HOUSE OF LORDS Library Briefing

Medicines and Medical Devices Bill
HL Bill 116 of 2019–21

The bill would provide new delegated powers to update or amend certain regulations governing the UK's regulatory framework for medical devices and for human and veterinary medicines. Much of this regulatory framework has come from EU regulations and directives, which the UK has implemented through powers available under the European Communities Act 1972. These powers to update existing legislation will not be available after the end of the transition period. The Government has stated that without the changes brought in by the bill, the existing regulations could only be updated in future through primary legislation.

The bill would also make some additional changes to the regulatory framework for medical devices. These changes would include powers to establish a new system for recording data on such devices and the consolidation of enforcement provisions and new sanctions.

The bill received cross-party support in the House of Commons, with each party agreeing the bill was necessary in the circumstances. However, MPs raised concerns about matters including:

- the scope of the delegated powers available under the bill;
- whether it would lead to less regulatory alignment with the EU;
- why the wording of the bill's regulation-making powers did not prioritise consideration of patient safety;
- tackling organ harvesting and other unethical practices; and
- the potential large policy changes it could lead to, including "hub-and-scope" dispensing.

The Government defended its position on these issues. It said the bill's delegated powers were limited, and those powers would be subject to sufficient scrutiny. For example, the exercise of most of the delegated powers would require prior consultation with appropriate bodies and would be subject to the draft affirmative process. The Government also said it did not intend to make any bold policy changes without full consultation.

No opposition amendments were made to the bill during its House of Commons stages. However, MPs agreed some government amendments at committee stage. A new clause proposed by the Government was added at report stage. The House of Commons agreed each of these without a vote.

Russell Taylor | 2 July 2020

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1. What is the purpose of the bill?

The Medicines and Medical Devices Bill would allow the Government to update, modify and maintain the regulatory regimes for human medicines, clinical trials of human medicines, veterinary medicines, and medical devices. The bill would give the Government delegated powers to make such changes.

These areas fall within EU competence. The EU has legislated in each of these fields to create "comprehensive regulatory frameworks".[1] These have primarily been enacted in UK law through the following regulations:

- Human Medicines Regulations 2012.
- Medicines for Human Use (Clinical Trials) Regulations 2004.
- Veterinary Medicines Regulations 2013.
- Medical Devices Regulations 2002.

These regulations were made and updated using delegated powers set out in section 2(2) of the European Communities Act (ECA) 1972.

The regulatory frameworks will form part of the UK's retained EU law at the end of the transition period. This is because of the provisions of the European Union (Withdrawal) Act 2018. However, the Government will no longer be able to update them through the ECA.

The bill's primary purpose therefore is to provide the Government with new delegated powers to enable it to update the regulations outlined above, and specific connected legislation, after the end of the transition period on 31 December 2020. Without this change, primary legislation would be needed to be update each of the regulations. The Government has explained that the medical devices regulatory framework is slightly different to the others, as this is also linked to powers provided by section 11 of the Consumer Protection Act (CPA) 1987. Those powers would still be available.[2] However, due to the limitations of the changes allowed under the CPA, the Government argues that the CPA cannot be relied upon to exclusively update the regulatory framework for medical devices.

The delegated powers provided in the bill would be "targeted". They would only be available to update specific features of the frameworks. The bill's explanatory notes explains:

> These delegated powers may only be exercised in relation to a finite list of matters specified on the face of the bill and only after consideration has been given to the safety and the availability of human or veterinary medicines or devices (as the case may be) and the attractiveness of the UK as a place to develop and supply these products.[3]

The Government's use of many of the delegated powers provided by the bill would also require parliamentary approval and prior consultation with people and bodies deemed appropriate.

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[1] Explanatory Notes, p 3.

[2] ibid, p 4.

[3] ibid.

In addition, the bill would make some further changes to the medical devices regime:

- providing a delegated power to establish one or more information systems in relation to medical devices;
- consolidating the enforcement provisions for medical devices and introduces sanctions; and
- providing an information gateway to enable the sharing of information held by the Secretary of State about medical devices; for example, to warn members of the public about safety concerns.[4]

2. Explanation of each part of the bill

The bill contains 46 clauses, split into five parts. It also has two schedules.

2.1 Part 1: Human medicines

Part 1 concerns the regulatory frameworks for human medicines and for the clinical trials of human medicines.

Human medicines framework

The regulatory framework for human medicines provides a "comprehensive scheme for regulating human medicines that covers their licensing, manufacture, importing, brokering, labelling, distribution, advertising and pharmacovigilance (safety monitoring), amongst other things".[5] The scheme is overseen in the UK by the Medicines and Healthcare Products Regulatory Agency (MHRA), acting on behalf of the secretary of state and the minister of health in Northern Ireland (together known as the licensing authority).

The UK framework for human medicines is based on the EU Human Medicines Directive and is set out in the Human Medicines Regulations 2012. The UK's regulations also cover limited matters outside of EU competence, including the framework around the supply of human medicines to the patient; for example, who may prescribe prescription-only medicines.

Clinical trials of human medicines framework

The regulatory framework for the clinical trials of human medicines covers the:

> Authorisation of clinical trials, their ethical approval, the conduct of the trial (including adherence to good clinical practice), the reporting of adverse events and breaches of the authorisation, the manufacture and importation of the medicinal products involved in the trial and their labelling.[6]

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[4] Explanatory Notes, p 3.

[5] ibid, p 4.

[6] ibid, p 5.

The MHRA oversees it, acting on behalf of the licensing authority.

The UK framework for clinical trials is based on the EU Clinical Trials Directive and is set out in the Medicines for Human Use (Clinical Trials) Regulations 2004.[7]

Provisions

Clause 1 would allow the secretary of state or/and the minister of health in Northern Ireland to make changes to the "law relating to human medicines" through regulations. The bill defines the law relating to human medicines as:

- sections 10 and 15, part 4, and section 131 of the Medicines Act 1968 (which make provision relating to pharmacies);
- the Human Medicines Regulations 2012;
- the Medicines for Human Use (Clinical Trials) Regulations 2004; and
- the Medicines (Products for Human Use) (Fees) Regulations 2016.

When making regulations under this clause, the bill stipulates the minister must consider:

- the safety of human medicines;
- the availability of human medicines; and
- the attractiveness of the relevant part of the United Kingdom as a place in which to conduct clinical trials or supply human medicines.

Clauses 2 to 4 then list matters that the regulations may address, for example:[8]

- matters relating to the manufacture, marketing, and supply of human medicines (for example, authorisation, labelling and registration requirements);
- the prevention of the supply of falsified medicines[9] and enabling information that is collected to prevent the supply of falsified medicines to be used, retained and disclosed for any purpose to do with human medicines; and
- matters relating to clinical trials; for example, authorisation and reporting requirements and making changes to align provisions with the EU Clinical Trials Regulation.

Clause 5 allows the regulations to set out enforcement provisions and fees. This includes granting certain powers of entry and the ability to create new criminal offences.

Clause 6 allows the regulations to relax certain regulatory requirements relating to medicines in the case of public health emergencies. The explanatory notes give the Covid-19 pandemic as an example.

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[7] Although the EU is repealing and replacing the regulations this directive is based on, it is not due to come into force until after the end of the transition period; therefore, the new EU regulations would not apply to the UK.

[8] Explanatory Notes, pp 9–13.

[9] Falsified medicines are defined in the Human Medicines Regulations 2012 as human medicines that falsely represent their identity, source or provenance.

The notes also suggest how the Government might use the power:

> It could allow stocks of medicines to be shared between persons who do not hold wholesale dealer's authorisations, such as doctors' surgeries, for quicker distribution within the community or it could allow for larger packs of pills to be split into smaller packs where necessary in an emergency by persons who do not hold the correct authorisation to do so and who are not otherwise exempt from the requirement to hold such an authorisation before doing so.[10]

Clause 7 contains definitions of some of the terms in part 1.

2.2 Part 2: Veterinary medicines

The regulatory framework for veterinary medicines aims to ensure animal welfare and to "protect the safety of treated animals, people handling the medicines, consumers of produce from treated animals, and the environment".[11] This is achieved by regulating the authorisation, manufacture, classification, distribution and administration of veterinary medicinal products.

The UK framework is set out in the Veterinary Medicines Regulations 2013. This implemented the EU Veterinary Medicinal Products Directive 2001 and other EU legislation.

Clause 8 would allow the Government to make regulations to amend the Veterinary Medicines Regulations 2013. As with the human medicines regulations, the Government would need to consider three factors when making regulations:

- the safety of veterinary medicines in relation to animals, humans, and the environment;
- the availability of veterinary medicines; and
- the attractiveness of the relevant part of the UK as a place in which to develop or supply veterinary medicines.

Clause 9 would provide for a list of matters that the regulations could cover. This includes registration, labelling and authorisation requirements, who may supply veterinary medicines, and the circumstances under which they can be used. The explanatory notes also state that the Government could use powers to amend provisions of the 'cascade', which sets out rules for how medicines can be used outside the terms of their authorisation if there is a clinical need and benefit.[12]

Clause 10 would allow for the regulations to set out enforcement provisions and fees and clause 11 provides definitions of some of the terms used in part 2.

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[10] Explanatory Notes, p 14.

[11] ibid, p 5.

[12] ibid, pp 15–16.

2.3 Part 3: Medical devices

Overview

The bill's explanatory notes define medical devices as follows:

> A medical device is an instrument, apparatus, appliance, software, material or other article that is used in the prevention, diagnosis or treatment of illness or disease, the alleviation of/compensation for a handicap or injury or the replacement of a physiological process or the control of conception. Some types of medical device, known as in-vitro diagnostic medical devices, are also used to conduct in-vitro diagnostic tests. These are tests done on samples such as blood or tissue that have been taken from the human body.[13]

Much of the regulatory framework for medical devices comes from EU regulations. The Medical Devices Regulations (MDR) 2002 implements these into UK law.

The MDR provides definitions for medical devices and places obligations on manufacturers to ensure that medical devices are safe and fit for their intended purpose. The MHRA is responsible for ensuring compliance with the regulations and for monitoring medical devices in the UK market. With limited exceptions, devices placed on the EU market must bear a CE mark, which shows the product has been assessed and meets required standards.

The EU has approved two new regulations on medical devices over recent years, the EU Regulation on Medical Devices 2017/745, and the EU Regulation on In-Vitro Diagnostic Medical Devices 2017/746. However, these will not fully come into force until after the transition period is due to end and will therefore not form part of the UK's retained EU law. Despite this, the MHRA has been planning for the introduction of these regulations and has said that the regulatory requirements should still be met.[14] It stated it would provide further guidance soon, following government decisions on the future of UK regulation.

General Provisions

As with the previous two parts, the bill would provide powers to make regulations concerning the regulatory framework for medical devices (clause 12). These regulations could amend or supplement the Medical Devices Regulations 2012 and would need to have regard to the:

- safety of medical devices;
- availability of medical devices; and
- attractiveness of the United Kingdom as a place in which to develop or supply medical devices.

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[13] Explanatory Notes, p 5.

[14] Medicines and Healthcare Products Regulatory Agency, 'Medical devices: EU regulations for MDR and IVDR', 24 April 2020.

Clause 13 sets out a list of matters that could be covered by the clause 12 regulations. For example, they could cover:

- the requirements that must be met in order for medical devices to be marketed, put into service or otherwise supplied;
- labelling and packaging requirements;
- investigation and surveillance of medical devices and the market; and
- registers of devices and manufacturers that must be recorded.

Clause 14 sets out the fees and information requirements the regulations may impose.

Clause 15 would allow for regulations to be made under clause 12 relaxing certain regulatory requirements when facing a public health emergency.

Clause 16 would grant the power to make regulations providing for a database of information in relation to medical devices to be established and managed by the Health and Social Care Information Centre (also known as NHS Digital). This clause was tabled by the Government and agreed during report stage in the House of Commons (see section 4.2 of this briefing).

The information database regulations may cover the establishment and operation of one or more information systems. The clause states they are restricted to matters relating to monitoring and acting to ensure:

- the safety and performance, including the clinical effectiveness, of medical devices;
- the safety of patients; and
- the use of advances in technology to improve the safety and performance of medical devices.

The rest of the clause provides non-exhaustive examples of the type of provisions that may be made by regulations. For example, the regulations may specify descriptions of information in relation to medical devices which may or must be entered or retained in an information system, and it could also specify the timescales for information to be supplied. It could cover unique identifiers of medical devices and information on those treated or providing treatment using a medical device. The regulations could also specify how the information is used, including possible publication and disclosure to specified people.

Enforcement provisions

Clauses 17 to 34 seek to consolidate the enforcement regime for medical devices and allow the secretary of state to impose civil sanctions as an alternative to criminal prosecution.

Currently, enforcement provisions regarding medical devices are contained in numerous pieces of legislation, including certain consumer rights legislation, such as the Consumer Protection Act (CPA) 1987.[15] The Government believes this hinders the MHRA and provides insufficient clarity to UK and

[15] Explanatory Notes, p 6.

international manufacturers on the enforcement regime. The explanatory notes also explain difficulties caused by the link to the CPA:

> The link to the CPA also means that the sanction for failing to comply with medical device regulations is the general offence of breaching safety regulations contained in section 12 (offences against the safety regulations) of the CPA. This offence contains four "limbs" and determining whether or not a failure to comply with a provision of the Medical Devices Regulations 2002 is an offence involves an analysis of whether the provision fits within any of the "limbs". This creates uncertainty for both the Secretary of State and industry.[16]

Therefore, the bill seeks to set out all the enforcement provisions in one place, in the process disapplying the CPA and the Medical Devices Regulations (MDR) 2002 powers. It would also set out criminal offences clarifying which contraventions of the MDR 2002 could result in prosecutions.

Clauses 17 to 23 contain provisions on enforcement notices, including compliance notices, suspension notices and information notices. For example, clause 17 would allow the enforcement authority to issue a compliance notice when it has reasonable grounds to suspect that a person involved in marketing or supplying a medical device is not complying with a medical devices provision. The notice would set out the grounds for suspecting non-compliance and what they are required to do. The clauses also set out provisions for appealing an enforcement notice or for applying for compensation.

Clauses 24 to 26 set out a new offence of breaching an enforcement notice and provide for a defence of due diligence if they took all reasonable steps to avoid committing the offence. The offence could result in imprisonment or a fine.

Clause 27 and schedule 1 set out details on the imposition of civil sanctions as an alternative to criminal proceedings. This includes provisions on enforcement costs (eg covering the costs associated with investigating the non-compliance), how parties could appeal orders and requiring the Secretary of State to publish reports on the use of civil sanctions "from time to time".

The explanatory notes set out an example of how the civil sanctions would operate:

> In particular, the bill provides the Secretary of State with powers to impose a monetary penalty on a person (where the Secretary of State is satisfied beyond reasonable doubt that the person has committed an offence) and accept an enforcement undertaking (where the Secretary of State has reasonable grounds to suspect a person has committed an offence and that person offers the undertaking).[17]

Clause 28 would allow the enforcement authority to apply to the courts for a forfeiture order so that they could seize medical devices which breach the medical devices provisions. Clause 29 sets out how the order could be appealed. Clause 30 would allow the enforcement authority to apply to the courts for a person convicted of an enforcement order to cover the costs of a forfeiture order or the costs of seizing any medical devices.

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[16] Explanatory Notes, p 6.

[17] ibid, p 7.

Clause 31 would allow the enforcement authority to take steps to recall a medical device when it deemed it necessary.

Clause 32 would provide powers for revenue and customs officers to seize medical devices and clause 33 makes it an offence to obstruct an officer doing this duty.

Clause 34 states that an obligation imposed by a medical devices provision is to be treated as a duty owed to any person who may be affected by a breach of the obligation. Therefore, a breach of the obligation gives rise to a right of action for breach of statutory duty.

Clauses 35 to 37 would provide the secretary of state with powers to share information about medical devices in limited circumstances. These include a power to share medical device information with the public due to safety concerns and to share information with persons "providing services or exercising functions in relation to medical devices".[18] Powers are subject to data protection legislation and to provisions placing restrictions on the disclosure of commercially sensitive information. Clause 36 would make it an offence for a person receiving certain information to wrongfully use it or disclose it to others.

Subsection 9 of clause 37 also introduces schedule 2 of the bill, which collates the offences for breaching various provisions of the Medical Devices Regulations 2002.

Clause 38 defines many of the terms in part 3 of the bill.

2.4 Part 4: Regulations

This part sets out the process for making regulations under the bill's provisions.

Clause 42 provides that most of the regulations made under parts 1, 2 and 3 would be subject to the draft affirmative process. Therefore, the regulations would require approval by both Houses of Parliament. The exceptions to this would be subject to the made negative process. Clause 42 sets out how the process would apply for regulations affecting Northern Ireland. Limitations on the scope of Northern Ireland's powers are outlined in clause 40.

With some exceptions, clause 41 states that before making regulations under parts 1, 2 and 3, the relevant authority must consult with persons it deems appropriate.

Clause 39 states that the regulatory powers can also be used to make:

- consequential, supplementary, incidental, transitional, transitory, or saving provisions;
- different provision for different purposes and different areas; and
- provision creating exceptions or limited in application to specified cases.[19]

[18] Explanatory Notes, p 7.
[19] ibid, p 30.

2.5 Part 5: Miscellaneous provisions

Clauses 43 to 46 contain miscellaneous provisions, including territorial extent and commencement provisions.

The bill would apply to the whole of the United Kingdom. Some of the provisions would come into force upon royal assent, while others would come into force two months later or when brought into force through regulations.

3. Second reading in the House of Commons

3.1 Support for bill

Opening second reading in the House of Commons, the Secretary of State for Health and Social Care, Matt Hancock, stressed the importance of the UK having a regulatory regime for medicines and medical devices that is "nimble enough" to keep up with rapid developments but also maintains public safety.[20] He stated that this was the purpose of the bill. He continued:

> Our goal is this: we want the UK to be the best place in the world to design and trial the latest medical innovations. This bill gives us the powers we need to make that happen. It will mean that the NHS has access to the most cutting-edge medicines and medical devices, with enhanced patient safety; it will help our life sciences seize the enormous opportunities of the 2020s, supported by a world-leading regulator; and it will help us pave our way as a self-governing independent nation.[21]

Both Labour and the Scottish National Party (SNP) indicated they would not be looking to obstruct the bill, agreeing its provisions were necessary due to the UK's exit from the EU. The Shadow Secretary of State for Health and Social Care, Jonathan Ashworth, stated:

> We understand the need for the bill because its purpose is for the UK Government to take the powers they need as a result of Brexit. In that respect, we broadly support the principles of the bill, and we offer to work constructively with the Government on strengthening and improving aspects of it.[22]

Speaking for the Liberal Democrats, Munira Wilson, the spokesperson for health, wellbeing and social care, stated that her party also did not oppose the bill, accepting it was important that the UK could continue to regulate the industry after the end of the transition period for leaving the EU.[23] However, she did express regret that the UK was in this position.

However, both parties indicated some concerns and outlined parts they would like to see changed or strengthened. Some of the concerns raised during the debate are outlined below.

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[20] HC *Hansard*, 2 March 2020, cols 659–93.

[21] ibid, col 662.

[22] ibid, col 682.

[23] ibid, cols 683–4.

3.2 Concerns raised about the bill

Extent of the bill's delegated powers

Several MPs mentioned the "extensive" delegated powers in the bill and expressed reservations about the level of scrutiny therefore available for possibly major policy decisions. For example, Jonathan Ashworth highlighted this, and suggested the delegated powers in the bill should be time-limited:

> The overall effect of the provisions is to confer on the Secretary of State an extensive range of delegated powers to make regulations that span the manufacture of medicines, marketing and supply, falsified medicines, clinical trials, fees, information and offences, and emergencies. That extensive range of powers risks inadequate scrutiny of what will become major policy decisions, and in committee Labour will press ministers to support time-limiting those delegated powers.[24]

The Government argued that the powers would simply replace those available under the European Communities Act 1972 (ECA) and were not new powers.[25]

However, the SNP spokesperson, Dr Philippa Whitford, stated that the delegated powers utilised under the ECA were to implement EU legislation that had already been debated in the Council of the European Union and the European Parliament.[26] She said this was not the case here. She believed primary legislation should be used for some of the more "significant" changes being proposed by the bill.

Prioritising patient safety

Another concern raised by the SNP and Labour related to the three matters (patient safety, availability, and attractiveness of the UK market) that must be collectively considered before making regulations about medical devices or human and veterinary medicines. Both parties argued that patient safety should be the priority consideration, and that the bill should be changed to specify this.[27]

Although not addressing that particular point, the Parliamentary Under Secretary of State for Health, Jo Churchill, described patient safety as "paramount".[28]

Alignment with EU regulations

Jonathan Ashworth stated that Labour considered close future alignment with the EU on medical regulation to be essential.[29] For example, he stated that divergence on clinical trial guidelines may

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[24] HC *Hansard*, 2 March 2020, cols 664–5.

[25] ibid, col 664.

[26] ibid, col 674.

[27] For example, see: ibid, col 663.

[28] ibid, col 689.

[29] ibid, col 664.

result in disruption for patients and funding:

> To ensure that the UK remains a world leader in scientific research and discovery, it is vital that we align with guidelines on clinical trials. Otherwise, patients could miss out on participating in trials and the UK could find it harder to access funding.[30]

Speaking for the SNP, Dr Whitford highlighted the possible impact on industry of less alignment, stating that proper alignment can reduce costs, delays, and bureaucracy.[31] She noted that the Association of the British Pharmaceutical Industry had also outlined opposition to too much divergence.

The Liberal Democrats said that their main concern about the bill was that it could allow "significant regulatory divergence" from the EU. Munira Wilson suggested that the medical research community and manufacturers were "united" in their desire for close alignment, preferably through associate membership of the European Medicines Agency.

Responding for the Government, Jo Churchill said it was open to continued cooperation and collaboration with the EU on medical regulation.[32] Turning specifically to clinical trials, she said that the MHRA was taking steps to ensure there was no disruption. She also spoke about the Government's vision for the future, stressing the importance of collaboration with countries around the world:

> We want a world-leading regulatory system for clinical trials that allows us to collaborate effectively—not only across Europe, but globally. We have one of the best life sciences industries in the world, for which effective collaboration is important.[33]

Cumberlege review

A number of MPs were concerned about the safety of medicines and medical devices. They highlighted the independent medicines and medical devices safety review being led by Baroness Cumberlege (Conservative). They asked whether the outcomes of the review would be reflected in the bill.

For example, Jonathan Ashworth stated:

> We eagerly anticipate the Cumberlege independent medicines and medical devices review, but there have been other scandals too—breast implants, hip replacements—that are not necessarily covered. We would welcome an update from the Minister about that review and some remarks on whether the Government expect to implement its findings.

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[30] HC *Hansard*, 2 March 2020, col 664.

[31] ibid, col 671.

[32] ibid, cols 690–1.

[33] ibid.

> My point is that a robust regulatory framework for medical devices to protect patients and users is paramount. We will be testing this bill to ensure that it provides the safety standards that our constituents deserve, while at the same time ensuring it is forward looking enough to be the correct framework to capture the fast pace of innovation in this field […][34]

The Cumberlege review was announced in February 2018 primarily to examine how the healthcare system responded to "concerns raised by patients and families about three medical interventions: the hormone pregnancy test Primodos; the anti-epileptic drug sodium valproate; and surgical mesh".[35] It can make recommendations on these issues, and also on how the healthcare system can improve its response to concerns raised about other medicines and medical devices in the future.

The publication of the review's report has been delayed until 8 July 2020 due to the Covid-19 pandemic. It was initially due to be published on 24 March.[36]

The Government responded to questions about the review during report stage, stating that it would consult on the review's outcome. Jo Churchill said:

> We are keen to take account of its recommendations and ensure we are taking the necessary steps to protect patients, as patient safety is paramount to the future of medicines and medical devices regulation.[37]

Pharmacies and prescriptions

There was also discussion about plans to use the delegated powers in the bill to change the rules about prescriptions and who could dispense medication, particularly how this might impact pharmacies.

For example, in his second reading speech, Matt Hancock, the Health and Social Care Secretary said the bill would allow the Government to remove barriers to "hub-and-spoke" dispensing.[38] Hub-and-spoke dispensing is defined in the bill's impact assessment as follows:

> [It] refers to arrangements where a retail pharmacy, notionally at the end of a spoke, receives prescriptions, and sends them electronically to a remotely located hub, which in turn takes in prescriptions from multiple spokes. At the hub, medicines are selected, packaged and labelled and then transported back to the spoke to be checked by the pharmacist and collected by the patient.[39]

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[34] HC *Hansard*, 2 March 2020, col 663.

[35] Independent Medicines and Medical Devices Safety Review, 'About the Review', accessed 29 June 2020.

[36] Independent Medicines and Medical Devices Safety Review, 'Revised publication date for the Review's report', 12 May 2020.

[37] HC *Hansard*, 23 June 2020, col 1239.

[38] HC *Hansard*, 2 March 2020, col 660.

[39] Department of Health and Social Care, *Impact Assessment for the Medicines and Medical Devices Bill*, 10 February 2020, p 31.

Matt Hancock suggested that changes to the rules would benefit community pharmacies.[40] He stated that large companies were already able to utilise this model of dispensing, but that there were currently legal barriers for small businesses.

However, Liz Twist (Labour MP for Blaydon), believed it could increase the competition pharmacies face from "prescription-by-post" services.[41] She stressed the importance of pharmacies in the community and called for them to be supported through any changes made.

Concerns about hub-and-spoke have also been raised by the National Pharmacy Association. It questioned the suggested economic and efficiency benefits of the hub-and-spoke model, noting some uncertainty in the bill's impact assessment.[42] It also argued it could reduce "competition and choice in the pharmaceutical wholesale market without a level playing field". It called on the Government to fully consider and consult on the proposed changes:

> The Government needs to fully assess and consider the potential unintended consequences of hub-and-spoke dispensing, including the potential impacts on patient choice, availability of medicines in the UK, medicines prices and competition and choice in the pharmacy and pharmaceutical wholesale markets.
>
> The Government needs to base proposed regulatory changes to enable hub-and-spoke dispensing on robust evidence and in full consultation with all of the relevant stakeholders. It is a concern that the Government has acknowledged in its own impact assessment of this bill that the costs and benefits remain uncertain.[43]

Human rights issues of medicines developed overseas

Some MPs expressed concerns about human rights issues linked to the development of some medicines overseas. This included specific mention of organ harvesting; for example, allegations that prisoners in some countries (such as China) are having organs removed or traded for medical testing.

Marie Rimmer (Labour MP for St Helens South and Whiston) outlined her concerns about the issue and said she would be tabling amendments to the bill to specifically address it. She stated:

> We must ensure that medicines entering the United Kingdom have not been tested on or developed using those organs or any other human rights abuses, and I am sure the Government are aligned with me on this issue.[44]

Responding for the Government, Jo Churchill stated that the clinical data used to support regulatory

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[40] HC *Hansard*, 2 March 2020, col 660.

[41] ibid, col 683.

[42] National Pharmacy Association, 'Written evidence submitted for the Medicines and Medical Devices Bill', accessed 29 June 2020, pp 3–4.

[43] ibid, p 4.

[44] HC *Hansard*, 2 March 2020, col 679.

activity in the UK needs to comply with "international good clinical practice standards, including ethical considerations, such as the critical principle of informed consent".[45]

The issue was discussed further during committee stage and report stage.

4. Amendments considered

4.1 Committee stage

Several government amendments were made to the bill during public bill committee, but no opposition amendments were successful.[46]

Some of the opposition amendments and proposed new clauses discussed were returned to at report stage and are covered in the next section of this briefing. These covered:

- introducing a sunset clause;
- prioritisation of patient safety when making regulations;
- establishing a register of medical devices; and
- power to make regulations to combat organ harvesting.

The organ harvesting amendment was defeated by nine votes to five on division at public bill committee. Each of the others were not moved to a vote. The proposed new clause to establish a register of medical devices was subsequently addressed by the Government at report stage by the adoption of clause 16 into the bill.

In addition, the committee discussed some other opposition amendments and proposed new clauses, including:[47]

- requirements to report to Parliament on medicines being developed or why medicines deemed "effective" are not made available to the NHS;
- prioritisation of tackling anti-microbial resistance;
- setting out specific reporting requirements on the fees regime and the use of civil sanctions;
- further regulations regarding the veterinary industry; and
- obligations to bear in mind the environmental impact of medical devices.

The Government rejected each of these as matters that were already in hand or that would be addressed by the regulations to be made under the bill. For example, Jo Churchill stated that the Government already had a published strategy for tackling anti-microbial resistance and that there was

[45] HC *Hansard*, 2 March 2020, cols 691.

[46] Public Bill Committee, *Medicines and Medical Devices Bill*, 8 June and 10 June 2020, session 2019–21, three sittings.

[47] ibid.

legislation covering environmental protection.[48] She also stated that the Government intends to publish reports and guidance on civil sanctions in a helpful manner.[49]

Further details on the committee stage proceedings can be found in the House of Commons Library briefing, *Medicines and Medical Devices Bill 2019–21*, 19 June 2020.

4.2 Report stage

Report stage was held in the House of Commons on 23 June 2020. Third reading was also held that day but was passed without debate.

Several government amendments were made to the bill at report stage. Most of these concerned the new information systems clause added to the bill (clause 16 of the bill as introduced in the House of Lords). All of these were agreed without a division.

In addition, Labour tabled five amendments, but none of these were agreed or moved to a division. These covered three issues:

- the prioritisation of patient safety over medical availability or consideration of the attractiveness of the UK market when making regulations;
- a three-year sunset provision for the legislation; and
- powers to make provisions regarding the process of developing medicines to tackle organ harvesting.

Each of these is considered below.

Government's New information systems clause

Jo Churchill stated that the new information systems clause (now clause 16) was introduced in recognition of the fact that medical devices are not subject to the same comprehensive regulatory system of pre-market assessment as medicines.[50] The Government saw that the system could be made stronger in respect of how devices are purchased, used and reviewed and believed this would be one of the recommendations coming out of the Cumberlege review.

The new clause would give the secretary of state powers to create a medical device information system for:

- the purposes of the safety and performance, including the clinical effectiveness, of devices;
- the safety of individuals who receive or are treated with a medical device;

[48] Public Bill Committee, *Medicines and Medical Devices Bill*, 8 June and 10 June 2020, session 2019–21, three sittings, cols 26 and 44.
[49] ibid, col 59.
[50] HC *Hansard*, 23 June 2020, col 1222.

- and the improvement of medical devices' safety and performance through advances in technology.[51]

Listing its potential benefits, Jo Churchill stated:

> Such a system would monitor the performance of devices and ensure that patient outcomes can be tracked. The longer-term aim is to intervene earlier, through clinical analysis of the data in the information system, to prevent patient harm before it happens by enabling the healthcare system to flag concerns, drive clinical system and regulatory action where appropriate, and use alternative and better devices and procedures to mitigate risk to UK patients.[52]

However, she did accept that there would be concerns over the protection of data, particularly patient data. On this, she said that the regulations would ensure there were appropriate safeguards, including anonymisation of data by NHS Digital.[53] She also stated that using secondary legislation would enable the Government to continue to review and update the information requirements and rules to ensure the system remained as effective as possible.

The Government said it hoped the clause would address concerns raised at committee stage.

Speaking for Labour, Alex Norris, the shadow minister for public health and patient safety, welcomed the new clause and thanked the Government for engaging with the concerns that had been raised. However, he also spoke about the need to engage with the result of the Cumberlege review, anticipating that its report would be published during the bill's Lords proceedings.[54] He believed the report could affect current and future views of the MHRA. He hoped the Government would show willingness to make amendments to the bill, or other legislative changes to the MHRA, to ensure it is fit for the future and addresses any challenges that come up in the review.

Prioritisation of patient safety

Speaking about his amendments to prioritise the consideration of patient safety when making regulations under the bill, Alex Norris said that he did not understand why it was being only given equal status to the attractiveness of the UK in the secretary of state's decision making. He questioned whether having it represented as such in the bill could lead to future issues:

> Are we certain that there is not 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?[55]

Speaking for the Government, Jo Churchill emphasised that patient safety was critical.[56] However, she explained that not all regulations would be easily linked to patient safety; for example, she talked

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[51] HC *Hansard*, 23 June 2020, col 1222.
[52] ibid, col 1223.
[53] ibid, col 1224.
[54] ibid, cols 1229–30.
[55] ibid, col 1231.
[56] ibid, col 1226.

about prior changes to how importers and manufacturers could appeal about decisions to the MHRA. She also said that there were other mechanisms in the NHS targeted at patient safety.

As a result, Jo Churchill rejected the need for the amendments, stating that the Government believed the best outcomes would be achieved by considering the three factors jointly:

> It is not a choice between having safe medicines and a strong and secure supply chain, nor is it a choice between having safe medicines and being an attractive place for the development of new medicines. Those considerations go hand and hand and must continue to do so, so that our regulations continue to ensure that safe and effective medicines reach UK patients and that our vibrant life sciences sector is supported.[57]

Sunset provision for the legislation

Alex Norris again expressed Labour's concerns about the delegated powers in the bill and the limited scrutiny available for potential policy changes. He did not accept the Government's view that the powers would be receiving the same scrutiny as before, as they would no longer go through the scrutiny process of the EU institutions. He stated that:

> Under the bill, we will have a secretary of state governing high-risk medicines and medical devices, with decisions essentially ratified by a committee or occasionally, perhaps, on the Floor of the House, where the secretary of state will have a majority come what may. I think in any terms that is a diminution, and the Government will need to be mindful of that.[58]

He said the three-year sunset provision would allow Parliament to consider the issue again in three years' time, by which point it could consider all the regulations made under the bill as a whole.[59] He specifically referred to the possible changes to enable hub-and-scope dispensing, describing this as "the most profound reform to community pharmacy in our lifetimes".[60] He noted that the change was not on the face of the bill, but that the impact assessment specifically referred to this as something that could be implemented. He stressed that it was important to give Parliament the chance to fully consider the impact of important changes like this.

However, the Government rejected the suggestion, with Jo Churchill stating that, allowing for royal assent and the bill's provisions coming into force, there would be little time to get the regulations on the statute book before the sunset period expired.[61]

Jo Churchill also said that the bill had been carefully drafted to ensure its delegated powers were limited and benefited from the right levels of scrutiny, including a duty to consult. She said the bill was not intended as a "stopgap" and believed the powers were a "proportionate approach" to regulating a fast-moving industry.[62]

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[57] HC *Hansard*, 23 June 2020, col 1226.
[58] ibid, col 1230.
[59] ibid, cols 1230–1.
[60] ibid, col 1231.
[61] ibid, col 1228.
[62] ibid, col 1227.

Regarding the possibility of large policy changes being introduced, the minister sought to reassure the House that this would only happen following consultation and parliamentary scrutiny:

> We have no intention of making bold changes to regulations without full consultation and bringing the issue back to the House with the expectation that we will be expected to justify those changes.[63]

Organ harvesting

Introducing her amendment targeted at organ harvesting, Marie Rimmer (Labour MP for St Helens South and Whiston) stated that under current UK legislation the "importing of human body tissue for medical research does not require any consent or traceability—it is only advised, not required".[64] Therefore, she said that human tissue can be imported into the UK without "traceability, documentation or consent".

She said that her amendment would give the Government the power to close this legal loophole and ensure that all human tissue imports were ethical. She continued:

> Without my amendment, we have no assurance that harvested organs cannot find their way into our national health service. Although the legislation and regulations provide guidance, it is just that: guidance. Why should we not want to make it clear that harvested organs will not find their way into this country?[65]

Although expressing support for the intention of the amendment, Jo Churchill stated that there was already "comprehensive legislation" covering the issue, namely the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the Human Tissue Act 2004.[66] She sought to reassure MPs the legislation provided "extensive safeguards to ensure the ethical and appropriate use of human tissues in medicines and medicinal products".

The Government also did not believe the medicines bill was the right place to address the issue, but did state that the Minister for Asia was looking into the matter.

5. Additional commentary and further reading

5.1 Written evidence

Several interested organisations set out their views on the bill in written evidence provided for the House of Commons committee stage. This included the Royal Pharmaceutical Society, the British Veterinary Association and Cancer Research UK. A full list can be found on the Parliament website.

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[63] HC *Hansard*, 23 June 2020, cols 1227–82.

[64] ibid, col 1233.

[65] ibid.

[66] ibid, col 1229.

For example, the Royal Pharmaceutical Society welcomed the bill, particularly its aim of providing better access to medicines.[67] However, it did note that a lot of the detail would only become clear when regulations were laid. On this point, it urged the Government to engage widely with stakeholders when deciding on how to develop the proposed hub-and-spoke dispensing model.

The British Veterinary Association set out some issues it would like to see the bill and subsequent regulations address. For example:[68]

- close alignment with the EU's regulatory framework and its process for authorising the manufacturing or marketing of medicines;
- reviewing whether the 'Cascade' can be made more flexible; and
- a mandatory registration scheme for those supplying veterinary medicines.

Cancer Research UK described the bill as an important foundation to "enhance the UK medical research sector and ensure innovation benefits patients as quickly as possible".[69] It said that it therefore was not suggesting any specific changes to the bill, but did set out views on how the regulatory powers should be used going forwards.

It also urged close collaboration with the EU, stating it was "crucial" that future arrangements:

- do not allow for any reduction in UK patients' access to new medicines; and
- do not close off future opportunities for the UK to participate as fully as possible in cross-border trials involving EU countries on the basis of the incoming EU Clinical Trial Regulation and associated infrastructure.[70]

5.2 Read more

- Department of Health and Social Care, 'Medicines and Medical Devices Bill: overarching documents', 18 June 2020 (this includes links to the impact assessment and illustrative statutory instruments)

- Department of Health and Social Care, *Memorandum to the Delegated Powers and Regulatory Reform Committee*, 24 June 2020

- House of Commons Library, *Medicines and Medical Devices Bill 2019–21*, 19 June 2020.

[67] Royal Pharmaceutical Society, 'Written evidence submitted for the Medicines and Medical Devices Bill', accessed 30 June 2020.
[68] British Veterinary Association, 'Written evidence submitted for the Medicines and Medical Devices Bill', accessed 30 June 2020.
[69] Cancer Research UK, 'Written evidence submitted for the Medicines and Medical Devices Bill', accessed 30 June 2020.
[70] ibid.