**Mr. Michel BARNIER**
Chief Negotiator
Task Force for the Preparation and
Conduct of the Negotiations with
the United Kingdom under Article 50 TEU
European Commission
Rue de la Loi / Wetstraat 200
1049 Brussels, Belgium

**Rt. Hon David DAVIS MP**
Secretary of State
Department for Exiting the European Union
9 Downing Street
SW1A 2AG
London

Brussels and London, 13 July 2017

Dear Mr Barnier and Dear Secretary of State,

We are writing to you as the associations representing the European and British pharmaceutical and life science industry (AESGP, EFPIA, EuropaBio, Medicines for Europe, ABPI, BGMA, BIA and PAGB) to underline the importance of securing ongoing cooperation between the UK and EU on medicines as part of the negotiations to agree a new relationship between the UK and the EU.

Securing such an agreement is the best way of ensuring that patients across Europe and the UK are able to continue to access safe and effective medicines and to ensure that there is no adverse impact on public health.

We take note of the phased approach of the negotiations as agreed at your first meeting. However, we feel that it is important to set out our position at this early stage given the significant time pressure to ensure that the necessary arrangements are in place to secure patient access to medicines, and avoid any adverse impact on public health and patient safety in both the EU-27 and UK after the UK leaves the EU.

**EU-UK partnership on the regulation of medicines**

As you will be aware, our industry is highly integrated across Europe, and regulated under EU law through a sophisticated system of legal and regulatory arrangements between EU institutions, Member States and national competent authorities. It is important that there is as much certainty as possible, as early as possible, to enable the pharmaceutical and life science industry to transition smoothly into the new framework, ensuring there is no disruption to patient access to medicines.

The recent letter published by the UK Business Secretary, Greg Clark MP and the Health Secretary, Jeremy Hunt MP, signalled an opportunity to secure cooperation on the regulation of medicines as part of the negotiations. We would like to explore this possibility to maintain close regulatory ties between the EU and the UK and to begin these discussions immediately.

The maintenance of previously granted European marketing authorisations both in the UK and the EU, and the continued cooperation between national competent authorities as facilitated by the EMA and European Commission, will be important in achieving this. Similarly, any changes to the EU-UK trading relationship should not adversely affect the research, development, manufacture and supply of medicines across Europe, including for clinical trials.

Securing such a cooperation agreement would be in the best interest of public health and patient safety. The UK's MHRA currently makes a significant contribution to the work of the European

regulatory network (EMA, HMA, CHMP, CMDh), and its withdrawal would mean a loss of capacity and expertise for the network for the review of medicines as well as the capacity across Europe for the surveillance and safety supervision of products. A capacity building exercise would be needed leading to duplication of assessment work at EU and national level. UK based Qualified Persons Responsible for Pharmacovigilance (QPPV) would need to be relocated, trained or replaced. This would have an overall impact on the running of the systems that ensure the safety and efficacy of medicines treating EU patients.

More importantly, in the case of an unorderly withdrawal there is a risk that all goods due to be moved between the UK and EU could be held either at border checks, in warehouses or manufacturing and/or subject to extensive retesting requirements. In fact, this would lead to a severe disruption of most companies' supply chains, which would lead to potential supply disruptions of life-saving medicines.

**Implementation period**

An implementation period that adequately reflects the time needed by pharmaceutical and biotech companies to transition to a new framework should be agreed on by negotiators. This will allow companies time to make the necessary arrangements to avoid any unintended consequences on the availability of the medicines that patient rely on, both in the UK and the EU-27. For example, pharmaceutical and biotech companies may need to submit applications for the transfer of marketing authorisation for specific products, move batch release for products or move personnel into the EU-27 from the UK, all of which would take a significant amount of time.

An implementation period will also be necessary for national competent authorities who need to ensure they are adequately resourced to deliver the procedures and maintenance activities associated with the new regulatory framework.

We are confident that, with your support, an agreement can be reached which provides for an EU-UK partnership on the regulation and supply of medicines. Alongside an adequate implementation period, this will ensure that patients continue to have access medicines after 29 March 2019.

As stated above, our organisations are committed to a continued and open dialogue with you and your officials and are ready to contribute our expertise to the negotiations in order to ensure patients are able to continue to access the medicines they need, and avoid adverse impact on public health across Europe. We also continue to engage in constructive conversations with EU and UK regulators to ensure that there can be a successful transition to new arrangements as determined by the negotiations. A continuing role for the MHRA in the EMA's committees and processes during this transition would be valuable for the continuity of the EMA's operations.

We look forward to hearing from you and would very much welcome the opportunity to set up meetings with your services for in-depth discussions around our priority issues, given our sector's technicality and complexity.

Yours sincerely,

**Hubertus Cranz**
Director General, The Association of the European Self-Medication Industry (AESGP)

**Nathalie Moll**
Director General, The European Federation of Pharmaceutical Industries and Associations (EFPIA)

**John Brennan**
Secretary General, EuropaBio

**Adrian van den Hoven**
Director General, Medicines for Europe

**Mike Thompson**
Chief Executive, The Association of the British Pharmaceutical Industry (ABPI)

**Warwick Smith**
Director General, British Generic Manufacturers Association (BGMA)

**Steve Bates**
Chief Executive Officer, BioIndustry Association (BIA)

**John Smith**
Chief Executive, The Proprietary Association of Great Britain (PAGB)

**AESGP**

The Association of the European Self-Medication Industry (AESGP) represents the manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe, an area also referred to as consumer healthcare products.

**EFPIA**

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.

**EuropaBio**

EuropaBio is the European Association for Bioindustries. EuropaBio's mission is to promote an innovative and dynamic biotechnology base in Europe. EuropaBio represents 75 corporate and associate members and bio regions, and 17 national biotechnology associations in turn representing over 1800 biotech SMEs. In the healthcare sector, our members include enterprises developing medicines, vaccines and diagnostic tools using biotechnology in their development or manufacturing processes

**Medicines for Europe**

Medicines for Europe represents the generic, biosimilar and value added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines for Europe, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members employ 160,000 people at over 350 manufacturers and R&D sites in Europe, and invest up to 17% of their turnover in medical innovation.

**Association of the British Pharmaceutical Industry (ABPI)**

The Association of the British Pharmaceutical Industry (ABPI) represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK.

The ABPI is recognised by government as the industry body negotiating on behalf of the branded pharmaceutical industry for statutory consultation requirements including the pricing scheme for medicines in the UK.

**British Generic Manufacturers Association (BGMA)**

The BGMA represents the interests of UK based manufacturers and suppliers of generic medicines and promotes the development of the generic medicines industry in the United Kingdom.

**BioIndustry Association (BIA)**

Established over 25 years ago at the infancy of biotechnology, the BioIndustry Association (BIA) is the trade association for innovative enterprises involved in UK bioscience. Members include emerging and more established bioscience companies; pharmaceutical companies; academic, research and philanthropic organisations; and service providers to the bioscience sector. The BIA represents the interests of its members to a broad section of stakeholders, from government and regulators to patient groups and the media. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.

**Proprietary Association of Great Britain (PAGB)**

PAGB is the UK trade association which represents the manufacturers of branded over-the-counter medicines, self-care medical devices and food supplements.