EUROPEAN COMMISSION

Task Force for the Preparation and Conduct of the Negotiations with the United Kingdom under Article 50 of the TEU

Deputy Chief Negotiator

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Brussels,
tf50(2019)371833

Dear Sirs,

Thank you for your letter of 20 November last to the Secretary-General, which he forwarded to me for reply.

In your letter, you outline the need for a specific reference to healthcare issues in the Withdrawal Agreement and the Political Declaration. You also regret that the Commission's contingency planning does not address specifically health aspects.

As a general remark, I would like to stress at the outset that the withdrawal of the United Kingdom from the European Union ('EU') will not impact the EU's regulatory framework for medicines, including in regard of specific populations and diseases (paediatric patients, rare diseases), medical devices and clinical trials. This regulatory framework, built over decades and updated regularly, will continue to ensure that patients in the EU continue to receive safe, efficacious, and innovative healthcare.

Whilst the draft **Withdrawal Agreement** does not specifically address healthcare, it ensures the orderly withdrawal of the United Kingdom with regard to many aspects that are directly relevant to public health. During the so-called 'transition period', there will be no change in practice for patients, researchers and industry (apart from the exclusion of the United Kingdom for certain lead roles, such as reference Member State in authorisation procedures for medicines). From the end of the transition period onwards, detailed winding-down provisions (for example with regard to goods that are moving between the EU and the United Kingdom or conversely at the end of the transition period) are also to the benefit of public health.

*Alliance for Biomedical Research in Europe*
*European Association of Bioindustries (EuropaBio)*
*European Blood Alliance (EBA)*
*European Brain Council*
*European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)*
*EURORDIS-Rare Diseases Europe*
*European Federation of Pharmaceutical Industries (EFPIA)*
*European Federation of Neurological Associations (EFNA)*
*European Industrial Pharmacists Group (EIPG)*
*European Patients' Forum (EPF)*
*European Society for Paediatric Oncology (SIOPE)*
*European Hospital and Healthcare Federation (HOPE)*
*Federation of European Dental Competent Authorities and Regulators (FEDCAR)*
*MedTech Europe*
*Medicines for Europe*

*By email only: kostas.aligiannis@eu-patient.eu*

Regarding the **future relationship**, I would like to highlight the joint-commitment of the United Kingdom and the EU, set out in the draft Political Declaration, to establish an "*ambitious, broad, deep and flexible partnership*" in many areas, including public health and research. The exact shape of the future cooperation can be negotiated between the EU and the United Kingdom only once the latter left the EU, namely during the transition period. However, from the end of the transition period onwards and under the current position of the United Kingdom, the EU legal framework will no longer apply to and in the United Kingdom. This will also result in the non-participation of the United Kingdom in the work of structures and bodies of the EU in the area of public health. This the consequence of the decision of the United Kingdom to withdraw from the Union – a decision which we continue to regret, but respect.

Moreover, as regards the future mobility of people (including patients, medical practitioners and researchers), the United Kingdom has insisted to clarify in the draft Political Declaration that the future relationship "*respects the results of the 2016 referendum including with regard to* [...] *the ending of free movement of people between the Union and the United Kingdom*". The future arrangements on mobility must, to date, be considered against this backdrop.

Finally, as regards **contingency measures**, the Commission has set out, in its Communications of 13 November and 19 December 2018, the principles that guide the Commission's approach. In particular, the Commission has made it clear that economic operators must prepare for the withdrawal of the United Kingdom by taking all necessary decisions. Neither the Commission nor the EU co-legislators can replace such decisions. The Commission has also set out in a series of 'Brexit preparedness' notices the consequences of the withdrawal from the standpoint of the EU rules for health products (medicines, medical devices and products of human origin). On that basis, operators and stakeholders are in a position to evaluate how best to advert any undesirable consequence of the withdrawal on their activities. In addition, the Commission has been and remains in close contacts with the European Medicines Agency, national medicines regulators, and industry in order to ensure adequate preparedness on the withdrawal date.

Yours sincerely,

Sabine Weyand