EFPIA contribution to DG Trade Consultation on "A renewed trade policy for a stronger Europe" - November 2020

Key Messages

With COVID-19 impacting people across the globe, and inescapably re-shaping the world economy, the innovative pharmaceutical industry believes that a clear and forward-looking EU trade agenda is needed. This entails mobilising all resources to support the recovery of the EU economy, including ensuring that it remains open to the world. The EU is one of the few strong global players that stands for a rules-based global trading system and can take a global leadership role to promote this.

The innovative pharmaceutical industry is one of Europe's core industries, contributing strongly to economic and social policy objectives, European values, as well as being at the forefront of combating the COVID-19 pandemic. We believe that the EU's renewed trade strategy provides a unique opportunity for the EU to support and strengthen its industry vis-à-vis global competitors in various ways:

- The EU should focus its efforts on **strategic resilience** by strengthening the industry's global value chains and supporting open trade, as also suggested by the OECD (2020)[1]. Ultimately, resilience that benefits patients in Europe (and globally) depends on strengthening the EU's R&D infrastructure, and maintaining a world-class incentives ecosystem for innovation and advanced manufacturing.
- **Innovation** is a key long-term driver for economic growth as well as economic resilience, and the COVID-19 pandemic has shown how critical a well-functioning R&D infrastructure is. Given its central role in Europe's economy, the EU's Trade Strategy should focus on strong IP protection and enforcement, combined with FTA implementation as well as improved market access for the EU's innovative and IP-intensive industries.
- The EU should build on its global leadership by continuing to tackle the growing threat of **forced localisation** of pharmaceutical manufacturing. Such measures will decrease resilience, are discriminatory and damaging for both EU exports and patient access.
- To ensure that Europe remains a global leader and exporter of innovative medicines, future **Free Trade Agreements (FTAs)** should maintain and promote the EU's existing high-level standards, notably by including: strong IP provisions, rules of origin that facilitate trade, provisions which guarantee equal and non-discriminatory market access, and ambitious e-commerce chapters to allow digital trade to flow freely.
- We strongly welcome **the European Commission (EC) initiative for a multilateral agreement on trade in healthcare products**. This would be a positive vehicle for **tariff liberalisation** and wider trade facilitation. More broadly, the EU should also continue to stand up for the global rules-based trading system by strongly supporting the WTO and co-leading reform efforts.
- To keep pace with the evolution of science, technology, and regulatory innovations in other regions, Europe's regulatory framework has to evolve. To that end, the EU should build on its strong regulatory framework to ensure it is fit for future innovations, including to address future public health crises. The EU should also promote global regulatory convergence as well as **international regulatory cooperation.**
- The EU has set high global standards when it comes to **good governance and transparency in setting regulations and decision making**. Raising the bar in markets globally would bring significant added value to exporters of innovative medicines.
- Industry is supportive of the appointment of a Chief Trade Enforcement Officer and of an **increased focus on implementation and enforcement** in EU trade policy. We also call for the establishment of a dedicated **pharmaceuticals working group**, in line with other key European sectors, within DG Trade's market access structure.

1 OECD (2020) "Building resilience in global supply chains for all", OECD TAD/TC (2020), November 2020.

<u>Question 1:</u> How can trade policy help to improve the EU's resilience and build a model of open strategic autonomy?

Innovative pharmaceutical companies have built robust global supply chains to ensure that patients in Europe and around the world have continuous access to innovative and quality medicines. Our industry fundamentally depends on international collaboration in terms of organisations and scientists driving life sciences R&D, as well as being able to drive economies of scale for manufacturing and supply of complex medical technologies. We therefore question whether greater national or regional autonomy will be able to improve the EU's resilience. Geographical diversity, rather than autonomy, is key to the resilience of global supply chains, as it enables manufacturers to adjust as needed in order to ensure supply quality, stability and affordability and avoid potential shortages and disruptions.

In response to the COVID-19 pandemic and the calls for re-shoring, which we believe are misplaced and will not prove effective, EFPIA advocates for a fact-based analysis of supply chain issues and a tailored response rather than the implementation of blanket measures. These would potentially unnecessarily disrupt otherwise efficient supply chains and increase costs, to the detriment of patients. EFPIA recognizes that the COVID-19 pandemic has caused supply chain disruptions for certain products needed in the fight against the virus, as the OECD (2020) has also found. However, what our members report and the OECD found through their research, is that the global shortages experienced at the height of the pandemic can rather be explained by an unexpected surge in demand rather than unprepared supply chains. This was further aggravated by protectionist measures, including export restrictions or full bans, which prevented the smooth adjustment of supply chains and further complicated supply issues. When it comes to pharmaceuticals in particular, the data are clear in terms of the supply chains structures and sources:

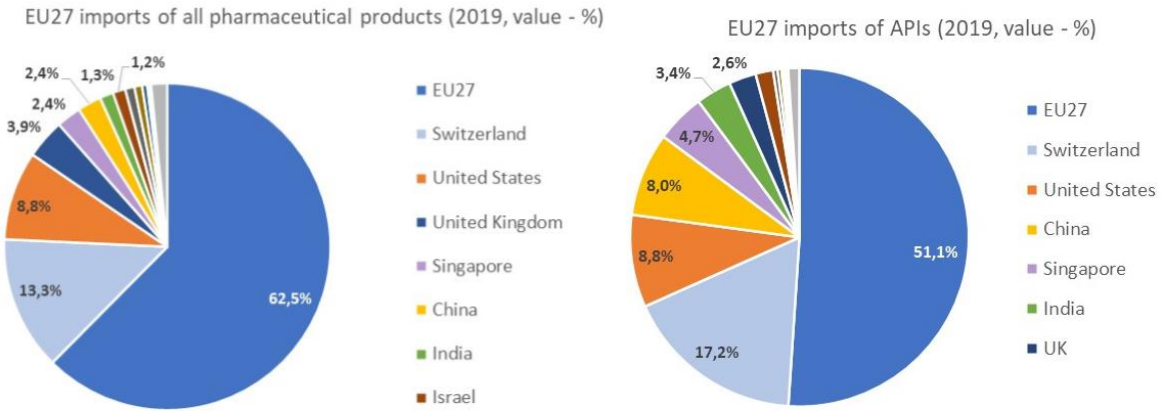
1. According to ECIPE (2020)[2], an analysis of Eurostat (2019) data for all pharmaceutical inputs (APIs and chemicals that are both early pharmaceutical inputs) as well as final products, show that dependence on China and India is limited. For all pharmaceutical products, Chinese and Indian imports are 2.4% and 1.3% respectively. For APIs, in value terms, Chinese and Indian imports are 8.0% and 3.4% respectively. The EU Internal Market constitutes 51.1% of all API imports. The EU's dependence on Chinese imports of APIs in volume terms is higher, amounting to 22.5%, which is still far below the share of intra-EU trade, which stands at 51.9%.[3] This is shown in Figure 1 below.

2. According to an EFPIA membership survey, 77% of Active Pharmaceutical Ingredients (APIs) used for producing innovative medicines in Europe are also manufactured in Europe itself (the EU, Switzerland and UK), 12% of APIs come from the United States and only 9% is sourced from Asia (including Japan and South Korea).4 This makes the EU a key manufacturing region for innovative medicines with a high level of strategic resilience. Moreover, in 2018, the EU had a €91 Bn trade surplus with its trading partners, making pharmaceuticals the largest contributor to the EU's positive trade balance.

3. According to Eurostat, the EU exports 63.8% of all medicines globally in terms of value, amounting to c. €367 billion in 2019.[5]

[2] ECIPE (2020) "Key Trade Data Points on the EU27 Pharmaceutical Supply Chain", July 2020.
3 ECIPE (2020) "Key Trade Data Points on the EU27 Pharmaceutical Supply Chain", July 2020.
4 EFPIA Internal Survey, Feb 2020
5 Eurostat (covering intra- and extra-EU trade). Global figures based on WTO data.

Figure 1: EU27 imports of all pharmaceuticals and APIs (2019, Euro, % shares)



The innovative pharmaceutical industry's limited international dependency for supply of innovative APIs and its strong export performance are based on a strong R&D infrastructure in Europe, which is currently losing ground to other economies (see question 6). The EU in general, and the innovative pharmaceutical industry in particular, would stand to lose much if the EU were to focus its strategies on getting back basic manufacturing at the expense of innovation and an effective R&D ecosystem overall. Rather than incentivising manufacturing of one particular segment of the supply chain, the EU should have a holistic set of initiatives supporting innovative, sustainable manufacturing and supply chain resilience to secure supply for patients. This requires consistency between pharmaceutical, chemical, and environmental legislative frameworks, along with financial and educational infrastructure that will ensure the EU is a competitive global location for advanced manufacturing, delivering high value jobs and a positive boost to the economy.

Against this backdrop, we believe the EU's trade policy should rely on the EU's strengths and aim to have more **strategic resilience**, focusing on: **open trade, strengthening innovation and promoting best practice standards and regulations on a global level.**

Trade

The EU accounts for 63.8% of exports of all pharmaceutical products, both innovative and generic medicines, supplying a large part of the world.[6] Through its trade policy, the EU could continue to display global leadership and build more strategic resilience in the following ways:

1. The EU should stand strong against export bans and export restrictions such as those implemented during the height of the COVID-19 pandemic, to avoid misallocation of scarce resources. EFPIA warmly welcomes and supports the EU's plurilateral initiative on trade and healthcare products (see Question 3);
2. The EU should continue to stand up for the global rules-based trading system by supporting the WTO and co-leading the reform efforts, and continue its push for tariff liberalisation and tariff-free trade;
3. The EU should continue to tackle the growing threat of forced localisation of pharmaceutical manufacturing. Such measures are discriminatory and particularly damaging for EU exports and EU competitiveness.

Trade and innovation

R&D and innovation are core pillars for Europe's global competitiveness, allowing the block to compete with other regions such as the US and China, while delivering value to the EU economy and to patients. Through its trade policy, the EU could display global leadership and focus on innovation in the following ways:

4. The EU should ensure strong Intellectual Property (IP) provisions in EU FTAs (e.g. effective and timely patent enforcement, clear patentability criteria, Regulatory Data Protection (RDP), Patent Term Extension). These

6 Idem.

would support the EU as a centre for R&D and innovation, create a level playing field with trading partners, increase legal and procedural certainty, and increase the EU's strategic resilience by creating an appropriate environment that stimulates innovation (see further details in question 4);

5. The EU should continue to oppose the use, or threat thereof, of compulsory licensing in situations other than the exceptional circumstances and conditions defined by global trade rules (WTO TRIPS agreement);
6. The EU should support biopharmaceutical SMEs by ensuring they too are able to benefit from the necessary IP protections to support their R&D investments into innovative treatments by encouraging SMEs to use the EU network of IPR helpdesks.

Trade and regulatory cooperation

One of the EU's strengths lies in its global regulatory reach. Through the EU's large bilateral trade network, the EU promotes comprehensive standards and regulations. By means of its trade policy, the EU could display global leadership and focus on regulatory cooperation in the following ways:

7. The EU should continue to work towards global regulatory convergence that ensures high quality manufacturing and standards:
   a) The EU should encourage other countries to join the Pharmaceutical Inspection and Cooperation Scheme (PIC/S) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH);
   b) The EU should include adherence to global PIC/S and ICH standards in bilateral EU FTAs.;
   c) The EU should add substantive Mutual Recognition Agreements to bilateral EU FTA negotiations with partners that have high regulatory standards. [7]

Question 2: What initiatives should the EU take – alone or with other trading partners - to support businesses, including SMEs, to assess risks as well as solidifying and diversifying supply chains?

Conscious of the global operating environment, the EU should focus on continuously promoting open trade, solidifying and diversifying supply chains to ensure strategic resilience. The focus should not be on increased basic manufacturing but rather on innovative advanced manufacturing. Any initiatives to attract manufacturing should be incentives-based rather than mandatory requirements and in full compliance with WTO rules. This viewpoint should also be addressed with the EU's trading partners and third countries both in multilateral (G20, WTO, WHO) and bilateral trade relations.

A comprehensive EU Trade Strategy should ensure predictable and non-discriminatory trade and investment conditions providing a transparent environment for European companies operating in third countries. This would entail including comprehensive provisions on transparency and good governance in EU FTAs and dialogues with other trading partners on ways to enhance transparency and ensure non-discriminatory measures. The EU itself as well as its trading partners should refrain from discriminatory requirements or domestic preferences in public procurement, which is an issue of concern for EFPIA members in several market, e.g. Russia.

Finally, as we note in other parts of the questionnaire, the EU's wide network of FTAs is important to support global supply chains and support their smooth functioning. To that end, it remains important for the EU to implement and enforce existing FTAs and ensure comprehensive provisions on e.g. customs, procurement and regulatory cooperation in the negotiations. At the same time, the EU should participate in multilateral and plurilateral initiatives and be a driver for positive and meaningful change for free, transparent and non-discriminatory trade. The recent initiative on trade in healthcare products proposed by the EU is a good step in this direction (see following question).

7 With substantive we mean that the MRAs should include both procedural clauses and clauses with respect to substantive rights and obligations.

<u>Question 3:</u> How should the multilateral trade framework (WTO) be strengthened to ensure stability, predictability and a rules-based environment for fair and sustainable trade and investment?

EFPIA strongly supports the rules-based multilateral trading system. The innovative pharmaceutical industry is global in nature; the multilateral trading system is critical for us in defining and supporting rules and commitments around intellectual property, tariffs, procurement and other fundamental aspects of our business model.

The EU should take a leadership role in defending multilateralism and open trade, especially when protectionism worldwide is growing and traditional strong supporters of the WTO seem to turn their back on it. We encourage efforts from the EU to make progress in the ongoing work of reforming the WTO system and solving the Appellate Body crisis. This requires further efforts for dialogue to restore the U.S. support for the Appellate Body, as well as working with like-minded countries to ensure that WTO members renew their commitment to the multilateral rules-based trade framework.

The multilateral trade framework should also play a role in the context of the global pandemic and its aftermath. The WTO, alongside or in partnership with a number of other actors, played an important role in helping anticipate and react to fast moving trends impacting trade at the height of the pandemic in Spring 2020. Among these challenges, we note in particular export restrictions, which 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 hinder the conduct of clinical trials, increase the risk of shortages, and disrupt distribution channels for medicine to ultimately reach patients.

As patients in many parts of the world depend on Europe for their supply of medicines, policies that artificially restrict global supply chain flexibility are counterproductive to the smooth functioning of global trade and patient access. Collaboration, flexible, innovative approaches and open communication between manufacturers suppliers and authorities are central to addressing the increasing challenges in medicine supply. There are two interlinked areas in which the WTO framework can be strengthened to achieve this:

1. Update the WTO's Zero-for-Zero Pharmaceutical Agreement[8]
The negative impact of tariffs goes well beyond the immediate impact on pharmaceutical products. Tariffs on medical products and inputs especially harm patients, who need them the most, as well as universities, private and government research institutions and private and public hospitals. Moreover, tariffs on R&D and manufacturing inputs can undermine the establishment and growth of local industries. The COVID-19 crisis has highlighted the challenges posed by any type of trade barriers to the pharmaceutical and medical devices industries ability to deliver products where and when they are needed.

A common element to address some of these concerns should begin with an update to the zero-for-zero agreement, sorely needed ten years after the prior one. This should include the update to the pharmaceutical products covered, and, if possible, expansion of the scope of the agreement with more Member States joining. EFPIA calls on the WTO signatories to update the annex of molecules and other products covered by the zero-for-zero agreement at the WTO to include all post-2010 intermediate chemical products, active pharmaceutical ingredients (APIs), inputs for pharmaceutical and bio-pharmaceutical production and R&D, exempting them from tariffs. Tariffs on any of these products increase costs for patients and healthcare systems, at a time when governments are concerned about ensuring universal healthcare coverage and managing healthcare costs.

2. A multilateral agreement on the permanent elimination of tariffs and export restrictions
EFPIA fully supports the Commission's initiative of a multilateral framework for trade in healthcare products as outlined in DG Trade Concept Paper's from June 2020. In our view, and in addition to permanent tariffs elimination for healthcare products, such an initiative should include:

8 Formally known as the WTO Pharmaceutical Tariff Elimination Agreement

- Parties refraining from imposing export restrictions, export licensing requirements, domestic priority programmes, or other barriers that will disrupt global supply chains, both within the EU and with regard to third country trading partners – also in a pandemic situation. This would allow manufacturers to organise their global supply chains for production to be as efficient as possible, for distribution channels to operate effectively and for supplies to reach those places where they are needed the most;
- In an emergency situation, facilitate border-related trade of essential equipment and medicines, and the inputs required for their development, manufacture and quality assurance, As seen during the COVID-19 pandemic, green priority lanes are essential and so is flexibility with regard to required documentation (e.g. import licenses);
- Parties refraining from using medicines and medicinal ingredients in any rebalancing or retaliatory tariff disputes. These policies disrupt supply chains and increase costs, harming patients as a result.

We also welcome the Concept Paper's focus on tackling domestic preference and increasing transparency in procurement and wider import-related measures.

We believe that Europe should be leading global efforts to facilitate trade in medicines and other critical medical supplies and to encourage countries to permanently eliminate tariffs on medicines and medical equipment. As such, Europe and the world as a whole would be better prepared and equipped for the next pandemic.

<u>Question 4:</u> How can we use our broad network of existing FTAs or new FTAs to improve market access for EU exporters and investors, and promote international regulatory cooperation – particularly in relation to digital and green technologies and standards in order to maximise their potential?

The EU is currently one of the few strong global players that stands for a rules-based global trading system and can take a global leadership role to promote this, including through its strong network of bilateral trade agreements. Many FTAs have played a key role in improving market access for innovative pharmaceutical companies, and support a globally competitive innovative industry in Europe. To ensure that Europe remains a global leader and exporter of innovative medicines, all future FTAs should maintain and promote the EU's high-level standards, notably addressing the following issues:

- Inclusion of **strong IP provisions** regarding patent enforcement, patentability criteria, Regulatory Data Protection (RDP), Patent Term Extensions (PTE), as closely as possible mirroring the EU's current standards. This would ensure adequate IP protection in third country markets to protect innovators and contribute to create a level-playing field for EU exporters, supporting EU's leadership in innovative pharmaceutical exports. This would also support the EU's potential as a leading centre of R&D and innovation, further increasing the EU's resilience by creating an appropriate environment that stimulates innovation. An ECIPE study (forthcoming, 2020) on the economic impact of stronger IP provisions (not only for the pharmaceutical industry, but for the core group of IP-intensive industries) in EU FTAs shows that:

    a. Stronger IP in EU FTAs contribute to more EU production (Euro 63.5 billion annually) and more exports (Euro 73.5 billion annually) – directly supporting increased strategic resilience and helping EU industries facing global competition;
    b. "Patents" are economically one of the most important types of IP (supporting sectors with an economic production value of Euro 4.3 trillion in the EU), especially when compared to copyrights, geographical indications and plant variety registrations;
    c. A very significant share of EU exports is IP-intensive (including intra-EU trade). Some of the main EU IP-intensive exports are, however, not covered by any FTA or one that includes IP provisions;
    d. The economic effects of strengthening IP provisions in EU FTAs are significantly positive for the EU and its Member States. If IP provisions in EU FTAs are brought to the level of the EU-Canada

CETA level, EU GDP is expected to be 0.4% higher each year, exports are expected to increase by 1.3 percent annually, meaning export driven jobs can be created, and imports by marginally less (1.3% rounded off). There is also a positive real wage effect that affects EU workers directly (see Figure 3 below);

e. Stronger IP in EU FTAs strengthen the EU's manufacturing base for strategic sectors (e.g. pharmaceuticals, electronics, chemicals) in a way that focuses on making Europe attractive for investments, increasing EU resilience; not via reshoring or near-shoring policies, but in a way that aligns private and public incentives;
f. Stronger IP in EU FTAs create a stronger innovation-driven global EU trade network with bilateral commitments the EU can enforce (linked to the much-welcomed EU focus on FTA enforcement via the appointment of the Chief Trade Enforcement Officer), both increasing future pandemic resilience and increasing security of supply for essential products;
g. Stronger IP in EU FTAs create the level playing field for bearing the increasing costs for R&D into new products and processes among the EU and its bilateral trade partners. The more symmetric the IP elements in EU FTAs are to the existing EU Framework, the more costs for innovation are spread out globally;
h. Pharmaceutical labour productivity is one of the highest of all sectors in the EU, implying the industry creates high value-added jobs for the EU economy (see Figure 2 below).

Figure 2 – Labour productivity for IP intensive sectors

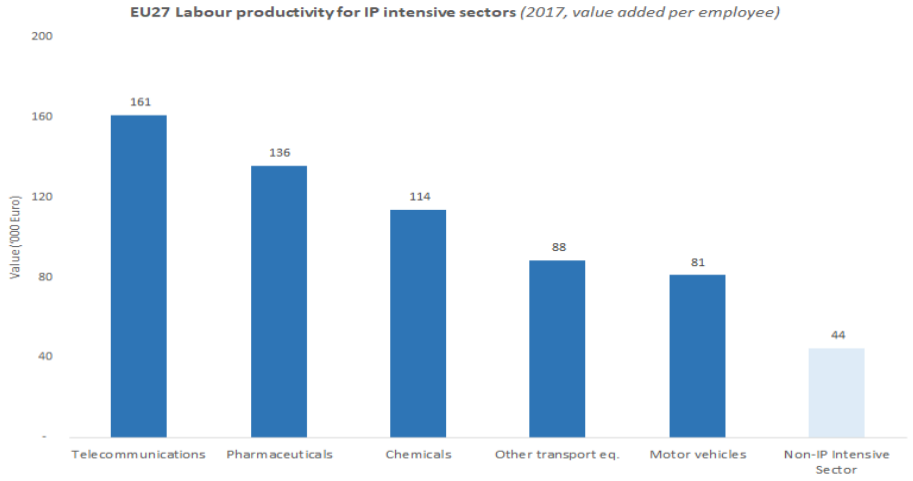
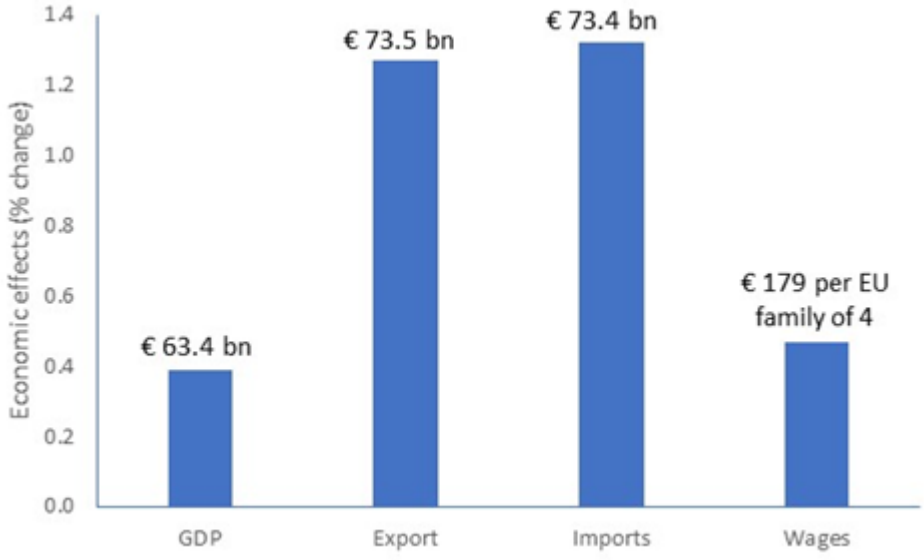


Figure 3 – Economic effects of strengthening IP provisions in EU FTAs



- Inclusion of provisions guaranteeing **equal and non-discriminatory market access** (e.g. transparency of pricing and reimbursement procedures, non-discriminatory access to public procurement etc.) While the EU has limited competence on pricing and reimbursement of pharmaceuticals, it can ensure the legislative and procurement processes to be fair, transparent and predictable e.g. through referencing and reinforcing the Transparency Directive.

- Inclusion of consistent, trade-facilitating, and transparent and easy-to-use **rules of origin** (also for SMEs) provisions with EU bilateral trading partners. These include a verification of origin procedure in which the Competent Authorities of the exporting trade partner performs the verification in order to safeguard the confidentiality, to facilitate the communication between exporting company and Competent Authority and to increase the Preference Utilisation Rate (PUR).

- Inclusion of ambitious **e-commerce** chapters that allow digital trade to flow freely, enabling digital health developments to continue and accelerate. Digital solutions, for instance for administering treatments and for conducting clinical trials are increasingly important for our industry, with major benefits for patients. Furthermore, digital solutions that generate data for secondary research are critical to driving evidence-based decision making and improving outcomes for patients. Efforts to advance digital health infrastructure and governance in order to improve both the uptake of digital solutions and the access and use of data generated within the digital health ecosystem have been accelerated due to the COVID-19 pandemic and will play an increasingly important role in the future.

- Given the EU's world-class regulatory system we believe that strong **regulatory convergence** provisions should be included in EU's FTAs. Over the past years, very important work has been done to tackle trade barriers in the regulatory sphere, for example non-science-based clinical trial requirements in Vietnam, which were removed via the FTA. Furthermore, we continue to support the EU's efforts to encourage key trade partners adherence to global PIC/S and ICH standards in bilateral EU FTAs.

  In addition, **Mutual Recognition Agreements on Good Manufacturing Practices (GMP) inspections** with key partners, such as the US and Japan have been a critical tool to (a) reduce duplicative work on manufacturing site inspections, (b) tangibly improve supply chain flexibility, by removing import testing requirements, and (c) raise the bar on pharma manufacturing standards globally, by allowing a stronger focus on at-risk countries. We strongly encourage the EU to continue to build on these results, including in the ongoing trade negotiations with the UK.

  In order to ensure that an appropriate feedback mechanism is in place to address regulatory matters, we advocate for the establishment of a structured dialogue on how regulatory provisions linked to FTAs (in general) could be strengthened in terms of their practical relevance for industry in its day-to-day operations.

  EFPIA is very supportive of the European Commission's recent appointment of a Chief Trade Enforcement Officer. Enforcement of FTAs and other aspects of EU trade policy should be key part of the EU's new trade strategy. It is critically important that these provisions included in the texts of the EU's trade agreements are duly enforced. We believe that dialogue mechanisms and a monitoring system needs to be put into place to anticipate, prevent and tackle potential divergences from agreed provisions. We believe that the establishment of a dedicated team in DG Trade concentrating on these issues will be highly beneficial. We also believe that the inclusion of a strong and effective dispute resolution mechanism is vital to be able to substantively follow through on disagreements on FTA implementation matters.

<u>Question 5:</u> With which partners and regions should the EU prioritise its engagement? In particular, how can we strengthen our trade and investment relationship with neighbouring countries and Africa to our mutual benefit?

Geographical diversity is key to the resilience of global supply chains. To that end EFPIA encourages the EU to consider building on the existing strong relationship with the following regions in the coming years:

United States

The European innovative pharmaceutical industry has deep-rooted ties with the US. The EU and US jointly account for more than 75% of global R&D in life sciences and create over 1.6 million high-paying jobs in the sector. The EU already enjoys a close relationship with its biggest trading partner, and despite the current turbulence of transatlantic trade relations, we believe that stronger trade links can be developed. One core element is strengthening regulatory cooperation, building off the EMA's and FDA's global leadership among regulatory agencies as well as transatlantic coordination on Intellectual Property including addressing counterfeiting and illegal trade of pharmaceuticals.

EFPIA encourages the EU to continue to build on existing cooperation between EU (EMA) and US (FDA) regulatory agencies and look into further opportunities to align regulatory procedures.

- The expansion of **the Mutual Recognition Agreement (MRA) on GMP inspections and batch testing** (in force since 2017, fully operational since July 2019) to include vaccines would be a helpful and natural next step in this regard. In addition, EFPIA is asking both parties to consider securing progress to implement the recognition of inspections of manufacturing sites in third countries (Art 8.3) and include US recognition of inspections performed by an EU member state inspectorate when they have already inspected processes associated with a new product submitted for authorization, thus avoiding the need for FDA pre-approval inspections (PAI). Further considerations should include biological products, where authorised by the Center for Biologics Evaluation and Research (CBER), and clarification around medicinal products containing medical devices (EU) / combination products (US).
- EFPIA is conducting yearly surveys on GMP inspections[9]. While concrete data will be available in one of the next year's survey editions, the MRA already shows tangible results for the regulatory agencies and for the industry, contributing to a quicker delivery of new medicines to patients. According to EFPIA's estimates, the MRA will eliminate the need for at least 80 inspections per year just across its member companies. EFPIA data further anticipates an approximate savings of just over € 11 mill. a year for industry, based on per company costs of € 137K for each EU GMP inspection.
- Since clinical research is global in nature and drawing upon the valuable learnings from and experience with the MRA on GMP inspection, EFPIA is calling for an establishment of **a Mutual Recognition Agreement in the area of Good Clinical Practice (GCP).** This would reduce burden and duplication of extremely resource intensive (for both applicant and regulatory authority) inspections and focus both regulatory authority and industry resources that could be used in other ways to oversee or reduce risk where needs are higher. As both agencies operate under harmonized ICH[10] GCP standards and have already significant experience in GCP collaboration, the agreement of a formal MRA would be a logical next step.

  In September 2009, the EU EMA and US FDA launched an 18 months GCP pilot initiative under the framework of their confidentiality arrangements. During the pilot and subsequent collaborative arrangement, EMA and FDA conduct periodic information exchanges, streamline sharing of GCP inspection planning information, communicate on inspection outcomes in a timely manner, and cooperate in the conduct of on-site inspections. However, there remains a high level of redundancy

9 EFPIA, "Annual Regulatory GMP/GDP Inspection Survey 2019 Data", May 2020. Available at: https://www.efpia.eu/media/547447/efpia-2019-reg-inspection-survey-v1-public.pdf

10 The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

and duplicity in the GCP inspection related activities of the EMA and FDA even within a joint onsite sponsor inspection.

According to an internal EFPIA survey, it is estimated that a GCP inspection costs around €550 000 on average. Based on conservative calculations and assuming the number of inspections could be decreased by half to around 100 inspections per year creating a potential savings of around 55 million euros per year for industry alone. If implemented, it is anticipated that regulator resources would also be conserved.

As science evolves, more potential areas for collaboration between EU and US arise. EFPIA is supportive of the EU's efforts in the framework of the EU-US Trade and Technology Council and encourages cooperation on various aspects of digital health and a special focus on new health technologies. It is important for the EU and US to remain world leaders in regulatory science by setting precedent on the use of regulatory technological innovations (e.g. cloud-based submissions, advanced analytics) to harness the power of these new technologies. EFPIA has also strongly suggested that the EU should refrain from using medicines and medical ingredients in any rebalancing or retaliatory (rebalancing) tariff disputes with third parties as such measures reduce agility of pharmaceutical supply chains. Such practices also counterbalance global public health objectives of ensuring timely access to treatments for patients. In this context, we are pleased to see that medicines were not included in the final Airbus- Boeing rebalancing tariff list.

United Kingdom

EFPIA encourages the EU to secure a comprehensive trade agreement with the UK, including an MRA on GMP inspections and batch testing, so that both remain close trading partners after the end of the Transition Period. We believe that the EU and UK should have the closest possible relationship for pharmaceuticals and chemicals, prioritising the health of citizens and the uninterrupted supply of medicines and vaccines. This is also in the EU's self-interest economically because a comprehensive agreement will best support EU competitiveness globally.

We believe that the agreement with the UK should secure the greatest possible regulatory cooperation on human medicinal products. The FTA should also include ambitious provisions on the protection of intellectual property, sharing of data, customs facilitation, as well as rules of origin, and cooperation in the area of R&D. We also believe the EU and UK should establish a Working Group on pharmaceuticals and medical devices to facilitate ongoing dialogue on regulatory cooperation and future participation in joint R&D programmes.

As immediate and urgent actions, the pharmaceutical industry continues to call for the two sides to agree on a Mutual Recognition Agreement (MRA) on GMP inspections and batch testing and agree on how to implement provisions in the Protocol on Northern Ireland in regard to human medicines. Securing these would lead to the least amount of disruption of medicine supplies and increase legal and business certainty to companies.

Switzerland

The EU is the main trading partner of Switzerland, where in 2019, around 52% of Swiss exports went to the Europe in terms of value[11], in which the pharmaceutical sector accounts for almost 41%.[12] Additionally, Switzerland is a key market for production of pharmaceuticals and intermediaries and is in the EUs top 3 markets for pharmaceutical trade. In 2019, the EU imported 13.3% and exported 5.9% of all pharmaceutical products to/from Switzerland.[13] Whereas 48% of Switzerland pharmaceutical exports go to the EU, making the EU its largest partner, only followed by the US at 24%.[14]

11 Swiss Confederation, Federal Statistical Office, "Swiss foreign trade: Key trading partners", May 2020. Available at: https://www.bfs.admin.ch/bfs/en/home/statistics/industry-services/foreign-trade/balance-import-export.assetdetail.13007488.html
12 Interpharma, "Health Panorama 2020: The most important facts and figures on Switzerland's healthcare system", August 2020. Available at: https://www.interpharma.ch/blog/neue-zahlen-und-fakten-zum-gesundheitswesen-und-zur-pharmalandschaft-schweiz/?lang=en
13 ECIPE (2020) "Key Trade Data Points on the EU27 Pharmaceutical Supply Chain", July 2020.
14 Interpharma, August 2020.

It would be important for the EU to continue ensuring the free movement of people with Switzerland, as this will allow around 330,000 cross border workers[15] and 1.4 million EU/EFTA nationals[16] to continue working/residing unhindered. Around 58% of the workforce in the Swiss pharmaceutical industry are highly qualified (with a university degree) [17] and EU employees make up a large part of this workforce, and will continue to do so as the Swiss labour market is too small to meet the high demand for a highly qualified workforce. As long-standing and important trading partners, the EU and Switzerland should prioritise the adoption of the EU-Switzerland Institutional Framework Agreement, which will allow to maintain and develop bilateral relations further to ensure smooth trade flows.

China

China is one of the EU's most important trading partners and a key player in the pharmaceutical supply chain. In 2019, EU imports from China totalled €362 billion (of which 0.9% pharmaceuticals), while EU exports to China totalled €198 billion (of which 5.9% pharmaceuticals).[18] In spite of political difficulties, EFPIA encourages the EU to continue the ongoing technical work, including in the framework of the very important annual High-Level Regulatory and IP Dialogues. Over the past years our sector has seen key policy initiatives as a result of these technical discussions, such as China joining ICH in 2017 and subsequent ICH committee management membership. We remain highly supportive of China's efforts towards improved regulatory and IP regimes, aligned with global standards. We also believe that it is critically important the EU continues its cooperation in capacity building to further promote its world-class regulatory system, which serves as a blueprint to many Chinese policy proposals. Furthermore, we encourage the EU and China to conclude the negotiations towards a meaningful Investment Agreement. The EU should include "health" as a high-level cooperation topic in the EU-Chinese relations. Topics of common interest could for example be intellectual property, regulatory approval and harmonization of standards, public procurement, and digitalization aspects. The EU should also continue working with China to encourage the development and implementation of regulations in line with international standards, including full implementation of ICH guidelines, enforcement of IP and RDP, cyber security, smoother administrative process related to human genetic resources and re-evaluation of 'new drug definition'.

Japan

Japan is one of the largest single markets for pharmaceuticals globally. In 2019, the EU exported €7.1 billion in finished pharmaceutical products to Japan and imported €0.7 billion from Japan.[19] Given this, changes to market access conditions have an extremely significant impact on our sector. In the past years, our sector has been faced with challenges including changes to the Price Maintenance Premium (PMP) eligibility criteria, to the pricing review system, and to the definition of what is an innovative medicine. The effects of these reforms are not the same for all companies and a disadvantage to international and small innovative firms in practice. It is clear that all these measures are resulting in a reduced appreciation and reward for innovation in Japan, undermining the effect of a strong IP system in the country.

Despite the positive developments via the EU-Japan EPA and flanking expanded MRA, there are also issues for the industry in Japan that could be looked at through the lens of the EPA. The Japanese regulatory and drug approval system could be improved further, for example, fully implementing the MRA for all products and situations and continue collaborate in international alliances e.g., ICH, PIC/S.

15 Swiss Confederation, Federal Statistical Office, "Foreign cross-border commuters by gender, canton of work and age class", February 2020. Available at: https://www.bfs.admin.ch/bfs/en/home.assetdetail.11847783.html
16 Swiss Confederation, Federal Statistical Office, "Foreign population", 2020. Available at: https://www.bfs.admin.ch/bfs/en/home/statistics/population/migration-integration/foreign.html
17 Interpharma, August 2020.
18 European Commission, Directorate-General for Trade, "European Union, Trade in goods with China", (2020).
19 ECIPE (2020) "Key Trade Data Points on the EU27 Pharmaceutical Supply Chain", July 2020.

Neighbouring countries

EFPIA encourages the EU to continue to pursue close ties with neighbouring countries, building on mechanisms and dialogues already in place.

Russia

Russia remains the sixth largest export market for European pharmaceuticals in terms of value, covering a total of 2.2% of total EU pharmaceutical exports.[20] However, the investment climate and market access continue to be challenging for the innovative pharmaceutical industry in Russia, with increased localisation efforts, delays in marketing authorization, discriminatory public procurement measures and a challenging intellectual property environment. EFPIA would therefore encourage the EU to continue pursuing bilateral technical discussions on issues, but to also take an active stance in tackling intellectual property violations in Russia, as well as other market access challenges there. We also welcome the initiative of the establishment of an EU-Russia healthcare dialogue, to which we stand ready to actively contribute and hope that this will become a recurrent bilateral platform for engagement with Russia.

Eurasian Economic Union

EFPIA has called for the EU's Regulatory Data Protection (RDP) provisions to serve as a reference point for the Eurasian Economic Union (EAEU) rules. The EAEU would benefit from greater convergence and utilizing the broad European experience while developing its regulatory system for medicinal products.

Turkey

A strong and forward-looking trading relationship between the EU and Turkey is a key objective for the European innovative pharmaceutical industry. In 2019, EU total exports to Turkey amounted to €68.3 billion, with pharmaceuticals making up 4.4% of these[21], and Turkey represents a strategic market of geographical proximity and importance. The innovative pharmaceutical industry continues to be impacted by a number of longstanding, as well as more recent, market access barriers and discriminatory measures on the Turkish market, including forced localisation, a Euro-Lira exchange rate specific to our sector, regulatory data protection failures and delays in regulatory approval. To that end, in the longer-term, moves to modernise the Customs Union would potentially allow progress on longstanding issues of concern in Turkey. This may also provide the possibility to improve the operating environment for innovative pharmaceutical companies, with for example stronger focus on improving the IP environment, securing positive regulatory elements and a level-playing field in public procurement. All of this would need to be underpinned with an effective enforcement mechanism. We also encourage the EU to continue the existing bilateral dialogues, such as the EU-Turkey IP WG. In addition, as Turkey is now a member of ICH and PIC/S, we encourage further alignment with global regulatory standards and a renewed EU-Turkey dialogue on the feasibility of an MRA on GMP inspections.

Africa

EFPIA is supportive of the EU's efforts to explore closer ties with African countries, building on the joint communiqué issued after the EU-African Union (AU) Ministers of Foreign Affairs meeting of 2019. We believe that joint initiatives could be pursued, focusing on health, health security and investment in health in general. Related to health security, the EU committed in June 2019 to increase funding to support health security, with the WHO and focusing on improving regional health systems in African, Caribbean, and Pacific countries. To that end, and to speed up access to medicines for patients in Africa, we are supportive of the work between EU and African medicines agencies to create closer cooperation towards better harmonisation of regulatory practices.

20 Idem.

21 European Commission, Directorate-General for Trade, "European Union, Trade in goods with Turkey", (2020).

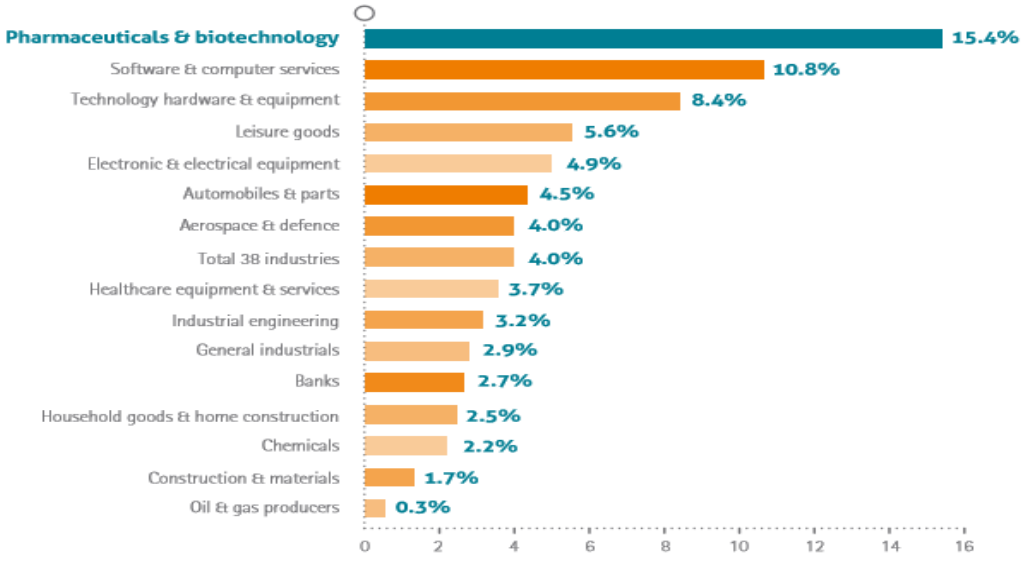
<u>Question 6:</u> How can trade policy support the European renewed industrial policy?

A renewed European industrial policy is an opportunity to spur the EU's competitiveness and recovery post-COVID-19 by fostering the best possible R&D infrastructure in the EU. While the COVID-19 pandemic caused a spike in demand and supply chain disruptions, due to export bans and other trade limiting factors, , the pandemic has also served to highlight the importance of having a well-functioning R&D infrastructure that can react quickly to such unexpected situations. The EU approach should be to avoid future disruptions by advocating for open borders and trade rather than attempting to step up manufacturing in low-added value products where the EU is not globally competitive. Instead, the EU should build on its strengths and take measures to ensure that the EU "remains an innovator and world leader", an aspiration outlined in President von der Leyen's Mission letter to Commissioner Stella Kyriakides.

The innovative pharmaceutical industry, both large multinationals and SMEs, is at the core of the Research and Development (R&D) in Europe to find diagnostics, treatments, and vaccines for COVID-19. In June 2020, over 1292 clinical trial were being conducted for COVID-19.[22] Activities of pharmaceutical companies contributed over €100 billion directly to the EU economy, with an additional €106 billion provided through the supply chain and employee spending.[23]

The EU accounts for 63.8% of global exports of finished medicines, and the pharmaceutical industry in the EU is the largest contributor to the EU's trade surplus, contributing over €100bn (in 2019) – creating many export-related jobs.[24] [25] The pharmaceutical industry is the most R&D intensive industry in the EU, with R&D investment constituting 15% of net sales, nearly twice that of any other industry (see Figure 4).[26] We therefore believe that our industry and focus on innovation should be central to the EUs industrial strategy.

Figure 4: Ranking of industrial sectors by R&D intensity (R&D as % of net sales, 2019)



<u>Note</u>:
Data relate to the top 2,500 companies with registered offices in the EU (551), Japan (318), the US (769), China (507) and the Rest of the World (355), ranked by total worldwide R&D investment (with investment in R&D above € 30 million).

<u>Source</u>: The 2019 EU Industrial R&D Investment Scoreboard, European Commission, JRC/DG RTD

22 https://clinicaltrials.gov/ct2/results?cond=COVID&age_v=&gndr=&type=Intr&rslt=&Search=Apply [accessed 23 June 2020]

23 https://www.efpia.eu/media/412939/efpia-economic-societal-footprint-industry-final-report-250619.pdf

24 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).

25 https://www.efpia.eu/media/413006/the-pharmaceutical-industry-in-figures.pdf

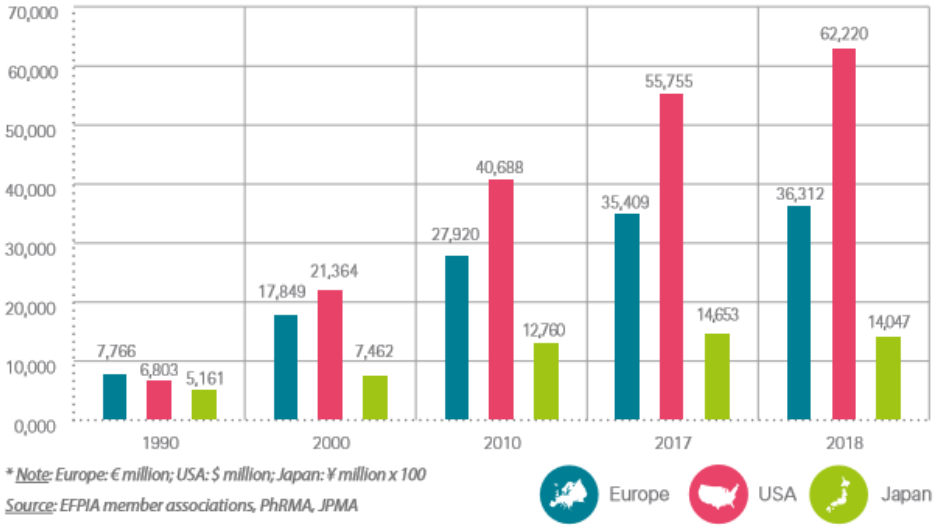
26 The 2018 EU Industrial R&D Investment Scoreboard, European Commission, JRC/DG RTD. The next highest sectors are Technology Hardware & Equipment (8.7%) and Software & Computer Services (8.4%).

To this end, EFPIA welcomes the focus on the resilience of the pharmaceutical industry at the forefront of EU initiatives. As noted before, we believe the best way to support resilience is via innovation as a key long-term driver for economic growth.

Promoting a robust global level- playing field with high standards of IP protection, including RDP and enforcement, should be core to the EU's trade strategy. This is critical to ensuring the success of Europe's IP-intensive industries on a global scale and for the European innovative pharmaceutical industry to remain a world leader in innovation. To strengthen strategic resilience, these EU initiatives must focus on strengthening Europe's medical research eco-system, enhance the region's resilience to global health threats and address our on-going health challenges while also positioning it as a key driver for the EU's economic recovery.

However, when it comes to innovation, Europe is currently losing ground to strong global competitors such as China and the US. The reality is that the EU no longer leads the world in medical innovation.[27] Today, 47 percent of new treatments originate from the US compared with just 25 percent from Europe.[28] This represents a complete reversal of the situation just 25 years ago. The EU's R&D base has also eroded due to new cutting-edge research being transferred out of Europe, mainly to the US and more recently to China. Unless the Commission acts now, the sustained loss of Europe's competitiveness will continue and even accelerate in the context of fierce global competition for life-science investment. Figure 5 shows the development of pharmaceutical R&D from 1990 (when the EU received the highest share in pharmaceutical R&D) to 2018 where that is no longer the case.

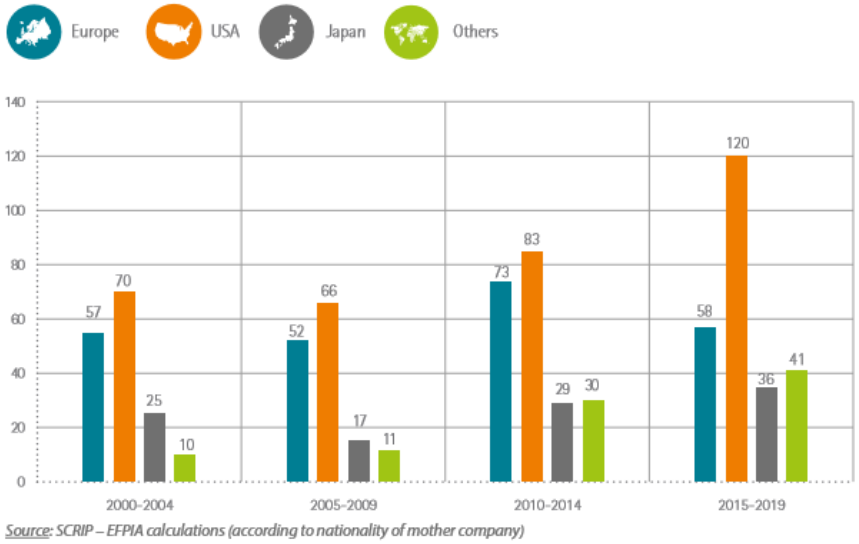
Figure 5: Pharmaceutical R&D expenditure in Europe, US, and Japan (1990-2018)



27 EFPIA, "The Pharmaceutical Industry in Figures", SCRIP - EFPIA calculations (according to nationality of mother company), page 8, (2020).
28 Idem.

Figure 6 shows the number of new chemical and biological entities introduced between 2000 and 2019. There too the relative position of the EU has deteriorated over time, not only compared to the US, but also compared to Japan and 'Others' (which includes China – which is catching up fast).

Figure 6: Number of new chemical and biological entities (2000 – 2019)



Source: SCRIP – EFPIA calculations (according to nationality of mother company)

The trade and renewed industrial strategies should focus on synergies how they can strengthen each other and propel the EU back to a competitive and R&D position it has gradually lost. In the upcoming years, the EU's strategy should aim to turn this trend around by creating, implementing, and enforcing comprehensive Trade, Industrial and Pharmaceutical Strategies, that seek to incentivise and promote Europe's global competitiveness. Strong IP rights and their effective enforcement are clearly correlated with R&D expenditures and investment[29] [30], access to and availability of latest technologies[31], clinical trial activities[32], and a reduction in trade in falsified medicines. An industrial strategy that supports an IP framework that protects investments in medical research, and a regulatory framework that is stable, fast, effective and globally competitive will enable Europe to compete with other regions like China and the US in the development of new medical technologies. With the right trade policy and industrial strategy as levers, we believe that Europe has the core capabilities to build on its strong R&D base and at the same time ensure preparedness for any future pandemics and health crises.

Question 7: What more can be done to help SMEs benefit from the opportunities of international trade and investment? Where do they have specific needs or particular challenges that could be addressed by trade and investment policy measures and support?

SMEs play a very important role in the innovative pharmaceutical industry. They are vital for the EU's R&D potential and growth and the pharmaceutical SMEs are among those with the highest R&D potential according to the Annual Report on SMEs 2018/2019.[33] When successful, SMEs grow to become larger companies with a global footprint, supporting the EU economy, including through high-quality jobs. 51% of

29 US Chamber International IP Index: "The roots of innovation" (2017).
30 OECD database (2017) [accessed, 20 June 2019].
31 GIPA "IP as a Development Tool: Supplementary Statistical Analysis to the US Chamber International IP Index" (2016).
32 ClinicalTrials.gov [accessed 23 June 2020].
33 EASME (2019), 'Annual Report on European SMEs 2018//2019 – Research & Development and Innovation by SMEs', Background document, SME Performance Review 2018/2019. Contract number EASME/COSME/2017/031, November 2019.

EU pharmaceutical companies with orphan designations (for rare diseases) in development are SMEs.[34] Moreover, the contribution of SMEs to innovative activities has increased over the last decades.[35] [36]

Strong IP protection and enforcement provisions via EU FTAs will reduce uncertainty and risks for SMEs, resulting in stronger domestic and international performance. The EU should also continue to provide support to exporting SMEs, for example through the EU network of IPR Helpdesks, to raise awareness and ensure SMEs are adequately protected regarding their inventions, while at the same time aiming to minimise regulatory burdens. In addition, smooth, simple and flexible rules in trade serve SMEs the best. The only way for SMEs to prosper is removing or reducing trade and investment hampering legislation.

There are two aspects that could be strengthened in the new trade strategy for SMEs:

1. Dedicated SME chapters in recent FTAs as well as the various Contact Points and Helpdesks that are mentioned in the Consultation Note, support SMEs significantly. However, more attention needs to be paid to ensuring SMEs are well aware of the available support and better understand how to benefit from FTAs in practice. This might require an improved information stream from the EC and Member States to the SMEs. In addition, as SMEs have limited administrative resources, simplification of provisions in FTAs, e.g. related to customs and Rules of Origin should be considered. Different approaches in different FTAs regarding customs procedures add to the complexity, which is more difficult to manage for SMEs than for larger companies;
2. SMEs should be able to better benefit from strong IP protection, incentives and reward mechanisms, as well as IP enforcement in its bilateral FTAs.[37]

<u>Question 8:</u> How can trade policy facilitate the transition to a greener, fairer and more responsible economy at home and abroad? How can trade policy further promote the UN Sustainable Development Goals (SDGs)? How should implementation and enforcement support these objectives?

EFPIA member companies strive to invent, produce and distribute new medicines and vaccines in a safe and environmentally responsible manner. We do this by driving an agile, innovative, evidence-based sustainability strategy to enable the pharmaceutical industry to embrace evolutions in science, technology & society and to integrate sustainability across our entire value chain to deliver quality-based, healthy and green outcomes while positively impacting the lives of patients. EFPIA welcomes the Commission's focus on the Green Agenda and a more sustainable Europe, and looks forward to engaging constructively on the roll-out of their policy priorities[38]. We believe that the specific role of our industry needs to be taken into consideration when new legislative proposals are introduced. Accordingly, the approval of manufacturing plants, clinical trials and marketing authorizations should be taken into account when implementing and interpreting some elements of other EU legislation (e.g. REACH, biocides, etc.), as well as legislation elsewhere. The long development timelines and highly regulated nature of our industry are fundamental aspects of the ability to react to changes in legislation, e.g. restriction of chemicals.

With regard to Pharmaceuticals in the Environment (PiE), EFPIA is supportive of the Commission's Strategic Approach to PiE and considers it a tool that will guide stakeholders in their work, in a collaborative approach, to minimize the impact of PiE, while safeguarding access to effective treatments for patients in Europe.

The European Commission's Trade Policy should build on its Strategic Approach to PiE, including by recognizing and promoting the added value of industry self-regulatory initiatives, as they exist in and outside

34 Lincker et al. (2014) "Regulatory watch: Where do new medicines originate from in the EU? Nature Review Drug Discovery (2014). Biotech company data: https://www.ebe-biopharma.eu/facts/
35 Acs, Z.J. and D.B. Audretsch (1990). Innovation and Small Firms. The MIT Press, Cambridge.
36 Acs, Z.J. and D.B. Audretsch (2005). Entrepreneurship, Innovation and Technological Change. Foundations and Trends in Entrepreneurship, 1 (4), p. 149-195.
37 PwC, "Economic & Societal Footprint of the Pharmaceutical Industry in Europe", June 2019.
38 EFPIA, "Environment, Health, Safety and Sustainability". Available at: https://efpia.eu/about-medicines/development-of-medicines/regulations-safety-supply/environment-health-safety-and-sustainability/

Europe, such as EcoPharmaco-Stewardship[39], AMR Alliance[40] and #MedsDisposal[41]. EFPIA believes that concerns and measures taken to mitigate environmental implications of medicines should not lead to a decrease in patient's accessibility to medicines caused by any delays in the approval process or even by rejecting authorization of use. There would be great value when addressing issues of PiE in Trade Policy, to take into account best practices already implemented ion EU Member States. Any designs to address PiE mitigation should be science-based, proportionate and involve all stakeholders along a medicine's lifecycle.

With its global trade policy, the EU can play a significant role to encourage its trade partners to maintain a proper balance between the regulation of pharmaceuticals and the introduction of innovative changes to product manufacturing processes and post-approval supply. On the multilateral level, the EU should also pursue these endeavours in the G20, WTO and WHO and take a lead in combining a pro-active trade agenda and UN Sustainable Development Goals (SDGs) goals. Our industry fully supports the UN Sustainable Development Goals (SDGs), makes significant contributions and will continue to work towards making further progress. Our contributions link to a number of goals including, but not only, SDGs 3 (Good health and Well-being); 4 (Quality Education); 5 (Gender Equality); 8 (Decent Work and Economic Growth); 9 (Industry, innovation and Infrastructure), 12 (Sustainable consumption and production) and 17 (Partnerships). Through its FTAs and overall global trade policy, the EU can work collaboratively with governments, the healthcare industry and other stakeholders to coordinate and support progress towards achieving the SDGs. In addition, the EU can actively support countries that are working on introducing Universal Health Coverage (UHC), by sharing expertise in constructing and financing UHC and in promoting collective responses to health challenges, e.g. COVID-19, future pandemics and collaboration to address antimicrobial resistance (AMR).

Finally, in terms of the proposed Carbon Border Adjustment Mechanism (CBAM), the pharmaceutical industry is, in absolute terms, generally considered a medium-impact sector (FTSE4Good) with regard to CO2 emissions and research driven pharmaceutical companies typically not belong to the high energy consuming companies that would be the main target of a CBAM. In addition, early evidence suggests that innovation that improves health outcomes while optimizing resources also reduces carbon impacts Our member companies are committed to contribute responsibly to progress in regard to CO2 reduction targets, specifically addressing increased energy efficiency and lowered energy intensity across our value chains.

<u>Question 9:</u> How can trade policy help to foster more responsible business conduct? What role should trade policy play in promoting transparent, responsible and sustainable supply chains?

The innovative pharmaceutical industry has a responsibility towards the communities in countries where it operates, and recognises that society has particularly high expectations of this industry. Consequently, and in addition to complying with extensive legal requirements, EFPIA members have adopted Codes to ensure that all interactions with patients and stakeholders take place in an ethical and transparent manner and meet the high standards of integrity that patients, governments and other stakeholders expect. Trade policy and FTAs could be leveraged as tools to ensure that trading partners also abide by the rules on ethical business conduct and transparency under which the industry operates in Europe.

In terms of supply chains, innovative pharmaceutical companies have carefully built robust global supply chains over decades to ensure patients in Europe and around the world have ongoing access to medicines. This enables manufacturers to make swift adjustments as needed to ensure stability and avoid potential shortages and disruptions (e.g. not all regions in the world were impacted by COVID-19 at the same time, cases of natural disasters in some regions).

Therefore, the European Commission's trade policy should:

39 AESGP, EFPIA, Medicines for Europe, "Care for People, Care for our Environment". Available at: https://www.efpia.eu/media/288586/pie-brochure.pdf
40 https://www.amrindustryalliance.org/
41 http://medsdisposal.eu/

- Remain aware of global interdependencies and the EU's strong position as medicines exporter;
- Ensure that the focus of strategic resilience is focused on strengthening the EU's R&D infrastructure and maintaining a world-class incentives ecosystem for innovation;
- Ensure that any vision on manufacturing in Europe is not about repatriating supply chains, but on exploring opportunities for enhancing production that is science-driven and high value-added, including advanced manufacturing. Any measures to support local manufacturing should be incentives-based and in line with international law, rather than rely on mandatory requirements;
- Fight illicit trade in medicines, including counterfeit medicines, in order to reduce the harm to patients, not only in the EU but worldwide.[42] In particular, we believe that the EU and US should enhance their cooperation in this critical issue;
- Build on the EU's global leadership by continuing to tackle the growing threat of forced localisation of pharmaceutical manufacturing. Such measures will decrease resilience, are discriminatory and very damaging for EU exports and patient access.

<u>Question 10:</u> How can digital trade rules benefit EU businesses, including SMEs? How could the digital transition, within the EU but also in developing country trade partners, be supported by trade policy, in particular when it comes to key digital technologies and major developments (e.g. block chain, artificial intelligence, big data flows)?

For the healthcare sector, digitalization and digital solutions based on enhanced data flows play an essential role in enhancing data flows in pharmaceutical manufacturing, supply (incl. customs) pharmacovigilance, drug development, clinical trials and understanding real-world treatment uptake and outcomes as well as benefits for patients. This in turn can contribute to a more efficient, value-based healthcare sector. The pandemic has clearly accelerated how consumers and patients leverage technology and this will play critical role in the future, if done right.

In addition, Artificial Intelligence (AI) has the potential to accelerate research through better target identification, trial execution, improving regulatory procedures and identification of novel scientific insight generation, which could be of benefit to European and worldwide patients alike. Data will be a key driver in this digital economy with the ability to streamline manufacturing quality and supply. In order to leverage the opportunities of AI and those provided by big data, the EU will need to find solutions to encourage health data sharing, whilst respecting privacy and security and support regulatory convergence and ensure that regulatory systems are agile to allow for purposeful adoption of technology. In particular, to support the free flow of data, the EU trade policy can help by facilitating convergence and interoperability in data protection approaches, agreement on data protection regimes adequacy with a specific focus on health, while also fighting against data localization requirements imposed by its trading partners. EFPIA particularly supports sectoral approaches to the assessment of adequacy of third countries' data protection regimes.

When it comes to cross-border trade, the importance of providing enhanced customs flexibility through digitizing customs procedures cannot be underestimated, saving time and both financial and human resources. Moreover, trade policy can support the further use of digital tools to address online trade of counterfeit and illegal medicines as well as export control authorizations. To that end, it would be important to use Trade Policy as a tool to align and converge the digital trade rulebook as much as possible, discussing regulatory alignment of standards and agile rules that enable digital developments to advance, as well as trade facilitation through digital means. This could be done via provisions in FTAs with relevant trading partners by including ambitious e- commerce chapters, or in bilateral and plurilateral discussions with non-FTA partners. In addition, EFPIA is supportive of the WTO plurilateral negotiations on e-commerce which we believe could be a helpful tool to set baseline global standards, and hope to see ambitious commitments by the parties that support free and safe data flows and data interoperability. While we support the EU's

42 Please refer to OECD-EUIP report for further details on strengthening cooperation on illicit trade in medicines: here.

ambition to be a trusted leader in the digital/AI economy, notably by exploring options, including in the IP framework, to best incentivize voluntary data sharing, it is important that any European approach to IP in relation to AI proceeds in coordination with its major trading partners. We also appreciate DG GROW's existing collaboration with WIPO.

In order to make use of the benefits of the digitalization, the EU's trade partners should refrain from data localization requirements (crucial for the protection of Intellectual Property Rights, Protection of Confidential Business Information, Privacy) (see next question for more details).

In bilateral discussions, provisions in trade agreements could be advanced so as to enable the deployment of cloud services to address he unique challenges that biopharmaceutical research and development face. For example, cloud services issues will be negotiated, and carried forward in current or emerging trade negotiations, including the EU-UK and EU-US agreements, among others. Also, multilateral discussions should be considered, such as the OCD and WHO. The OECD could be used as a forum to develop knowledge, best-practices sharing, and "standard-setting" to shape national policies on digital trade. The WHO may be a further venue to build political support and awareness among health ministries, patient groups, and other stakeholders for the implications of digital trade policies on patients and people.

<u>Question 11:</u> What are the biggest barriers and opportunities for European businesses engaging in digital trade in third countries or for consumers when engaging in e-commerce? How important are the international transfers of data for EU business activity?

Firstly, data interoperability systems need to be put in place. There is a need for dialogue and to create trust and transparency with third countries to ensure we do not miss the opportunity to adopt, align and converge digital technology within an appropriate policy framework that encourages its use and brings benefits to patients and consumers. Our members report that different rules in different countries and regions create significant hurdles to cross-border data flows. Access to data and cross border data flows of anonymised clinical data are key for our industry in order to derive insights about how different populations respond to different health interventions, particularly medicines and disruptions to flows of health data can jeopardise public health. Such international data transfers are vital to the goals of improving patient treatments and patient safety, cultivating public health, and accelerating the availability of innovative therapies. International transfers of personal information for purposes of medical research and monitoring drug reactions are therefore, necessary for important reasons of substantial public interest. These transfers take place pursuant to legal and ethical frameworks that ensure the confidentiality of the data and protection of individual privacy rights. The EU should work with its major trading partners to ensure that the rules on international data transfers take full account of these sectoral safeguards. With appropriate governance, validation and internationally and globally recognized standards, we can assure interoperability of the digital infrastructure, reliability of the technology and mitigate the risks of error, concerns about privacy, bias or inequality as we rely on this new data.

Data collection and AI development need to ensure equal benefits for all consumers and patients both in the EU and in third countries, and facilitate the conduct of clinical research both in the EU and globally. Differing rules and regulations create a significant barrier to this. While the EU's GDPR provides strong protection for data and data flows, this is not the case for all countries. In the case of the pharmaceutical industry, patient data is highly sensitive and therefore proper privacy and consistent data governance needs to be ensured. Further discussions are needed in order to allow data to flow freely across borders without jeopardizing data privacy.

Trade negotiations and bilateral discussions should also address and prevent data localisation requirements such as those we face in for example Russia, India and China. These countries expect industry to locally store sensitive data and restrict access and transfer of patient data for foreign companies. For instance, the Chinese Regulation on human genetic resources (HGR) controls the collection, preservation, utilization, and export of

Chinese human genetic resources to third parties, which includes also data, not only the material itself and does not permit foreign biopharmaceutical companies and other so-called "foreign entities" to directly collect Chinese HGR and to supply it overseas. In Russia, our members face data localisation requirements as part of clinical trials, and using Russian IT infrastructure does not provide sufficient safeguards when it comes to the protection of the data. Such requirements, although they apply to both local and foreign companies, result in a disadvantage for foreign companies, who need to invest in setting up IT infrastructure in Russia. In July 2020, India commissioned a report on non-personal data, which suggested setting up a data regulator (or central authority for data business) and requiring companies to disclose how they collect and store data devoid of personal details (or which has been anonymised) and potentially can be forced to share proprietary data with the government and third parties. Industry has concerns that this report on non-personal data could force IP intensive companies, such as biopharmaceutical and technology companies, to hand over sensitive and proprietary data sets. We would urge DG Trade to ensure the free flow of data and address these data localisation measures in their bilateral exchanges with these countries.

Question 12: In addition to existing instruments, such as trade defence, how should the EU address coercive, distortive and unfair trading practices by third countries? Should existing instruments be further improved or additional instruments be considered?

EFPIA appreciates the ongoing efforts from the European Commission to refine the trade defence instruments and the support to tackle tariff and non-tariff trade barriers in international markets. We are very supportive of the concept of the Chief Trade Enforcement Officer and of the renewed focus of the EU's trade policy on implementation and enforcement. We therefore ask the European Commission in its trade strategy to:

1. **Strengthen the role of the Market Access Advisory Committee** as a monitoring tool, including the setting up of a **specific working group on pharmaceuticals** (could be merged with the existing one for medical devices), as has been done for other important industrial sectors;

2. **Ensure close monitoring of implementation and enforcement of FTAs,** covering commitments other than tariff reductions, such as e.g. IPRs and procurement. Create a **single point of contact for issues regarding implementation and enforcement of FTAs via the Chief Trade Enforcement Officer**, backed up by a focused team in DG Trade as well as by an EU equivalent of the US 'Interagency Centre on Trade Implementation, Monitoring, and Enforcement' (ICTIME). Beyond other Directorates-General, this could also include, for example, the European Medicines Agency, EMA;

3. Include and enforce an **effective dispute resolution mechanism**.

EFPIA November 2020