THE IMPACT OF BREXIT ON PATIENT ACCESS

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With eight months until a hard Brexit, the British government is experiencing some turnover and there remain more questions than answers. On July 8, 2018, Brexit Secretary David Davis resigned from the cabinet, citing his lack of enthusiasm for Prime Minister Theresa May's approach to Brexit. The next day, Foreign Secretary Boris Johnson also resigned from the government over Brexit disagreements. Both Davis and Johnson believe Prime Minister May's plan is too accommodating to the European Union (EU). Former housing minister Dominic Raab will replace Mr. Davis at the head of the Department for Exiting the European Union (DexEU). Jeremy Hunt has been appointed as the new foreign secretary replacing Johnson.

The United Kingdom's (UK) Brexit plan (hereinafter "The Plan") that caused Davis and Johnson to resign was released in a detailed white paper on July 12. The Plan would establish a free trade area for goods. Under this plan, the UK and EU would maintain a common rulebook for all goods, and the UK would commit by treaty to ongoing harmonization with EU rules on goods, covering only those necessary to provide frictionless trade at the border. This would ensure a seamless border between Ireland and Northern Ireland. It would also continue the supply chains for plasma protein therapies.

Item Number 28 of The Plan states, "The UK believes that manufacturers should only need to undergo one series of tests in either market, in order to place products in both markets. This would be supported by arrangements covering all relevant compliance activity, supplemented by continued UK participation in agencies for highly regulated sectors including for medicines, chemicals, and aerospace."

PPTA is hopeful that the EU is able to work with the UK in ensuring something like the proposed free trade area for goods. In a letter to Brexit negotiators for the EU and UK, we raised concerns with the impact of regulatory changes on the import and export requirements of plasma protein therapies, as well as the regulatory procedures that could cause disruptions to the supply of plasma protein therapies to patients in the EU and the UK.

The EU responded to our letter with a reassurance that the withdrawal of the United Kingdom from the EU is not going to impact the EU's regulatory framework for substances of human origin and medicinal products. The European Commission is working closely with other EU institutions and bodies, as well as Member States, to ensure preparedness. Stakeholders have also been made aware of the need to prepare for the withdrawal.

In response to our call for future cooperation between the EU and the UK to ensure patients have access to their medically appropriate therapies, the EU mentioned the key principles set out in the guidelines of the European Council of March 23, 2018, on the framework for the future EU-UK relationship. In this document, the heads of state and government of the EU hope to maintain the UK as a close partner in the future but caution that the UK shall not have the same rights and enjoy the same benefits as a Member State.

This response warns of the need to prepare for a scenario where the two parties cannot come to an agreement and the UK becomes a third country. In preparation for this, the European Medicines Agency (EMA) has already advised stakeholders to move all UK-based activities to EU/European Economic Area (EEA) countries, including:

- Transfer of all Marketing Authorization (MA) activities, including orphan designation: Any MA Application (MAA) Orphan medicinal product UK-designation must be transferred to an EU/EEA Orphan Designation-Holder;
- Transfer of all safety activities: The Qualified Person for Pharmacovigilance will need to be located in an EU/EEA country;
- Transfer of all manufacturing and quality/batch release activities: Any active substance manufactured in the UK will be classified as an imported substance; any finished product manufactured in the UK will be classified as an imported finished product and will thus need to have an authorized importer established in EU/EEA. The UK site of batch release will need to be transferred to the EU/EEA, and any clinical/bioequivalence/ biosimilar and other studies done with substances sourced in the UK can only be used in the MAA if the MA is granted before March 30, 2019; any batch of finished product must be certified by a Qualified Person within the EEA before being released for placing on the market in the EEA or for export. Certification can only be performed by a Qualified Person of the manufacturer and/or importer who is identified in the Marketing Authorization and is located in the EEA.

In response to our call for FUTURE COOPERATION between the EU and the UK to ENSURE PATIENTS HAVE ACCESS TO THEIR MEDICALLY APPROPRIATE THERAPIES, the EU mentioned the key principles set out in the guidelines of the European Council of March 23, 2018, on the framework for the future EU-UK relationship.