European Federation of Pharmaceutical Industries and Associations

Industry Recommendations to prevent medicines shortages

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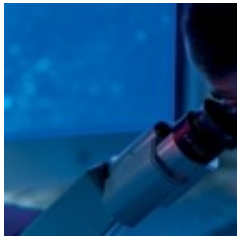




FMD and Regulatory Affairs Symposium

2 October 2020

Shortages

Frequent confusion

Unavailability does not sum up to Shortages

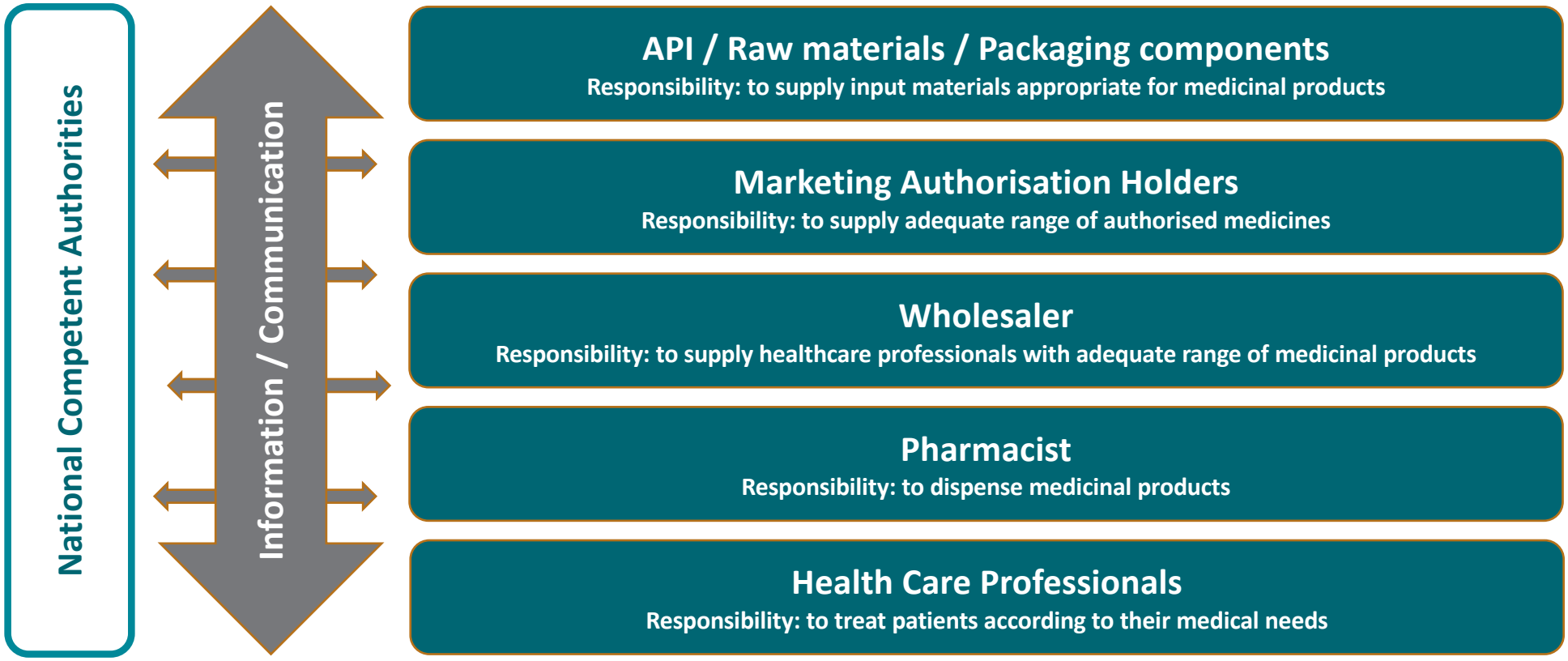
Definition?

Scale?

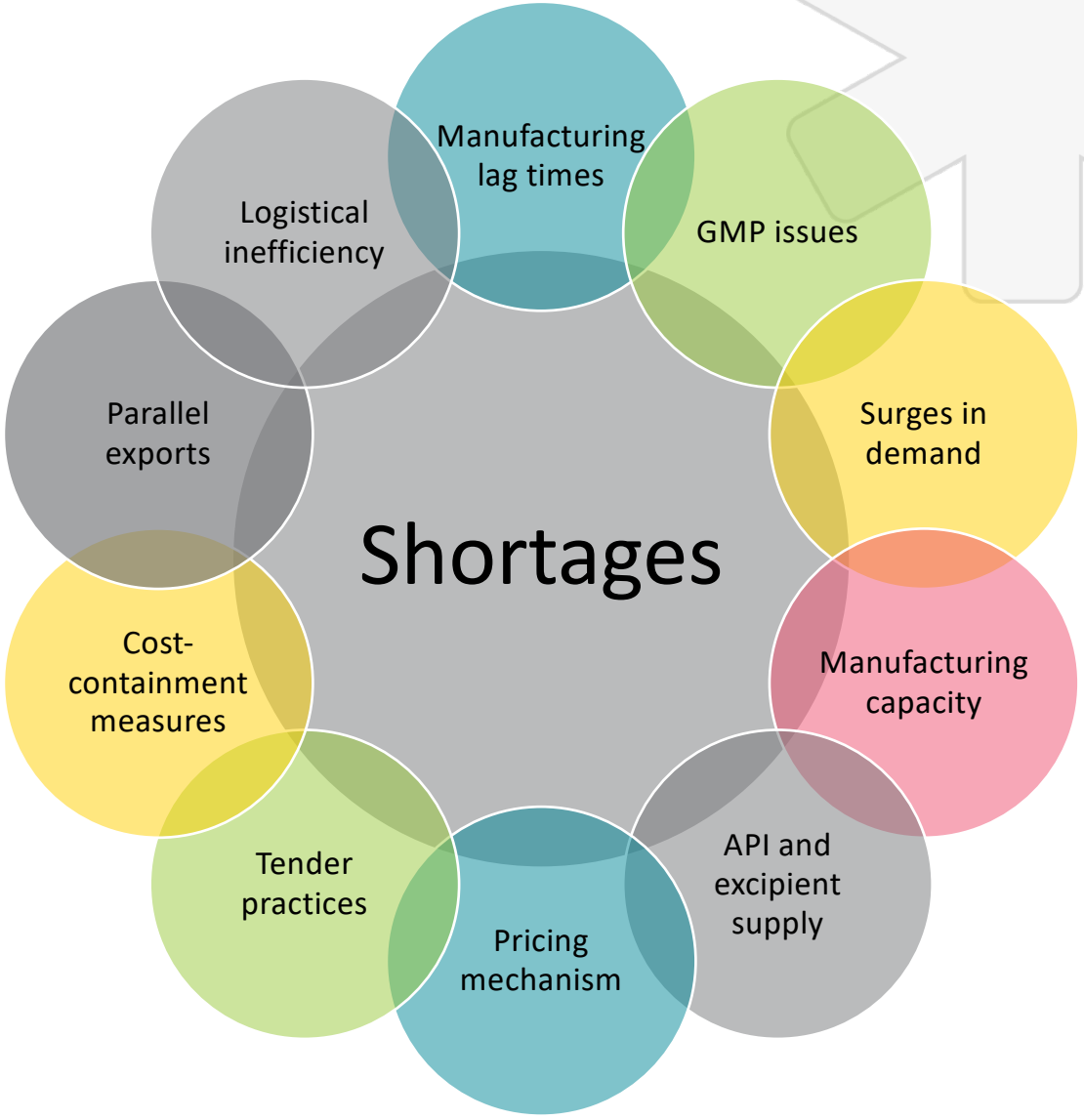
Patient impact?

Complex supply chains for medicines

Common Goal: Patients should have continuous access to the medicines they need



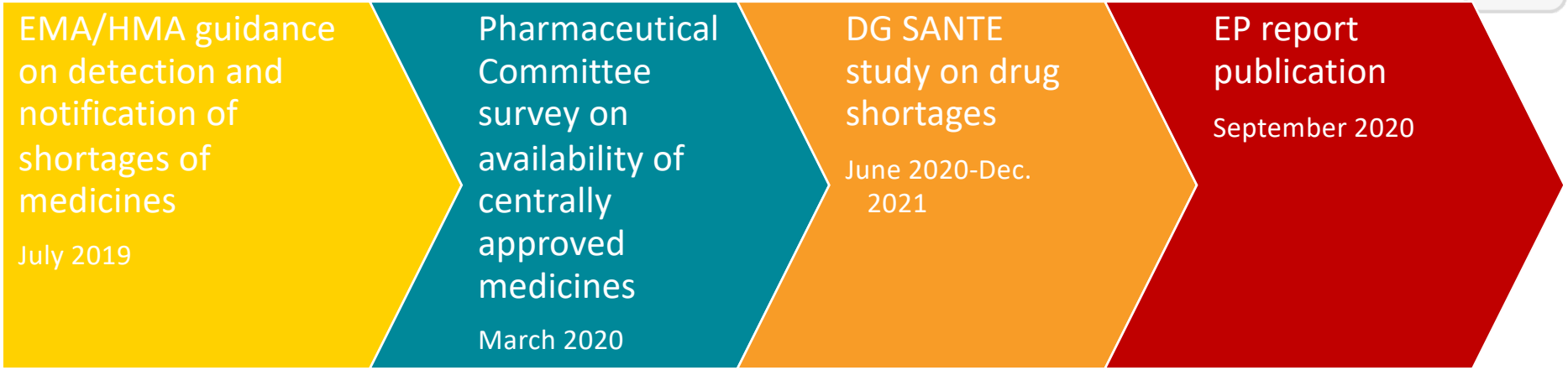
Shortages have various, intertwined root-causes



FDA lists 3 root causes:

- Lack of incentives to produce less profitable medicines
- Market does not reward manufacturers for mature quality management systems
- Logistical and regulatory challenges make it difficult for the market to recover after disruption

Drug shortages is high on the political agenda at both EU and country levels



Urge for action and multiplication of uncoordinated country action plans with increasing requirements on MAHs

- Medicine shortages are a multi-factorial issue ; root-causes are poorly documented
- Industry and supply chain stakeholders are seeking concrete and balanced common solutions.

EFPIA survey to member companies

Respondents: 17 EFPIA member companies, February 2020

API issues root-cause for shortage

- 9% in 2018
- 5.4% in 2019

API sourcing mainly European

- on-patent 76.6%
- off-patent 61.5%

API manufacturing disruptions in 2018/2019

- EU 80% / 79%
- Asia 19.8% / 11%
- USA 0% / 10%

Lessons learnt from the COVID19 crisis

NEEDS:

Clear, harmonized definition of a shortage, based on patients needs

A shortage of a medicinal product for human use occurs when supply does not meet patient need at a national level for a period of more than two weeks.

Understanding of root-causes of shortages

Use of European Medicines Verification System data

Understanding and transparency of patient needs and demand

ECDC (current and forward-looking) epidemiological data to forecast (medical) demand

Solidarity among MS

Address unilateral stockpiling requirements, achieve careful Balance of Free Movement of Goods and effective supply

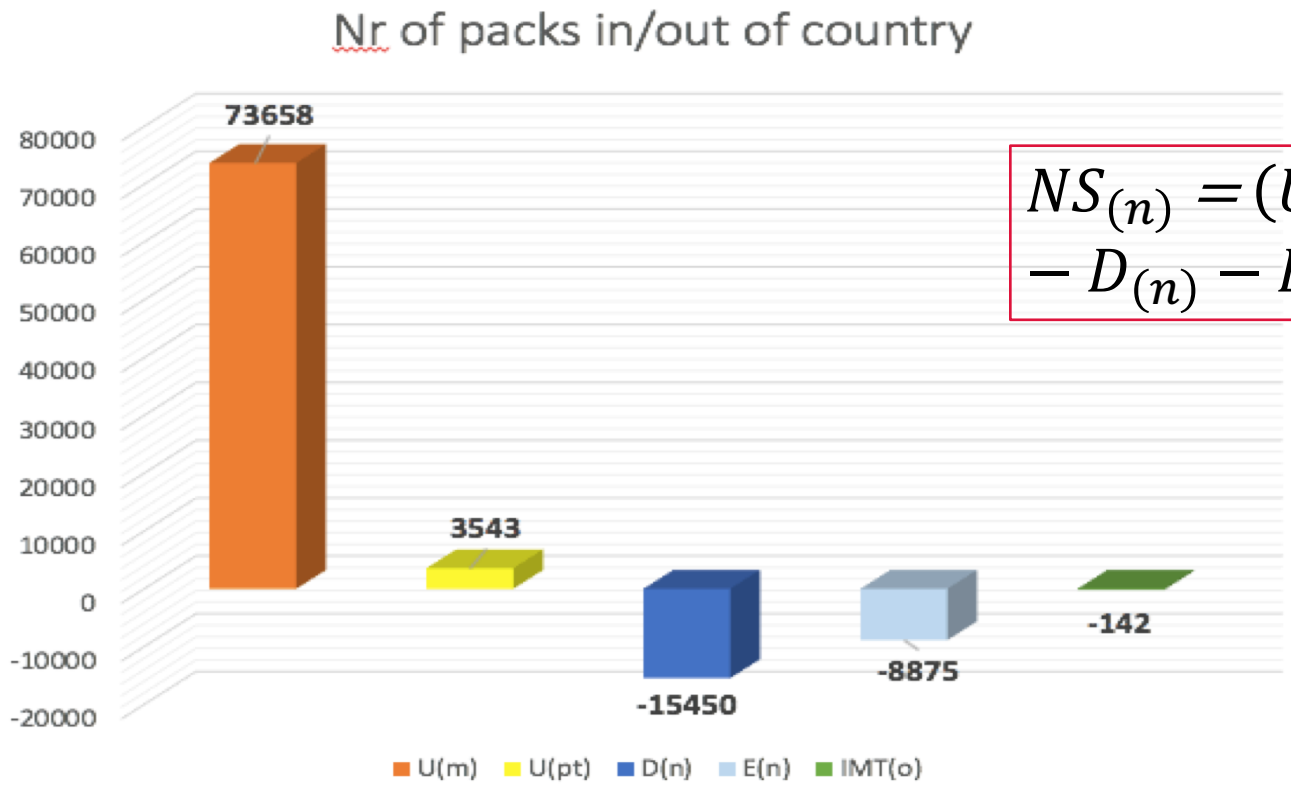
Facilitated supply

Green lanes, Corridors, regulatory emergency flexibilities…

Recommendations for public policy action

EMVS / FMD interoperable network data can support addressing shortages

FMD Data can be used to 'feed' a dashboard on national stocks in real-time



$$NS_{(n)} = (U)_{(m)} + U_{(pt)} - D_{(n)} - E_{(n)} - IMT_{(o)}$$

Illustrative example

A Successful shortages prevention policy requires a collective, holistic approach

Collaboration and Transparency	• Between MS / EMA / HMAs and supply chain stakeholders • Solidarity between MS • Information flow on patient needs/demand, stock levels and supplies
Collect facts / data before action	• Requires a common, European definition of shortages, integrating the notion of patient needs • Strong monitoring system (EMVS/FMD Data are readily available)
Establish Diagnosis	• Based on monitoring and data, establish diagnosis on root-causes of shortages
Coordinated policy	• Unilateral measures (e.g. stockpiling requirements, export restrictions) are disruptive and should be limited to emergency • Develop a European, holistic policy addressing shortages in a holistic way

efpia

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THANK YOU

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BACKUP

COVID-19 – lessons learned and way forward
10 proposals from diagnosis to action

ENSURE OBJECTIVITY (right diagnosis)	MAKE RECOMMENDATIONS IN LINE WITH EXISTING EU POLICIES
1. **Ensure a consistent and workable definition of medicine shortages** - A shortage of a medicinal product for human use occurs when supply does not meet patient need at a national level for a period of more than two weeks.	**Revise the scope and definition of shortages included in the July 2019 Guidance on detection and notification of shortages of medicinal products for Marketing Authorization Holders** (MAHs) in the Union endorsed by EMA and Heads of Medicines Agencies, which has yet to be implemented through a pilot with MAHs. The definition included in the EMA/HMA Guidance refers to national demand rather than patients needs and therefore implies that it is the supply chain (e.g. wholesalers) that defines the existence of manufacturers' shortages irrespective of patient needs. The EMA/HMA definition goes beyond the responsibilities of a marketing authorisation holder and the scope as identified in Article 81 of Directive 2001/83/EU.
2. Ensure a better understanding of the root causes and drivers of shortages.	**Use by competent national and EU authorities of the information contained in the EMVS (European Medicines Verification System) data repositories set up in the context of the EU Falsified Medicines Directive** to monitor, at aggregate level, when and how various medicinal products/INNs are placed on which markets as well as the rate of their 'consumption' at national level.

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3. Improve understanding and transparency of patient needs at member state level for appropriate planning forecasting.	**Call for the European Centre for Disease Control (ECDC) to release modelling data about the likely progression of the pandemic in each country as well as patient need and hospital capacity data in the Member States.** This information is crucial for manufacturers to adequately forecast demand and make the necessary planning in terms of manufacturing capacity and detailed distribution arrangements to supply those medicines to the right regions at the right time.
4. Address national stockpiling requirements.	**Oppose Member States introducing unilateral stockpiling requirements that put at risk the overall supply of critical medicines in Europe and work with Marketing Authorisation Holders in order to build safety stocks for critical medicines enabling to buffer unexpected increased EU patient demand.** An increasing number of EU countries but also wholesalers/traders, healthcare professionals and patients are requesting stockpiles. These are not commensurate with respect to expected demand following from company epidemiological estimates (especially for non COVID-19 treatments, e.g. cardio-metabolic). Effective enforcement is needed for existing regulatory requirements on all actors in the supply chain at national level, coupled with measures to enhance transparency within the supply chain and further dialogue/best practice sharing between stakeholders. These tools are already easily

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5. Facilitate the production and supply of treatments impacted by the pandemic through regulatory flexibility to meet patients needs.	**Ensure emergency measures are applicable to ongoing manufacturing and distribution operations for all medicines to avoid shortages (not just for medicinal products intended for use in COVID-19 patients)**. To avoid exacerbating co-morbidities in vulnerable patient groups or creating additional concerns about supply in the general population, suitable regulatory measures should be introduced for all medicines at risk of shortage in all Member States. An increase in production and supply facilitated through timely and continued dialogue with competent EU and national authorities, on optimal regulatory processes, is needed to ensure rapid COVID-19 therapies availability to a broad population whilst maintaining medicines supply to all patients.
6. Reach a careful balance between free movement of goods and the need to efficiently supply medicines based on patient needs as well as re-balance stocks across borders.	**Request Members States to abolish the distortive effects of national schemes incentivizing parallel imports from lower income to higher income Member States and incentivize the application of the non-extraterritoriality principle. Similarly, national requirements to maintain a significant national stock or limiting supply for other EEA markets should be abolished or at least reduced respecting the proportionality principle.** These practices hinder the much-needed visibility in times of crisis, as the quantities of parallel traded medicines are not known to the manufacturer nor to the authorities, therefore shared liability concept and rules should be implemented.

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7. Ensure that procurement policies do not nullify the intended effects of supply side policies.	**Issue specific guidance for medicinal products for the proper application and implementation of the EU Public Procurement Directive by Member States.** Procurement bodies to use the MEAT (Most Economically Advantageous Tender) criteria to ensure continuous supply and avoidance of 'winner takes it all' approach to award contracts for procurement of medicines. The repetitive, yearly focus on lowest possible price, led to consolidation and search for economic efficiencies overseas (industry relocation in third countries). A variety of medicines should be available for physicians and patients instead of a single medicine. Public procurement should foster this diversity of suppliers by ensuring the final award of contract is not limiting doctors/patients to one choice of treatment.
8. Ensure the availability of critical medicines at EU level in line with Member States' patient needs.	**Establish proper pandemic preparedness plans - under strong medical supervision - for critical medicines at EU level based on solidarity between Member States, and ensuring that non-pandemic related medicines continue to reach the patients in need.** Such plans must use the learnings from the current crisis such as: ensuring free movement of essential goods and workers, need for proper data at Member States level on resources available as well as needed, use of EU level mechanisms (such as rescUE) to coordinate material (PPE, lab equipment, ventilators etc) purchase and distribution, etc.

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9. Ensure continuous dialogue between competent EU and national competent authorities, and manufacturers with a view to addressing any imbalances between demand and supply.	**Set up a collective dialogue with respect to which medicinal products need to be produced, and in which quantity.** There is a strong common need for a coordinated, structured and reliable way to discuss and plan any future waves/pandemics, elaborating on the existing I-SPOC system that would be forward looking. Companies are becoming increasingly hesitant to continue operating and producing in the dark without evidence-based information on Member States' demand, concerned that supply might well exceed the demand for some medications considered to be under shortages by Member States.

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10. Provide an environment where the research-based pharmaceutical industry can develop solutions to today's unmet needs, and ensure that Europe continues to be an attractive location for R&D investment and industrial development to respond to tomorrow's patients' needs. Based on a survey in January 2020 to which 17 global EFPIA member companies responded, 76,6% of APIs for on-patent products are sourced from the EU-28, 11.9% from US and 9% from Asia (including Japan and South Korea). For off-patent products APIs, companies source 61,5% from the EU-28, 7.2% from the US and 26,8% from Asia (including Japan and South Korea). In addition, economic data (here) shows that the EU27 already accounts for 60% of all global exports of finished pharmaceuticals (ex- and intra-EU trade).	**Provide global leadership on trade policy** by continuing to promote an open multilateral trading system, to take an active stance against forced localisation of pharmaceutical manufacturing and promote the creation of added value in Europe and beyond. Including pro-trade and pro-innovation policies in the EU's industrial strategy remains essential in linking trade to strengthening Europe's global competitive position. **Champion trade policies that strengthen globally integrated supply chains, promote innovation in Europe and global regulatory convergence.** This would include driving customs facilitation measures, pushing to update the WTO Zero-for-Zero Pharmaceutical Tariff Agreement and widen its membership, including strong IP provisions in EU FTAs and promoting regulatory convergence (via promoting membership of PIC/S and via mutual recognition agreements on GMP standards). **Set up a worldwide dialogue on the optimal regulatory processes to ensure rapid COVID-19 therapies availability to a broader population in need** eg.: