

## Prioritising patient safety and public health across Europe post- Brexit

The UK leaving the EU will have significant implications for patients and the public. It is essential that patients' interests are put first in Brexit negotiations. Our organisations are working together to ensure that decision-makers are clear on what steps are needed to ensure patients are put first.



*\*FEAM has endorsed this statement on behalf of its Academies in the European Union*

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As a decision-maker, we ask you to focus on achieving the following objectives in negotiations, to ensure the best deal is struck for patients and public across Europe.

- 1. To ensure that EU27 and UK patients continue having access to life-saving drugs and medical technologies\*, and early access to new health technologies post-Brexit, we urge you to achieve:**
  - Close cooperation and mutual recognition between the EU and the UK on the regulation of medicines and medical technologies.
  - Full alignment of the UK to the EU regulatory framework for medicines and medical technologies.
  - Seamless trade between the EU and UK to avoid disruptions in the manufacturing and supply of medicines and medical technologies.
  - The highest standards of patient safety through the UK's continued participation in EU systems, such as data sharing networks, pharmacovigilance and the clinical trials portal, Eudamed (the EU database for medical devices and *in vitro* medical devices) and all related-databases post-Brexit.

Securing continuing cooperation and mutual recognition between the EU and UK regarding the authorisation, conformity assessments, testing and surveillance of medicines and medical technologies should be a priority outcome of the negotiations.

Ongoing alignment between the EU and UK on the regulation of medicines will also help ensure that European patients have timely access to innovative new medicines and to generic and biosimilar medicines. The European Medicines Agency (EMA) acts as a regulatory network, licencing pharmaceutical products for sale across Europe. Patient organisations are closely involved with the activities of the EMA and represented throughout the working-process of the organisation in, amongst others, the Patient and Consumer Working Party.

On medicines, over 2,600 final products have some stage of manufacture based in the UK and 45 million patient packs are supplied from the UK to other EU-27/EEA countries each month and over 37 million patient packs are supplied from the EU-27/EEA to the UK each month.<sup>1</sup> This demonstrates the importance of maintaining frictionless trade to meet patient needs for medicines across Europe.

The UK also participates in the EudraVigilance system for pharmacovigilance, operated and monitored by the EMA, which reports on and captures medicines safety, and Eudamed, the EU-wide database for medical devices and *in vitro* medical devices. The loss of the UK's engagement in these systems would significantly reduce their effectiveness, at a time when there are more medicines and devices coming on the market than ever.

Furthermore, the likely implications of a divergence in regulatory frameworks given the newly adopted In Vitro Diagnostic Medical Devices (IVDs) and Medical Devices (MDs) Regulations, are of great concern to the medical technology sector.<sup>2</sup> The EU-wide IVDs and MDs legislations have played a key role in delivering high-quality care to patients for over 25 years, allowing them timely access to safe and effective medical technologies. In the event that there are two divergent regulatory systems as a result of Brexit, patient access to medical technologies risks being hindered. As a consequence, both parties need to ensure the full availability of medical technologies for patients once the negotiations have come to an end.

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<sup>1</sup> [Brexit EFPIA survey results](#)

<sup>2</sup> [MedTech Europe Position Paper on Article 50 Negotiations between the European Union and the United Kingdom \(Brexit\)](#)

\* medical devices and in vitro diagnostic medical devices

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The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) is a significant contributor to EU systems and processes, both for medicines and medical technologies. This includes, but is not limited to, scientific and clinical assessments, surveillance and supervision of products, and reporting adverse events. A continued regulatory alignment between the EU and UK will ensure that European patients have timely access to innovative new medicines, generic and biosimilar medicines, and medical technologies.

### **2. To ensure the EU remains a world class hub for research and collaboration post-Brexit, we collectively urge you to seek:**

- A common framework for collaboration in research and information-sharing between the EU27 and the United Kingdom to ensure that post-Brexit EU27 and UK patients, the public, researchers and organisations can take part in pan-European research and innovation networks and clinical trials.

The UK has the highest number across the EU of phase I clinical trials, those testing a new drug or treatment for the first time, and the second highest number of phase II and phase III clinical trials. It has also the highest number of trials across the EU for both rare and childhood diseases<sup>3</sup>.

There are over 1500 clinical trials being conducted in multiple EU member states that have a UK-based sponsor and over half of these trials are scheduled to continue beyond March 2019.<sup>4</sup>

Linked to the research agenda are the recently established European Reference Networks (ERNs)<sup>5</sup> for rare and complex conditions. Here the intention is to achieve better outcomes for rare disease patients through clinical and research collaboration across Europe. A quarter of all ERNs are led by UK/NHS hospitals and all but one ERN include partners from the UK.

Furthermore, UK investment in medical technologies including biopharmaceuticals (life sciences) corresponds to 25% of all expenditure in R&D; for UK businesses that is £11.5 million invested in the UK per day in research and development<sup>6</sup>.

Besides research, the UK has provided a great deal of expertise on Health Technology Assessment, and Adaptive Pathways<sup>7</sup>. Furthermore, the UK has leading expertise in assessing medical technologies and ensuring appropriate stakeholder involvement. Next to that, the benefit of digital healthcare, healthcare data, genomics and research are being explored throughout Europe, but with a major contribution of UK or UK-based institutes and stakeholders. Patient and public involvement (PPI) representatives have an ever-increasing role in all aspects of medicines research and development (R&D). The UK is setting a great example for the EU in this area, given that much state of the art research and many internationally recognised good practices originate here<sup>8</sup>. UK universities play a leading role in areas that benefit many European countries and this source of knowledge should not be lost because of Brexit. On the other side of the coin, even if the UK matches science funding from current EU sources, UK science loses out by having many collaborations made significantly more

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<sup>3</sup> Technopolis, [The impact of collaboration: the value of UK medical research to EU science and health](#)

<sup>4</sup> [Brexit EFPIA survey results](#):

<sup>5</sup> [European Reference Networks](#), European Commission:

<sup>6</sup> [Life Sciences UK, From Vision to Action Delivery of the Strategy for UK Life Sciences](#)

<sup>7</sup> [Patient Involvement in Health Technology Assessment](#), *Facey, Karen, Ploug Hansen, Helle, Single, Ann (Eds.)*

<sup>8</sup> Sue Pavitt, EUPATI: [An initiative to provide expertise in patient advocacy and in medicines development processes](#) :

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complex. Ultimately it will be patients who suffer if international health research collaboration is jeopardised by the UK leaving the EU.

### **3. To ensure that EU27 and UK patients continue to receive the best possible care, wherever they need it, we call on you to achieve:**

- Continued reciprocal healthcare arrangements for both those who have crossed the border before Brexit day and for post-Brexit flows.
- EU citizens travelling to the UK and vice versa continue to benefit from the EHIC for urgent and emergency care.

Under current EU law, if an EU citizen falls ill or has an accident in another EU/EEA Member State, they can use their European Health Insurance Card (EHIC) to get healthcare on the same basis as the local population. Also, the 1.2 million UK citizens residents in other EU Member States, and around three million EU citizens living in the UK benefit from getting the same healthcare as the citizens of the country they live in under EU law. Member States reimburse each other subsequently, but the patient doesn't have to get involved. Special arrangements also apply where patients travel to another Member State for the specific purpose of receiving treatment, for example, because it isn't available in their home country.

There are about 53 million visits made to the EU from the UK each year, and 25 million visits from the EU to the UK. Only around 1 per cent of these visits results in an EHIC claim, but EU countries receive about £150 million per year from the UK to compensate for EHIC use by UK citizens. Consequently, a significant new administrative burden could emerge for hospitals in the event of the EHIC being discontinued.

### **4. To ensure that public health for all EU and UK citizens is maintained post-Brexit we collectively call on you to secure:**

- Strong coordination between the EU and UK to deal with pandemics, as well as other health threats.
- Highest possible level of coordination between the EU and UK on health promotion and disease prevention programmes.

European patients benefit from the UK's engagement in systems designed to protect public health across Europe. For example, the UK is substantially involved in the surveillance activities of the European Centre for Disease Control, which provides EU countries with protection from the 52 notifiable communicable diseases, outbreaks and public health risks, through a single database.

As diseases know no borders, and as many of Europe's health and demographic challenges are shared, we call for a framework to be put in place between the EU and the UK post-Brexit to ensure that there is knowledge sharing to strengthen public health and to support the response to public health threats.

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- 5. To ensure that EU27 and UK health professionals continue to benefit from mutually beneficial training and education opportunities, automatic recognition of their qualifications, and can continue to provide healthcare services to EU27 and UK patients, we call on you to achieve:**
- In the EU27 and the UK, continued recognition of professional qualifications of general practice nurses, medical doctors, dentists, pharmacists and midwives trained in the EU27 and UK before Brexit day and for post-Brexit.
  - That EU27 and UK competent authorities continue to use the alert mechanism through the Internal Market Information System to alert each other of health professionals who are prohibited or restricted to practice.

Healthcare professions, namely general practice nurses, dentists, doctors, midwives and pharmacists, have a special status under the Recognition of Professional Qualifications Directive 2005/36/EC which makes their mobility easy and safe. The legislation also enables students of those professions to benefit from educational systems other than that of their home country, making the expertise and knowledge in each country available to a much broader public. At the same time, patients and consumers are adequately protected by an alert mechanism established by the Directive. This allows the competent authorities of all Member States to quickly warn each other if health professionals have been prohibited or restricted from practicing the profession in one country or have used falsified diplomas for their application for the recognition of their qualification.

This framework allows a high degree of professional mobility without jeopardising patient safety and quality of care. Patients and professionals benefit from this transfer of knowledge and specialised expertise which contributes to continuously improving the quality of healthcare in Europe.