

EFPIA Brexit Briefing



The integrated nature of supply chains for medicines across Europe, and the shared regulatory framework, mean that Brexit may affect the supply, regulation and safety monitoring of medicines for patients across the EU as well as the UK.

EFPIA Brexit Priorities

EFPIA has established five clear priorities for the European Commission and the UK Government in negotiating the UK's withdrawal from the EU. These priorities are essential to secure the best possible outcome for patients and public health across Europe.



TRADE & SUPPLY

Medicines used by patients across Europe have integrated supply chains, which include the UK. The UK and EU should conclude a comprehensive agreement that ensures maximum alignment between EU and UK pharmaceutical laws. This agreement needs to avoid causing any disruption to existing quality control arrangements and must not disrupt the supply of medicines to patients in Europe of the UK.



REGULATION

Securing ongoing alignment, cooperation and mutual recognition between the UK and the EU regarding the authorisation, testing and surveillance of medicines.



PEOPLE

Providing certainty for EU and UK citizens working in the pharmaceutical industry. Agree a straightforward immigration system that allows pharmaceutical companies to employ the best talent from around the world, and that facilitates skilled UK and EU nationals working across Europe.



RESEARCH

Scientific research collaboration between the UK and EU should be maintained after the UK leaves the EU. UK/EU scientific collaboration strengthens the EU's global position in life sciences, attracting global life sciences investment to the EU.



INTELLECTUAL PROPERTY

Equivalent standards of IP should continue to apply in the UK after Brexit and the existing level of strong IP incentives across the EU should be maintained.

On 13 July 2017, EFPIA set out these priorities in a joint letter addressed to David Davis MP, the UK Secretary of State for the Department of Exiting the European Union and Michel Barnier, the Chief Negotiator, Task Force for the Preparation and Conduct of the Negotiations with the UK under Article 50. This letter was signed by seven other organisations representing the different sectors within the broader pharmaceutical industry in Europe and in the UK¹.

Key Messages

1. The integrated nature of supply chains for medicines across Europe and the shared regulatory framework, mean that Brexit may have a negative impact on the supply, regulation and safety monitoring of medicines for patients in the EU and UK.
2. Continued cooperation and alignment between the EU and the UK on the regulation of medicines is the best outcome for patients across Europe.
3. Given the specific importance of medicines, the EU and the UK should prioritise reaching an agreement to solve the issues around medicines as early as possible in the negotiations.
4. Appropriate transitional arrangements need to be put in place to ensure that European patients can continue to access their medicines without disruption.

Key statistics

1. Every month, 45 million patient packs of medicine are supplied from the UK to the EU27/EEA, with 37 million patient packs supplied from the EU27/EEA to the UK.
2. There are 2,900 individual medicine products produced in the UK that are supplied to EU27/EEA patients, with 3,200 individual products produced in the EU27/EEA and supplied to UK patients.
3. 1,300 products are batch released or tested in the UK. 40% of EFPIA members see challenges to ensuring there is sufficient capacity in the EU27 to replace this infrastructure.
4. The relocation of manufacturing facilities can take between 12 – 18 months. This excludes the time for the necessary regulatory approvals necessary for a new facility.
5. The pharmaceutical industry is one of the EU's most important and fastest-growing industries, investing an estimated €35bn in R&D in Europe and employing 745,000 people.
6. The UK is a key player in European pharmaceuticals, constituting 10% of the EU's total production and contributing approximately 20% of the EU's total R&D.
7. The UK makes a significant contribution to the work of the EMA, and in 2016 was the Rapporteur for one in five EU centralised approval procedures for medicines.

¹ <https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/13-july-2017-joint-trade-association-letter-on-brexit/>



Medicines used by patients across Europe have integrated supply chains, which includes the UK. The UK and the EU should conclude a comprehensive agreement with a pharmaceutical protocol that ensures maximum alignment between EU and UK pharmaceutical laws. Any such agreement needs to avoid causing any disruption to existing quality control arrangements and must not disrupt the supply of medicines to patients in Europe or the UK.

EFPIA supports the negotiation of an agreement which maintains the ability to import or export pharmaceutical products between the EU, the UK and the rest of the world. EFPIA would not support anything that undermines the EU single market.

An implementation period beyond the Article 50 negotiations is essential. Pharmaceutical companies across Europe support an implementation period beyond the two years of Article 50 negotiations. This period should adequately reflect the time needed to ensure relevant customs and regulatory procedures are in place and pharmaceutical companies are able to transition to a new framework. Due to the highly complex regulatory arrangements, it is extremely difficult for companies to accelerate contingency planning. The implementation period should be agreed as part of the negotiations to allow companies the time to make the necessary arrangements to avoid any unintended consequences regarding the availability of medicines to European patients.

Between January and October 2016, EU pharmaceutical product imports from the UK were valued at €11bn, with EU pharmaceutical product exports to the UK totalling €17bn. For medicinal products, a pharmaceutical protocol that ensures maximum alignment between EU and UK pharmaceutical laws should be agreed to ensure that European patients can continue to access their medicines without any disruption. This is important for the following reasons:

- **EU patients rely on medicines supplied from the UK, and vice-versa.** Every month, 45 million patient packs of medicine are supplied to patients in the EU27 from the UK, with 37 million patient packs of medicine supplied from the EU27 to the UK. There are 2,900 individual medicine products produced in the UK that are supplied to EU patients, with 3,200 individual products produced in the EU and supplied to UK patients. The UK leaving the EU single market and customs union may result in new customs compliance procedures for all products moving between the UK and EU. It is essential that the new customs arrangements do not delay moving products between the UK and EU or lead to goods being held at border checks, in warehouses or manufacturing sites.
- **WTO trading arrangements would present significant barriers.** In the event of 'no deal', the EU and the UK would fall back to WTO terms and tariffs. This may affect EU-UK medicines trade due to duty requirements at several stages of the supply chain. The WTO Pharmaceuticals Agreement includes a 'zero-for-zero' arrangement on most pharmaceutical goods and products in supply chains. However, the list of pharmaceutical products included in this 'zero-for-zero' agreement has not been updated since 2010, and therefore many components of existing medicines and pharmaceutical products are not included in the agreement. EFPIA recommends that the current discussion to update the WTO Pharmaceuticals Agreement be concluded. In the event of 'no deal', the UK should ensure it is a signatory of the 'zero-for-zero' annex.
- **Significant VAT registration barriers.** Companies also have multiple VAT registrations and VAT filing requirements across the EU. Import VAT will be payable on all non-UK sourced goods before they can be brought into free circulation within the UK, which may lead to considerable cash flow costs for exporting goods to the UK.



Securing ongoing alignment, cooperation and mutual recognition between the UK and the EU regarding the authorisation, testing and surveillance of medicines should be a priority outcome of the negotiations.

The pharmaceutical industry is highly integrated across Europe, and regulated under EU law through legal and regulatory systems and arrangements between EU institutions, member states and national competent authorities.

- **Ensuring timely access to innovative new medicines.** The European Medicines Agency (EMA) acts as a regulatory network, licencing pharmaceutical products for sale across Europe. The UK's national regulator, the MHRA, makes a significant contribution to the work of the EMA, and in 2016 was the Rapporteur, leading the scientific assessment in up to 20% of all centralised procedures, and contributed to 40% of decentralised procedures. Should the UK's MHRA no longer participate in the European regulatory network, the capacity and expertise for the review of medicines as well as the capacity across Europe for the surveillance and safety supervision of products would be significantly disrupted.

The need for companies to transfer existing marketing authorisations for medicines from the UK to the EU and vice versa, or to obtain new ones in either the UK or the EU, will present a challenge to the capacity of the EU regulatory system in the time available before the UK leaves the EU.

- **Additional testing requirements would delay the release of medicines to patients in the EU.** Without cooperation on the regulation of medicines, medicines are likely to be subject to extensive retesting requirements such as import testing and Qualified Person (QP) release of products into the EU. 60% of EFPIA members have a batch release site in the UK, supporting 3,298 products. Such a situation would lead to a severe disruption of supply chains, leading to potential disruptions to the supply of medicines for patients across Europe.
- **Avoidance of duplicative and divergent regulation.** Duplicative regulation may affect how quickly patients in the UK and the EU have access to medicines. Any divergence over time of policy approaches by EU agencies affecting pharmaceuticals would cause further disruption. Securing regulatory alignment and cooperation will be the best way of avoiding onerous duplication and the immediate issues of re-testing and re-release. Duplication of regulatory processes for new or existing marketing authorisations, would create additional and unnecessary delays and would impact on the availability of medicines to patients.
- **Supporting Public Health.** The UK's engagement in systems designed to protect public health across Europe helps to ensure that these systems are as robust as possible. These include:
 - ◇ Infectious disease control. The European Centre for Disease Control provides EU countries with protection from the 52 notifiable communicable diseases, outbreaks and public health risks, through a single database.
 - ◇ Pharmacovigilance. Reporting on medicines safety is captured through the EudraVigilance system, operated and monitored by the EMA.
 - ◇ Falsified Medicines Directive. Verifying authenticity at the point of dispensing, due to be introduced across Europe in 2019.

The loss of the UK's engagement in these systems would significantly reduce the effectiveness of these systems.



Relocation of the EMA

On 20 November 2017, it was confirmed that the headquarters of the European Medicines Agency (EMA) will move from London to Amsterdam, The Netherlands. It is crucial that this relocation is carried out in such a way as to minimise disruption that could have a negative impact on the functioning of the Agency, business continuity and hence access to medicines for patients.

PEOPLE



Providing certainty for EU and UK citizens working in the pharmaceutical industry. Agree a straightforward immigration system that allows pharmaceutical companies to employ the best talent from around the world, and that facilitates skilled UK and EU nationals working across Europe.

EFPIA supports an immigration system that facilitates ease of movement for employees, researchers and students. This should be agreed through the negotiations. The system should be needs-based, straightforward, rapid, avoid additional costs to industry and provide certainty of outcome. The negotiations should also provide certainty for EU and UK citizens working in the pharmaceutical industry, retaining the Intra-company Transfer process to allow movement of people currently employed.

- It is crucial for pharmaceutical companies to have confirmation that UK nationals currently working in the EU can remain in post, and vice-versa. This is critical in ensuring that there is sufficient capacity for some supply chains to sustain their current levels of production and in ensuring that active research and development projects are not relocated, delayed or stopped altogether.
- The life sciences industry relies on highly skilled operational, managerial and scientific staff and the ability to move people across borders to meet business needs. Any restrictions in this area are likely to affect the levels of efficiency and innovation of the industry across Europe.
- The strength of the UK's academic institutions and the breadth of the Life Sciences industry contribute to the global competitiveness of the pharmaceutical industry in Europe. The UK contributes significantly to the global research workforce, second only to the USA in terms of the number of science graduates trained. Approximately 16,000 students from other EU countries are registered on biomedical courses at UK higher education institutions, of whom around 6,500 are postgraduates.



Scientific research collaboration between the UK and EU should be maintained after the UK leaves the EU. UK/EU scientific collaboration strengthens the EU's global position in life sciences, attracting global life science investment to the EU.

The terms of the UK's withdrawal from the EU should include continued participation in Horizon 2020 and its successor (for example, through an 'associate member' status akin to Switzerland, Israel and Turkey) as well as continued participation in the European Investment Bank and European Investment Fund. Doing so will ensure that the EU life sciences sector remains globally competitive for the following reasons:

- **The UK plays a significant part in strengthening EU scientific research.** The UK contributed to almost 20% of the total research work carried out within EU health programmes between 2007 and 2016. Existing research funding and collaboration frameworks enable EU researchers to access the UK's world-leading academic institutions, increasing the global attractiveness of the EU's research and life sciences sector.
- **The UK has unique research facilities which strengthen Europe as a global leader in life sciences.** There are a number of unique research facilities in the UK, which benefit EU research. For example, biorepositories such as the Mary Lyon Centre are widely used by EU researchers and The Wellcome Trust Sanger Institute is one of the largest bioinformatics centres in the world, hosting joint European scientific projects. This contributes to accelerating medical science innovation and delivering innovative treatments to patients across the EU.
- **UK venture capital investment provides significant financial returns for the European Investment Fund (EIF).** The UK venture capital market makes up more than a third of the total venture capital raised in Europe. The combined venture capital of the UK and Switzerland is now 55% of the European total. If this trend continues, more than half of biotech financing in Europe will be outside of the European Union post Brexit and may be detrimental to the European life sciences sector.



Equivalent standards of IP should continue to apply in the UK after Brexit and the existing level of strong IP incentives across the EU should be maintained.

The EU has a framework of intellectual property incentives, which protects innovation and drives research to areas of unmet medical need. Following the UK's exit from the EU, there must continue to be strong, well-functioning intellectual property systems in place across the UK and EU.

- The Unified Patent Court (UPC) will provide a single patent right enforceable across Europe, and was due to be operational from December 2017. The UK has signalled its intention to ratify the UPC in the short term, although delays in both the UK and Germany have postponed the likely implementation until mid-2018. There is a risk that these delays may make it difficult for the UK to join the UPC before the UK leaves the EU, and may have a knock-on effect on the viability of the system as a whole.

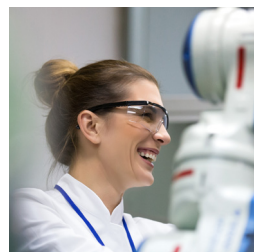
About EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.

The EFPIA Brexit Taskforce

EFPIA established a Brexit Taskforce to coordinate the work of the pharmaceutical industry across Europe on Brexit. The Taskforce has brought together experts from across the pharmaceutical industry to understand the impact that the UK leaving the EU will have on patients and the industry across Europe.

EFPIA is working closely with the European institutions and other stakeholders to ensure that these priorities are understood and are resolved through the negotiations between the European Commission and UK Government.



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