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European Federation of Pharmaceutical Industries and Associations

To: EFPIA Board Members

Brussels, 12 June 2020

Ref: JCT.KB.20200611

Dear Colleagues,

The United Kingdom formally left the European Union on 1 February 2020. This provides for a transition period until 31 December 2020, allowing 11 months for a bilateral trade agreement to be negotiated between the UK and EU and its entry into force. Without an EU-UK deal and without an agreement for a transition period extension by 30 June 2020, the transition period will expire on 31 December 2020 with no deal.

Progress in the negotiations so far has not been sufficient, and the possibility of the transition period ending without a trade deal is very high. Given the potential ramifications for the supply of medicines to patients, I deem it critical that the EFPIA Board is aware of the current dynamics, and member companies take necessary steps to be ready for this possible situation.

EFPIA and ABPI have highlighted the need for a sectoral agreement for pharmaceuticals. EFPIA's EU-UK position paper calls for a Mutual Recognition Agreement on GMP inspections similar to what the EU has with many third countries, in addition to an ambitious IP chapter and cooperation on regulatory, customs, and data. Both associations continue to meet with their respective key stakeholders, including at EU Member State level, to stress the importance of reaching a comprehensive and ambitious agreement on pharmaceuticals for patients, healthcare systems, and industry.

However, the EU and UK positions remain very far apart, especially regarding the issues of level playing field and future governance of the EU-UK relationship. The EU argues that a level playing field is what was agreed in the Political Declaration, and an agreement on this issue is necessary given the geographic proximity of the UK and the EU-UK's economic interdependence. The lack of an accord would allow the UK to gain competitive advantage by undercutting EU standards. The UK has argued that similar provisions are not found in other EU Free Trade Agreements and made clear that it chose to leave the EU in order to no longer be subject to its rules. Progress on sectoral issues will require that these points be addressed first. As outlined below, uncertainty around the implementation of the Northern-Ireland Protocol is another critical issue with ramifications for the supply of medicines.

To date, the UK has stated that it will not ask for an extension of the transition period and will reject this if offered by the EU. This would mean that the EU and UK will start trading on WTO Most Favoured Nation terms (the equivalent to the previous 'no deal' scenario) from 1 January 2021. In addition, even with an FTA in place, certain areas will see a change in practice, for example increased customs checks, as the UK leaves the Single Market and Customs Union. As

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currently written in the Protocol on Northern Ireland, at the end of the transition period, medicinal products in Northern Ireland will be governed by EU regulations and any changes the EU adopts. UK authorities will be entrusted with the application of EU rules. Given that immediately following the end of the transition period, packs of medicines for the UK market might not be compliant with EU regulations, there is a risk that they may not be lawfully dispensed in Northern Ireland. This may threaten the continuity and consistency of supply of medicines to patients in Northern Ireland. With time running short, agreed guidance between the EU and UK is critical to enabling the implementation of the Protocol and ensuring continuity of the supply of medicines to patients in Northern Ireland.

We understand that member companies have previously made preparations for a no-deal outcome, in accordance with EU guidance and as recommended by the EFPIA Presidency in 2018[1], and the efforts made by industry in this regard were much appreciated by our stakeholders. Whilst it is not the place of EFPIA to direct business decisions, given the state of play of the negotiations, I would like once again to call on EFPIA member companies to ensure that all necessary preparations are made to ***be ready for a no-deal outcome on 31 December 2020***. These preparations will also need to account for the implementation of the Northern Ireland Protocol which will come into force at the end of the transition period regardless of the outcome of the EU-UK negotiations.

In its detailed sectoral readiness papers[2], the European Commission, has called on stakeholders to intensify preparations at all levels and has encouraged all stakeholders that may be affected by the end of the transition period without an EU-UK trade deal, to take the necessary readiness actions. I would like to recommend that you reach out to the European Commission and the EMA/national competent authorities, in case of specific concerns about supply chain or other issues stemming from your company's portfolio.

EFPIA believes that maintaining EU and UK patients' continued access to high quality human medicinal products is a key public health objective. EFPIA, and I personally, are continuing to underline the importance of as smooth as possible a transition for medicines supply at the highest political levels.

Please do not hesitate to contact me if you have any further questions.

Yours sincerely,

Jean-Christophe Tellier
EFPIA President

[1] https://www.efpia.eu/media/361694/scan-1.pdf

[2] https://ec.europa.eu/info/european-union-and-united-kingdom-forging-new-partnership/future-partnership/getting-ready-end-transition-period_en. This includes specific EU notices on Medicinal Products, and on Clinical Trials. Other areas may also be relevant to EFPIA member companies.

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