusivity prevents would-be generic competitors to make use of existing clinical data to support fast approval applications. A further two years' market exclusivity might also be granted to the patent holder, as well as an additional year if the originator develops the drug for a new indication – like to fight Covid-19. Medical devices can be granted data exclusivities as well. The EU pharmaceutical legislation should be amended, and TRIPS+ provisions in EU trade agreements on data exclusivity temporarily disregarded.

Short-term protection and facilitation of existing supply chains. The EU and Member States are still heavily dependent on imports of life-saving protection equipment, pharmaceuticals and certain active ingredients for drugs, of medical devices and of crucial components for their production. The EU should:

- Ensure that requirement of export authorisations do not lead to final products being delayed – for example when some key producers for the single market are located outside of it, and rely on imports of parts from EU countries to be able to build medical devices.
- Ensure that requirement of export authorisations do not penalise neighboring countries of the EU, or countries in need in the Global South, as explained in the INTA letter to Phil Hogan of March 3, 2020.
- In the middle term, enact legislation on supply chain human rights due diligence, and due diligence requirements for public buyers. In the current crisis, workers in the global South are at an increased risk of exploitation, including in the supply chains of products for which the international demand is exploding like protection rubber gloves. European and national legislation on due diligence could have helped mitigating some impacts, and ensuring that the human right to health of workers in the Global South is respected.

Supporting new producers and scaling up production capacity within the EU. Protecting international supply chains and relaxing monopolies linked to intellectual property rights is unlikely to be enough to ensure sufficient supply of key pharmaceuticals and medical devices. Production capacities must be scaled up. In normal times, doing so might infringe on WTO rules on State aid. However, the current emergency should allow the EU and Member States to take any needed measure. The EU and Member States should:

- Subsidise European producers to shift their production to critical goods and pharmaceuticals, independently from WTO rules on subsidies.

- Support or mandate the sharing of existing, approved manufacturing procedures, quality assurance programmes and certificates of conformity held by existing medical device manufacturers.
- In the middle term, strategically rethink the EU's dependence on long and fragile global supply chains for critical equipment and pharmaceuticals.

Trade-related measures are only one aspect of international efforts needed to address the pandemic. Though needs are at a critical level in Europe, policy efforts must look beyond the EU borders and ensure international solidarity, especially with developing countries. The WHO will play a key role in coordinating this solidarity, and must be supported. Only a global answer will be able to put a stop to the current emergency.