

Call for a Mutual Recognition Agreement on Good Manufacturing Practice (GMP) in the Context of Ambitious and Comprehensive EU-UK Future Relationship Negotiations

The pharmaceutical industry in Europe has worked to support the EU27 and UK to reach an agreement that will allow patients to receive medicines and medical technologies without disruption and provide long term co-operation between the EU and the UK in areas such as research, clinical trials, pharmacovigilance and access to talent. Our industry's stance remains that the EU and UK should have the closest possible relationship for pharmaceuticals, prioritising the health of citizens and the uninterrupted supply of medicines.

In positioning communicated to date, we have consistently called for the UK to remain closely interlinked with the EU's regulatory framework for pharmaceuticals. This reflects a number of core drivers: to secure patients' safety and the unhindered supply of medicines to patients in both the UK and the EU, the mutual benefits of UK life sciences expertise alongside peers in the EU, and securing the competitiveness of one of the EU and UK's most significant sectors. It is also underpinned by our industry's watchword at global level, of regulatory convergence.

The positive impacts of such a close relationship are reflected in the Political Declaration published in October 2019, which included a willingness to explore cooperation between UK authorities and the European Medicines Agency, alongside a reference to continued global cooperation on public health. We would also like to see this commitment reiterated in both the UK and EU negotiating mandates.

The below positioning reflects a pragmatic approach to achieve the most ambitious and mutually beneficial EU-UK relationship feasible in the short amount of time available. As the UK and EU discuss the terms of the new relationship, we ask that there is openness at the earliest opportunity to exploring continued cooperation and collaboration in the interests of public health, patient safety and driving progress in medical science. We recognise that the timetable for the negotiations is ambitious, but we ask that medicines and health are prioritised in talks.

In the coming months, the EU and UK should conclude an agreement that secures the **greatest regulatory alignment and cooperation on human medicinal products**. Reflecting precedents from previous agreements, an FTA should also include ambitious provisions on **sharing of data**, the **protection of intellectual property (IP)**, **customs facilitation**, as well as **rules of origin (RoO)**. We also believe the EU and UK should establish a **working group on pharmaceuticals and medical devices** as per the EU-South Korea Free Trade Agreement.

Given the current complete alignment of regulatory standards, the EU-UK negotiations represent a unique opportunity to continue this high level of compatibility and to secure streamlined processes and procedures between the EU and the UK in the interest of patients.

At the start of the negotiations, we wish to highlight one critical recommendation for immediate action, namely **completing a Mutual Recognition Agreement (MRA) on Good Manufacturing Practice (GMP)**.

- An MRA on GMP would cover waiving batch and import testing by manufacturers and OMCLs (official medicines control laboratories) and recognition of GMP inspections between the EU and UK (covering EU and UK territories, as well as third countries).
- This would have an immediate positive impact on the resources of the regulatory agencies, the European Medicines Agency (EMA), National Competent Authorities (NCAs) of the EU, the UK Medicines and Healthcare products Regulatory Agency (MHRA), and on the pharmaceutical sector, with benefits for patients in terms of timely access to medicines and treatments, and would help to secure the continuity of supply of medicines in both markets.
- The resource savings for regulators should allow for the agencies 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 also be in line with current EU practice on MRAs, as further outlined below.

Both the UK and the EU are participants (via the individual Member States) of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), which provides for active collaboration in the field of GMP and is expanding into other 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, this should be a comprehensive MRA that encompasses inspections by European inspectors within the European Economic Area (EEA), MHRA inspections of UK sites, inspections that both European and UK inspectors conduct outside the UK and EEA, as well as batch testing (similar to MRAs that the EU has with several trading partners).

The EU currently has GMP MRAs with many key global partners: Switzerland, Canada, the United States, Japan, Australia, New Zealand, and Israel. These markets represent over 50% of EU pharmaceutical exports, and over 75% of imports into the EU (EUROSTAT data).

The UK and the EU Regulatory Network (including EMA) have played leading roles in the current GMP standards, which are global and not bilaterally determined. We believe that both the EU Regulatory Network and the UK can continue their commitments to working with other leading global regulators to maintain and update these standards to meet our new medicine and manufacturing technologies. Global alignment is central to allowing the global supply chain to function, and this is why notification of regulatory revisions is regularly included in MRAs.

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.