European Federation of Pharmaceutical Industries and Associations

EFPIA position on the future trade relationship between the EU and UK

Summary of key asks

- A **Mutual Recognition Agreement (MRA)**, covering mutual recognition of import testing by manufacturers for medicines and vaccines based on global Good Manufacturing Practice standards, as well as Official Medicines Control Laboratories (OMCLs) batch release testing for vaccines and blood plasma products.
- Maintaining the **greatest possible cooperation in regulatory standards** to ensure early and efficient patient access to innovative treatments.
- **Continued alignment on data protection legislation** between the EU and UK, and a comprehensive sectoral adequacy assessment to support data transfers. UK access to relevant EU databases and processes, including those supporting regulatory procedures, pharmacovigilance and security against falsified medicines, and a comprehensive sectoral adequacy assessment to support data transfers.
- **Smooth import clearance processes** to avoid disruption of delivery of sensitive goods and **simplified and rational rules of origin**, based on common, defined chemical and pharmaceutical processing activities.
- **Strong Intellectual Property Rights (IPRs) and effective mechanisms for IPR enforcement.**
- Inclusion of a **pharmaceutical-specific annex** to provide a platform for cooperation on wider policy issues for pharmaceuticals and creation of a **Working Group on Pharmaceutical Products and Medical Devices**.

Introduction

The pharmaceutical industry in Europe is committed to working with the EU to reach an agreement that will allow:

- Patients to receive medicines and medical technologies without disruption and provide long-term cooperation between the EU and the UK in areas such as research, clinical trials, pharmacovigilance and access to talent;
- The industry in the EU to remain strong and competitive and for the EU to continue to be a top life science hub globally.

Our industry's stance remains therefore that the EU and UK should have the closest possible relationship for pharmaceuticals, prioritising the health of citizens and the uninterrupted supply of medicines and vaccines, as well as supporting global EU competitiveness for our industry.

Ever since the UK referendum, the industry has been consistently calling for the UK to remain closely interlinked with the EU's regulatory framework for pharmaceuticals. This reflects a number of core drivers:


EFPIA Brussels Office
Leopold Plaza Building ✱ Rue du Trône 108
B-1050 Brussels ✱ Belgium
Tel: + 32 (0)2 626 25 55 ✱ Fax: + 32 (0)2 626 25 66
www.efpia.eu ✱ info@efpia.eu

- To secure patients' safety and the unhindered supply of medicines to patients in the EU;
- To minimize unnecessary burdens and regulatory misalignments that will take time to address and negatively affect supply as well as EU pharmaceutical competitiveness globally; and,
- To minimize the increase in, and negative impact of, regulatory burdens due to the UK regulatory agency no longer inspecting on behalf of the EU's medicines (and vice versa).

Potential elements for a close relationship are reflected in the Political Declaration and EU's mandate for the negotiations, alongside a reference to continued global cooperation on public health. The need for these elements is very clear in terms of the EU's, UK's and global responses to the Covid-19 pandemic. Given the current complete alignment of regulatory standards, the EU-UK negotiations represent a critical opportunity to develop a sustainable framework for future cooperation. This would continue the high level of compatibility and secure streamlined processes and procedures between the EU and UK in the interest of patients, regulators and industry.

The EU negotiating mandate also includes general references to regulatory cooperation on cross-sectoral level. The UK mandate goes a step further and outlines specific proposals for medicines and public health, including the provision of a pharma annex within the FTA covering areas like a Mutual Recognition Agreement (MRA) on Good Manufacturing Practices (GMP). We ask that there is openness to exploring these asks and that both parties recognise where there are mutual benefits and opportunities to streamline processes between the UK and EU, based on high global standards that exist between many other nations, to secure the best outcome for patients, EU citizens and our sector's growth and competitive outlook.

A level playing field between the EU and UK, based on global standards, is vital for the competitiveness and agility of the EU pharmaceutical industry. From an economics viewpoint, the value chain integration between the EU and UK is deep and the UK is an indispensable life science hub in the world's pharmaceutical global value chains: the UK provides 33% of the value added for EU final demand and the EU provides 54% of all value added in UK final demand.[1] Severing these ties will therefore not lead to reshoring of activities from the UK to the EU, but rather reduce Europe's value chain attractiveness and competitiveness vis-à-vis for example China and the US overall. Close cooperation, including upholding high labour and environmental standards, as well as strong IP provisions, post December 2020, between the EU and UK would also help to diversify value chain risks in case of global challenges in the area of public health (e.g. in the case of a pandemic). Therefore, from an EU competitiveness and agility point of view, a close alignment with the UK is in the clear interest of the EU as well as a necessity.

We recognise that the current timetable for the negotiations is short, but we ask that medicines and health are prioritised in the talks as disruptions and uncertainty in the supply of medicines can have significant effects on the health of patients in the EU.

[1] Source: OECD TiVA Database (TiVA = Trade in Value Added) (2015). The meaning of these statistics: for every Euro spent in the EU, the UK contributes 33 cents (of value added created in the UK). Vice versa: for every Euro spent in the UK, the EU contributes 54 cents in value added generated in the EU for UK final demand. Essentially: both countries need each other's value chains to be successful – it is a win-win or lose-lose situation for both countries. The UK needs the EU value chain a bit more than vice versa (54% versus 33%), but the UK demand for medicines generates more value for the EU than the UK itself.


EFPIA Brussels Office
Leopold Plaza Building ✱ Rue du Trône 108
B-1050 Brussels ✱ Belgium
Tel: + 32 (0)2 626 25 55 ✱ Fax: + 32 (0)2 626 25 66
www.efpia.eu ✱ info@efpia.eu

So, we ask that the EU should conclude a Free Trade Agreement (FTA) with the UK that secures **the greatest possible regulatory cooperation on human medicinal products**. The FTA should also include ambitious provisions on the protection of **intellectual property (IP)**, **sharing of data**, **customs facilitation**, as well as **rules of origin (RoO)**, and cooperation in the area of **Research & Development**. We also believe the EU and UK should establish a **Working Group on pharmaceuticals and medical devices** to facilitate ongoing dialogue on regulatory cooperation.

Immediate Priority: Mutual Recognition Agreement (MRA) on Good Manufacturing Practice (GMP)

One critical recommendation for immediate action is securing a Mutual Recognition Agreement (MRA) on Good Manufacturing Practices (GMP). An MRA on GMP should cover waiving of batch testing on import by manufacturers for medicines and vaccines, including investigational medicinal products, and recognition of GMP inspections between the EU and UK (covering EU and UK territories, as well as third countries). In addition, the MRA needs to cover mutual recognition of OMCLs (Official Medicines Control Laboratories) batch release testing for vaccines and blood plasma products.

This would have an immediate positive impact and reduce potentially significant negative effects:

- First of all, an MRA would avoid imposing import testing requirements for medicines manufactured in the UK for European patients and investigational medicinal products needed for ongoing clinical trials across the EU (and vice versa). This would benefit patients' timely access to medicines and treatments and would help mitigate disruption to supply. An MRA would also eliminate the need for additional or duplicated processes in the supply chain, which would introduce increased risk of delays to patients. Tests in each jurisdiction take 4-8 weeks. Import testing requirements impose a 30-day average delay in delivering medicines to patients and a commensurate reduction of shelf life.[2] This is of particular importance for critical and high-demand medicines as well as medicines with limited shelf-lives, such as radio isotopes for cancer therapy as well as vaccines.
- Second, an MRA would mitigate the negative impact on the – already limited – resources of the regulatory agencies (the European Medicines Agency (EMA), National Competent Authorities (NCAs) of the EU and the UK Medicines and Healthcare products Regulatory Agency (MHRA)). This impact has two dimensions:
    - The loss of the MHRA will lead to significantly more demand for inspection capacity on the EU agencies, since the MHRA annually conducted on average around one third of all annual EU GMP inspections over the past years[3].
    - EU and UK regulators could continue to work together to focus on high-risk sites in need of inspection, including in third countries, and to ensure resources are committed to addressing such high priority needs. This would avoid the need to increase costs and resources for regulators or avoid a *de facto* reduction in inspection coverage which would imply increased risks or more delays. It would also be in line with current EU practice on MRAs, as further outlined below.
- Third, without an MRA in place, the regulatory burden would not only fall onto the regulators, but also the (innovative) medicines industry both in terms of cost and manufacturing operations. GMP inspections, for example, are estimated to cost €1 million per inspection because of regulator fees,

[2] https://www.ifpma.org/subtopics/import-testing/
[3] MHRA (2020)


EFPIA Brussels Office
Leopold Plaza Building ✱ Rue du Trône 108
B-1050 Brussels ✱ Belgium
Tel: + 32 (0)2 626 25 55 ✱ Fax: + 32 (0)2 626 25 66
www.efpia.eu ✱ info@efpia.eu

staff costs to prepare, accompany and support inspections, as well as costs related to shutting down production lines for inspections.[4] In addition, extra GMP inspections will likely lead to supply delays because supply has to be halted for machine inspections as part of the GMP site inspection.

MRAs align with the EU's aim to promote the use of international standards as a basis for technical regulations, as well as streamlined testing and certification requirements. MRAs follow globally set standards defined by the Pharmaceutical Inspection Co-operation Scheme (PIC/S)[5] – as per the agreements the EU already has in place with other third countries such as Australia, New Zealand, Canada, Japan, Switzerland, Israel and the US. The UK has already been able to roll over a number of existing EU MRAs – showing continued commitment to alignment of manufacturing standards.

Both the UK and EU are participants (via the individual Member States) of PIC/S, which has global membership, and sets global guidelines for active collaboration in the field of GMP as well as expanding into other good practice (GxP) areas.

As the UK has been an integral part of the EU regulatory system for several decades, and given that the current UK and EU legal framework is the same, the MRA should comprehensive and encompass inspections by European inspectors within the European Economic Area (EEA), MHRA inspections of UK sites, inspections that both European and UK inspectors conduct in third countries outside the UK and EEA, as well as batch testing (similar to MRAs that the EU has with several trading partners). Our industry is committed to working in partnership with all relevant services, departments and agencies to make this proposal a reality in order to ensure that medicines continue to reach patients without disruption or delay.

Further key priorities for a future EU-UK relationship

We believe that the following key priorities are within the scope of the EU mandate (and UK mandate) for the negotiations. Including these will provide the necessary stability needed for patients, regulators and industry, and support the continued development and supply of innovative medicines in Europe and European competitiveness globally.

1. Regulatory cooperation on human medicinal products

Regulatory cooperation post-Brexit is the top priority for our industry. Over many years, the MHRA has been a key EU regulatory agency working hand in hand with other EU agencies to shape and define global standards through formal bodies like the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This has led to increasingly harmonised standards for the approval of medicinal products across the globe.

EFPIA believes that continued EU-UK cooperation to create streamlined processes and procedures would be in the best interests of patients, regulators and industry in the EU. Further cooperation on regulatory matters between the EU, the UK, and third markets could also be important to progressively

[4] Cost estimate based on an industry survey in light of the EU's goal to quantify the positive effect of the EU-US MRA on GMP inspections that came into force in July 2019.

[5] https://picscheme.org/en/publications?tri=gmp. To note that the PIC/S GMP Guide and the EU's GMP Guide have been developed in parallel.


EFPIA Brussels Office
Leopold Plaza Building ✱ Rue du Trône 108
B-1050 Brussels ✱ Belgium
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www.efpia.eu ✱ info@efpia.eu

move towards a globally harmonised regulatory system. This cooperation could include for instance coordinated GMP inspections in third countries, as the EU has agreed with Canada[6].

EFPIA would like to see the following principles addressed within the scope of the agreement:

- Maintaining the greatest possible cooperation on regulatory standards is critical to ensure early and efficient patient access to innovative treatments. These standards include:
    - Safety requirements, including post-marketing surveillance and requirements for evaluating and reporting safety information;
    - Requirements for life cycle management of quality (CTD Module 3), including process validation guidelines and post-authorization variations' requirements;
    - Regulatory assessment of innovation and new manufacturing technologies;
    - Standards for risk/benefit assessments, requirements for evaluating and reporting safety information;
    - Good manufacturing practice (GMP) requirements, including guidelines on dedicated production facilities for particular products, such as high-risk products;
    - Standards for the development and approval of paediatric medicines;
    - Therapeutic area guidelines for development of new medicines;
    - Consideration of regulation of companion diagnostics;
    - Framework to incentivize the development of orphan drugs, including orphan drug designations;
    - Clinical trial requirements and approval standards, and
    - Pharmacopoeia standards and requirements.
- Sharing of scientific and technical expertise through cooperation between EU and UK regulators to facilitate predictability and consistency of assessment outcomes. This could include:
    - MHRA participation in established and newly formed EMA/3rd country "clusters";
    - MHRA observer status or – where possible - participation in committees, working parties and other relevant groups of EMA, and reciprocal EMA involvement in equivalent MHRA structures;
    - Cooperation in the development of standards, requirements and guidelines concerning medicinal products (as described above in the areas in which to avoid divergence);
    - Providing a mechanism to obtain joint scientific advice between EMA and MHRA, similar to that available from EMA and US FDA, to allow for innovator companies to establish development programmes that meets the harmonised needs of both agencies;
    - Providing a pathway for joint advice on development of biomarkers and joint acceptance of biomarkers;
    - Providing an option for companies to seek coordinated assessments of marketing authorization applications (MAA), such as have been established between other countries and regions (e.g. US FDA's Project Orbis). Such optional coordinated assessment could apply to the entire MAA or to particular aspects of the file, e.g. quality aspects.
- Work to address supply chain security, including falsified and substandard medicines, to be pursued jointly.

[6] https://ec.europa.eu/health/sites/health/files/files/international/doc/mraeccan_en.pdf


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B-1050 Brussels ✱ Belgium
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www.efpia.eu ✱ info@efpia.eu

In addition to an MRA on GMP, the EU and UK should develop a roadmap for full Mutual Recognition between the EMA/EC and MHRA of other good practices inspections including Good Clinical Practices, Good Laboratory Practices, Good Distribution Practices and Good Vigilance Practices.

Consistent with other FTAs, we believe that a pharmaceutical annex could also address key issues relating to transparency of technical regulations. Such an annex should reinforce the need for the EU and UK to address existing transparency concerns specific to pharmaceuticals (in addition to the baseline transparency chapter standards of an EU FTA agreement).

Our industry would like to see the establishment of a Working Group between the EU and UK to focus on harmonisation and establishment of proportionate requirements as science evolves and to address regulatory barriers that may arise. This will support Europe's industrial competitiveness and increase our agility to act together in the event of global challenges.

Industry seeks the closest possible cooperation between EU and UK regulatory agencies, including a Mutual Recognition Agreement on Good Manufacturing Practices. These will ensure that streamlined processes and procedures continue to serve the best interests of patients, regulators and industry.

2. Data protection and data flow issues

The responsible sharing of data, both intra-regionally and internationally, is essential for pharmaceutical innovation and patient safety. Making research data available to qualified researchers has the great potential to advance medical research to benefit patients, by accelerating the development of new medicines and improving patient care. The biopharmaceutical industry has been at the forefront of initiatives to improve access to clinical trial data and has led the way in sharing patient-level data. Our industry calls for the EU and UK to embrace high-standard principles to promote cross-border data flows and discourage data localisation. In addition, with respect to the sharing of data between the EU and UK, the governments should ensure that procedures for drug safety reporting, which are governed by both EU and international regulations, are unchanged, and for the UK to still participate in the relevant EU databases, in order to combat traffic in falsified medicines and opening up to other security risks.
The research and development of new medicines also involves the gathering and analysis of personal health data. The transfer of this data within and outside the EU is governed by the GDPR (General Data Protection Regulation). In addition, medicines regulators may request access to this data as may academics under institutional and industrial transparency policies. As the UK becomes a third country, unless the UK is granted an adequacy decision, it will be necessary to use the transfer mechanisms foreseen in GDPR to preserve the ability to transfer data. These include standard contractual terms, binding corporate rules, codes of conduct and certifications. None of these can be put in place quickly.

We therefore ask for continued alignment of data protection legislation between the EU and UK post-Brexit, mutually recognizing existing high standards, UK access to relevant EU databases and processes, including those supporting regulatory procedures, pharmacovigilance and security against falsified medicines, and a comprehensive sectoral adequacy assessment to support data transfers.

3. Customs trade facilitation, Rules of Origin (RoO) and the WTO Zero-for-zero Agreement

EFPIA has concerns about reinstating **customs controls** at the border issued by both veterinary and customs administrations. Many medicines are temperature-controlled products (i.e. cold-chain), which


EFPIA Brussels Office
Leopold Plaza Building ✱ Rue du Trône 108
B–1050 Brussels ✱ Belgium
Tel: + 32 (0)2 626 25 55 ✱ Fax: + 32 (0)2 626 25 66
www.efpia.eu ✱ info@efpia.eu

in numerous cases require deliveries in fewer than 3 days. These include vaccines, biological products, and other lifesaving products that must be delivered without delay. The same is true for the movement of investigational medicinal products and test kits as well as time sensitive biological samples that must be imported and exported as part of drug development processes. Possible logistic bottlenecks at the border would lead to disruption in deliveries and destruction of pharmaceuticals needed by millions of patients. Additionally, if temperature or moisture levels are breached, this can destroy a product, with possible health consequences. "Green Channels" using specific maritime routes, as initially proposed by the UK for securing the procurement of pharmaceutical goods, should be maintained and developed. We therefore ask the EU and UK to minimise the emergence of new controls at the border. We ask that the EU and UK continue to prioritise medicines on the both sides of Channel ports, as was done pre-Brexit, when medicines were designated in the UK as Category 1 goods. In addition, the parties should simplify any newly emerging customs procedures as much as possible, to allow self-certification of originating status of products, and promote the Authorised Economic Operator (AEO) programme. Pharmaceutical products containing psychotropics, narcotics or drug precursors should be subject to specific trade facilitation procedures for AEO laboratories or to acknowledged companies that have succeeded in the recognition of their compliance status, in order to prevent stops at the border for containers, which partly contain these sorts of products. We also ask the EU27 and UK to invest in hard and soft infrastructure to ensure efficient customs clearance to mitigate costs, and enforce, in practice, instruments provided by the Union Customs Code and related regulation such as self-assessment, and entry in the declarant's records, to reduce the administrative impact of cross-border flows.

Rules of Origins (RoO) provisions should aim for maximal alignment and be modelled on recent agreements for list rules, and agreements signed before CETA for controls of origin in EU trade agreements, allow for extensive diagonal cumulation of origin for materials, and to closely involve industry in defining RoO and cumulation between the EU and UK. In that respect EFPIA has delivered a position paper in December 2019 to the European Commission.

With regard to **tariffs**, the EU and UK should agree to exempt from tariffs all R&D products, from discovery molecules up to phase III (including placebo), all traded active ingredients (APIs) and finished drug products. This should include those having come on the market after the last 2010 update of the WTO Zero-for-Zero agreement. Inter alia, the WTO zero-to-zero pharmaceutical agreement should be updated.[7] We recommended the UK to replicate the EU Customs Code to ensure alignment with the EU customs processes and IT connections and to remain a party to the WTO zero-to-zero pharmaceutical agreement. In addition, any FTA should include provisions on transparent and non-discriminatory public procurement, going above and beyond the WTO Government Procurement Agreement (GPA).

Industry seeks smooth import clearance processes to deliver drug to patients as fast as possible, simplified and rational rules of origin, based on common, defined chemical and pharmaceutical processing activities, and zero tariffs on all R&D products, all trade active ingredients (APIs) and finished drug products – including those having come on the market after 2010.

[7] The WTO Zero-for-Zero agreement allows members to benefit from duty exemption for a majority of active pharmaceutical ingredients, with the exception of research products up to phase III (products in phase III are eligible to exemptions in the Pharmaceuticals WTO agreement at the time of list revision, due to rules edicted by CBP).


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Leopold Plaza Building ✱ Rue du Trône 108
B-1050 Brussels ✱ Belgium
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www.efpia.eu ✱ info@efpia.eu

4. Intellectual Property Rights (IPRs)

Intellectual property incentives and awards are the foundations on which innovation is built, especially for the pharmaceutical industry, the most R&D intensive industry in the EU. The ability to protect and enforce Intellectual Property Rights ("IPRs") is essential to secure the continued development of innovative pharmaceuticals. They refer to all the exclusivity-based incentives, specifically available to the pharmaceutical industry to stimulate research and development of innovative medicines under EU law. These include: **Patents (and their enforcement), Supplementary Protection Certificates (SPCs), their potential extension as a reward for paediatric studies, Regulatory Data Protection (RDP), Orphan Market Exclusivity** and its potential extension as a compensation for paediatric studies.

To ensure legal certainty for the pharmaceutical industry operating in Europe, it is imperative that an FTA secures **well-functioning IP incentives systems** in the EU and UK. Not doing so will also be a negative signal that could impact EU objectives on IP in a number of ongoing, and potential future, EU FTA negotiations. As a result, EFPIA urges the EU and UK to ensure that the level of protection afforded via pharmaceutical incentives in the UK should, as a minimum, be of a scope and duration equivalent to that currently in effect in the EU.

Regarding **EU Trademarks and Community Designs**, we encourage that the UK ensures that the transition from EU Trademarks and Community Designs to national trademarks is implemented efficiently, automatically and without creating costs for owners of rights.

Industry believes a comprehensive and enforceable IP chapter to secure a world-leading IP system will further enhance the ability of research-based pharmaceutical companies to develop and bring new medical treatments to patients. IP measures should include at least:

- The provision of **strong patent rights** for all categories of medical innovation without prejudice as to when they arise in the development process;
- **Supplementary Protection Certificates** that provide compensatory periods of protection to mitigate effective patent term lost is eroded due to the long development and authorization timelines. This should also provide for the SPC paediatric extension. The compensatory period of protection in a particular territory should be calculated based on the date of marketing approval in that territory.
- **Regulatory Data Protection**, as a minimum, reflecting the EU's current 8+2+1 years system, i.e. comprising of a period of exclusivity for the data generated by innovators and submitted in support of applications for marketing authorisation and a period of market exclusivity. The period of protection in a territory should start from the date of marketing approval in that territory.
- **Sui generis rights** e.g. orphan market exclusivity to promote innovation in areas where there are insufficient market incentives, such as rare diseases with relatively low patient populations and unmet medical needs;
- **Effective IPR enforcement mechanisms** reflecting the particular nature of the pharmaceutical industry, notably enforcement in a timely and effective manner prior to launch of the follow-on product.

In addition, consideration should be given to the incorporation of an IP Dialogue between the EU and UK within the institutional framework.

The FTA should include ambitious IPR provisions and enforcement mechanisms, reflecting at least current EU standards.


EFPIA Brussels Office
Leopold Plaza Building ✱ Rue du Trône 108
B-1050 Brussels ✱ Belgium
Tel: + 32 (0)2 626 25 55 ✱ Fax: + 32 (0)2 626 25 66
www.efpia.eu ✱ info@efpia.eu

5. Collaboration on Research & Development (R&D)

The FTA should include provisions that help to foster an innovation-friendly investment environment that allow the EU and UK to provide the necessary policies to spur both academic and private research and development. Furthermore, ensuring the EU and UK scientists continue to collaborate and playing a joint active role to tackle the global health and scientific challenges we face. As such, it is important that:

- An adequacy agreement is in place to enable free flow of data between the EU and UK. This would mean a continued free flow of data to facilitate research, based on mutually recognised high standards of data protection.
- Discussion takes place for the UK to be able to join the EU Framework Programmes (i.e. Horizon Europe). This would mean continued participation of the UK, e.g. EU/UK patients, researchers and organisations, in pan-European research and ensuring scientists have access to world-leading scientific and academic institutions in both the UK and EU.
- EFPIA is supportive of the UK participating in the EU system for exchange of scientific talent as well as maintaining the mutual recognition of professional qualifications, which means employees with relevant qualifications from the other jurisdiction will continue to be able to perform their job as they can today, based on their existing qualification. This would ensure the continuation of essential business operations.

Scope and Enforcement

The EU-UK FTA should include a definition of "pharmaceuticals" to include various categories of medicinal products of relevance to European Industry in line with the definition of Medicinal Products in the Community law. The definition of "pharmaceuticals" under the EU-Korea FTA is an appropriate basis with this regard. In addition, the FTA should include provisions that help to foster an innovation-friendly investment environment that allows the EU to provide the necessary policies to spur both academic and private research and development and increase EU competitiveness for the innovative pharmaceutical industry.

Provisions on the enforcement of a comprehensive trade agreement should be consistent with other FTA enforcement mechanisms (e.g., EU-Korea FTA as well as current views on stronger enforcement in FTAs under the current European Commission) and should seek to establish optimal standards.

- **Creation of a Working Group on Pharmaceutical Products and Medical Devices**. Parties should be able to bring issues for discussion in the framework of a Pharmaceutical Working Group (WG). The WG should ensure adequate representation of each Party's officials of agencies and departments responsible for health care and other matters. The WG could also address issues of common interest in engagement with third countries including IP, regulatory and other matters.
- **Creation of necessary coordination platforms between stakeholders.** Similar to the proposals under the Korea FTA implementation, we would welcome the creation of coordination platforms between European Commission, Member States and Industry (e.g. Market Access Teams) that should complement and enhance the existing bilateral coordinator tools.

Conclusion

The research-based pharmaceutical industry wishes to express our commitment to working with the EU to achieve an effective and mutually beneficial relationship with the UK: this will be vital to ensure that patients continue to benefit from a stable supply and innovative therapies, the future security of both economies and the global competitiveness the EU pharmaceutical industry.


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Leopold Plaza Building ✱ Rue du Trône 108
B-1050 Brussels ✱ Belgium
Tel: + 32 (0)2 626 25 55 ✱ Fax: + 32 (0)2 626 25 66
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