

## COVID-19 Key Messages regarding International Trade

### Key messages

- Export restrictions have a seriously negative and immediate impact on globally integrated supply chains that ensure quality, safety, innovation, and distribution across the health sector. Furthermore, restrictions increase the risk of shortages, disrupt distribution channels, and hinder conducting clinical trials.
- Global supply chains give companies the flexibility needed to respond to developments in a particular region or country. Policies that would artificially restrict this flexibility would be counterproductive.
- The perception that the EU suffers from a widespread overreliance on foreign producers for pharmaceuticals does not match the reality:
  - The EU exports around 60% of all medicines globally in terms of value, amounting to c. €367 billion in 2019.<sup>1</sup>
  - 76.6% of Active Pharmaceutical Ingredients (APIs) for Europe's innovative pharmaceutical industry come from Europe and 11.9% come from the United States.<sup>2</sup>
  - The US and Switzerland account for 63% of imported medicines in Europe by value.<sup>3</sup>
- The EU27 should maintain its diverse global supply chains as driver for Europe's welfare and engine for the post-Covid-19 recovery, while at the same time investigating how to address 'strategic resilience'.
- The EU27 should continue to tackle the growing threat of forced localization of pharmaceutical manufacturing. It is not only economically flawed, but also hurts the EU's competitiveness given the potential retaliation from other economies and hinders patient access to essential treatments in those markets.
- The EU should focus on the following trade measures in response to Covid-19:
  - Encourage countries to permanently eliminate tariffs on medicines and medical equipment by updating and expanding the WTO zero-for-zero agreement.
  - Facilitate trade by digitizing customs procedures.
  - Avoid listing intermediate or final medicinal products and other medical goods in any retaliatory or rebalancing measures in trade disputes.
  - Leverage EU FTAs, MRAs and other fora to advance global standards for manufacturing (GMP) and other key regulatory areas.
  - Support a strong framework for innovation by including high IP standards in EU FTAs and championing them within the EU.
- The forthcoming pharmaceutical strategy is an opportunity to help the EU's competitiveness and recovery post-Covid-19 by fostering the best possible research and development (R&D) infrastructure.

<sup>1</sup> [Eurostat](#) (covering intra- and extra-EU trade). Global figures based on [WTO data](#).

<sup>2</sup> Survey data from 17 EFPIA Member Companies, January 2020

<sup>3</sup> [Eurostat](#)

## Introduction

Our first thoughts are with all those affected by the coronavirus pandemic. We are committed to working collaboratively across the research and healthcare communities, utilising our world-leading science, people, and resources to tackle this outbreak. Our aims are to:

- Ensure the safe supply of medicines to the patients that need them.
- Research and develop new vaccines, diagnostics, and treatments in the fight against COVID-19.
- Partner and support organisations on the ground to fight against COVID-19.

Our industry has [publicly declared its commitment](#) to fighting COVID-19, including working with governments and health systems to ensure that when new treatments and vaccines are approved, they are available and affordable. We stand united with citizens, health systems and governments in the knowledge that innovation, through the development of effective vaccines and treatments, is the only way out of the coronavirus epidemic.

## Trade today and tomorrow

At this moment, EFPIA member companies are meeting the exponential rise in the demand for medicines by working around the clock to increase capacity and ensure supply of critical medicines to patients, both across the EU and globally. In order to do this successfully, we need continued coordinated and collective action, based on EU solidarity, from the EU and Member States to address the challenges in getting medicines through to the patients that need them by keeping trade and supply chains functioning.

Our industry is committed to play a key role in Europe's economic recovery from both a healthcare and economic perspective. In order to be able to contribute fully to the fight against Covid-19 today and support an economic recovery tomorrow, several important elements need to be considered.

## Export Restrictions

A number of countries in Europe and globally have introduced export bans or other measures that restrict the manufacture or supply of medicines. While driven by the intention to protect the local population, these risk doing more harm than good, both for the availability of medicines and undermining global cooperation on solutions:

- Export restrictions have an immediate impact on globally integrated supply chains that ensure quality, safety, innovation, and distribution across the health sector. By driving mismatches between supply and demand, they increase the risk of shortages, disrupt distribution channels, and hinder the conduct of clinical trials.
- They also result in delays and costs at a time when companies should be dedicating their time and resources to increasing global supply and finding durable solutions to the current crisis.
- In the medium-term, restrictions inhibit innovation and endanger the manufacturing of the medicines and medical equipment needed to combat this pandemic, and its aftermath.
- Patients in many parts of the world depend on Europe for their supply of medicines: the EU is by far the largest global exporter of medicines, accounting for over 60% of all medicines export globally in terms of value, amounting to c. €367 billion in 2019.<sup>4</sup>

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<sup>4</sup> Global figures based on [WTO data](#), [Eurostat](#) (covering intra- and extra-EU trade). Largest exporters: DE (€81.7 bn); BE (€49.9bn); IE (€49.7bn); NL (€44.4bn); FR (€32.5bn); IT (€31.5bn).

- In an already challenging global trade environment, export restrictions also impact patients outside Europe, and risk retaliation that could likewise impact patients in Europe.
- Collaboration, flexible innovative approaches and open communication between manufacturers and competent authorities are central to addressing the increasing challenges in medicines supply.
- Beyond collaborating with industry on alternative approaches to export restrictions, Europe should lead global efforts to facilitate trade in medicines and other critical medical supplies.

### Policy measures to support trade in medicines and medical goods

Following the Covid-19 crisis, global institutions, governments, academics, and industry have responded by co-operating to propose policy measures to support trade in medicines. This has focused not only on tackling the immediate crisis, but also on facilitating the supply of future treatments or vaccines, and on building a sustainable path to economic recovery.

From a trade viewpoint, these areas all remain underpinned by the need to maintain diverse and flexible global supply chains to facilitate the post-Covid-19 recovery.

- Specific initiatives to support this should include:
  - Encouraging countries to permanently eliminate tariffs on medicines by working together on the WTO Pharmaceutical Zero-for-Zero Tariff Agreement<sup>5</sup>: updating the product coverage from 2010 to now, broadening its current membership, and extending it to all pharmaceutical and medical goods.
  - Facilitating trade by providing enhanced customs flexibility (e.g. via electronic documents).
  - Avoiding listing intermediate or final medicinal products and other medical goods in any retaliatory or rebalancing measures in response to trade disputes with third countries.
- The EU should also strengthen focus on the following existing trade policy approaches:
  - Leverage EU FTAs, MRAs and other fora, such as ICH and PIC/S to advance global regulatory standards, including for manufacturing (GMP).
  - Support a strong framework for innovation by including high IP standards in EU FTAs and championing them within the EU. This would further encourage investment into R&D for much-needed new treatments to patients. Ensuring that Europe's innovation ecosystem remains strong is the most effective way to be prepared to respond to the next pandemic.

A comprehensive EU Trade Strategy has to ensure predictable and non-discriminatory trade and investment conditions so companies can operate in the EU in a transparent and predictable environment. This enables patients across the world to have better and faster access to innovative medicines.

### Reshoring to Europe

- Pharmaceutical companies, over decades, have carefully built robust global supply chains to ensure patients in Europe and around the world have ongoing access to medicines.
- Geographical diversity is key to the resilience of global supply chains. It enables manufacturers to make adjustments as needed to ensure stability and avoid potential shortages and disruptions.

<sup>5</sup> [https://www.wto.org/gatt\\_docs/English/SULPDF/91770009.pdf](https://www.wto.org/gatt_docs/English/SULPDF/91770009.pdf)

- Pharmaceutical companies prepare for unforeseen events through robust adaptable business continuity plans to ensure they can meet the needs of the healthcare system.
- With other countries increasing incentives and also pushing to re-shore, the EU needs to be globally competitive for R&D and manufacturing not only now, but in the future. Production and exports of medicines is important but only follows after the science has been carried out.
- Any moves to re-shore manufacturing should look beyond the lens of ‘vulnerabilities’:
  - Focusing on global interdependencies: the EU27 accounts for over 60% of exports of finished medicines, so much of the world depends on Europe for medicines.
  - Being cognizant that the EU’s strong position means that other countries may also push for reshoring – with an ultimate impact on the EU’s global competitiveness.
  - Building on the EU’s global leadership in tackling the growing threat of forced localization of pharmaceutical manufacturing.<sup>6</sup> Such measures are not only based on the flawed idea of self-sufficiency; they are also discriminatory and particularly damaging for EU exports.
  - Being driven by data on any vulnerabilities in the value chain. For the innovative pharmaceutical industry, 76.6% of API supply in Europe is manufactured in Europe.
  - Recognising that clinical / medical needs for the Covid-19 pandemic may fundamentally differ from future medical crises that Europe and the world may face.
- Policies mandating wholesale changes to global supply chains could fundamentally disrupt the manufacturing of medicines supplied to Europe and the world.
- The EU therefore needs a pharmaceutical strategy that:
  - Strengthens Europe’s global competitiveness and resilience its R&D infrastructure so that Europe continues to be a leading source of future vaccines and treatments.
  - Provides the conditions for industry that allows the EU to maintain its position as the largest exporter of pharmaceutical goods globally.

This centres on strong IP provisions and agile regulatory provisions to encourage innovation, as well as strong public-private partnerships for research, and continuous education to maintain a well-trained and adaptable workforce.

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<sup>6</sup> For example, the EU’s [WTO case](#) against forced localisation measures by Turkey, launched in April 2019.