













Europe's life science industry urges the UK and EU27 to safeguard patients' access to medicines with a clear transition period and a future cooperation agreement after Brexit

The associations representing the European and British life science industry (AESGP, EFPIA, EuropaBio, EUCOPE, Medicines for Europe, ABPI, BGMA, BIA, PAGB) have today underlined the importance of securing cooperation between the UK and EU on medicines regulation.

Whilst we respect the phased approach of negotiations, we urge progress to be made in the negotiations as soon as possible.

We urge Brexit negotiators on both sides to agree on a transition period that adequately reflects the time needed by companies, as well as all relevant authorities at EU and national level to adapt to changes in view of the UK exiting the EU. The transition period should provide for continued EU-UK partnership on the regulation and supply of medicines, to avoid supply disruption while moving forward towards a future cooperation agreement between the EU and the UK.

Our industry is highly integrated across Europe, and regulated under EU law through a sophisticated system of legal and regulatory arrangements involving EU Institutions, Member States and national competent authorities.

For our sector Brexit represents a challenge in several areas, notably regulatory procedures, quality testing of medicines, supply chain, trade, and intellectual property. For example, medicines companies may need to submit applications for the transfer of marketing authorisation for many products, move batch release sites and duplicate quality testing for products or move personnel into either jurisdiction. This will take a significant amount of time and will result in capacity issues which cannot be resolved before March 2019.

Clarity and certainty are needed as early as possible to enable our industry to make the necessary changes and to transition smoothly into the new framework. This is key to ensure that there is no disruption in the supply of medicines tor patients after March 2019¹.

Even in the context of the Brexit negotiations where all sectors are looking for clarity on the future, it's important to recognise that medicines are different. Our goal is ensuring that patients across Europe and the UK are able to continue to access safe and effective medicines through Brexit and beyond, and to ensure that there is no adverse impact on public health. This goal should be front of mind for both the EU and UK negotiating teams.

Brussels, 28 November 2017

1. In a recent <u>survey EFPIA</u> has counted that every month 45M patients' packs are supplied from the UK to EU and 37 from EU to UK. The situation would be even more dramatic if we counted the whole life science sector.