The British Medical Association (BMA) is a professional association and independent trade union, representing doctors and medical students from all branches of medicine across the UK and supporting them to deliver the highest standards of patient care. The BMA is committed to safeguarding the future of the medical profession following the UK’s vote to leave the European Union (EU). The BMA has published a series of BMA Brexit Briefings to assist decision makers on both sides of the negotiations to reach the best outcome for the health of our nations.

Collaboration across borders on the way medicines and medical devices are regulated has been a key advantage of the UK’s membership of the EU. The establishment of a robust common framework for assessing and monitoring drug safety and efficacy has meant patients across Europe have had timely access to new therapies, while the “Conformité Européenne” marking (CE) system for medical devices has facilitated access to innovative medical devices from across Europe. Following the UK’s departure from the EU, we are urging the UK Government to continue to work closely with the European Medicines Agency (EMA) after the UK leaves the EU, and specifically, to negotiate a new, formal agreement with the EMA to regulate the future of medicines, as well as mutual recognition of the CE mark.

Key points
• We are urging the UK Government to continue to work closely with the EMA after the UK leaves the EU over the future regulation of medicines and medical devices.
• The UK Government should seek to negotiate a formal agreement with the EMA, which would enable the Medicines and Healthcare products Regulatory Agency (MHRA) to continue to support and participate in their assessments for medicines and approvals and to agree mutual recognition of and ongoing participation in the CE-mark scheme.
• This will be vital in ensuring patients and health services in the UK continue to have timely access to new medicines, medical devices and robust pharmacovigilance systems, which monitor adverse drug reactions.
• Divergence between the UK and EU systems for regulating medicines and medical devices presents a number of risks including delayed access to new medicines and devices, weaker post-approval regulation and pharmacovigilance, and loss of expertise in regulatory processes and pharmacovigilance, which monitors adverse drug reactions.

Ensuring close collaboration between the UK and the EU on medicines and medical devices regulation after Brexit
The BMA welcomed the publication of a letter by the UK Secretaries of State for Health and Business which set out the Government’s plans for the regulation of medicines post exiting the EU in July 2017,
and outlined the Government’s intention to find a way to collaborate with the EU, in the interests of public health and safety\(^1\). The letter set out three key principles for medicines regulation in the UK:

- patients should not be disadvantaged
- innovators should be able to get their products into the UK market as quickly and simply as possible
- and the UK should continue to play a leading role promoting public health.

The BMA supports these principles as the cornerstone of a new system to govern the future of medicines regulation.

In August 2017, the Government set out its position and principles to ensure minimal disruption on withdrawal from the EU, with regards to the availability of goods\(^2\). A position paper stated the Government would be negotiating on the key principles of ensuring continued availability of products in the EU and UK market, at the date of withdrawal and ensuring goods in circulation continue to comply with product legislation and market surveillance authorities can take the necessary action with respect of non-compliant goods. This includes a specific proposal that assessment bodies should continue to be recognised to fulfil any ongoing obligations (pharmacovigilance) for the lifetime of products and activities (medicines and medical devices).

Given these recent developments, we are urging the UK Government to continue to work closely with the EMA after the UK leaves the EU. Specifically, we are calling on the UK Government to negotiate a formal agreement with the EMA, which would enable the Medicines and Healthcare products Regulatory Agency (MHRA) to continue to support and participate in their assessments for medicines and approvals and to agree mutual recognition of and ongoing participation in the CE-mark scheme.

We believe there are a number of benefits for the UK in seeking to negotiate such an agreement on the future of medicines regulation including:

- limiting potential delays incurred by pharmaceutical companies and device manufacturers seeking a licence for their products in the UK, and thus ensuring timely access to medicines and medical devices
- avoiding the burden and cost of establishing an independent regulatory and pharmacovigilance system
- minimising the risk of pharmaceutical companies based in the UK from re-locating to a country working within the jurisdiction of the EMA, and the consequential impact on the UK’s research community and its economy
- preventing any lessening of the UK’s capacity for pharmacovigilance by providing access to the EMA’s networks
- supporting close collaboration with clinical research institutions across the EU.

Such an approach also contains a number of benefits for the EU including:

- maintaining access to the extensive network of expertise in the UK in medicines, medical devices regulation and pharmacovigilance
- continuing the close working relationship with the UK’s world-leading clinical research institutions
- ensuring pharmaceutical companies based in the EU can readily access the UK market
- ensuring medicines and devices developed in the UK reach EU citizens quickly, well in advance of the rest of the world

\(^1\) Financial Times (4.7.2017) We will continue to work with EU on medicines.
• maintaining the EU’s current capacity for pharmacovigilance by providing access to the UK’s networks.

Potential consequences of divergence in the UK and EU systems for regulating medicines and medical devices

Delayed access to new medicines and devices
We are concerned that the development of a significantly different regulatory process for medicines in the UK, compared to the EMA, would place an increased regulatory burden on pharmaceutical companies; this, in turn, could lead the sector to prioritise the much larger European Economic Area (EEA) market over the UK. We note that the Government acknowledged this risk in its recent life sciences industry strategy, which stated that the UK market would be too small to stand on its own.

The risks of delayed access to new medicines and devices for patients and health services arising from a separate regulatory system in the UK are deeply concerning. Reports suggest potential delays of 12 to 24 months for UK patients being able to access life-saving cancer drugs and conversely, medicines developed in the UK not reaching patients in the EU market as quickly3.

Similarly, a separate system for accreditation of medical devices in the UK (away from the CE marking scheme) would increase the burden on device manufacturers through the need to satisfy different safety, health and environmental protection requirements4. This would likely lead to delays in devices developed in other countries reaching the UK market, and vice versa. This would be particularly detrimental for the UK, as most medical devices are imported. While the UK has a limited number of large manufacturers, those that do exist tend to concentrate on the US market. The strength of UK manufacturers lies in orthopaedics but also in imaging, diagnostics and cardiovascular disease. Those manufacturers that do exist often rely on components made in the rest of the EU and would thus face higher costs if the UK was outside the customs union.

Weaker post-approval regulation and pharmacovigilance
The EMA coordinates a large network of pharmacovigilance, including post-approval regulation, surveillance and information sharing of medicines and medical devices across their life-cycle. This operates through cooperation between EU Member States, the EMA and the European Commission (EC). By collecting and sharing real-time data on approved medicines and devices, the EMA can identify trends and quickly act to inform patients and healthcare professionals about any safety concerns. The specific advantage of this collaboration at an EU level is the wider coverage area for surveillance and reporting of adverse effects, as there is a greater number of patients using a drug compared to within an individual country. This increases the likelihood of the data collected being more accurate, as well as concerns being picked up at an earlier stage.

We are concerned that a reduction in UK involvement in this network and a more selective approach to pharmacovigilance data and information sharing would significantly lessen the capacity to detect and manage issues such as adverse drug reactions. This would potentially cause harm and uncertainty for patients and their doctors who rely on accurate reporting. While this would have an impact on both the EU and the UK, it would be particularly significant for the UK given the smaller population size for detecting problems.

Loss of expertise in regulatory processes and pharmacovigilance

The MHRA plays a key role in supporting the EMA, handling around 40% of the EMA’s decision making on medicines\(^5\). This has meant that a significant network of medicines and medical devices regulation and pharmacovigilance expertise is based in the UK, with the MHRA being viewed as the pre-eminent competent global authority for medicines and medical devices regulation\(^6\). The UK’s expertise includes specialists from across Europe working for the MHRA, as well as those employed by pharmaceutical companies – each company has to employ a qualified person for pharmacovigilance (QPPV) working within the EU, and many are based in the UK to facilitate close working with the EMA.

While a move away from working collaboratively with the EMA, coupled with its re-location away from London, will increase the likelihood of expertise moving abroad, this would be particularly challenging should the UK decide to establish its own, separate regulatory systems. The impact of the UK’s loss of expertise would be reflected in a loss of regional and international influence in pharmacovigilance practice and make the UK reliant on other countries for sharing expertise.

**Implications of a ‘no deal’ scenario for the regulation of medicines and medical devices in the UK**

We are deeply concerned that a failure by the UK and EU to reach an agreement by March 2019 would lead to considerable uncertainty in the UK’s approach to medicines and medical devices regulation. This would likely lead to a shift away from products being developed for the UK market, with significant ramifications on timely access to new medicines and medical devices, as well as on the UK’s pharmaceutical and medical devices industries. There would also be considerable adverse impacts on the future capacity of the UK and EU in relation to pharmacovigilance, which for the UK would be compounded by a potential loss of expertise.

**For further information, please contact:**
Susan Bahl, Brexit Lead
T: 020 3058 7457 | M: 07919 228 506 | E sbahl@bma.org.uk

**What does Brexit mean for the medical profession?** Visit the BMA website to find out more

---
