



Mrs. U. von der Leyen, President of the European Commission
Mr. C. Michel, President of the Council
Mr. D. Sassoli, President of the European Parliament
Mr. P. Hogan, Commissioner for Trade
Mr. M. Barnier, Head of Task Force for Relations with the United Kingdom

Subject: Need for a Mutual Recognition Agreement between the EU and UK

Brussels, 17th of June 2020

Honourable Presidents and Commissioner,
Honourable Chief negotiator,

We welcome the recent outcome of the High-Level meeting of 15 June 2020 to intensify the talks in July and to create the most conducive conditions for concluding and ratifying a deal before the end of 2020. We also appreciate your efforts to constructively negotiate with the UK to come to an EU-UK agreement. Nonetheless, we are extremely concerned about the lack of progress with only 6 months until the end of the Transition Period, which could lead to a failure to reach a negotiated outcome on the future EU-UK relationship. For the life science sector, irrespective of our readiness, such a result will, in the short-term, introduce disruptions to medicine supply chains causing delays in access to medicines for both EU and UK patients and, in the long term, reduce the competitiveness of the EU and UK life science hubs vis-à-vis the US, Japan and China.

The pharmaceutical and biotechnological industries previously made preparations for a no-deal Brexit outcome in accordance with EU guidance in 2018 and continue to put in place measures in line with the detailed sectoral readiness papers to prepare for such an unfortunate outcome, also factoring in the implications of the Northern Ireland Protocol for post-Transition Period planning.

In addition to Brexit, Covid-19 has underlined the importance of global medicine supply chains, and the industry has undertaken a sustained global effort to ensure continued access to medicines for patients throughout the crisis. The crisis has highlighted the need for closer international health collaboration and dialogue, and the need for governments to work together with industry to ensure a resilient health sector and medicine supply chains. Failing to agree key medicine provisions, such as a Mutual Recognition Agreement (MRA), in the EU-UK negotiations will only introduce unnecessary uncertainty and disruption and divert resources at a time when governments and industry need to fully focus on finding a solution to end this pandemic.

As such, **we would like to respectfully call on you to prioritize health and patients' access to medicines in the EU-UK negotiations** and shield them from larger political considerations.

First, it is crucial to ensure as much cooperation as possible with regard to regulatory processes and the import and export of medicines and medical supplies across UK/EU borders, in order to minimise delays in products reaching patients. This could be easily achieved with a **Mutual Recognition Agreement (MRA)**, similar to existing agreements with many third countries, covering batch and import testing by manufacturers and Official Medicines Control Laboratories (OMCLs) as well as GMP inspections, based on global Good Manufacturing Practice standards, as well as CE-marking of medical devices and technologies.

Such an MRA and fruitful regulatory cooperation are of fundamental importance to patients on both sides and could also be negotiated outside of the political trade talks, in a close dialogue between the respective regulatory authorities. For instance, this was the case during the TTIP negotiations between the EU and the US. The two regulatory bodies, FDA and EMA, engaged in a direct dialogue and closed the MRA outside of the TTIP negotiations that were never concluded.

Second, it is also important to ensure **simplified and rational rules of origin**, based on common, defined chemical, pharmaceutical and biotechnology processing activities, and **smooth import clearance processes** to avoid any disruption in the delivery of sensitive goods.

The pharmaceutical and biotechnology industries are doing everything in their power to prepare for all scenarios and need the support of the European Union to ensure that we can fulfil our promise to the patients who we serve. In such challenging times, and in view of the upcoming negotiating rounds, we hope that you are able to eliminate additional complexities and favour cooperation and close dialogue, based on international definitions.

We remain at your disposal for further clarifications on this topic and thank you in advance for your time and kind consideration.

Yours sincerely,

Mr. Adrian Van den Hoven
Director General Medicines for Europe

Mrs. Jurate Svarcaite
Director General AESGP

Mr. Bernard Grimm
Director General ad interim EuropaBio

Mrs. Nathalie Moll
Director General EFPIA

Dr. Oliver Sude
Deputy Secretary General EUCOPE

Mrs. Magdalena de Azero
Executive Director Vaccines Europe