

Medicines and Medical Devices Bill

House of Lords: Grand Committee

Commencing Monday 19th October

About the BMA

The BMA (British Medical Association) is a professional association and trade union representing and negotiating on behalf of all doctors and medical students in the UK. It is a leading voice advocating for outstanding health care and a healthy population. It is an association providing members with excellent individual services and support throughout their lives.

The BMA has briefed throughout the scrutiny of the Medicines & Medical Devices Bill in the House of Commons and the House of Lords.

For a more detailed overview of the BMA's position on the Bill, please refer to our Second Reading briefing available at: www.bma.org.uk/media/3082/bma-briefing-medicines-medical-devices-bill-hol-2-sept-2020.pdf

Regulatory alignment with EU standards

We are supportive of the amendment tabled by Baroness Thornton and Lord Hunt which 'would require the appropriate authority to have regard to the desirability of regulatory alignment with EU regulations'.

We are supportive of the amendment tabled by Baroness Thornton, Lord Patel, Lord Hunt and Lord Mackay which would 'allow the Secretary of State to make regulations to continue the UK's collaboration with clinical trials involving multiple EU countries'.

We are supportive of the amendment tabled by Lord Lansley and Lord Kakkar which 'would have the effect that regulations should correspond to the EU Clinical Trials Regulation' and 'seeks to establish whether, and to what extent, Minister intend to depart from the EU Regulation'.

The BMA believes that any potential regulatory divergence from current standards must be kept under constant evaluation to ensure that there is no negative impact upon the timely supply of safe medicines to UK patients. Beneficial changes, orchestrated at the EU level, must still reach UK patients once we are no longer part of the EU's centralised processes.

The EU and UK markets for medicines and medical devices are closely linked. According to the ABPI (Association of British Pharmaceutical Industry), on a monthly basis, at least 45 million packs of medicines are exported from the UK to the EU, and 37 million packs supplied from the EU to the UK¹. The UK also relies heavily on the EU for its supply of medical devices, with more than half of its £5 billion imported medical technology originating from the EU.²

¹ Business, Energy and Industrial Strategy Committee, 'The impact of Brexit on the pharmaceutical sector', May 2018: <https://publications.parliament.uk/pa/cm201719/cmselect/cmbeis/382/38205.htm>

² 'Brexit is Coming: What's in it for Medtech?', Dec 2018: www.guidedsolutions.co.uk/blog/brexit-is-coming-whats-in-it-for-medtech/



Using the example of medicines, the EMA is responsible for ensuring that all medicines available on the EU market are safe, effective, and of a high quality. In particular, it provides a centralised approval procedure for licensing to allow pharmaceutical companies to submit a single marketing authorisation, which, once granted, is valid across the EU and EEA. The EMA also oversees the monitoring of drug safety across Europe through its pharmacovigilance procedures – via its shared infrastructure and data networks, the EMA allows EU countries to rapidly identify and address any possible threat to patient safety stemming from pharmaceuticals currently on the market.

Furthermore, the EMA also has a lead role in harmonising the regulation of clinical trials – which are often undertaken on a cross border basis across the EU – and agreeing post-approval regulation to monitor the safety of medicines across their lifecycle.

It was noted during the Commons’ scrutiny of the Bill that future changes to the law on medicines and medical devices in the UK could lead to a ‘butterfly effect’ whereby even small, incremental amendments lead to a divergence of standards that risks manufacturers prioritising the EU market over our own. Any delays in accessing medicines in this way would be detrimental to patient safety and quality of care in the UK.

Impact of divergence

Medicines – Should the UK develop a significantly different regulatory process to the EMA for medicines regulation, the increased regulatory burden on pharmaceutical companies could lead them to prioritise the much larger EEA market over the UK’s. This would potentially cause delays in new drugs being made available for patients in the UK – and would likewise mean that medicines developed in the UK do not reach patients in the EU market as quickly. For example, [it has been reported that](#) a separate regulatory system to the EMA could lead to delays of 12 to 24 months for UK patients being able to access life-saving cancer drugs.

Medical devices – Establishing a separate system for accreditation of medical devices in the UK (away from the CE marking scheme) would also increase the burden on device manufacturers through the need to satisfy different safety, health, and environmental protection requirements. This would likely lead to delays in devices developed in other countries reaching the UK market, and vice versa, which would be particularly detrimental for the UK, as most medical devices are imported.

The new EU regulation on medical devices – the [EU Medical Device Regulation](#)¹ – is an example of a change coming through from the EU that the UK should seek to capture in the future regulatory framework around medical devices, facilitated by this Bill. Expected to come into force in 2021, the revised rules were drafted in the aftermath of the metal-on-metal hip and PIP implant scandals and will introduce stricter requirements on the bodies authorising medical devices and ensure greater post-market surveillance.

International trade agreements

We are supportive of the amendment tabled by Baroness Thornton which ‘would protect medicines and medical devices regulations from any form of control from outside the UK in the event of a trade deal’.

The BMA is clear that legislative protections are needed to ensure that NHS price control mechanisms and the UK’s current intellectual property regime are maintained, so that patients continue to have access to essential and lifechanging medicine. Any weakening of current cost

containment mechanisms or extension of patent protections would increase overall NHS spend on pharmaceuticals, necessitating either increased funding or restricting the medicines the NHS can afford.

It is vital that future trade deals do not adversely affect the safety and regulation of medicines and medical technologies distributed in the UK. This is particularly crucial in the context of the COVID-19 pandemic, which has created increased global pressure to rapidly approve new interventions. Trade agreements must not be used as a vehicle to weaken standards for approving medicines and medical devices or standards of post-approval marketing and surveillance. They must not pose a barrier to cooperation with EU partners on safety surveillance and pharmacovigilance across the European region, and they must not undermine a confidential medical service.

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