
Medicines and Medical Devices Bill

House of Lords: Second Reading
Wednesday 2 September

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.

Background: regulation of medicines & medical devices

Status quo

The regulation and licensing of medicines and medical devices in the UK until now has derived from EU law and is overseen by the DHSC's executive agency, the MHRA (Medicines and Healthcare products Regulatory Agency).

Medicines – the EMA (European Medicines Agency) is responsible for managing the centralised marketing authorisation process for all drugs seeking to enter the EU market; as well as monitoring the safety of these medicines across their life cycle. Working within the EMA's structures and processes, and building on EU law, the UK has developed a well-functioning medicines regulatory system which ensures that patients have timely access to safe and effective drugs.

Medical devices – once approved by the MHRA (or the equivalent notified body in each Member State), devices can be sold across the EU and EEA (European Economic Area) through the CE marking scheme. This labelling system signifies that products sold in the EU and EEA have been tested and assessed to meet safety, health, and environmental protection requirements set by EU regulations. Products made in countries outside the EU must be compliant with these requirements if they are to be made available on the EU market.

End of the Transition Period (31st December 2020)

From January 2021, changes to legislation on these issues will no longer flow through from updates at EU level. As such, the **Medicines and Medical Devices Bill** creates the structure for the UK Government, and the Department of Health in Northern Ireland (for areas of legislative competence),¹ to legislate for updates or changes to our existing laws on human and veterinary medicines, clinical trials, and medical devices at the end of the Transition Period.

The Medicines & Medical Devices Bill

Regulation-making, delegated powers – scope/scrutiny

The Bill gives government extensive powers to amend or update the law relating to medicines and medical devices once we are no longer party to EU legislation. According to the UK health

¹ The Bill extends to England, Northern Ireland, Scotland and Wales. Parts 1 and 2 of the Bill (relating to human and veterinary medicines, including clinical trials of human medicines) are within the legislative competence of the Northern Ireland Assembly.



minister², the Bill *‘in the main, does not deliver any immediate change to the regulation of medicines and medical devices’* – rather, *‘it provides a framework of powers to ensure that regulatory change can be made as and when necessary’*.

During the Commons’ scrutiny of the Bill, concerns were expressed that the Bill’s regulation-making, delegated powers could allow government to *‘make hundreds or more individual decisions to change our current regulatory regime into a markedly different one, one statutory instrument at a time’*. Furthermore, the shadow minister noted that some changes – covering *‘very important things’* – are only subject to the negative procedure for secondary legislation.

In view of these concerns, the BMA is seeking clarity as to why some powers listed in the Bill will not be covered under the affirmative procedure. These include powers beyond those required in the event of an emergency – such as the labelling, advertising, prohibiting, and charging of fees for human medicines.

Regulation-making, delegated powers – falsified medicines

The EU’s falsified medicines directive introduced tougher rules to ensure medicines are safe and their trade is rigorously controlled. The UK Government agreed to implement the directive from 9 February 2019, which means GP practices must now be able to demonstrate compliance.

All prescription medicines are required to carry a unique identifier – this safety feature means that any prescription item is fully traceable, and it’s easier to identify false products. The Bill enables the secretary of state or the ‘appropriate authority’³ to bring forward regulations under this Bill to set out who should set up, pay for, and maintain the necessary systems required to check that medicines meet these safety standards.

The BMA has previously expressed concerns that the funding to ensure GPs are equipped to comply with the directive – the costs associated with tracking and decommissioning medicines – has not been considered. We have made representations to the Department of Health and Social Care that the NHS should fund the necessary equipment for GPs to be compliant.⁴

We urge the secretary of state or the ‘appropriate authority’ to use the Bill’s provision in relation to falsified medicines to clarify how the cost of compliance with safety standards is to be achieved.

Regulation-making, delegated powers – primacy of patient safety

According to the Bill, the secretary of state or the ‘appropriate authority’ must take account of three principle factors when bringing forward new regulations relating to medicines and medical devices:

- The **safety** of human medicines / medical devices
- The **availability** of human medicines / medical devices
- The **‘attractiveness’** of the relevant part of the UK as a place in which to conduct clinical trials or supply human medicines / supply or develop medical devices

² The Parliamentary Under-Secretary of State for Health and Social Care, Committee Stage of the Medicines and Medical Devices Bill, 8 June 2020

³ The House of Commons library briefing explains: For medicines, the “appropriate authority” is recognised in the Bill as the Secretary of State in England, Wales and Scotland. In Northern Ireland it is the Department of Health in Northern Ireland, either acting on its own or jointly with the Secretary of State. For medical devices, it is the Secretary of State.

⁴ Read more about the BMA’s position on the falsified medicines directive here: www.bma.org.uk/advice-and-support/gp-practices/prescribing/the-falsified-medicines-directive

It was noted on all sides of the Common's committee stage debate that the UK life sciences sector is 'an anchor for the UK economy' and there is a desire to 'cement our position as a world leader' in this field. The 'attractiveness' principle in the Bill speaks to this priority. However, concerns were expressed⁵ that situations could arise in which 'attractiveness' could run into conflict with patient safety, and that greater protections or clarity are needed within the Bill. Furthermore, the shadow minister queried whether there is a 'vulnerability' facing a future secretary of state 'who is said to have prioritised patient safety over the attractiveness of the UK market for litigious and exceptionally powerful pharmaceutical companies'.

In responding, the minister assured that 'It is absolutely the case that we would never seek to make a regulatory change that puts somebody's health at risk', and indicated the priority of patient safety when making new regulations under the Bill: 'the reason why the safety of medicines is listed first is because safety is the paramount objective in everything'. However, the minister rejected attempts to clarify a hierarchical approach to these considerations within the Bill⁶ – stating, 'there need be no hierarchy' because the combination of all three considerations 'provides the best outcomes for patient safety'.

The BMA is seeking clarity as to whether each of the three considerations are on the same statutory footing if a prospective regulation is expected to have an impact on patients.

Regulation-making, delegated powers – divergence

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 UK⁷. 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.⁸

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

⁵ First sitting of the Committee Stage on the Medicines and Medical Devices Bill, 8 June 2020, available at https://publications.parliament.uk/pa/cm5801/cmpublic/Medicinesandmedical/PBC090%20Medicines%20and%20Medical%20Devices_1st-3rd%20Combined_10_06_2020.pdf

⁶ The Minister's response to 'amendment 21' – details of the amendment available at: <https://hansard.parliament.uk/commons/2020-06-23/debates/EA598F76-B5FD-42C7-8B71-3B5EA8B3950D/MedicinesAndMedicalDevicesBill#contribution-CBE925FA-D7E3-4D4A-84DE-D6EEC5BAAA72>

⁷ 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>

⁸ 'Brexit is Coming: What's in it for Medtech?', Dec 2018: <https://www.guidedsolutions.co.uk/blog/brexit-is-coming-whats-in-it-for-medtech/>

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 BMA believes any potential divergence in standards must be kept under constant evaluation to ensure that such changes do not negatively impact upon the timely supply of safe medicines to UK patients.

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.

Beneficial changes such as these, orchestrated at the EU level, must still reach UK patients once we are no longer part of the EU's centralised processes.

Brexit: securing a future relationship that protects health

Beyond establishing the legal framework of the Medicines and Medical Devices Bill, it is crucial that the Government considers the foundations that are needed to protect and improve health and healthcare in the UK through its negotiating of our future relationship with the EU.

The impact of moving away from the existing collaborative approach between the UK and the EU could be substantial. The centralised processes that we are currently part of reduce the burden on the regulatory authority in each Member State, create a larger European market for the pharmaceutical industry and medical device manufacturers, and thereby facilitate the timely access of new therapies and technologies to patients across the EU and EEA area. The EMA accounts for 25% of world sales of medicines, second only to the United States. The UK in comparison accounts for only 3% of the total world market⁹.

⁹ BMA briefing, 'Brexit Briefing: medicines and medical devices regulation', 2017. Available at: <https://www.bma.org.uk/media/1346/bma-brexit-briefing-medicines-and-medical-devices-regulation-2017.pdf>

Therefore, the Bill and the negotiations must complement one another to ensure that the country's legal apparatus for medicines and medical devices facilitates the arrangements we want to have in place once we leave the Transition Period. The BMA has been clear¹⁰ that these arrangements should include:

Medicines & medical devices – negotiating a formal agreement for continued participation in EMA assessments for medicines approvals, and for mutual recognition schemes for medical devices. Additionally, the UK should negotiate a formal future partnership with Euratom to facilitate a secure and consistent supply of radioisotopes, which have a range of important applications in medicine. It is also important that the implementation of the Northern Ireland/Ireland Protocol does not result in delays to the importation of vital medicines to Northern Ireland from Great Britain.

Medical research – negotiating a formal agreement to maintain access to EU funding programs, ensure alignment with clinical trials regulations, and secure the participation of the MHRA in clinical trials that cross the EU and UK in order to maximise collaboration between researchers in the UK and EU. This is particularly important if UK researchers are to benefit from the EU's new Clinical Trials Regulation, due to be introduced in 2022, which is expected to significantly improve the current research climate via the introduction of a single clinical trial database and a centralised clinical trial portal.

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¹⁰ BMA briefing, 'Brexit briefing: securing a future relationship that protects health', 2020. Available at: <https://www.bma.org.uk/what-we-do/working-with-europe/brexit/bma-and-brexit>