HOUSE OF COMMONS LIBRARY

BRIEFING PAPER

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Medicines and Medical Devices Bill 2019-21

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Summary

Update 27 January 2021

Consideration of the Lords amendments of the Medicines and Medical Devices Bill will take place on 27 January 2021.
This briefing paper has been updated to include new Section 2.4 on the Lords Stages of the Bill but otherwise, the paper remains as it was when last published on 4 September 2020.

The Medicines and Medical Devices Bill 2019-21 (Bill 136) was introduced in the Commons on 13 February 2020 and had its Second Reading on 2 March 2020. The Committee Stage ran from 8-10 June 2020 and remaining Commons stages took place on 23 June 2020. The Bill received its Second Reading in the Lords on 2 September 2020.

Context for the Bill

A large proportion of the legal framework for medicines and medical devices in the UK derives from EU Directives and has been implemented into domestic legislation through section 2(2) of the *European Communities Act 1972* (ECA). This enables EU Directives to be transposed into UK law through secondary legislation and has been used to create a body of regulations that include the:

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

At the end of the Transition Period, the *European Union (Withdrawal) Act 2018* will have preserved these frameworks as "retained EU Law". The ECA, however, will no longer be available to the UK at this point to amend the regulations. There is no other 'general power' for updating these regulations, except through the introduction of primary legislation.[1]

What does the Bill do?

The Medicines and Medical Devices Bill seeks to address this regulatory gap through introducing regulation-making, delegated powers covering the fields of human medicines, clinical trials of human medicines, veterinary medicines and medical devices. Its purpose is to enable the existing regulatory frameworks to be updated at the end of the Transition Period. The Bill has been drawn to create 'targeted' delegated powers which can only be exercised in relation to a restricted number of matters. The Government stated in the Explanatory Notes to the Bill that it intends to use these powers to keep the existing regulatory frameworks updated, while also consolidating the enforcement regime for medical devices. In addition, the Bill will provide the Secretary of State with the ability to impose civil sanctions – as an alternative to criminal prosecution – for breaches of the medical device regime.

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1 In the case of Medical Devices, legislation in the UK is made jointly under section 2(2) of the ECA and section 11 of the *Consumer Protection Act 1987*. However, section 11 of the CPA only allows for provisions to be made for the "purpose of securing that goods to which this section applies are safe". The CPA does not therefore allow regulations to be update that relate to the clinical effectiveness, for example, of medical devices.

The Government has indicated in the background briefing to the Queen's Speech and in a press release that they intend to use these powers to support the development of medicines and medical devices within the NHS and amend prescribing powers.

Part 1 of the Bill creates a delegated power to amend or supplement human medicines law. The power is restricted to amending four pieces of legislation: the *Human Medicines Regulations 2012*, the *Medicines for Human Use (Clinical Trials) Regulations 2004*, the *Medicines (Products for Human Use) Regulations 2016* and limited parts of the *Medicines Act 1968* (specifically those parts which make provision related to pharmacies). It is then further restricted to amending or updating only those provisions stated on the face of the Bill. These are:

- the manufacture, marketing and supply of human medicines;
- falsified medicines;
- clinical trials;
- the charging of fees in relation human medicines provision;
- creating an offence for failing to comply with human medicine regulations;
- supply of human medicines in an emergency.

Part 2 of the Bill confers a delegated power to amend or supplement the *Veterinary Medicines Regulations 2013* and specifically those regulations that relate to:

- the manufacture, marketing, supply and field trials of veterinary medicines;
- the charging of fees in relation human medicines provision;
- creating an offence for failing to comply with veterinary medicine regulations;
- the powers of a Veterinary Medicines Directorate Inspector.

Part 3 of the Bill creates a delegated power to enable the *Medical Devices Regulations (MDR) 2002* to be updated, though the Bill stipulates that the Regulations may only be amended in relation to a limited number of areas, namely:

- the manufacture, marketing and supply of medical devices;
- the charging of fees in relation to medical devices (eg to register a device);
- recording information about the safety of devices;
- creating offences of breaching the provisions in the MDR; and
- the supply of medical devices in emergencies.

Part 3 of the Bill also aims to consolidate the enforcement regime for ensuring the safety and quality of medical devices. It provides the Secretary of State with new information sharing powers relating to the safety of a medical device.

Part 4 of the Bill creates a duty to consult before any changes to regulations are made under Clauses 1(1), 8(1) and 12(1) and also provides that the statutory instruments made under these clauses will be subject to the affirmative resolution procedure. Exceptions to the duty to consult, and to the use of the affirmative procedure, are outlined in the paper.

How does the Bill apply to UK nations?

The Bill extends to England, Northern Ireland, Scotland and Wales. Parts 1 and 2 of the Bill (relating to Human Medicines and Veterinary Medicines respectively) are within the legislative competence of the Northern Ireland Assembly and a legislative consent motion has been sought for those parts.

Committee Stage

The Committee Stage of the Bill ran from 8-10 June 2020. Technical amendments were moved by the Government and agreed. No other amendments were made. The Government promised to discuss a UK registry for medical devices, outside of the Committee, following a proposed new clause on this matter.

Report Stage and Third Reading

The Report Stage and Third Reading of the Bill in the Commons took place on 23 June 2020. The Government tabled New Clause 1, giving the Secretary of State the power to create a "database of information in relation to medical devices", by regulations, that would be established and managed by the Health and Social Care Information Centre. The Clause was welcomed by the Opposition. No Opposition or backbench amendments were moved to a division. The Government amendments were agreed to and the Bill was read for a third time on the same day (23 June) and passed without debate.

1. Background

The *Medicines and Medical Devices Bill 2019-20* was announced in the Queen's Speech in December 2019 and had its first reading on 13 February 2020. The Bill, as introduced, does several things: first, it creates delegated powers relating to human medicines, clinical trials in humans, veterinary medicines and medical devices. A large proportion of the current legal framework for medicines and medical devices in the UK derives from EU Directives and has been implemented into domestic legislation through section 2(2) of the *European Communities Act 1972* (ECA). This enables EU Directives to be transposed into UK law through secondary legislation and has been used to create a body of regulations that include the:

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

At the end of the Transition Period, the *European Union (Withdrawal) Act 2018* will have preserved these frameworks as "retained EU Law". The ECA, however, will no longer be available to the UK at this point to amend the regulations. The purpose of the delegated powers in the Bill is to enable the UK's existing medicines and medical devices regulatory frameworks to be updated, following the UK's departure from the European Union, without needing to introduce subsequent primary legislation.

The Delegated Powers Memorandum to the Bill states that the powers are:

> vital in terms of ensuring in future years that the Government can respond to changes in innovation; public health challenges; and global developments in medicines […] It is important that we retain the ability to make changes, most of which are highly technical provisions, so as not to inadvertently create a regulatory barrier to health service or product innovation changes that could not have been anticipated at the point that detailed processes were laid down.[2]

Second, the Bill consolidates the enforcement regime for ensuring the safety and quality of medical devices. At present, these powers are spread across several pieces of legislation which, the Explanatory Notes state, can hinder the regime from operating efficiently:

> currently, the Secretary of State has enforcement powers to restrict the supply of devices in both the Medical Devices Regulations 2002 and the CPA [Consumer Protection Act 1987] (see regulation 63 (restriction notices) of the Medical Devices Regulations 2002 and sections 13 (Prohibition notices and notices to warn) and 14 (suspension notices) of the CPA), and it is not clear in what circumstances each power should be used.[3]

In addition, the Bill introduces new powers to impose civil sanctions (such as a monetary penalty) for breaches of the *Medical Devices Regulations 2002*, thereby offering an alternative to criminal prosecution.

Third, the Bill creates a new power for the Secretary of State to share information on medical devices and sets out the circumstances under which this information could be disclosed.

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2 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p1, 4-5

3 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p9

A number of Government documents were published alongside the Bill. These are:

- Explanatory notes [Bill 90-EN]
- Impact assessment
- Delegated powers memorandum
- Press release

The Background Briefing Notes to the Queen's Speech indicate that the Government is intending to use the powers in the Bill to:

> - Ensure that our NHS and patients have faster access to the best innovative medicines while supporting the growth of the UK life sciences sector to ensure we remain at the forefront of the global life sciences industry.
> - Allow the UK to take a leading role in global research to develop rapid diagnostics and advanced therapies and devices to provide transformational care for patients around the world after Brexit.
> - [Make] it simpler for NHS hospitals to manufacture and trial the most innovative new personalised and short life medicines, as their usage increases, and they are taken up in local clinics and theatres.
> - [Increase] the range of professions able to prescribe and supply certain medicines to make the most effective use of the NHS workforce where recommended by experts, as well as developing more innovative ways of dispensing medicines in local pharmacies.
> - [Remove] unnecessary bureaucracy for the lowest risk clinical trials, to encourage rapid introduction of new medicines. [4]

Similarly, the Government press release accompanying the publication of the Bill suggests that the Government will use the powers in the Bill to enable:

> - hospitals [to] use patient tissue and DNA samples to tailor treatments to individual patients when other medicines have failed, or to develop drugs that have a shelf-life of minutes and would otherwise be unavailable to them. This has the potential to streamline access to treatments for patients with rare cancers and brain tumours.[5]

1.1 Life Sciences Sector Deals & NHS Long Term Plan

The *Medicines and Medical Devices Bill* sits within the context of the Government's wider ambitions to invest in, and grow, the life sciences in the UK. During a debate on the Address in January 2020, the Secretary of State for Health and Social Care, Matt Hancock, highlighted some of the links between the Medicines and Medical Devices Bill and the life science industry, stating:

> We are at an important moment in the life sciences. This country can and will be at the forefront as the NHS gets access to new medicines and new treatments earlier, so patients can benefit from scientific breakthroughs sooner.[6]

The Parliamentary Under-Secretary of State in the Department of Health and Social Care, Baroness Blackwood, similarly noted in a debate on the *European Union (Withdrawal Agreement) Bill* in January 2020 that the Government's commitment to the life sciences sector was:

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4 HM Government, Queen's Speech December 2019: background briefing notes, 19 December 2019, p33
5 New bill gives hospitals power to develop personalised treatment, gov.uk, 13 February 2020 [accessed on 19 February 2020]
6 HC Deb 16 January 2020 c1194

> clearly demonstrated through the medicines and medical devices Bill [...] The Bill is to ensure that the UK remains competitive and at the cutting edge of innovation, to the benefit of patients.[7]

Two life science sector deals have been signed since 2017. The first deal included commitments to:

- Raise total research and development (R&D) investment to 2.4 per cent of GDP by 2027;
- Strengthen the environment for clinical trials (including speeding up approvals for clinical trials);
- Establish the Health Advanced Research Programme (HARP - through which industry, charities, the NHS, universities and the government will collaborate on long term healthcare projects with industrial benefits);
- Implement the Accelerated Access Review to develop a streamlined pathway to bring breakthrough products to market and then to patients;
- Support life sciences manufacturing;
- Support development of measures to improve the UK's health data infrastructure.[8]

The second life sciences sector deal reported on the progress made since the publication of the first deal. It also highlighted the role of Medicines and Healthcare products Regulatory Agency (MHRA) in delivering parts of the deal, in supporting innovation, facilitating the development of new products and promoting patient access and safety.[9] The second sector deal particularly emphasises that the MHRA should be "the most forward-thinking regulator" by:

- Supporting advanced therapies manufacturing by developing a framework for point-of care manufacture.
- Leading the way on precision medicine by developing a clear UK regulatory pathway for genomic medicines and tests.
- Promoting patient access and safety.[10]

The Bill's Delegated Powers Memorandum goes on to state that being a 'forward-thinking regulator' also means:

> taking approaches to regulation that can maintain a swift response to scientific advice, ensuring that the Department can effectively manage regulatory routes suitable for the authorisation of innovative types of medical products.[11]

NHS Long Term Plan

The NHS Long Term Plan, published in January 2019, sets out how the NHS will "accelerate the redesign of patient care to future-proof the [Service] for the decade ahead". Part of the Plan focuses specifically on using "research and innovation to drive future outcomes improvement" and explicitly states that "NHS endorses and will play its full part in the recently announced Life Sciences sector deal".[12] This includes commitments to:

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7 HL Deb 15 January 2020 c815
8 HM Government, Industrial Strategy, Life Sciences Sector Deal, 2017
9 HM Government, Industrial Strategy, Life Sciences Sector Deal 2, 2018
10 HM Government, Industrial Strategy, Life Sciences Sector Deal 2, 2018, p15
11 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p4
12 NHS, The NHS Long-Term Plan, January 2019 p75

- speed up the pipeline for developing innovations in the NHS, so that proven and affordable innovations get to patients faster;
- focus targeted investment in areas of innovation that we believe will be transformative, particularly genomics;
- [accelerate the] uptake of proven, affordable innovations through a new Medtech funding mandate.[13]

[13] NHS, The NHS Long-Term Plan, January 2019 p76-77

2. Reaction to the Bill

To date, comment on the Medicines and Medical Devices Bill has not been extensive. Dr Malcolm Finlay, Consultant Cardiologist, Barts Heart Centre, Queen Mary University of London (QMUL), and founder of a medical devices company, told the Science Media Centre that he particularly welcomed the Government's plans to increase patient access to "cutting edge medicines" which, he said, can often:

> be seen as experimental right now, but many of the innovative approaches that we're now thinking about to treat severe and previously intractable disease don't fit into current frameworks of regulation. Indeed, the government's approach must be welcomed, giving opportunity to patients as well as a boost to the incredibly important biotech sector of the economy.[14]

Dr Finlay also raised concerns about whether the Bill might have the effect of "increas[ing] the regulatory burden required" for medical devices.[15]

Law firm Mills & Reeve suggested that the publication of the Bill, and what it describes as the "extensive powers it gives to the Health Secretary", indicate that while UK legislation is "not expected to diverge rapidly from EU law […] there are clear signals in the Bill and Explanatory Notes that a separate approach is likely to evolve".[16] The law firm Pinsent Masons also noted that "to some degree at least changes to existing frameworks will be determined by future developments as well as by the outcome of the continuing UK-EU negotiations".[17]

Academics specialising in law at the University of Birmingham published an overview of Parts 1 and 3 of the Bill, which deal with human medicines and medical devices, ahead of the Second Reading. While several aspects of the Bill are welcomed, including the introduction of "consolidated and expanded enforcement provisions", the authors write that there are:

> aspects of the Bill which are less positive. It does not appropriately address patients' and users' safety. There is an overreliance on the use of delegated powers to achieve its aims. And, as it stands, it will increase, rather than reduce the complexity of the existing regulatory framework.[18]

The authors recommend the following:

- Ensure that patient and user safety is prioritised over competing considerations. Clauses 1(2), 8(2), and 12(2) should be amended to reflect this.
- Clarification should be provided as to any future intention regarding possible regulatory divergence regarding medicines between Northern Ireland and the rest of the UK.
- The life of the subsequent Act, and thus the extensive use of delegated powers contained therein, should be time-limited. New sub-clauses reflecting this should be inserted into Clauses 1, 8, and 12 of the Bill.
- Separate pieces of primary legislation for medicines and medical devices should be introduced by 2022. This will enable the successive amendments to be

14 Science Media Centre, Expert reaction to the Medicines and Medical Devices Bill, 13 February 2020
15 Science Media Centre, Expert reaction to the Medicines and Medical Devices Bill, 13 February 2020
16 Mills & Reeve, UK life sciences regulation begins to diverge - the Medicines and Medical Devices Bill, 25 February 2020
17 Pinsent Masons, Medicines and Medical Devices Bill introduced in the UK, 19 February 2020
18 Professor Muireann Quigley, Professor Jean McHale, Dr Rachael Dickson, Dr Laura Downey, Note: Medicines and Medical Devices Bill 2019-20, February 2020

> integrated and consolidated, making the regulatory framework more streamlined and easier to understand.[19]

2.1 Second reading

The Second Reading of the Medicines and Medical Devices Bill 2019-20 took place on 2 March 2020. A Medicines and Medical Devices Bill: Money resolution was also passed, along with a Programme Motion committing the Bill to a Public Bill Committee to be concluded by Thursday 23 April 2020.

Government position

The Secretary of State for Health and Social Care, Matt Hancock, opened the debate, stating that "while the world grapples with the challenge of coronavirus" it was "vital" not to "lose sight of the important long-term reforms that we must make" to the medicines and medical device regulatory system. He set out the aims of the Bill as follows:

> First, it gives us the means to depart from EU rules and regulations in future, moving at a faster pace, if that is what we choose to do as an independent, self-governing nation. Secondly, it ensures that we can easily amend regulation through secondary legislation without having to bring a new Bill before the House every time we need to revise the rules. That means our system of regulation will be flexible and responsive, quick to adapt to innovation and quick to respond when a safety issue emerges. Thirdly, the Bill will strengthen patient safety by strengthening the Medicines and Healthcare Products Regulatory Agency, our world-class medicines and medical devices regulator. That includes giving it powers that were not available under the EU, including over registration of devices and disclosure. Fourthly, the Bill will ensure that we strike the right balance between capturing the benefits of innovation without compromising patient safety.[20]

He added that "nothing in the Bill changes all the regulations immediately. Instead, it is about getting ahead of the game and giving us the power to make these changes as and when we need to, suitably scrutinised by Parliament".[21]

Opposition views

The Shadow Secretary of State for Health and Social Care, Jonathan Ashworth MP, confirmed that Labour "broadly support[ed] the principles of the Bill" and offered "to work constructively with the Government on strengthening and improving aspects of it".[22] Several areas were identified by Mr Ashworth as requiring further clarification and/or improvement, including the extent of the delegated powers in the Bill, the Government's attitude to new EU regulations that will apply after the Transition Period (such as the in vitro diagnostic medical devices regulation), whether there were plans to extend prescribing powers to physician associates and surgical care practitioners, the identification and labelling of medical devices, and how a medical device register might work in practice.

The SNP Spokesperson, Dr Philippa Whitford, stated that the Bill was "necessary because of Brexit" but that she had "concerns" about it, particularly regarding the "extensive delegated powers" and the provision for "maximum sentences for offences against the Bill to be set at six months".[23] Dr Whitford explained that in Scotland:

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19 Professor Muireann Quigley, Professor Jean McHale, Dr Rachael Dickson, Dr Laura Downey, Note: Medicines and Medical Devices Bill 2019-20, February 2020
20 HC Deb 2 March 2020, c659
21 HC Deb 2 March 2020, c661
22 HC Deb 2 March 2020, c662
23 HC Deb 2 March 2020, c674

> the maximum sentence in a summary case is 12 months. Removing that sentencing power in Scotland with no consultation does not seem right, and a presumption against sentences below 12 months there would make custodial sentences less likely […] The Lord Advocate in Scotland should have been consulted on both issues, and I suggest that that should be corrected as the Bill proceeds.[24]

The Liberal Democrat Spokesperson for Health, Munira Wilson, stated that she also supported the legislation. Her main concern was that "the provisions of this Bill could allow for significant regulatory divergence for medicines and medical devices from the rest of the EU", adding that any divergence from European regulation:

> should take account of three principles: patient safety; early access for British patients to the latest innovations; and the competitiveness of the UK life sciences sector.[25]

Key themes

Delegated powers

Labour and the SNP both expressed concerns about what they described the "extensive delegated powers" in the Bill. Jonathan Ashworth stated that the range of delegated powers risked "inadequate scrutiny of what will become major policy decisions", and that, in Committee, Labour would "press Ministers to support time-limiting those delegated powers".[26] The Secretary of State responded that the delegated powers existed under the European Communities Act 1972:

> The Bill proposes to replace existing delegated powers from the 1972 Act with new powers to make such regulations under the new Act. This is not a new set of delegated powers; it replaces one set with another—indeed, the Bill replaces those powers with clearer safeguards on those matters to which the Secretary of State must have regard.[27]

Dr Whitford (SNP) questioned this analysis:

> The Secretary of State said that the same powers had been in place when the United Kingdom was in the European Union, but their purpose in the past was to enact EU directives which had been debated and consulted on in the European Council and the European Parliament. They had been worked out before agreement was reached, and were therefore purely about enacting something that had been hammered out and agreed within Europe. That is not the case here. Almost every clause in the Bill simply hands over a delegated power, but I think some of the major changes that are being introduced in the Bill are significant and should be in primary legislation.[28]

Patient safety

There was agreement among Members that patient safety was of paramount importance and that it must not be compromised. Dr Whitford (SNP) raised concerns, however, that the Bill put "attractiveness as a place to do trials and supply medicines almost on a par with safety and drug availability".[29] Jonathan Ashworth (Labour) stated that the Bill would "allay concerns":

> …if the Government accepted an amendment in Committee to indicate that the Secretary of State, or some other appropriate authority, would always prioritise safety.[30]

Many Members also acknowledged that the existing regulatory framework for medical devices had become too "complex". The Conservative MP Chris Green noted that this

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24 HC Deb 2 March 2020, c674
25 HC Deb 2 March 2020, c684
26 HC Deb 2 March 2020, c664
27 HC Deb 2 March 2020, c664
28 HC Deb 2 March 2020, c674
29 HC Deb 2 March 2020, c671
30 HC Deb 2 March 2020, c664

could mean it was difficult for the system to respond quickly to problems, "especially when patient safety is at risk".[31] Some Members highlighted Baroness Cumberlege's independent review of 'Medicines and Medical Devices Safety' – the results of which are due to be published on 24 March – and asked whether the Government intended to implement its recommendations (see section 5.6).[32]

Registration of medical devices

Provisions in the Bill to introduce a "comprehensive" UK statutory register of medical devices were generally welcomed,[33] though Members had questions about how the register would work in practice, what type of information it would record and whether it would facilitate data sharing. Anne Marie Morris (Conservative) expressed concern that the legislation did not go far enough and would not help with:

> the challenges of breast implants, vaginal mesh and spinal implants that crumble, because the registry that is to be created is within the constraints and confines of existing registries that, by and large, collect information about devices. They do not collect information about the journey of those devices through the patient experience […] including where the device may be defective.[34]

Clinical trials

Members questioned to what extent the UK would align with the new EU Clinical Trials Regulation, which is due to come into effect after the Transition Period (see section 3.7). Several Members highlighted the possible impact non-alignment may have on clinical trials relating to rare diseases. Dr Lisa Cameron (SNP) stated that it was "extremely important that those with rare diseases still have access to the clinical trials that can perhaps only take place in the EU, because they need to have so many participants".[35] Responding for the Government, the Parliamentary Under-Secretary of State for Health and Social Care, Jo Churchill, stated that the Government was "committed to ensuring that we remain the best place for those on rare disease trials", adding that the Medicines and Healthcare products Regulatory Agency had "taken steps" to ensure that there was "absolutely no disruption to clinical trials and that they can continue seamlessly".[36]

Prescribing and pharmacy hubs

MPs generally welcomed the provisions in the Bill to extend the range of professions that can prescribe low-risk medicines. Both Labour and the SNP questioned whether such rights would be extended to physician associates, while Liz Twist and Sharon Hodgson (both Labour) asked for clarification about the establishment of 'pharmacy hubs' through Henry VIII powers in the Bill and how such hubs would work in practice. The Minister Jo Churchill, stated that the Government would extend prescribing rights to physician associates "through other means", rather than through the Bill.[37]

Matters not covered in the Bill

Dr Luke Evans (Conservative) thought that the Bill had missed the opportunity to address "prescription waste". He suggested that pharmacies and other dispensers could be asked "to legally collect the statistics on returns [to] allow us to see how big the problem actually is, and allow us to create solutions".[38] Sharon Hodgson (Labour) agreed that

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31 HC Deb 2 March 2020, c669
32 The Independent Medicines and Medical Devices Safety Review, Publication of the Review's report, 18 February 2020 [accessed on 11 March 2020]
33 HC Deb 2 March 2020, c661
34 HC Deb 2 March 2020, c680
35 HC Deb 2 March 2020, c671
36 HC Deb 2 March 2020, c690
37 HC Deb 2 March 2020, c691
38 HC Deb 2 March 2020, c676

"there has to be a way to reduce [medicines] waste" and noted that she had discussed the matter recently with the Minister.[39]

The report of the independent China Tribunal, investigating allegations of forced organ harvesting from prisoners of conscience in China, was also raised by several MPs.[40] Marie Rimmer (Labour) stated that it was vital to "ensure that medicines entering the United Kingdom have not been tested on or developed using those organs or any other human rights abuses" and planned to move an amendment in Committee on this issue.[41]

Against the backdrop of COVID-19, Labour, SNP and Liberal Democrat Members questioned the UK's preparedness. They particularly highlighted reports in the press that the UK was planning to withdraw from the EU Early Warning and Response System (EWRS).[42] Jonathan Ashworth (Labour) stated that it would be "foolhardy to pull out of something like this at the best of times, but to do so at the time of an outbreak such as this is surely putting narrow dogma before the public health of the country".[43]

2.2 Commons Committee Stage

Overview

There were 3 sittings of the House of Commons Public Bill Committee on the Medicines and Medical Bill, running from 8 to 10 June 2020. No oral evidence was taken, although 19 written submissions were published.

Of the 22 motions moved relating to the Bill itself – rather than programming motions – 6 were agreed (Government amendments), 15 were withdrawn and one was negatived on division. One new clause was withdrawn after debate. Debate on several clauses was brief and no amendments were moved in relation to many sections of the Bill.

The changes made to the Bill were non-controversial, technical amendments which aimed to amend provisions relating to the 'defence of due diligence' (**clause 24**). The Parliamentary Under-Secretary of State for Health and Social Care, Jo Churchill, explained that **clause 23** made it an offence to fail to comply with a compliance, suspension, safety or information notice served on a person involved in marketing or supplying a medical device. Clause 24 and **Schedule 2** provide that there is a defence of 'due diligence' available to persons charged with an offence under clause 23; namely that they took all reasonable steps to avoid committing an offence. The Government's amendments, which Dr Philippa Whitford, the SNP spokesperson for health, also put her name to, sought to ensure the provisions in clause 24 operated effectively in relation to Scotland.

Opposition view

In his opening comments on **clause 1**, the Shadow Minister for Health and Social Care, Alex Norris, set out the Opposition's overall position on the Bill:

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39 HC Deb 2 March 2020, c686

40 The China Tribunal has been initiated by the International Coalition to End Transplant Abuse in China (ETAC), an international not for profit organisation, with headquarters in Australia and National Committees in the UK, USA, Canada, New Zealand and Australia see: https://chinatribunal.com/about-etac/

41 HC Deb 2 March 2020, c679

42 EWAS is described by the European Centre for Disease Prevention and Control as a "web-based platform linking the European Commission, ECDC and public health authorities in EU/EEA countries responsible for measures to control serious cross-border threats to health, including communicable diseases. The platform was set up in 1998 to allow exchange of information on risk assessment and risk management for more timely, efficient and coordinated public health action" (see European Centre for Disease Prevention and Control, Early Warning and Response System (EWRS), not dated)

43 HC Deb 2 March 2020, c662

> we understand the need for, and urgency of, the Bill. We will therefore be supportive during its passage, but we will seek to improve it [...] This is an enabling Bill. It is a necessary Bill, but we cannot give the Government a blank cheque.[44]

Mr Norris explained that the Opposition's amendments were focused on improving the Bill across three areas, namely "patient safety, […] promoting greater transparency about the development and use of medicines and medical devices, and seeking to contain the massive and extraordinary powers the Secretary of State is securing for himself".[45]

Powers and duties

The Opposition tabled, and subsequently withdrew, an amendment (9) to clause 1, seeking to introduce a 'sunset' clause into the Bill. This would have required the Government to return with primary legislation two years after the Medicines and Medical Devices Bill had received Royal Assent. Mr Norris stated that, as the Bill stood, the proposed arrangements allowed the Secretary of State to make "hundreds or more individual decisions to change our current regulatory regime into a markedly different one, one statutory instrument at a time".[46] He was particularly concerned that the Bill would mean that significant decisions – such as whether to introduce higher-risk medical devices, and an "entire model change for pharmacy" dispensing – would sit with a "statutory instrument Committee".[47]

The Minister, however, argued that the proposal would "cause a potential risk to patient safety":

> To have the Act fall away after two years would run the serious risk that we would cease to have the legal powers we need available to us to make regulatory change to address a patient safety risk or to improve access to medicines and all innovative therapies that might be coming onstream at that point.[48]

She added that the positioning of the amendment – "where it falls in clause 1(1)"– meant that it was unclear what its intent would be "with respect to regulations already made under that clause":

> We would not wish inadvertently to undo change to the statute book, for good reasons and in the interests of Parliament, so that Parliament can return to the principles of the Bill on each occasion, rather than the specific changes necessary to improve the regulation of human medicine.[49]

She considered that the Bill would enable more Parliamentary scrutiny "than we have had thus far" on the grounds that "use of the affirmative resolution is made near universal, other than in the event of an emergency and for very minor changes"; a point which Mr Norris later challenged.[50]

Patient safety

The Opposition moved an amendment (22), and had tabled several others that were related to veterinary medicines and medical devices (23-27), which would remove the requirement to consider the "attractiveness" of the relevant part of the UK when making regulations under **clause 1(1)**. Mr Norris was concerned that the Bill, as it stood, placed

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44 PBC (Bill 90) 2019 - 2021, Public Bill Committee: Medicines and Medical Devices Bill, Compilation of Sittings, 10 June 2020 p4
45 ibid
46 PBC (Bill 90) 2019 - 2021, Public Bill Committee: Medicines and Medical Devices Bill, Compilation of Sittings, 10 June 2020 p4
47 ibid p6
48 ibid p8
49 Ibid p9
50 PBC (Bill 90) 2019 - 2021, Public Bill Committee: Medicines and Medical Devices Bill, Compilation of Sittings, 10 June 2020 p8-10

attractiveness on the same footing as patient safety when amending or supplementing the law relating to human medicines. He questioned whether having attractiveness on the face of the Bill as something that the "appropriate authority" must consider when making Regulations could:

> create a set of circumstances where there will be lobbying or even legal pressure regarding attractiveness being on the same footing as patient safety? A Secretary of State's decision might as a result be challenged for not giving the same regard to attractiveness as it did to safety.[51]

Ms Churchill emphasised that patient safety was "paramount":

> The safety of patients and the environment, people and animals—when moving into the area of veterinary medicine—absolutely underpins the regulatory decisions that are made. It is absolutely the case that we would never seek to make a regulatory change that puts somebody's health at risk.[52]

She emphasised that there was nothing nefarious in the term "attractiveness" and that the consideration of the UK's attractiveness would not mean a reduction in regulation or that safety concerns would rise.[53]

Organ harvesting

Ms Marie Rimmer unsuccessfully moved an amendment (1) to **clause 2**. This aimed to give the Government powers to make Regulations to ensure that medicines developed and manufactured in the UK met basic human rights standards, particularly in relation to the use of organs when developing medicines. Ms Rimmer pointed towards evidence of forced organ harvesting in China, adding that China was "conducting medical testing on organs forcibly harvested from Uighurs, the Falun Gong, conscientious objectors and political prisoners". She emphasised that the amendment did not "force the Government to implement these regulations now" but rather that it "empower[ed] the Government and the relevant authorities to take the necessary steps to regulate around this issue when they are prepared to do so".[54]

The Minister was sympathetic to the intention behind Ms Rimmer's amendment and stressed that it was "absolutely right that medicines that enter the UK supply must not have been manufactured or developed to using organs or human tissues that do not come from authorised sources".[55] She stated, however, that legislative safeguards were already in place and that the amendment was therefore unnecessary. The amendment was negatived on division (Ayes 5, Noes 9).[56]

Veterinary medicine

The Opposition moved an amendment (13) to **clause 9** that the Secretary of State must, by regulation, make provision about the use of the Cascade. The Cascade is a process by which veterinarians can use a medicinal product to treat a disease outside of its authorisation or to treat a different species from that which the medicine is authorised. It also enables vets to use human medicines on animals, should an appropriate animal medicine not be available. Mr Norris noted that the continuation of the Cascade was "not

51 PBC (Bill 90) 2019 - 2021, Public Bill Committee: Medicines and Medical Devices Bill, Compilation of Sittings, 10 June 2020 p12
52 Ibid p14
53 Ibid p15
54 Ibid p18-19
55 Ibid p19
56 Ibid p18-22

on the face of the Bill" and that the Government would, on Royal Assent, "have the immediate ability to diverge away from the Cascade quite quickly".[57]

In response, the Minister stated that the provisions relating to the Cascade were set out in schedule 4 to the *Veterinary Medicines Regulations 2013 (SI 2033)* and that the Bill conferred powers for the appropriate authority to decide "following consultation, whether and how cascade requirements in the existing regulations might be amended in the future".[58] It was the Government's position that the regulations relating to the Cascade should be updated when it was "necessary to do so", rather than "operating under a compulsion to do so".[59]

Medical devices

Medical need for devices

The opposition tabled several amendments to **clause 13** regarding the manufacture, marketing and supply of medical devices.

Amendment 16 required the Secretary of State to evaluate the extent to which the medical devices market is meeting medical need. Mr Norris explained that the amendment was in response to a "legitimate anxiety about the risk […] that manufacturers prioritise the EU market over us and therefore we are behind in the queue and cannot get access to meet medical need".[60] He argued that divergence with the EU, even on a small points such as changing "something on a leaflet", would create a moment where "there will be a choice, and manufacturers will have to try to work out whether they prioritise bigger markets or smaller ones, or try to do something that pleases everybody".[61]

Ms Churchill stated that she fully understood the motivation behind the amendment and the Member's concerns that "small, incremental changes might lead to a divergence further down the line".[62] She said that the purpose of the clause, however, was "to enable" so that "come January, we are in exactly the same place".[63] She also pointed to **clause 12(2)** which requires the Secretary of State to consider the safety and availability of medical devices, as well as the attractiveness of the United Kingdom as a place in which to develop or supply medical devices, when seeking to amend the regulatory regime for medical devices.[64]

Medical device register – manufacturers

Amendment 17 to clause 13, moved by the Opposition, sought to enable the Secretary of State to compile a register of representatives for non-UK manufacturers of medical devices. Mr Norris explained that the purpose of such a register was to ensure that manufacturers of medical devices, based outside the UK, have a UK representative who is accountable for the manufacturer's actions and the impact of its products, thereby increasing transparency. He added that it might also help to "tease […] out" if there were

57 PBC (Bill 90) 2019 - 2021, Public Bill Committee: Medicines and Medical Devices Bill, Compilation of Sittings, 10 June 2020 p37
58 Ibid p37
59 Ibid p38
60 PBC (Bill 90) 2019 - 2021, Public Bill Committee: Medicines and Medical Devices Bill, Compilation of Sittings, 10 June 2020 p46
61 ibid
62 Ibid p47
63 ibid
64 ibid

circumstances where one individual "might be acting as a representative for multiple manufacturers".[65]

The Minister acknowledged the importance of establishing a UK device register that records UK representatives for non-UK manufacturers. She stated that the Government's policy was to "record the responsible person for all devices available on the UK market after the transition period" and added that she wished to "reassure" the Opposition that the regulation-making powers in the Bill were "sufficiently robust to enable the Secretary of State to conduct effective market surveillance".[66] The Minister pointed to **clause 13(1)(h**) in particular, which empowered the Secretary of State to make provision for the creation of a device register.

UK registry for medical devices

New Clause 6 on the registration of medical devices was moved by Mr Norris, on behalf of Dr Philippa Whitford of the SNP, who was unable to be at the Bill Committee. NC 6 asked the Secretary of State to establish, by Regulations, a UK Registry of all devices implanted into patients on a long-term basis. To avoid duplication of registration, NC 6 also specified that the UK Registry "shall require linkage from all currently established speciality device registries, in current operation".[67]

Ms Churchill said she was "enthused and excited about the register", adding that it was important to consider it in the context of the forthcoming Cumberlege Report, namely the:

> report from the independent medicines and medical devices safety review and the matters it looked into, particularly the use of pelvic mesh, and how we oversee medical devices, including post-market surveillance.[68]

The Minister then went on to distinguish between establishing a medical device register, which is currently provided for in the Bill, and the UK Registry, as proposed in NC 6:

> Clause 13(1)(h) provides for the creation of a register of medical devices to capture which devices are available on the UK market and to ensure that the MHRA can identify which device has been produced by which manufacturer. There has been some confusion in some of the written evidence as to whether that is intended to constitute a registry. A registry as in new clause 6 suggests bringing together patient and clinical information with device information.[69]

While the Minister did not think that the UK Registry, as proposed in NC 6, was practical, she stated that it was "heading in the right direction", adding that "we need to work on it".[70] She committed to follow up with "arrangements to have those discussions in a timely fashion", following the publication of Baroness Cumberlege's review (which is now scheduled to be published on 8 July 2020).[71]

Sanctioning powers relating to medical devices

Two amendments (20 and 21) were moved by the opposition to **schedule 1** of the Bill, which outlines how the new civil sanctions regime for medical devices will operate. Amendment 20 sought to compel the Secretary of State to provide guidance on these

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65 PBC (Bill 90) 2019 - 2021, Public Bill Committee: Medicines and Medical Devices Bill, Compilation of Sittings, 10 June 2020 p48
66 Ibid p48-49
67 PBC (Bill 90) 2019 - 2021, Public Bill Committee: Medicines and Medical Devices Bill, Compilation of Sittings, 10 June 2020 p67
68 ibid p68; see section 5.6 for further details on the Independent Medicines and Medical Devices Review.
69 PBC (Bill 90) 2019 - 2021, Public Bill Committee: Medicines and Medical Devices Bill, Compilation of Sittings, 10 June 2020 p68-69
70 Ibid p69
71 Ibid p70

new sanctioning powers within three months of the Act receiving Royal Assent. The Bill currently states at **paragraph 13 of schedule 1** that such guidance will be provided, but it does not specify a time frame for doing so.

Ms Churchill noted that the introduction of the new civil sanctions regime for medical devices would "require further provision, to be set out in supplementary regulations made under paragraph 9 of schedule 1 […] [which] will cover matters such as enforcement and monitoring of compliance with enforcement undertakings and appeals".[72] In addition, **clause 40** requires that any regulations made under paragraph 9 of Schedule 1 must be consulted on. The Minister indicated that the effect of the Opposition amendment would be that the Government was:

> required to consult on, and publish guidance on, the civil sanctions within a tight three-month period before the regulations have been made, and at a point when the consultation might still be ongoing, so that we arrive at the best place.[73]

Amendment 21 also sought to commit the Secretary of State to publish reports on the use of civil sanctions every 12 months, rather than "from time to time" as **paragraph 15(1) of Schedule 1** currently stipulates. The Minister explained that the requirement to publish reports on the use of civil sanctions was "in line with existing obligations on other Government agencies that already operate a civil sanctions regime for their sector", such as the Environment Agency.[74] She reiterated, however, the point made in relation to amendment 20, namely that "as the new regime will require secondary legislation, which must be consulted on before it comes into force", it was therefore "not practical to specify at this point the frequency of Government reports on the use of civil sanctions".[75]

Recall of a medical device

Clause 30, enabling the recall of a medical device by an enforcement authority, applies when the authority considers that the availability of a device needs to be restricted to protect the health and safety of the public. The Opposition moved an amendment (28) to require the Government to review any use of the recall powers, within the first 2 years of the Act, by laying a report before Parliament. Mr Norris said that the purpose of the amendment was two-fold:

> first, it would allow us to evaluate how effectively recall was being used; and, secondly, it would act as a further publicity tool, so that people understood that the device has been recalled and, if they were still in possession of it, that they could do something about it.[76]

He was also concerned that the Bill was not explicit about whether any recall of unsafe devices would be publicised.

The Minister emphasised that **clause 30(3)** specified that a recall by an enforcement agency was a power to be used only as a last resort, where a manufacture is either unwilling or unable to carry out a recall imposed under **clause 18.** She added that the Bill "already provides the Government with the power to make public the details of recalls they conduct, because clause 34(2) allows the Secretary of State to disclose information for the purpose of warning the public".[77]

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72 PBC (Bill 90) 2019 - 2021, Public Bill Committee: Medicines and Medical Devices Bill, Compilation of Sittings, 10 June 2020 p59
73 ibid
74 Ibid p62
75 ibid
76 PBC (Bill 90) 2019 - 2021, Public Bill Committee: Medicines and Medical Devices Bill, Compilation of Sittings, 10 June 2020 p63
77 Ibid p64

2.3 Commons Report Stage and Third Reading

Overview

The Report Stage and Third Reading of the Medicines and Medical Devices Bill took place on 23 June 2020. The Government tabled **New Clause 1**, to be inserted after **Clause 15**. New Clause 1 gives the Secretary of State the power to create a "database of information in relation to medical devices" that would be "established and managed by the Health and Social Care Information Centre".[78] The Government also moved several non-controversial, technical amendments to the Bill, with amendments "2, 3, 4, 5, 6 and 7 and 18 all [making] minor changes in order to enable new clause 1".[79]

In addition, Government amendments 8-17 aimed to:

> enable regulations under powers in the Bill which are subject to negative procedure to be combined in a single statutory instrument with regulations under powers which are subject to affirmative procedure, or with regulations under powers in other legislation which are subject to negative procedure.[80]

The junior Health and Social Care Minister, Jo Churchill, stated that by "allowing for different provisions to be combined in a single statutory instrument" amendments 8-17 would enable "greater efficiency within the parliamentary timetable".[81]

Four Opposition amendments were tabled by the Shadow Minister for Health and Social Care, Alex Norris. Amendment 20 to **Clause 1** sought to insert a "sunset provision" (similar to that tabled by the Opposition during the Committee Stage of the Bill) that would have required the Government to return with primary legislation three years after the Medicines and Medical Devices Bill had received Royal Assent.[82] Amendments 21, 22, 23, to **Clauses 1, 8** and **12** respectively, sought to prioritise patient safety when making regulations relating to human medicines, as well as prioritising animal, human and environmental safety when making regulations relating to veterinary medicines.[83]

Marie Rimmer (Lab) tabled an amendment to **Clause 2** that would have enabled the "appropriate authority to make provisions on the process of developing or manufacturing medicines in relation to the origin and treatment of human organs", so as to ensure that medicines manufactured in the UK met basic human rights standards.[84]

No Opposition or backbench amendments were moved to a division. The Government amendments were agreed to and the Bill was read for a third time on the same day (23 June) and passed without debate.

The Bill had its First Reading in the House of Lords on 24 June 2020, with its Second Reading scheduled for 2 September 2020.

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78 House of Commons, Consideration of Bill (Report Stage), Medicines and Medical Devices Bill, As Amended, 23 June 2020, p3
79 HC Deb 23 June 2020 c1225
80 House of Commons, Consideration of Bill (Report Stage), Medicines and Medical Devices Bill, As Amended, 23 June 2020, p6
81 HC Deb 23 June 2020 c1225
82 House of Commons, Consideration of Bill (Report Stage), Medicines and Medical Devices Bill, As Amended, 23 June 2020, p3
83 House of Commons, Consideration of Bill (Report Stage), Medicines and Medical Devices Bill, As Amended, 23 June 2020, p3-4
84 House of Commons, Consideration of Bill (Report Stage), Medicines and Medical Devices Bill, As Amended, 23 June 2020, p3

Medical device information systems

New Clause 1

New Clause 1 was introduced by the Government to provide a power for the Secretary of State to create one or more "medical device information systems through regulations" that would be established and managed by the Health and Social Care Information Centre (also known as NHS Digital). The information systems would be for purposes relating to:

- the safety and performance, including the clinical effectiveness, of medical devices;
- the safety of individuals who receive or are treated with a medical device; and
- the improvement of medical devices' safety and performance through advances in technology.[85]

Speaking to New Clause 1, the Minister, Ms Churchill emphasised why the new clause was needed, stating that medical devices were "not subject to the same comprehensive regulatory system of pre-market assessment that medicines are" and that the Government recognised "that the system could be made stronger in respect of how devices are purchased, used and reviewed".[86] The Minister went on to describe the benefits of the new system as "broad":

> 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. It would support the registries, both present and future, to take action underpinned by the national data from all four corners of the United Kingdom.[87]

The Minister acknowledged that Members may have concerns about "about how data is safeguarded, how it might be used and by whom" in respect to the device information systems. She emphasised that the Government intended to ensure, through regulations, that data would be:

> subject to appropriate safeguards such as anonymisation by NHS Digital, and able to be shared within the NHS system and with the regulator so that patients get the benefit immediately of improved product safety and the comfort of knowing they can be traced if there is information that they need about their specific advice. That can and should be in place before we are in a position to put in place the vision of a system of clinical registries.[88]

The Shadow Minister for Health and Social Care, Alex Norris, welcomed New Clause 1, stating that he was "so pleased to see the Government introduce what we spoke of in Committee as a device registry, which is now called the information centre". He added that he was "committed to continuing to develop the idea" with colleagues in the House of Lords.[89]

Patient safety

Amendments 21, 22 and 23, tabled by the Opposition, all related to prioritising patient safety (both human and animal) in the Bill. Mr Norris questioned whether there was a "vulnerability facing a future Secretary of State who is said to have prioritised patient

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85 HC Deb 23 June 2020 c 1222
86 ibid
87 ibid
88 HC Deb 23 June 2020 c1224
89 HC Deb 23 June 2020 c1229

safety over the attractiveness of the UK market for litigious and exceptionally powerful pharmaceutical companies".[90] Mr Norris stated that he would not "push" the matter to a Division but asked "that it be considered in the other place".[91]

In response, the Minister emphasised that patient safety was "paramount to the future of medicines and medical devices regulation".[92] She stated that the Government viewed all three considerations in Clause 1 to which the Government must have regard when making regulations about human medicines (namely the safety and the availability of human medicines, and the attractiveness of the UK as a place in which to conduct clinical trials / supply human medicines) as, together, providing "the best outcomes for patient safety".[93]

Sunset provision

The Opposition tabled an amendment (20) to Clause 1 that sought to introduce a 'sunset' clause, similar to that which was tabled during the Committee Stage of the Bill. This would have required the Government to return with primary legislation three years after the Bill had received Royal Assent. The tabling of amendment 20 partly reflected the Opposition's concerns about the delegated powers in the Bill and whether these potentially represented a "downgrade" from the previous level of scrutiny afforded to medicines and medical devices legislation by EU institutions:

> 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.[94]

The Shadow Minister also stressed that a sunset clause would enable Parliament to evaluate the operation of "hub and spoke" pharmacies which, while not on the face of the Bill, are referred to in its accompanying impact assessment (IA). The IA defines hub and spoke pharmacies as an arrangement whereby:

> 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.[95]

At present, such an arrangement can only operate if the hub and spokes are part of the same pharmacy business.

Mr Norris described this potential change to the way pharmacies operate as "the most profound reform to community pharmacy in our lifetimes".[96] Once again, the Shadow Minister stated that he did "not intend to press the amendment to a vote" but that he hoped the Government would "bear it in mind in the other place".[97]

Pointing to the "practical consequence of a sunset provision", the Minister stated that returning with primary legislation in three years would likely mean that the Government would need to do so within two years, "given the need to have sufficient parliamentary

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90 ibid
91 HC Deb 23 June 2020 c1231
92 HC Deb 23 June 2020 c1239
93 HC Deb 23 June 2020 c1226
94 HC Deb 23 June 2020 c1230
95 Department of Health and Social Care, Medicines and Medical Devices Bill Impact Assessment, 10th February 2020, para 170
96 HC Deb 23 June 2020 c1231
97 HC Deb 23 June 2020 c1230

time for the passage of the Bill". She added that this timescale was further reduced by the fact that there are:

> two months after Royal Assent before we can make the regulations, other than in emergencies, and those regulations are subject to a statutory consultation and then the affirmative procedure, which all takes time. This would mean that we would have 18 months, at most, of practical operation of the legislation before we had to go back to its principles.[98]

The Minister emphasised that the Bill had been drafted carefully and that the ability to make regulatory change via secondary legislation did not mean a "diminution in protection".[99] According to the Minister, the Government had "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".[100] On the point raised by the Shadow Minister on hub and spoke pharmacies, the Minister stated that the Government aimed to give:

> smaller community pharmacies the same opportunity that large pharmacy businesses already enjoy. We will support them, and remove the legal barrier that allows such an arrangement only when the spoke pharmacy and the central dispensing hub are part of the same retail pharmacy business.[101]

Medicines and human organs

Amendment 19 to Clause 2, tabled by Marie Rimmer (Lab) sought to enable the "appropriate authority" to "make provisions for the process of developing or manufacturing medicines in relation to the origin and treatment of human organs".[102] Ms Rimmer stated that, under the current legislation, namely the *Human Tissue (Quality and Safety for Human Application) Regulations 2007* and the *Human Tissue Act 2004*:

> importing of human body tissue for medical research does not require any consent or traceability—it is only advised, not required—meaning that human tissue from countries like China can legally be imported to the UK for the purpose of medical research without traceability, documentation or consent.[103]

The purpose of the amendment, Ms Rimmer explained, was to "close the hole in the existing legislation" and ensure trade in medicines between the UK and China is "ethical".[104] Mr Norris similarly stated that it was clear from correspondence he had received from constituents that "there might yet be gaps in the current arrangements and that we must act either today or in the other place" to address those gaps.[105]

The Minister sought to reassure Members "that the current legislation provides extensive safeguards to ensure the ethical and appropriate use of human tissues in medicines and medicinal products".[106] She added that while she was "entirely sympathetic" to Ms Rimmer's concerns, she did "not believe that the amendment would have the intended effect".[107]

Ms Rimmer did not push to amendment to a vote, but stressed that she would "not let [the] matter lie":

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98 HC Deb 23 June 2020 c1228
99 HC Deb 23 June 2020 c1227
100 HC Deb 23 June 2020 c1228
101 HC Deb 23 June 2020 c1239
102 HC Deb 23 June 2020 c1232
103 HC Deb 23 June 2020 c1233
104 ibid
105 HC Deb 23 June 2020 c1232
106 HC Deb 23 June 2020 c1229
107 ibid

> A growing group of cross-party parliamentarians, both here and in the other place, are determined to stop this from happening. We now need the Government to do their bit.[108]

Cumberlege Review

At the time of the Report Stage and Third Reading of the Bill in the Commons, the Independent Medicines & Medical Devices Safety Review, chaired by Baroness Cumberlege, had not reported (see Section 5.6 for further details of the review). The Shadow Minister stated that he had:

> rather hoped that the remaining stages of the Bill might fall after the review reports on 8 July [...] because the report could have a profound impact on how we view the Medicines and Healthcare Products Regulatory Agency and on how we view the past and what we need to do in the future.[109]

He asked the Minister to commit that the Government would engage seriously with the review:

> but that crucially they will be willing to make amendments to this Bill or changes more generally to the MHRA through other legislation, regulations or in other ways to ensure that it is fit for the future and addresses the challenges that come up in that review.[110]

The Minister replied that the Government would "consult when the Cumberlege report is published", adding that it was "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".[111]

The Government subsequently published a Written Statement in response to the report of the Independent Medicines and Medical Devices Safety Review on 8 July 2020.[112]

During an oral statement on 9 July on the Cumberlege Report, the Minister for Patient Safety, Mental Health and Suicide Prevention, Nadine Dorries, said that it made for "harrowing reading". She apologised on behalf of the health and care sector "to those women, their children and their families for the time the system took to listen and respond". The Minister added that was "imperative for the sake of those who have suffered so greatly" that the Report be given full consideration. [113]

When asked by the Chair of the Health and Social Care Committee, Jeremy Hunt, for an update to the House by the end of September on proposed actions, the Minister said she could not commit to that timescale but gave the House "my absolute assurance that I will chase this daily".[114] As of 1 September 2020, the Government has not published a formal response to the Cumberlege Report.

2.4 Lords Stages of the Bill

Overview

The Lords Stages of the *Medicines and Medical Devices Bill* took place between September 2020 and January 2021. Links to the debates at these stages are provided at the Parliament webpage on the Bill.

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108 HC Deb 23 June 2020 c1234
109 HC Deb 23 June 2020 c1230
110 ibid
111 HC Deb 23 June 2020 c1239
112 Written statement - HCWS347 [on Publication of the Independent Medicines and Medical Devices Safety Review (Cumberlege Review)], 8 July 2020
113 HC Deb 9 July 2020, c1147
114 HC Deb 9 July 2020, c1151

A number of amendments were added to the Bill during these stages.

Government amendments included:

- a new clause on disclosure of information;
- a new clause introducing a Patient Safety Commissioner; and
- Several amendments in response to concerns about the structure of the Bill, such as changes to Parliamentary procedure for regulations made under the Bill, and a requirement that any regulations be made only where the appropriate authority "*is satisfied that the regulations promote the health and safety of the public*"

Several Opposition amendments were also agreed and added to the Bill, including:

- The introduction of sunset clauses to the three parts of the Bill;
- A requirement for the Secretary of State to consolidate the regulatory regimes for medicines, medical devices and veterinary medicines into primary legislation; and
- Changes to the Parliamentary Scrutiny of Secondary legislation under the Bill, to introduce requirements for the Super-affirmative procedure in some instances.

Consideration of Lords amendments in the House of Commons is tabled for 27 January 2021.

This section of the paper will include a brief discussion on the debate and some of the amendments that were added to the Bill during the House of Lords stages.

The following reports and documents may also be useful:

- Commons Consideration of Lords Amendments, 27 January 2021
- House of Lords Delegated Legislation and Regulatory Reform Committee, 19th Report of Session 2019–21, Medicines and Medical Devices Bill, 22 July 2020
- House of Lords Select Committee on the Constitution, 10th Report of Session 2019–21 HL Paper 119, Medicines and Medical Devices Bill, 29 July 2020
- Department of Health and Social Care, Medicines and Medical Devices Bill: overarching documents

Patient Safety Commissioner

The Independent Medicines and Medical Devices Safety review was established by the then Secretary of State for Health, Jeremy Hunt, in 2018 to review how the health system responds to reports from patients about harmful side effects from medicines and medical devices. The review, chaired by Baroness Cumberlege, particularly examined the cases of Primodos (a hormone-based pregnancy test), sodium valproate (a drug used to treat epilepsy and bipolar disorder) and pelvic mesh. The review and its findings had been raised during Commons debate on the Bill, see section 2.3 of this paper. Further background on the review is provided in section 5.6.

The final report of the review, First Do No Harm, was published in July 2020, prior to the Lords Stages of the *Medicines and Medical Devices Bill* and made a number of recommendations which the report states will make the system safer in the future. One recommendation was the appointment of an independent patient safety Commissioner who would "*champion the patient voice and from this unique perspective would support and encourage the efforts of the healthcare system to improve patient safety around the use of medicines and medical devices.*"[115]

[115] The report of the Independent Medicines and Medical Devices Safety Review, First Do No Harm, July 2020, para 1.31

The Government tabled amendments 1 and 54 to introduce a Patient Safety Commissioner at Report Stage of the Bill on 12 January 2021. The Health Minister, Lord Bethell, said that patient safety was "*the golden thread that runs through this entire Bill*" and that the Government had heard the calls to establish a patient safety commissioner for the health service in England:

> Of course, this was the centrepiece recommendation of the Independent Medicines and Medical Devices Safety Review helmed by my noble friend Lady Cumberlege, to whom I pay profound tribute for her tireless championing on behalf of patients. I am delighted that Amendment 1 in my name—with which it is convenient to debate Amendments 54, 65, 70 to 72, 74, 86, 87, 91, 95 and 97—delivered upon that recommendation. These amendments provide for an independent advocate to champion the safety of patients. The patient safety commissioner will promote their interests and those of other members of the public in relation to the safety of medicines and medical devices.[116]

The Minister went on to explain that that the Commissioner's core duties would be to promote the safety of patients and ensure that they are heard, and that proposed new Schedule A1 to the Bill outlines the way the Commissioner must consult and involve patients.[117]

Baroness Cumberlege had also tabled amendment 65 to introduce a Patient Safety Commissioner at Report Stage of the Bill. She welcomed the Government amendment and withdrew hers but asked for further reassurance on three matters in relation to the Patient Safety Commissioner, that the role be established quickly, that the Commissioner should be able to seek information from any public body necessary, and that manufacturers of medicines and medical devices should be required to cooperate and share information with the Commissioner.[118]

The Government amendment was agreed and added to the Bill, it is now Clause 1.

A Department of Health and Social Care factsheet provides further information about the proposed Patient Safety Commissioner.[119]

On 11 January, a Written Statement provided an update to Parliament on the Government's response to the Medicines and Medical Devices Review.

Concerns about the structure of the Bill

There was support for the aims of the Bill in the Lord's Second Reading debate but a number of Peers from across the House raised concerns about the structure of the Bill and the wide-ranging Regulation-making powers.

Prior to the Second Reading debate for the Bill, the Constitution Committee and the Delegated Powers and Regulatory Reform Committee published reports on the Bill.[120] These both raised concerns about the structure of the Bill.[121]

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116 HL Deb, 12 January 2021, c615
117 ibid
118 HL Deb, 12 January 2021, c620
119 Department of Health and Social Care, Factsheet: Patient Safety Commissioner, 25 January 2021
120 House of Lords Delegated Legislation and Regulatory Reform Committee, 19th Report of Session 2019–21, Medicines and Medical Devices Bill, 22 July 2020 and House of Lords Select Committee on the Constitution, 10th Report of Session 2019–21 HL Paper 119, Medicines and Medical Devices Bill, 29 July 2020
121 House of Lords, Delegated Powers and Regulatory Reform Committee, Medicines and Medical Devices Bill, 22 July 2020, HL Paper 109, 2019–21;
House of Lords, Select Committee on the Constitution, Medicines and Medical Devices Bill, 29 July 2020, HL Paper 119, 2019–21

The House of Lords Delegated Powers and Regulatory Reform Committee's report had highlighted the skeleton nature of the Bill, and broad regulation making powers within it.[122] The Committee also criticised the use of the negative procedure for these regulations. It said that this was not the only solution in instances where the Government needed to act quickly to make regulations, and argued that, in a number of cases, the affirmative or made affirmative procedure should apply.[123]

Highlighting the report of the Delegated Powers and Regulatory Reform Committee at Second Reading, its Chair, Conservative Peer, Lord Blencathra, raised concerns about the structure of the Bill:

> […]it grieves me to say that the structure of the Bill is absolutely atrocious and an affront to parliamentary democracy. Of course, it is not unique; it is just one more Bill stuffed full of Henry VIII clauses but devoid of substantive content. It is the barest skeleton, all to be filled in with negative secondary legislation.[124]

Lord Bethell, Parliamentary Under-Secretary of State for Health and Social Care, responded to these criticisms. He said that the delegated powers in the Bill were not new but said that the Government would consider the specific recommendations of the Delegated Powers and Regulatory Reform Committee and consider how it might go further.[125]

Government amendments

In order to address concerns about the structure of the Bill raised by some Members in the Second Reading debate, and the reports from the Constitution Committee and Delegated Powers and Regulatory Reform Committee, the Government brought forward a group of amendments at the first sitting of Committee Stage of the Bill. Lord Bethell explained that Amendments 2 and 68 would require that any regulations made under the Bill, could only be made where "*the appropriate authority is satisfied that the regulations promote the health and safety of the public.*"[126]

He said that the amendments did not prevent the Government from making regulations to enable the development of new medicines and devices, but the new requirement will protect against any impact on the health of the public.[127] Amendment 51 made similar changes to regulations on veterinary medicines and other amendments in the group were consequential to these changes. These amendments were agreed and added to the Bill.

The Government also introduced amendments to change the Parliamentary procedure for regulations made under certain parts of the Bill. Background information on the different Parliamentary procedures for Statutory instruments is provided in a Commons Library background paper, Statutory Instruments.

Baroness Penn introduced these amendments at Committee Stage on behalf of the Minister. She said that amendment 133 would change the procedure for reactive emergency regulations to the "made affirmative procedure" and would change the procedure for regulations made about prescribing, advertising, packaging and labelling in relation to human and veterinary medicines to the draft affirmative procedure (rather than the negative procedure). Baroness Penn said that changing to the made affirmative for

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122 House of Lords, Delegated Powers and Regulatory Reform Committee, Medicines and Medical Devices Bill, 22 July 2020, HL Paper 109, 2019–21, paras 28 & 53
123 House of Lords, Delegated Powers and Regulatory Reform Committee, Medicines and Medical Devices Bill, 22 July 2020, HL Paper 109, 2019–21, eg paras 37 & 38, 45 & 48
124 HL Deb, 2 September 2020, c415
125 HL Deb, 2 September 2020, c432
126 HL Deb, 26 October 2020, c26GC
127 HL Deb, 19 October 2020, c332GC

emergency regulations allowed the Government to move at speed, whilst ensuring parliamentary scrutiny. She said that amendment 133 provided:

> a significant lift in parliamentary scrutiny of the regulations made in relation to human and veterinary medicines in particular. Taken in conjunction with the other government amendments, the Government's accountability to Parliament and the public in making regulatory change is very strong[128]

Amendment 131 was also introduced at Committee stage and would require the Secretary of State to report to Parliament on the operation of any regulations made under the three parts of the Bill every two years. Lord Bethell, introducing the amendment said that the report must provide information on regulations made, and any plans for future regulations. He said that it would have two significant effects:

> First, it offers an opportunity to inform Parliament on how the regulations are operating, with reference to concerns and proposals made by consultees. Secondly, Parliament will have early indication of possible plans for further regulatory changes under Clauses 1, 8 and 12. It would be an indication of the Government's intended direction of travel and, naturally, I do not doubt Parliament's capacity to offer views on that direction of travel.[129]

Amendments 133 and 131 were agreed and added to the Bill.

Sunset Clauses and consolidation

At Report Stage, amendments 2, 27 and 40 were tabled by the Opposition to introduce a sunset provision for regulation making powers in parts 1, 9 and 14 of the Bill - those concerning the regulation of medicines, medical devices and veterinary medicines. These amendments would mean that the Bill would expire after 3 years.

Shadow health spokesperson, Baroness Thornton, said that the amendments built on the improvements that had already been made to the Bill:

> We believe that this suite of amendments, in a way, builds on those improvements that have already been made to the Bill. They propose a very simple objective that was articulated from the very beginning. It is neither democratic nor safe to run medicines, devices and veterinary medicines through regulation alone in the long run. Our regulatory framework needs to be in primary legislation. This must be achieved in a timely fashion, hence these amendments. Sooner or later—and there is agreement on this—there will need to be consolidation in primary legislation. We would prefer it to be sooner. We think that some agreement is necessary on this.[130]

Crossbench Peer, Lord Patel, introduced amendments 26,39 and 63 alongside these amendments at Report Stage[131] These would require the Government to draft primary consolidating legislation in respect of human medicines, medical devices and veterinary medicines, so that it is easily accessible and understandable. Lord Patel stated, both during Report Stage and in Committee, that the existing regulatory regimes for medicines and medical devices were "complex and unwieldy, spanning multiple pieces of primary and secondary legislation that implement several EU directives" and that, as it stands, the Bill would further add to the existing regulatory complexity by granting "powers to create future regulations through statutory instruments".[132]

The Minister, Lord Bethell, said that the proposed amendments would leave insufficient time for the Government to draft, consult on and pass primary legislation. He said that the assessment of what regulation would be appropriate to consolidate and the

128 HL Deb 19 October 2020, c376GC
129 HL Deb 11 November 2020, c462GC
130 HL Deb, 12 January 2021, c634
131 HL Deb, 12 January 2021, c635
132 HL Deb, 12 January 2021, c636-7

development of policy proposals take time and three years was not enough.[133] He said he was sympathetic to how Parliament viewed the Government plans but he highlighted the opportunities for scrutiny of Government policy through Select Committees, and noted the reporting requirement in the Bill that gives Parliament the option to look at the legislation made under the Bill in the first two years (amendment 131).

Amendment 2 was moved to a division and agreed to (Content 324, Not Content, 241). Amendments 26, 27, 39, 40 and 63 were agreed to.

Super-affirmative procedure

Amendment 3 was tabled at Report Stage by the Liberal Democrat Peer, Lord Sharkey. It requires regulations relating to human medicines, veterinary medicines and medical devices that introduce significant new policy, or changes to existing policy, to be subject to the super-affirmative procedure. Under the super-affirmative procedure, a Minister lays a proposal for a SI in draft form. Both Houses then have a set period of time (in this instance 30 days) for Parliamentary consideration of the proposal. Lord Sharkey's amendment also stipulates that the draft SI must be referred to, and reported on, by a "Committee of either House whose remit includes health, science or technology to report on the draft regulations within a 30 day period".[134] After the 30 day period, the Minister can lay an SI for approval by affirmative resolution of both Houses.

While the power to amend the draft instrument continues to rest with the Minister, Lord Sharkey's amendment provides for any related, subsequent SI to be accompanied by a statement, laid before Parliament by the Secretary of State, setting out the details of "any representations, resolutions or recommendations" that were made during the 30 day period and explaining any changes made to the draft of the regulations by the Minister.

Lord Sharkey explained that he was tabling the amendment to "restore an element of meaningful parliamentary scrutiny" to the Bill following repeated criticisms of its 'skeletal' nature.[135] In response, the Minister, Lord Bethell, emphasised the "practical realities of what [the] use of the super-affirmative procedure would involve", stating that it would require "an additional layer of scrutiny" that could take "significantly more than 30 days, since any period when Parliament is adjourned for more than four days is not taken into account in those 30 days".[136] He also called attention to a lack of a definition in the amendment of what would constitute a 'significant' policy change, adding that this created a "real risk that the most urgent of [regulatory] changes would be ensnared by the super-affirmative procedure without a clear and unambiguous distinction on when the higher threshold must apply".[137]

Amendment 3 was moved to a Division and agreed to (Content 320, Not Content, 236).

Disclosure of information

At the fourth sitting of the Committee Stage of the Bill, the Minster, Lord Bethell brought forward Amendment 48, a new clause, with the stated purpose of making clear:

> that information held by the Secretary of State or the Department of Health in Northern Ireland in connection with human medicines can be disclosed, subject to certain restrictions, to persons outside the United Kingdom in order to give effect to a relevant international agreement or arrangement.[138]

133 HL Deb, 12 January 2021, c645
134 Lords Amendments to the Medicines and Medical Devices Bill, 21 January 2021, p13
135 HL Deb, 12 January 2021, c651
136 HL Deb, 12 January 2021, c659
137 HL Deb, 12 January 2021, c660
138 HL Deb, 4 November 2020, c336GC

The new clause was subsequently amended by the Minister during the Report Stage (Amendment 17) to restrict the persons to whom information may be disclosed to "relevant persons" (as defined in the amendment), on the grounds that "including in the Bill an exhaustive list of named organisations we share data with [was] not practical".[139]

Amendments 18, 36 and 57, which sought to limit the purpose for which information could be shared internationally under the powers of the new clause, were tabled at Report Stage by Baroness Thornton, Lord Patel and Lord Clement-Jones. Amendment 18 (which was moved to a Division and agreed to (Content 312, Not Content 249)) stipulated that disclosure would only be permitted under two circumstances:

a) it is required as part of international cooperation for pharmacovigilance; or

b) it is in the public interest[140]

Baroness Thornton explained that, in her view, the Government Amendment (17) "still potentially [allowed] for the disclosure of patient data without consent to commercial partners for undefined, and therefore unknown, purposes" and that the public interest "test" introduced by Amendment 18 would "offer reassurance that substantive and ethical issues relating to the sharing of data would at least be considered".[141] Amendment 18 was moved to a Division and agreed to (Content 312, Not Content 249). Amendments 36 and 57, which introduced the same 'public interest test' for disclosure of information relating to veterinary medicines and medical devices respectively, were agreed to without a division.

Use of tissues and cells in human medicine

At Report Stage, the Labour Peer Lord Hunt moved Amendment 13 to enable regulations made under Clause 1(1) of the Bill to make provision about the use of human tissues or cells in relation to human medicines. He explained that the Amendment was designed to address specific "gaps in current UK human tissue legislation":

> the Human Tissue Act does not require appropriate consent for imported human tissue. In addition, imported human tissue for use in medical research does not require traceability. Currently, neither the Human Tissue (Quality and Safety for Human Application) Regulations nor the Human Tissue Act require appropriate consent for imported human tissues for use in medicines. My amendment gives powers to Ministers to put this right. I should explain that the words "tissues" and "cells" are terminology which encompass all the human material that is used for the purposes of medicines. This includes organs.

The Amendment, he stated, was proposed as a means to "prevent British complicity" in forced, live organ harvesting; a practice which, he added, was occurring in China among "prisoners of conscience" and particularly among Uyghur Muslims in the region of Xinjiang.[142] The issue was also raised by MPs during the Commons stages of the Bill (see sections 2.2 and 2.3). The Amendment was supported by the Government and agreed to without a Division. Earlier the same day, the Foreign Secretary, Dominic Raab, set out a package of measures in the Commons to ensure that that "no company profits from forced labour in Xinjiang, and that no UK business is involved in their supply chain".[143]

139 HL Deb, 14 January 2021, c901
140 HL Deb, 14 January 2021, c 915
141 HL Deb, 14 January 2021, c 912-13
142 HL Deb, 12 January 2021, c 697
143 HC Deb, 12 January 2021, c161

3. Human medicines

Part 1 of the Bill confers a delegated power to amend or supplement specific parts of the law relating to human medicines, including the clinical trials of human medicines.

3.1 Current regulatory framework

The Human Medicines Regulations 2012 (HMRs) came into effect in August 2012, repealing or revoking most existing UK legislation regulating the authorisation, sale, supply and monitoring of medicinal products for human use and consolidating their effect in one place. The previous legislation was based on *The Medicines Act 1968* as well as a range of regulations introduced under powers in the *European Communities Act 1972*. The current regulatory framework for human medicines in the EU is based on Directive 2001/83/EC (medicinal products for human use).

The Medicines and Medical Devices Bill Explanatory Notes explain that the HMRs are overseen by the UK licensing authority which consists of the Secretary of State for Health and Social Care, and the Minister of Health in Northern Ireland.[144] In practice, the HMRs are overseen by the Medicine and Healthcare products Regulatory Agency (MHRA) acting on behalf of the Secretary of State.[145]

Medicines and Healthcare products Regulatory Agency (MHRA)

The MHRA is an executive agency of the Department of Health and Social Care and acts as the UK's licensing authority. Its responsibilities include:

- ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy;
- ensuring that the supply chain for medicines, medical devices and blood components is safe and secure;
- promoting international standardisation and harmonisation to assure the effectiveness and safety of biological medicines;
- helping to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use;
- supporting innovation and research and development that's beneficial to public health;
- influencing UK, EU and international regulatory frameworks so that they're risk-proportionate and effective at protecting public health.[146]

European Medicines Agency

The Medicines and Healthcare products Regulatory Agency is the UK-based regulator through which medicines can be licensed, medical devices are regulated, and a medicine's safety is monitored. The European Medicines Agency also performs all these roles on an EU and EEA (European Economic Area) country wide basis. The future relationship between the EMA and the UK is uncertain. The Political Declaration setting out the framework for the future relationship between the European Union and the United Kingdom states:

144 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p6
145 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p6
146 About us, MHRA, [accessed 19 Feb 2020]

> The Parties will also explore the possibility of cooperation of United Kingdom authorities with Union agencies such as the European Medicines Agency (EMA).[147]

More recently, The Future Relationship with the EU, The UK's Approach to Negotiations, published by the Government on 27 February 2020, states that the "Comprehensive Free Trade Agreement" between the UK and EU should contain an annex on medicinal products to "facilitate trade in medicinal products and support high levels of patient safety". In addition it states that the annex should include:

> commitments to cooperate on pharmacovigilance and to develop a comprehensive confidentiality agreement between regulators, in line with agreements between the European Medicines Agency and Swiss, US and Canadian authorities. This should facilitate information sharing and enable regulators to act promptly to safeguard patient safety and public health, such as by responding to urgent adverse drug reactions.[148]

3.2 Existing legislation affected by the Bill

Clause 1(1) of the Bill confers a delegated power to the "appropriate authority" to amend or supplement "the law relating to human medicines". **Clause 7** defines "the law relating to human medicines" as including four specific pieces of legislation only:

- *The Human Medicines Regulations 2012*
- *The Medicines for Human Use (Clinical Trials) regulations 2004*
- *The Medicines Act 1968*
- *The Medicines (Products for Human Use) (Fees) Regulations 2016*

The Medicines Act 1968

Following the events surrounding thalidomide in the 1950s and 60s, European governments introduced stricter controls on the development and marketing of new medicines.

The *Medicines Act 1968* was the first comprehensive licensing system for medicines in the UK. It regulated the manufacture, distribution and importation of medicines for human use, medicines for administration to animals and medicated animal feeding stuffs.

The 1968 Act introduced three classifications of medicines; prescription only medicines, pharmacy medicines and general sale list medicines, each with specific conditions for sale and supply. A Gov.uk webpage – Medicines: reclassify your product – provides more information about each class.[149]

Since 1968, a number of provisions in the Act have been repealed and replaced by newer legislation, such as The Veterinary Medicines Regulations and the HMRs. Some sections of the 1968 Act that make provision relating to pharmacies are, however, still in force.

The Medicines for Human Use (Clinical Trials) Regulations 2004

The Clinical Trials Directive 2001/20/EC was introduced to simplify and harmonise the administrative provisions governing clinical trials in Europe. The Directive is due to be

147 HM Government, Political Declaration setting out the framework for the future relationship between the European Union and the United Kingdom, 19 October 2019, para 23
148 HM Government, The Future Relationship with the EU The UK's Approach to Negotiations, February 2020 [accessed on 17 March 2020]
149 Medicines and Healthcare products Regulatory Agency, Guidance: Medicines: reclassify your product, 3 October 2019 [Accessed on 26 February 2020]

repealed by the Clinical Trials Regulation (EU) No 536/2014, but is not expected to apply until after the transition period.[150]

The Medicines for Human Use (Clinical Trials Regulations) 2004 implement the 2001 Directive in the UK and provide that the licensing authority (the Medicines and Healthcare products Regulatory Agency - MHRA) shall exercise the functions of the competent authority under the Directive, unless these functions are conferred to another body or person.

The Explanatory Note explains that the Regulations make provision for ethics committees to give opinions on the ethics of clinical trials involving medicinal products, and for the United Kingdom Ethics Committees Authority to be responsible for establishing, recognising and monitoring ethics committees.[151] The Regulations also provide that a clinical trial may only be conducted if it has been authorised by the licensing authority and an ethics committee and has given a favourable opinion.[152]

The Human Medicines Regulations 2012

Prior to The HMRs, medicines legislation consisted of various Acts of Parliament and many statutory instruments.[153] The HMRs consolidated much of the existing legislation regulating the authorisation, sale and supply of medicinal products for human use. They also regulate who can prescribe, supply and administer specific medicines in both general circumstances and in specific situations, such as epidemics.[154]

The HMRs implemented Directive 2010/84/EU. The Explanatory Memorandum to the HMRs described the Directive as introducing "a strengthened, clarified and more proportionate regime for pharmacovigilance in the EU market".[155]

The HMRs regulate a wide range of matters concerning human medicines including:

- Manufacturing and wholesale dealing
- Application for UK marketing authorisation
- Pharmacovigilance
- Sale and supply of medicines
- Emergency sale of medicines and exemptions for supply of medicines.

The Medicines (Products for Human Use) (Fees) Regulations 2016

The Medicines (Products for Human Use) (Fees) Regulations 2016 revokes and re-enacts in consolidated form the legislation setting out the fees payable by the pharmaceutical industry in relation to the services provided, and regulatory functions carried out, by the MHRA in relation to medicinal products for human use.[156]

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150 European Medicines Agency, Clinical Trial Regulation, not dated [accessed on 26 February 2020]
151 Explanatory Note, Medicines for Human Use (Clinical Trials) Regulations 2004
152 Explanatory Note, Medicines for Human Use (Clinical Trials) Regulations 2004
153 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p5
154 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p5
155 Explanatory Memorandum to The Human Medicines Regulations 2012 No 1916, para 4.5
156 Explanatory Memorandum to the Medicines (Products For Human Use) (Fees) Regulations 2016, para 2.1

The Explanatory Notes further explains that the Regulations "decrease a wide range of fees in line with reduced costs of providing these services and introduces new fees for registration with the EU Falsified Medicines Directive (FMD) common logo scheme".[157]

The decreased fees, payable to the MHRA, follow a number of efficiency savings that the MHRA have achieved.

3.3 Extent of the powers for human medicines

In addition to restricting the powers at Clause 1(1) to amending only the four pieces of legislation outlined above, the power is further limited to amending only those matters set out on the face of the Bill at **Clauses 2 to 6.** These matters relate to five areas:

- Manufacture, marketing and supply
- Falsified medicines
- Clinical trials
- Fees, offences, powers of inspectors
- Emergencies

The "appropriate authority" is recognised in **Clause 1(4)(a)** 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.

Clause 1(2) of the Bill stipulates that when making regulations, the appropriate authority must also have regard to:

a) the safety of human medicines;

b) the availability of human medicines;

c) the attractiveness of the relevant part of the United Kingdom as a place in which to conduct clinical trials or supply human medicines.

3.4 Manufacture, marketing and supply

Clause 2(1) provides an exhaustive list of matters for which the regulation making power may address:

- **Subsection 2(1)(a)** enables provisions to be made about authorisations to manufacture human medicines. Subsection 17(1a) of the HMRs stipulates that a person must possess a manufacturer's licence in order to manufacture, assemble or import any medicinal product from a non- European Economic Area (EEA) State. The MHRA is responsible for issuing manufacturer licences, subject to compliance with EU Good Manufacturing Practice (GMP) and passing regular GMP site inspections. Further information can be found on a Gov.uk webpage; Licences to manufacture or wholesale medicines.
- **Subsection 2(1)(b)** enables provisions to be made about authorisations to import human medicines. In addition to the licence requirements above, Section 38 of the HMRs makes provisions concerning the import of medicinal products from non-EEA states, including compliance with the principles and guidelines on good manufacturing practice.
- **Subsection 2(1)(c)** enables provisions to be made about authorisations to distribute human medicines by way of wholesale dealing. Subsection 18(1) of

[157] Explanatory Memorandum to The Medicines (Products for Human Use) (Fees) Regulations 2016 No. 190, para 2.2

the HMRs stipulates that a wholesale dealer's licence (WDL) is required for the distribution of a medicinal product by way of wholesale dealing, or the possession of a medicinal product for the purpose of such distribution. A Gov.uk webpage, Apply for manufacturer or wholesaler of medicines licences, explains that a WDL permits import and export between the UK and EEA countries. Further information is available in an MHRA guide; Notes for applicants and holders of a Wholesale Dealer's Licence (WDA(H)) or a Broker Registration.[158]

- **Subsection 2(1)(d)** enables provisions to be made about marketing authorisations. A product licence must be obtained in order for a medicine to be marketed in the UK; this is commonly known as a marketing authorisation (MA). MAs can be issued by a Member State licensing authority, (such as the MHRA in the UK), or by the European Medicines Agency (EMA).[159] Further information about MAs is available on a Gov.uk webpage; Apply for a licence to market a medicine in the UK.[160]
- **Subsection 2(1)(e)** enables provisions to be made about manufacturing, importing or distributing active substances. Section 37 of the HMRs stipulates that manufacturer's licence holders must use active substances as starting materials only if these have been manufactured or assembled in accordance with Directive 2003/94/EC.
- **Subsection 2(1)(f)** enables provisions to be made about brokering in relation to human medicines. Section 16 of *The Human Medicines (Amendment) Regulations 2013* stipulates that a person may only broker medicinal products that are covered by an MA, and that the broker must be registered. In the UK, brokers must register their activities with the MHRA. The MHRA guide, Notes for applicants and holders of a Wholesale Dealer's Licence (WDA(H)) or Broker Registration, provides more information on broker registration.[161]
- **Subsection 2(1)(g)** enables provisions to be made about the registration of the premises of pharmacy businesses. Section 74 of *The Medicines Act 1968* makes provisions for the registration of pharmacies. Section 75 imposes a duty on the registrar, The General Pharmaceutical Council (GPhC), to keep a register of pharmacy premises.
- **Subsection 2(1)(h)** enables provisions to be made about the recording of information about the supply of human medicines. Regulation 253 of the HMRs stipulates that a person lawfully conducting a retail pharmacy business must keep written or computerised records of every sale (with some exceptions) or supply of prescription only medicines.
- **Subsection 2(1)(i)** enables provisions to be made about notification and reporting requirements in relation to human medicines that have been placed on the market. These requirements broadly concern pharmacovigilance, requirements for which are currently outlined by Regulation (EU) No 1027/2012 and Directive 2012/26/EU. The practical measures to support

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158 Medicines and Healthcare products Regulatory Agency, Notes for applicants and holders of a Wholesale Dealer's Licence (WDA(H)) or Broker Registration, Guidance Note 6, 2018

159 For centrally authorised medicinal products, licenced through the European Medicines Agency, the marketing authorisation holder must be "established" in the EEA. Pharmaceutical companies with a marketing authorisation holder established in the UK have until 31 December 2020 to make the necessary changes to ensure the marketing authorisation is transferred to a holder in an EEA country, see European Medicines Agency, Brexit-related guidance for companies, not dated

160 Medicines and Healthcare products Regulatory Agency, Apply for a licence to market a medicine in the UK, 18 February 2020

161 Medicines and Healthcare products Regulatory Agency, Medicines: notes for applicants and holders of a wholesale dealer licence or broker registration, MHRA, 19 Jun 2018

pharmacovigilance are outlined in the guidelines on good pharmacovigilance practices (GVP) (see section 3.5 below for further details).

- **Subsection 2(1)(j)** enables provisions to be made about the labelling and packaging of human medicines or the information that must be supplied with them or made available in relation to them. This is currently regulated by Part 3 of the HMRs and approved by the MHRA prior to sale. The Medicines and Medical Devices Bill Explanatory Notes suggest that new provisions in the Bill may require manufacturers to make information that is normally available on the patient information leaflet, available at all times in electronic format.
- **Subsection 2(1)(k)** enables provisions to be made about advertising with regard to human medicines. Part 14 of the HMR stipulates the conditions for advertising medicinal products. The Medicines and Medical Devices Bill Explanatory Notes suggest that regulations made under **Clause 1(1)** of the Bill may, for example, permit some of the information required to be presented in advertisements to healthcare professionals, to be made available via a web link, rather than in an advert's small print.
- **Subsection 2(1)(l)** enables provisions to be made about the registration of persons who supply or offer to supply human medicines by means of the internet. Part 12A (sale of medicines at a distance) of the HMRs stipulates the conditions in which a person may sell a medicinal product at a distance. Such persons must Register for the Distance Selling logo with the MHRA and comply with the Electronic Commerce (EC Directive) Regulations 2002. The Medicines and Medical Devices Bill Explanatory Notes suggest that regulations introduced under Clause 1(1) of the Bill may be used to introduce a national scheme to replace the EU scheme.
- **Subsection 2(1)(m)** enables provisions to be made about the requirements that must be met in relation to a prescription. Regulations 217 to 219A in Part 12 (Dealing with Medicinal Products) of the HMRs set out the requirements for prescriptions to be valid for dispensing in the UK and in an EEA state other than the UK. The Medicines and Medical Devices Bill Explanatory Notes suggest that regulations made under **Clause 1(1)** of the Bill, may amend the particulars that must be included in a prescription or the types of prescriptions that can be sent electronically.
- **Subsection 2(1)(n)** enables provisions to be made about prohibitions mentioned in **subsection 2(2).** A number of regulations in the HMRs govern who can supply human medicines and from where they can be supplied; the Bill makes provision to amend the restrictions on supply outlined in specific regulations of the HMRs.
- The Medicines and Medical Devices Bill Explanatory Notes suggest that regulations made under Clause 1(1) used to allow additional healthcare professionals to be given appropriately restricted prescribing rights, or to amend the exemptions to the requirement for a prescription.[162] It is also proposed that the range of healthcare professionals permitted to make prescribing decisions will expand under this new power (see section 3.5 below for further details).

The Regulations made under this part of the Bill require the affirmative procedure, apart from the provision in 2(1)(j),(k) and (n) which are subject to the negative procedure. [163]

[162] HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p15
[163] Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p10

3.5 Extending the range of professions able to prescribe medicines

The Bill provides that amendments may be made to provisions in the *Human Medicines Regulations 2012* (the HMRs), which set out general rules on who can supply human medicines and from where they can be supplied. The rules are set out in **Clause 2(2)** of the Bill and include:

> …regulations 214 (sale or supply of prescription only medicines), 215 (prescribing and administration by supplementary prescribers), 220 (sale or supply of medicinal products not subject for general sale), 221 (sale or supply of medicinal products subject for general sale) and 249 (restrictions on persons to be supplied with medical products) of the HMRs. These provide that prescription only medicines (POMs) can only be supplied in accordance with a prescription and set out who can issue prescriptions. They also set out that medicinal products that are not subject to general sale (POMs and pharmacy medicines) must be supplied from a registered pharmacy, while general sale medicines need to be supplied from premises that can be closed off to exclude the public. Finally, they restrict who can be supplied with medicinal products by way of wholesale dealing. There are multiple exemptions from these rules set out in Chapter 3, Part 12 of the HMRs and the associated Schedules.[164]

The Government has highlighted that the Bill would allow the further extension to the range of healthcare professions that able to prescribe medicines in what it describes as "low-risk circumstances".[165]

The HMRs set out which groups of healthcare professionals are regarded as having the appropriate qualifications to make prescribing decisions and such groups are granted the responsibility to prescribe, either generally or in a defined set of circumstances. The Explanatory Notes state that:

> Over time the roles of staff within the health service will evolve and using this proposed power, certain professionals will be added to this list by amending the HMRs.[166]

The Explanatory Notes also state that there are a number of exemptions from the rules on who can supply human medicines and from where they can be supplied. There are set out in Chapter 3, Part 12 of the HMRs and the associated Schedules. An example of an existing exemption is one that allows schools to obtain asthma inhalers and to supply them in an emergency to pupils who are known to suffer from asthma.[167] The Government press notice accompanying the publication of the Bill states that there will "be safeguards and limits on what medications are eligible" and that the "government will work with the NHS and stakeholders to determine what medicines could be eligible and in what circumstances".[168]

The Government's Delegated Powers Memorandum for the Bill notes that that regulations relating to the HMR rules on the supply of human medicines should be subject to the negative resolution procedure. It explains that:

> This is because proposals to make changes to existing provisions, or to introduce new provisions enabling the supply, administration or prescribing of medicines are made to reflect shifts in best practice following extensive consideration and scrutiny by the relevant professional bodies. These types of amendments to the HMRs have been made frequently in recent years by way of regulations made under section 2(2) ECA

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164 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p15
165 'New bill gives hospitals power to develop personalised treatment', *gov.uk*, 13 February 2020
166 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p15
167 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p15
168 'New bill gives hospitals power to develop personalised treatment', *gov.uk*, 13 February 2020

> [the *European Communities Act 1972*], which are subject to the negative procedure.[169]

Who can currently prescribe medicines?

The range of healthcare professionals authorised to prescribe medicines has broadened since the 1999 Review of Prescribing, Supply and Administration of Medicines.[170] This proposed that prescribing rights be extended to a range of health professionals in order to improve services to patients, make better use of the skills of professional staff and thus make a significant contribution to the modernisation of the health service.

In particular, prescribing responsibilities have been extended to appropriately trained health professionals, including nurses, pharmacists and paramedics. These professionals are termed 'non-medical prescribers', in order to distinguish them from doctors and dentists.

There are two types of non-medical prescriber:

- Independent Prescribers – who are able to prescribe medicines under their own initiative.
- Supplementary Prescribers – who can prescribe medicines in accordance with a pre-agreed care plan that has been drawn up between a doctor and their patient.

The list of drugs which non-medical prescribers can administer can be found in Schedule 17 to the Human Medicines Regulations 2012.

Further information on non-medical prescribing can be found on the website of the Royal Pharmaceutical Society.

3.6 Falsified medicines

The EU Falsified Medicines Directive (2011/62/EU) (FMD) was adopted in 2011. It introduced new harmonised measures to "ensure that medicines in the European Union (EU) are safe and that trade in medicines is properly controlled".[171] **Clause 3(1)(a)** permits the introduction of regulations, made under Clause 1(1), to prevent the supply of falsified human medicines, while **subsection (1)(b)** allows "any information that is collected for the purpose of the prevention of the supply of falsified medicines to be used, retained and disclosed for any purpose to do with human medicines". A falsified medicine is defined as one which falsely represents its "identity, source or provenance".[172]

3.7 Clinical Trials

Clause 4 makes provision for regulations to be made under section 1(1) of the Bill that amend or supplement clinical trials regulations.

Clinical trials in the UK are currently regulated under the Medicines for Human Use (Clinical Trials) Regulations 2004, which implemented the Clinical Trials Directive (2001/20/EC) (see section 3.2 for further detail) The regulations define a clinical trial as:

> any investigation in human subjects, other than a non-interventional trial, intended—

169 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p16
170 Department of Health, Review of Prescribing, Supply and Administration of Medicines (1999), chaired by Dr June Crown
171 Medicines and Healthcare products Regulatory Agency, Guidance: Implementing the Falsified Medicines Directive: Safety Features, 11 July 2019
172 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p16

> (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products,
>
> (b) to identify any adverse reactions to one or more such products, or
>
> (c) to study absorption, distribution, metabolism and excretion of one or more such products, with the object of ascertaining the safety or efficacy of those products.[173]

The regulations are overseen by the MHRA and cover:

> 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.[174]

The UK's contribution to Europe's clinical trial expertise was set out in a paper published by the Wellcome Trust, Brexit and Beyond: Clinical trials, in 2019.[175] It stated that besides:

> holding 13 per cent of the EU's potential patient population, the UK runs the most early-stage phase I trials in Europe, and the second most phase II and III trials, which in total make up 25–30 per cent of all trials in the EU. The UK leads and participates in more pan-EU clinical trials on rare diseases than any other Member State, and ranks in the top four across the EU for clinical trials in mental health, cancer, cardiovascular disease and musculoskeletal disorders.[176]

Both the Wellcome Trust and the Royal College of Physicians (RCP) have also emphasised the importance of cross-border collaboration on clinical trials, with the RCP stating:

> the UK is very successful at conducting clinical trials, sponsoring around 1,500 trials that include other EU countries – half of these will still be occurring in 2019. Particularly for rare disease trials, it is important to collaborate internationally, as there are not enough patients within one country alone.[177]

The Clinical Trials Directive is due to be replaced by the EU Clinical Trials Regulation. The European Commission website provides more information about the Regulation:

> Although the Regulation entered into force on 16 June 2014 the timing of its application depends on the development of a fully functional EU clinical trials portal and database, which will be confirmed by an independent audit. The Regulation becomes applicable six months after the European Commission publishes a notice of this confirmation. The entry into application of the Regulation is currently estimated to occur in 2019.
>
> The Regulation will ensure a greater level of harmonisation of the rules for conducting clinical trials throughout the EU. It introduces an authorisation procedure based on a single submission via a single EU portal, an assessment procedure leading to a single decision, rules on the protection of subjects and informed consent, and transparency requirements.
>
> It will also make it easier for pharmaceutical companies to conduct multinational clinical trials, which should increase the number of studies conducted within the EU. More detailed information on the regulation is available on the European Medicines Agency (EMA)'s website.[178]

The website further advises that due to technical difficulties with the development of the IT systems, the EU Clinical Trial Regulation will come into application during 2020.

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173 Regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004, (S.I. 2004/1031)
174 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p7
175 The Wellcome Trust is an independent health foundation in the UK supporting scientific and health research.
176 The Wellcome Trust, Brexit and Beyond: Clinical trials, February 2019 [accessed on 25 February 2020]
177 Royal College of Physicians, Brexit: What does it mean for medical research?, not dated [accessed on 25 February 2020]
178 European Medicines Agency, Clinical Trial Regulation, not dated [accessed on 26 February 2020]

The EU Regulation sets out provisions for a number of matters, including; authorisation for clinical trials, clinical trials on minors and pregnant and breastfeeding women, compliance with trial protocol and good clinical practice, safety reporting, informed consent and an electronic database for safety reporting.

The Medicines and Medical Devices Bill Explanatory Notes advise on the applicability of the Regulation in the UK with respect to the Transition Period:

> The EU legislation on which the CTRs are based is due to be repealed and replaced by a new EU Regulation. Whilst this EU Regulation is in force, it is not expected to apply in the EU until after the end of the transition period meaning it will not form part of retained EU law.[179]

Speaking in a Debate in the House of Lords on the *European Union (Withdrawal Agreement) Bill* in January 2020, Baroness Thornton stated that the:

> medical research sector has been clear that continued close co-operation should be a priority in the negotiations. Indeed, the Government have recognised the international nature of the life sciences sector. They are committed to aligning as closely as possible with the European Union clinical trial regulation when it comes into effect, safeguarding vital UK-EU clinical trials.[180]

The Parliamentary Under-Secretary of State in the Department of Health and Social Care, Baroness Blackwood, provided further detail on the Government's position on Clinical Trials regulation, stating that the Government was:

> as part of EU exit negotiations […] working to ensure that we will continue to have the best possible environment to support clinical trials. Our overall aim is to ensure not only that patients in the UK have access to the best and most innovative medicines but that we improve UK trials applications—so that they continue to be authorised by the MHRA and ethics committees, as they are now—and that the UK's ability to participate in multinational trials will not change. We will also have a simpler way of allowing a single application to a single national decision in the UK, which we have been working on very hard.[181]

The Explanatory Notes state that **Clause 4(1)(a)** enables Regulations to be made which make provisions for "corresponding or similar to provision in the EU Clinical Trials Regulation if the Government were to choose to do so".[182] The remaining subsections on Clinical Trials allow provision to be made:

> (b) about authorisations concerning clinical trials in the United Kingdom, including applications for an assessment of the ethics of a proposed clinical trial,
>
> (c) about notification and reporting requirements in relation to clinical trials,
>
> (d) about requirements that must be met before a clinical trial may be carried out.

Subsection (1)(e) also allows provision to be made relating to the conduct of clinical trials. The Explanatory Notes state that this provision would enable the principles of 'good clinical practice', which clinical trials must be conducted in accordance with in the UK (as set out in Schedule 1 of the *Medicines for Human Use (Clinical Trials) Regulations 2004*), to be amended and updated.[183]

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179 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p16
180 HL Deb 15 January 2020 c813
181 HL Deb 15 January 2020 c815
182 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p16
183 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p16

The background briefing notes to the December 2019 Queen's Speech suggest that these provisions will be used to remove "unnecessary bureaucracy for the lowest risk clinical trials, to encourage rapid introduction of new medicines".[184]

Clause 5(1)(a) makes provision for fees to be charged when exercising a function conferred by the regulations made under Clause 1(1) of the Bill, the HMRs or the 2004 Clinical Trial Regulations, while **subsection (1)(b)** allows regulations to be introduced that make a failure to comply with regulations introduced by the Bill a criminal offence. In addition, **Clause 6** makes provision for the "disapplication" of certain regulatory requirements relating to human medicines during an emergency; namely when there is a need to protect the public from "a risk of serious harm to health".

Clause 5(1)(a) and Clause 6 are both subject to the negative procedure. The Delegated Powers Memorandum notes that the negative procedure for the charging of fees "mirrors the procedure for making regulations in relation to fees under section 1 of the Medicines Act 1971".[185] The application of the negative procedure for regulations relating to the supply of human medicines in emergencies (Clause 6) is stated in the Delegated Powers Memorandum to be appropriate on the grounds it will enable the regulations to "come into force immediately and provide an efficient means of addressing an imminent serious public health risk".[186] It is expected in the Memorandum that such regulations:

> would only need to be in place for a very short period of time, potentially shorter than it would take to schedule and hold debates, which is another reason why the negative procedure is most appropriate for these urgent regulations.[187]

184 HM Government, Queen's Speech December 2019: background briefing notes, 19 December 2019, p33
185 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p18-19
186 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p18
187 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p18

4. Veterinary Medicines

Part 2 of the Bill confers a delegated power to amend or supplement the Veterinary Medicines Regulations 2013.

4.1 Veterinary Medicines Directives and Regulations

Controls on the manufacture, authorisation, marketing, distribution and post-authorisation surveillance of veterinary medicines, applicable in all European Union Member States, were set out in the Veterinary Medicinal Products Directive 2001/82/EC (as amended). This EU Directive, along with others, was implemented in the UK, through section 2(2) of the *European Communities Act 1972* (ECA), as the Veterinary Medicines Regulations (VMR), which together govern the animal health industry. The VMRs consolidated all UK regulations pertaining to veterinary medicines. They are regularly amended, most recently in 2013 as the Veterinary Medicines Regulations 2013 , which came into force on 1 October 2013.[188] The VMRs help to ensure animal welfare as well as protecting the safety of "treated animals, people handling the medicines, consumers of produce from treated animals and the environment".[189]

4.2 Updating Veterinary Medicines Regulations

The purpose of **Clause 8(1)** is to give the "appropriate authority" delegated power to amend or supplement the Veterinary Medicines Regulations 2013 after the Transition Period. In England, Wales and Scotland, the appropriate authority is defined in **Clause 8(4)(a)** as the Secretary of State. In Northern Ireland it is the Department of Agriculture, Environment and Rural Affairs, either acting on its own or jointly with the Secretary of State. Part 2 of the Bill sets out the circumstances under which the appropriate authority could make such regulations, what factors they must consider before any changes could be made, and what provisions the regulations could cover.

The power under Clause 8(1) is further restricted to the provisions specified in **Clauses 9** and **10** of the Bill, namely:

- Manufacture, marketing, supply and field trials and;
- Fees, offences, powers of inspectors, costs.

Clause 8(2) also sets out three factors that the Secretary of State must consider when making regulations. They include:

a) the safety of veterinary medicines in relation to animals, humans and the environment;

b) the availability of veterinary medicines;

c) the attractiveness of the relevant part of the United Kingdom as a place in which to develop or supply veterinary medicines.

The Delegated Powers Memorandum states that the affirmative procedure is to be applied when making regulations under Clause 8(1), with the exception of regulations made in reliance on:

- clause 9(1)(f) – who can supply veterinary medicines;

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188 A detailed list of the EU Veterinary Medicines Regulations and Medicated Feed and Feedingstuffs Regulations can be found on the gov.uk website, see Veterinary Medicines Directorate, Guidance: Veterinary Medicines Regulations, 31 January 2020

189 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p7

- clause 9(1)(k) –the labelling and packaging of veterinary medicines clause;
- 9(1)(l) – the advertising of veterinary medicines;
- clause 10(1)(a) – charging of fees.[190]

Further discussion of these exceptions can be found below.

4.3 Manufacturing and marketing authorisation

A range of authorisations are required to manufacture, market and supply veterinary medicines. Much like medicines intended for humans, veterinary medicines must obtain a marketing authorisation (MA) before they can be sold and supplied. In the UK, the national competent authority and independent regulator, with the power to grant an MA, is the Veterinary Medicines Directorate (VMD). The VMD is responsible for conducting an independent scientific assessment to ensure that the medicine meets safety, quality and efficacy criteria. An authorised product will have the symbol 'Vm' on its product literature.

MAs can either be obtained through the national route, via the VMD, or through the 'centrally authorised product' route, whereby a single marketing-authorisation application is submitted to the European Medicines Agency (EMA).[191] The latter route allows the marketing-authorisation holder to market the medicine, and make it available throughout the EU, on the basis of a single marketing authorisation.[192] This route is mandatory for certain medicines, including:

- veterinary medicines for use as growth or yield enhancers;
- medicines derived from biotechnology processes, such as genetic engineering, and;
- advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines.[193]

Only a small percentage of veterinary medicines are authorised through the EMA. Speaking in a debate on Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019 in March 2019, Baroness Vere stated:

> Medicines approved by the EMA account for a small percentage of all veterinary medicines in the UK—about 13%. However, they are often novel treatments and substances and it is highly important that these medicines remain on the UK market.[194]

Those wishing to manufacture and distribute an authorised medicine must obtain a manufacturing authorisation (ManA) and comply with Good Manufacturing Practice (GMP). Further details can be found on the gov.uk website.[195] For those looking to sell or

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190 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p10

191 Veterinary Medicines Directorate, Guidance: Apply for a Marketing Authorisation for a veterinary medicine or expiry, 1 April 2019 [accessed on 24 February 2020]

192 Europeans Medicines Agency, Authorisation of Medicines [accessed on 21 February 2020]. For centrally authorised medicinal products, licenced through the European Medicines Agency, the marketing authorisation holder must be "established" in the EEA. Pharmaceutical companies with a marketing authorisation holder established in the UK have until 31 December 2020 to make the necessary changes to ensure the marketing authorisation is transferred to a holder in an EEA country, see European Medicines Agency, Brexit-related guidance for companies, not dated

193 Europeans Medicines Agency, Authorisation of Medicines [accessed on 21 February 2020]

194 HL Deb 20 March 2019, c 297GC

195 Veterinary Medicines Directorate, Guidance: Authorisations to manufacture veterinary medicines, 17 January 2020 [accessed on 24 February 2020]

supply medicines to anyone other than the end user, a 'wholesale dealer's authorisation' is also required.[196]

Clause 9(1) and its subsections set out the aspects of the manufacture, marketing and supply of veterinary medicines that can be covered in regulations made under Clause 8(1). It includes making provisions about different types of medicine authorisations, including marketing authorisations, manufacturing authorisations, authorisations to import veterinary medicines and wholesale dealing authorisations.

Clause 10(1)(a) covers the charging of fees when exercising functions conferred by the regulations, while **subsection (1)(b)** creates a criminal offence of failing to comply with the regulations made under Clause 8(1). Powers of entry and inspection by a VMR inspector, including recovering costs related to an inspection, are set out in the remaining subsections and in **Clause 10(2)**. These are not 'new' measures as such; the VMRs contain provision under Schedule 7 to charge fees, while powers of entry and criminal offences are covered under Regulations 34, 35 and 43.

Clause 10(1)(a) is subject to the negative procedure. The Delegated Powers Memorandum states that the@

> charging of fees is technical in nature and the Bill sets out the functions in respect of which the appropriate authority could be permitted to charge. The appropriate authority would also be required to consult before making these regulations.[197]

For these reasons, it is "the Department's view [that] the negative procedure would be appropriate for these regulations". [198]

4.4 The Cascade

Veterinary medicines are authorised for specific conditions and species. If, however, there is "no suitable veterinary medicine authorised in the UK for the specific condition in the animal being treated", vets are permitted to use their clinical judgement to treat animals under their care, to avoid that animal suffering.[199] This decision must be taken in accordance with "The Cascade". The Cascade is a risk-based decision tree which sets out the steps, in descending order of suitability, which should be followed, namely:

- a veterinary medicine authorised in the UK for use in another animal species, or for a different condition in the same species

If there is no such product that is clinically suitable, either:

- a human medicine authorised in the UK, or
- a veterinary medicine not authorised in the UK, but authorised in another member state for use in any animal species in accordance with the Special Import Scheme; in the case of a food-producing animal the medicine must be authorised in a food producing species

If there is no such product that is suitable:

- a medicine prescribed by the vet responsible for treating the animal and prepared especially on this occasion (known as an extemporaneous

196 Veterinary Medicines Directorate, Guidance: Veterinary medicine wholesale dealer's authorisation (WDA), 7 January 2020 [accessed on 24 February 2020]
197 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p22
198 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p22
199 Veterinary Medicines Directorate, The cascade: prescribing unauthorised medicines, 20 June 2019, [accessed on 24 February 2020]

> preparation) by a vet, a pharmacist or a person holding an appropriate manufacturer's authorisation (ManSA).[200]

The Explanatory Notes to the Bill suggest that a combination of **subsections 9(1)(a)**, **(1)(b)**, **(1)(d)** and **(1)(g)** could "be used to make provision to use a medicine outside the terms of its authorisation", as currently permitted under "The Casade".[201]

4.5 Classification and prescription of veterinary medicines

There are four different categories of authorised veterinary medicine, each with varying controls regarding who can prescribe and supply the medicine. The categories are:

a) Prescription-only Medicine – supplied only by a Veterinarian; abbreviated to POM-V;

b) Prescription-only Medicine – this category may be supplied by a Veterinarian, Pharmacist, Suitably Qualified Person (SQP); abbreviated to POM-VPS;

c) Non-Food Animal – these are medicines for companion animals and may be supplied by a Veterinarian, Pharmacist, Suitably Qualified Person; abbreviated to NFA-VPS; and,

d) Authorised Veterinary Medicine – General Sales List; abbreviated to AVM-GSL. These medicines have no supply restrictions in the VMR.[202]

Subsections 9(1)(f) and **9(1)(l)** allow provisions to be amended on who can supply veterinary medicines and the circumstances under which such medicines can be administered, while **Subsection 9(1)(h)** covers the registration of persons supplying veterinary medicines via the Internet. While a voluntary registration scheme, run by the VMD, is currently in operation[203], Subsection (1)(h) could, according to the Explanatory Notes, enable mandatory registration to be introduced.[204]

Subsection (1)(f) – categories of persons who may supply veterinary medicines – is subject to the negative procedure. The Delegated Powers Memorandum states that this is because:

> any proposals to make changes to existing powers or to introduce new powers for veterinary professionals to supply, administer or prescribe medicines will be subject to extensive consideration and scrutiny by professional bodies.[205]

4.6 Pharmacovigilance

Medicines and food safety

In the case of medicines that will be used in food-producing species, the application for an MA must also include "the proposed withdrawal period necessary to ensure that the maximum residue limits specified in Regulation (EC) No 470/2009 of the European

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200 Veterinary Medicines Directorate, The cascade: prescribing unauthorised medicines, 20 June 2019 [accessed on 24 February 2020]
201 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p18 [accessed on 24 February 2020]
202 Royal College of Veterinary Surgeons, Veterinary Medicines, 15 January 2020 [accessed on 21 February 2020]
203 Veterinary Medicines Directorate, Online list: Accredited internet retailer scheme (AIRS), not dated [accessed on 24 February 2020]
204 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p 20
205 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p22

Parliament and of the Council are not exceeded".[206] The 'Maximum Residue Limit' (MRL) for the 'active ingredient' in the medicine (the substance which gives the medicine a therapeutic effect) is the highest level of residue that does not pose a risk to the consumer. The withdrawal period is the "time that must elapse since the last treatment before the animal or its products can enter the food chain, which ensures any remaining residues are below the MRL".[207] Residue surveillance is undertaken by the VMD and also covers surveillance for prohibited substances and various contaminants. Results are published regularly by the VMD.[208]

Adverse events

In addition to residue surveillance, the VMD is responsible for monitoring the safety and efficacy of a medicine after it has been authorised. This includes monitoring, and receiving reports of, adverse events, a summary of which is published in the Veterinary Pharmacovigilance in the UK Annual Review.[209] The most recent Annual Review reported that, during 2018, the VMD:

> received and assessed 7,159 adverse event reports. This was an increase of 6.5% on the previous year, compared to 2.5% from 2016 to 2017. As a result of the adverse event information received; veterinary pharmaceutical companies improved the product literature of 50 products.[210]

Provisions relating to post-authorisation surveillance, the labelling, packaging and advertising of medicines are set out in subsections **(9)(1) (j), (k)** and **(l)** respectively of the Bill. The Explanatory Notes indicate that the provision on advertising veterinary medicines "could […] allow an inclusion of a definition of advertising to provide clarity to industry and improve compliance with the Regulations".[211]

Subsections (1)(k) and (1)(l) are both subject to the negative procedure. The Delegated Powers Memorandum states that "detailed requirements" for the labelling and packaging of veterinary medicines are already set out in Schedules 1 and 2 of the VMR and that it is therefore suggested that the:

> negative procedure will provide Parliament with the appropriate level of oversight on changes to labelling and packaging requirements; this would also not take up unnecessary parliamentary time.[212]

Similar reasoning is also set out in the Delegated Powers Memorandum as to why regulations made concerning the advertising of veterinary medicines should be subject to the negative resolution procedure.[213]

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206 Schedule 1, Marketing authorisations, The Veterinary Medicines Regulations 2013
207 National Office of Animal Health, Controls on veterinary medicines, May 2016 [accessed on 24 February 2020]
208 Veterinary Medicines Directorate, Residues: Statutory Surveillance Results 17 April 2019 [accessed on 24 February 2020]
209 Veterinary Medicines Directorate, Veterinary Pharmacovigilance in the UK Annual Review 2018, 20 February 2020
210 Veterinary Medicines Directorate, Veterinary Pharmacovigilance in the UK Annual Review 2018, 20 February 2020, p2
211 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p20 [accessed on 24 February 2020]
212 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p22
213 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p22

4.7 New EU regulations

Two EU Regulations, put forward as part of legislative package on improving animal and human health, entered into force on 27 January 2019 and will apply from 28 January 2022, after the Transition Period has ended. Regulation (EU) 2019/4 on the 'manufacture, placing on the market and use of medicated feed', aims to ensure that medicated feed can only be manufactured from specifically authorised veterinary medicines and by approved manufacturers. EU wide residue limits for veterinary medicines in ordinary feed are also established at a limit which aims to avoid the development of antimicrobial resistance.[214]

Regulation (EU) 2019/6 on 'veterinary medicinal products' aims to make more medicines available in the EU to treat and prevent diseases in animals through simplifying procedures for obtaining a marketing authorisation, and reviewing incentives for breakthrough medicines.[215] **Clause 9(2)** of the Bill provides the means to make "corresponding or similar provision" to both these EU regulations.

[214] European Sources Online (Cardiff University), Regulation (EU) 2019/4 on the manufacture, placing on the market and use of medicated feed, 7 January 2019 [accessed on 24 February 2020]

[215] European Sources Online (Cardiff University), Regulation (EU) 2019/6 on veterinary medicinal products, 7 January 2019 [accessed on 24 February 2020]

5. Medical Devices

Part 3 of the Bill covers medical devices and confers a delegated power to amend or supplement the *Medical Devices Regulations 2002*.

A medical device is any instrument (other than a medicine) that is used to diagnose or manage a medical condition. The definition covers a wide range of products including syringes, dressings, surgical tools, scanners and some medical apps. A more detailed definition of a medical device is set out in Article 1.2 of Directive 93/42/EEC (as amended) and is used in the UK Medical Devices Regulations. This defines a medical device as:

> any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination [...] for the purpose of:
>
> - diagnosis, prevention, monitoring, treatment or alleviation of disease
> - [...] alleviation of or compensation for an injury or handicap,
> - investigation, replacement or modification of the anatomy or of a physiological process,
> - control of conception.[216]

In 2011, an article published in the British Medical Journal estimated that there were approximately 80,000 different types of devices on the market in the UK and over 200,000 across Europe.[217]

5.1 EU Medical Device Directives

Much of the regulation of medical devices in the UK derives from EU legislation. The regulatory procedures for medical devices are currently set out in the *Medical Devices Regulations 2002* (as amended) which implemented into domestic legislation (through section 2(2) of the European Communities Act 1972) the following three EU Directives :

- Medical Devices Directive (93/42/EEC) (as amended by 2007/47/EC)
- Active Implantable Medical Devices Directive (90/385/EEC); and
- In Vitro Diagnostic Medical Devices Directive (98/79/EC).[218]

Some aspects of the General Product Safety Regulations 2005 also apply to devices that are consumer products.

In April 2017, two new EU regulations were adopted by the European Parliament and the Council. Regulation (EU) 2017/745 will regulate general medical devices and will apply after a 3 year transition period, and Regulation (EU) 2017/746 will regulate in vitro diagnostic medical devices and will apply after 5 years. Together, these EU regulations will replace and consolidate all previous EU Directives on medical devices. The European Commission website provides information about the changes introduced by the new Regulations:

> The new Regulations contain a series of extremely important improvements to modernise the current system. Among them are:

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216 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Article 1, subsection 2(a)
217 Cohen D, Billingsley M. Europeans are left to their own devices. BMJ 2011;342(d2748).
218 In vitro diagnostics (IVDs) are a subset of medical devices. They are used to test samples that have been taken from the human body, such as blood, urine and tissue and can assist with diagnosing a condition or disease. IVDs can also be used to monitor and manage a treatment.

- stricter ex-ante control for high-risk devices via a new premarket scrutiny mechanism with the involvement of a pool of experts at EU level;
- the reinforcement of the criteria for designation and processes for oversight of Notified Bodies;
- the inclusion of certain aesthetic devices which present the same characteristics and risk profile as analogous medical devices under the scope of these Regulations;
- the introduction of a new risk classification system for in vitro diagnostic medical devices in line with international guidance;
- improved transparency through the establishment of a comprehensive EU database on medical devices and of a device traceability system based on Unique Device Identification;
- the introduction of an "implant card" containing information about implanted medical devices for a patient;
- the reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorisation of multi-centre clinical investigations
- the strengthening of post-market surveillance requirements for manufacturers;
- improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance.[219]

Regulation (EU) 2017/745, which covers all general medical devices, will apply across the EU and in the UK from 26 May 2020. Regulation (EU) 2017/746 will apply across the EU from 26 May 2022. The Explanatory Notes to the Medicines and Medical Devices Bill acknowledge that the in vitro diagnostic medical devices regulations are not expected to apply in the EU until after the end of the Transition Period, meaning that it "will not form part of EU retained law".[220] The Explanatory Notes also state that the UK "will need to make its own decisions about the future regulation of IVDs using the powers proposed in the Bill".[221]

5.2 Updating medical device regulations

To enable the *Medical Devices Regulations 2002* to be updated after the Transition Period, **Clause 12(1)** gives the Secretary of State a delegated power to amend or supplement these Regulations. This power is subject to restrictions: **Clauses 13 to 15** of the Bill specify the matters relating to medical devices that regulations made under Clause 12(1) can cover. They are:

- the manufacture, marketing and supply of medical devices (Clause 13)
- fees, information and offences (Clause 14)
- emergencies (Clause 15)

Clause 12(2) also sets out three factors that the Secretary of State must consider when making regulations, namely the:

> (a) safety of medical devices;
>
> (b) availability of medical devices;
>
> (c) attractiveness of the United Kingdom as a place in which to develop or supply medical devices.

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219 European Commission "New Regulations" [accessed on 24 February 2020]
220 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p8
221 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p8

The Delegated Powers Memorandum states that the power in Clause 12(1) will give the Secretary of State the "ability to keep pace with [technological] advances and adapt and improve the medical devices regulatory regime accordingly" while also:

1. maintain[ing] acceptable levels of safety for the public;
2. maximis[ing] the accessibility of medical devices; and
3. keep[ing] the UK as an attractive place to develop and market medical devices so as to retain its strong life sciences sector.[222]

5.3 Assessing and certifying the safety of medical devices

The current Medical Devices Regulations 2002 place obligations on the manufacturers of those device to ensure that the products are safe and fit for purpose. Under these regulations, a medical device must be 'CE' (Conformité Européenne) marked before it can be sold anywhere in the EU. The letters "CE" on a product which is traded in the EU and EEA signifies that it has been assessed to meet safety, health and environmental protection requirements. The requirements vary according to the 'class' of the medical device; Class I devices represent the lowest risk and Class III devices the highest risk. By affixing the CE marking to a product, a manufacturer declares that the product meets all the legal requirements for CE marking for its class and can be sold throughout the EU and EEA.

The certification process is different for each class of device; guidance on the classification and certification process is provided by the European Medicines Agency. Higher-risk devices (such as Class IIa, IIb and III medical devices and in vitro diagnostic devices in list A and list B in Annex II of the EU Directive, plus those for self-testing) must also be certified by an independent conformity assessment body, called EU Notified Bodies.

A notified body is a privately-run organisation that has been designated by an EU Member State to assess whether manufacturers and their medical devices meet the requirements set out in legislation.[223] There are currently around 50 notified bodies in the EU - five of these are in the UK.[224] The designating authority in the UK is the MHRA, acting on behalf of the Secretary of State. The MHRA "administers and enforces the law on medical devices in the UK" and has a "range of investigatory and enforcement powers to ensure their safety and quality".[225]

The provision to amend and update the manufacturing, marketing and supply requirements that medical devices must meet before being put into service are set out in **Clause 13(1)**. The Clause includes provisions for:

> (i) requirements in terms of design, manufacture, composition or other characteristics of the devices, or
>
> (ii) requirements imposed on persons involved in marketing or supplying the devices,

The subsections of Clause 13(1) make provision for the assessment of medical devices to ensure they comply with regulatory requirements. They include the power to evaluate, investigate and monitor device safety, performance and clinical effectiveness. **Subsection (1)(h)** also creates a provision to establish and maintain a register of medical devices,

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222 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p25

223 Medicines & Healthcare products Regulatory Agency, Guidance: Notified bodies for medical devices, 29 January 2020 [accessed on 24 February 2020]

224 BSI, Want to know more about the Notified Body?, December 2018 [accessed on 24 February 2020]

225 Medicines and Healthcare products Regulatory Agency, Guidance: Medical devices: the regulations and how we enforce them, 26 February 2019

alongside the ability to make some or all of the information held on the register publicly available.

Clause 14 covers the charging of fees when assessing medical devices, as well as the collection and recording of information about device safety and quality and to whom that information may be disclosed.

Clause 15 enables regulations to be made under Clause 12(1) that relate to the supply of a medical device in an emergency. It makes provision for the "disapplication" of certain regulatory requirements if there is a need to "protect the public from a risk of serious harm to health".

The Delegated Powers Memorandum states that the affirmative procedure is to be applied when making regulations under Clause 12, with the exception of two clauses where the negative procedure applies:

a) clause 14(1)(a) – charging of fees

b) clause 15 - supply etc of medical devices in emergencies, where they contain a declaration that they need to be made urgently.[226]

Regarding the charging of fees, the Delegated Powers Memorandum states that any amendments are likely to be "minor updates" and:

> therefore the negative resolution procedure would provide Parliament with the appropriate form of oversight that would not unnecessarily take up Parliamentary time.[227]

It adds that any regulations made relying only on Clause 15 should also be subject to the negative procedure. This is on the grounds that, during a public health emergency, regulations need to be made "as quickly as possible":

> The negative resolution procedure will enable regulations to be made and brought into force immediately if the regulations were required to protect the public in an emergency. We also expect that such regulations would only need to be in place for a very short period of time, potentially shorter than it would take to schedule and hold debates, which is another reason why the negative procedure is most appropriate for these urgent regulations.[228]

If regulations made under Clause 15 do not contain a declaration about their urgency, the Delegated Powers Memorandum states that they will be subject to the affirmative procedure.[229]

5.4 The MHRAs enforcement powers

The Medicines and Healthcare products Regulatory Agency (MHRA) is the competent authority in the UK for monitoring the safety of medical devices through post marketing surveillance and vigilance. It explains its current responsibilities regarding this role on its website:

> To ensure that medical devices placed on the market and put into service in the UK meet [the] regulatory requirements we perform the following activities:

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226 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p11

227 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p26

228 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p25-26

229 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p26

- assess all allegations of non-compliance brought to us, using a risk-based system.
- monitor the activity of notified bodies designated by MHRA to assess the compliance of manufacturers
- investigate medical devices as a result of adverse incident reports or intelligence indicating a potential problem
- carry out proactive risk-based projects with other member states in Europe to identify emerging risks.[230]

The MHRA has investigatory and enforcement powers under the Consumer Protection Act 1987, the Medical Devices Regulations 2002 and General Product Safety Regulations 2005 to ensure the safety and quality of medical devices. Enforcement powers are exercised through the issuing of 'notices' which may, for example, prohibit or suspend the supply of products that do not comply with the regulations. Further information on the different types of notices that can be issued is set out on the MHRA's website.

The purpose of **Part 3, Chapters 2 and 3** of the Bill is to consolidate the enforcement regime for medical devices. As noted above, the MHRA's current enforcement powers are set out in multiple pieces of legislation. The Explanatory Notes to the Bill state that the:

> structure of these legislative powers does not enable the MHRA to operate efficiently or provide clarity to UK and international manufacturers on the operation of its enforcement regime.[231]

The consolidation of powers is, according to the Explanatory Notes, intended to "significantly improve the MHRA's ability [to] promote and support industry compliance" while also providing industry with "clarity and certainty regarding legal obligations".[232]

Chapter 2 also provides the Secretary of State with new powers to impose civil sanctions for breaches of the *Medical Devices Regulations 2002* which, the Explanatory Notes state, would offer an alternative to criminal prosecution.[233]

Enforcement notices

Clause 16 gives the "enforcement authority" the power to issue a "compliance notice" on "a person involved in marketing or supplying a medical device" when it is suspected that the person is "not complying with a medical devices provision". Detail is provided in **Clause 16(2)** on who the notice can be issued to and what information it must contain.

Clauses 17, 18 and **19** outline three other types of notices: suspension notices, safety notices and information notices respectively. A suspension notice will suspend the availability of the device. A safety notice imposes "prohibitions or requirements that the enforcement authority considers necessary to restrict the availability of a medical device in order to protect health or safety". An Information Notice requires a person to provide information that the enforcement authority will then use to decide whether to issue or revoke a compliance, suspension or safety notice.

Clauses 20 and **22** outline the process through which those subject to a notice can challenge this via the courts. **Clause 20** and its subsections provide a procedure to apply to an "appropriate lower court" (defined in **Clause 37** as a magistrates' court in England and Wales, the Sheriff in Scotland and a court of summary jurisdiction in Northern Ireland) to set aside a notice or vary its provisions. The circumstances under which each type of

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230 Medicines & Healthcare products Regulatory Agency, Guidance: Medical devices: the regulations and how we enforce them, February 2019
231 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p9
232 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p25
233 HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p9

notice could be varied or set aside are also outlined. For those whose compliance, suspension or safety notices have been varied or set aside, **Clause 21** provides for the ability to apply to an appropriate lower court for compensation. A provision to appeal against a decision, following an application made under section 20(1), is laid out in **Clause 22**.

Offences

Clause 23 makes it an offence to breach an enforcement notice, while the subsections set out the maximum conviction a person may receive if found guilty of an offence, namely:

a) on summary conviction in England and Wales, to imprisonment for a term not exceeding 51 weeks, to a fine or to both;

b) on summary conviction in Scotland or Northern Ireland, to imprisonment for a term not exceeding 6 months, to a fine not exceeding level 5 on the standard scale or to both.

Clause 24 provides for a defence of "due diligence" to those charged with an offence under section 23 if they took "all reasonable steps" to avoid committing the offence. If an offence is proved to have been committed under section 23 by a corporate body, **Clause 25** outlines the circumstances under which an "officer" (eg a director, manager, secretary) of the body may be liable to be proceeded against.

Civil Sanctions

Clause 26 of the Bill makes provision for civil sanctions – notably the imposition of a monetary penalty – that will be applicable to any person committing an offence in relation to medical devices. **Schedule 1** sets out how the civil sanctions regime will operate. It also includes a requirement under paragraph 13(1) for the Secretary of State to publish guidance regarding the sanctions that may be imposed under section 23 (or under regulation 60A of the Medical Devices Regulations 2002 – see below), as well as a requirement under paragraph 15(1) to publish reports, "from time to time", about the uses of the powers contained in Schedule 1.

Paragraph 9 of Schedule 1 gives the Secretary of State the power to make supplementary regulations regarding the operation of the civil sanctions regime. It is subject to the negative procedure. The Delegated Powers Memorandum states that the power will:

> ensure that the new civil sanctions regime can be supplemented with more detailed provision setting out procedural steps and relevant appeals processes, so that it functions appropriately and can be updated accordingly.[234]

Under **Clause 40** the relevant authority is required to consult before making regulations under Paragraph 9 of Schedule 1 (see section 7.2 below for further detail).

Schedule 2 inserts "60A offence of breaching certain provisions" into the Medical Devices Regulations 2002, together with a definition of what constitutes an offence, the maximum penalty a person may be subject to if found guilty of an offence, the provision to use the defence of due diligence, and offences committed by bodies corporate (as also covered in Clauses 23 to 25 of the Bill). The Delegated Powers Memorandum states that making these amendments to the Medical Devices Regulations 2002 will ensure "that future regulations made under clause 12(1) do not fall outside of the criminal offence

[234] Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p12

framework".[235] Part 2 of Schedule 2 lists the regulations of which a breach would constitute an offence.

Forfeiture, recall and detaining medical devices

Clause 27 gives the enforcement authority the power to apply to a lower court for a forfeiture order, and sets out how this process should be handled, if there has been a breach of a medical devices provision. As a last resort, and where there are no alternative intermediate steps to protect health and safety, **Clause 30** outlines the circumstances under which a medical device could be recalled by an enforcement authority, while **Clause 31** sets out the power of a customs officer to temporarily detain a medical device for the purpose of an enforcement officer to exercise a function under Part 3 of the Bill, or under Schedule 5 to the Consumer Rights Act 2015.

Commenting on the enforcement provisions, the law firm Mills & Reeve stated that introducing:

> a method for affected individuals to bring civil proceedings if they are affected by a breach of medical devices legislation [...] raises the prospect of a clear path to damages claims, without resorting to general product safety legislation.[236]

5.5 Disclosure of information

Chapter 3 creates a new power for the Secretary of State to share information on medical devices and sets out the circumstances under which this information could be disclosed. Such occasions include warning the public about safety concerns relating to a medical device (**Clause 34(1)**), civil and criminal proceedings (**Clause 34(4)**) and sharing information specifically with "a person who provides services or exercises functions relating to medical devices" (**Clause 34(2)**). **Clause 34(5)** places restrictions on the disclosure of "commercial sensitive information" by the Secretary of State while **Clause 34(8)** makes clear that disclosures must not contravene data protection legislation or the Investigatory Powers Act 2016.

5.6 Independent Medicines and Medical Devices Review

On 21 February 2018, the then Secretary of State for Health and Social Care, the Rt Hon Jeremy Hunt MP, announced a review into how the health system responds to reports from patients about harmful side effects from medicines and medical devices.[237] The review is particularly examining the cases of Primodos (a hormone-based pregnancy test), sodium valproate (a drug used to treat epilepsy and bipolar disorder) and pelvic mesh. Within the scope of the review is:

- the robustness, speed and appropriateness of those processes and actions followed by the relevant pharmaceutical/ medical device manufacturers and applicants for and holders of licenses to manufacture and sell pharmaceutical products and medical devices, the regulatory authorities, healthcare providers, public and clinical bodies and policy makers;
- whether problems could have been recognised by the relevant bodies, authorities, manufacturers and license holders and others sooner and more effectively;

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235 Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p59

236 Mills & Reeve, UK life sciences regulation begins to diverge - the Medicines and Medical Devices Bill, 20 February 2020 [accessed on 24 February 2020]

237 HC Deb 21 February 2018, c165

- whether the same bodies could, and should, have acted upon concerns sooner and if they did not, the reasons why.[238]

The Review is Chaired by Baroness Cumberlege. It was originally scheduled to publish its report on 24 March 2020 but was subsequently delayed until 8 July 2020 due to Covid-19. Further information, including detailed terms of reference, can be found on the Review's website.

5.7 Criticisms of existing medical device regulations

Prior to the introduction of the new EU medical device regulations, which entered into force in May 2017, the limits of the existing regulations had been subject to repeated criticism. An overview can be found in the 2011 BMJ article "Europeans are left to their own devices" which compares the EU with the US system of medical device regulation. Giving evidence before the House of Representatives subcommittee on Health in February 2011, the Director of the Center for Devices and Radiological Health at the Food and Drug Administration, Dr Jeffery Shuren, called particular attention to what he saw as the limitations of the EU's reliance on 'notified bodies' to review the safety of a medical device:

> The EU lacks the requirement in U.S. law that devices be shown effective. Device manufacturers in Europe select from a list of private companies for safety reviews and pay the chosen company for that review. The result is a European review process that does not have adequate public accountability, consistency, and transparency and is thus almost impossible to compare directly with FDA's. This is in part why the European Commission has proposed that the EU regulatory framework be strengthened to better meet European public health expectations and to make European industry more competitive globally.[239]

Medical device regulation more generally – rather than EU specific – has also been criticised. In November 2018, *The Guardian* reported on an investigation it had undertaken with "organisations including the BBC, Le Monde and Süddeutsche Zeitung, coordinated by the International Consortium of Investigative Journalists (ICIJ)" on the global medical device industry. It reported that:

> Patients around the world are suffering pain and many have died as a result of faulty medical devices that have been allowed on to the market by a system dogged by poor regulation, lax rules on testing and a lack of transparency.[240]

In the case of the UK, a freedom of information request to the Medicines and Healthcare products Regulatory Agency (MHRA) identified that:

> 62,000 "adverse incident" reports linked to medical devices had been received between 2015 and 2018. More than 1,000 of these incidents had resulted in death.[241]

The report questioned "the level of scrutiny devices undergo before and after they go on the market, and whether regulators detect and act upon findings quickly enough". [242] Commenting on the findings, the Chair of the Independent Medicines and Medical

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238 The Independent Medicines and Medical Devices Safety Review, Terms of Reference [accessed on 19 February 2020]

239 "Impact of Medical Device Regulation On Jobs And Patients" – Hearing Before the Subcommittee on Health of the Committee on Energy and Commerce, House Of Representatives, One Hundred Twelfth Congress, First Session, February 17, 2011

240 'Revealed: faulty medical implants harm patients around world', The Guardian [online], 25 November 2018 [accessed on 19 February 2020]

241 Safety regulations for medical implants condemned by review chair, The Guardian [online], 26 November 2018 [accessed on 19 February 2020]

242 'Revealed: faulty medical implants harm patients around world', The Guardian [online], 25 November 2018 [accessed on 19 February 2020]

Devices Review, Baroness Cumberlege, stated that "patients certainly can't rely on that system [...] If you look at the regulation of medicines, it's pretty strict. We know it takes nine years for a medicine … to be brought to market [...] With devices, that rigour is not there." [243]

Much of the recent criticism of existing medical device regulations has occurred against the backdrop of growing concerns about the safety and effectiveness of surgical mesh implants. In July 2018, following the evidence it had heard, the Independent Medicines and Medical Devices Safety Review called for the immediate halt of the use of surgical mesh in stress urinary incontinence procedures.[244]

The Government accepted this recommendation and said the pause should also apply to vaginally inserted mesh to treat pelvic organ prolapse. Halts in the use of mesh in Scotland, Wales and Northern Ireland are also in place. For further information see the House of Commons Library Briefing Paper on Surgical Mesh Implants.

During a debate on the Licensing of Medical Devices in February 2019, which touched upon the case of surgical mesh, the then Under-Secretary of State for Health, Jacqui Doyle-Price MP, stated that there was clearly a "need to improve the existing system of regulation" for medical devices:

> The hon. Gentleman has highlighted some of the weaknesses. It is fair to say that perhaps in the past regulation has focused excessively on what is in the commercial interests of businesses to maintain competition, rather than having patient safety at its heart; I think that, when it comes to medical regulation, it should have that at its heart. Naturally, he referred to mesh, which he and I have discussed many times before. There is no doubt that mesh has transformed the lives of some women when they were living with the debilitating consequences of stress incontinence, but it is becoming clear that mesh was deployed far too insensibly—far too many women were given this treatment, often at comparatively young ages, given that this was going to stay in their body for a long time.[245]

The Minister highlighted the new EU regulations for medical devices, adding that the Government was:

> confident that the regulation will drive system-wide improvement, including to the levels of clinical data mandated before products can be placed on the market. That will establish a strong and improved baseline for any system we implement after our departure from the EU. These changes to our system will place more stringent requirements on those manufacturing and supplying medical devices and will enhance the MHRA's market surveillance responsibilities, resulting in clearer obligations to conduct inspections and the ongoing safety monitoring of devices.[246]

The Safety of Medicines and Medical Devices was also the subject of a debate moved by Lord O'Shaughnessy, a former Health Minister, in the House of Lords in February 2019. He identified "an innate tension between innovation and safety", particularly in the context of medical devices, and stated that it was:

> imperative that the Government support the MHRA and other agencies to use technology and other innovations to improve post-licensing surveillance of medicines and medical devices.[247]

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243 Safety regulations for medical implants condemned by review chair, The Guardian [online], 26 November 2018 [accessed on 19 February 2020]

244 'Independent Review calls for immediate halt of the use of surgical mesh for stress urinary incontinence', The Independent Medicines and Medical Devices Safety Review 'News', 10 July 2018

245 HC Deb 12 February 2019, c862

246 HC Deb 12 February 2019, c863

247 HL Deb 28 February 2019, c330

Lord Bethell highlighted a briefing he had received from Professor Derek Alderson, President of the Royal College of Surgeons, about:

> the rising use of medical devices and the urgent need for a unified national medical devices registry to make it easier to keep track of what products are on the market and to measure performance and issues.[248]

He added that the Government "would be wise to support" such a registry.[249]

Responding for the Government, the Parliamentary Under-Secretary of State in the Department of Health and Social Care, Baroness Blackwood, stated that the Government was:

> fully committed to a system of regulation for medicines and medical devices which intelligently provides access to new, innovative and world-leading products to improve the lives of millions of patients—especially those with diseases that are rare and hard to treat—while simultaneously protecting UK patients from harm, and ensuring that patient voices are heard loudly and clearly throughout the system if something does go wrong.[250]

In its press release, following the publication of the Bill, the Government stated that the Medicines and Medical Devices Bill will:

> allow the government to ensure medical devices are subject to the highest standards of regulation, further boosting patient safety and ensuring the UK leads the way in developing pioneering health technology. With a faster, more flexible system in place, regulators will be able to respond to changes in technology or patient safety concerns as soon as possible.
>
> Companies will need to register medical devices with the Medicines and Healthcare products Regulatory Agency (MHRA), ensuring suppliers follow strict safety checks and enabling tough enforcement action if something goes wrong.
>
> The Health and Social Care Secretary will be given the power to disclose specific information about devices to members of the public and the healthcare system, subject to appropriate safeguards, when there are serious patient safety concerns.[251]

248 HL Deb 28 February 2019, c343
249 HL Deb 28 February 2019, c343
250 HL Deb 28 February 2019 c362
251 New bill gives hospitals power to develop personalised treatment, gov.uk, 13 February 2020 [accessed on 19 February 2020]

6. Regulations under Parts 1,2 and 3

6.1 Territorial extent of the Bill

The Bill extends to England and Wales, Scotland and Northern Ireland. Parts 1 and 2 of the Bill (human and veterinary medicines, including clinical trials of human medicines), however, relate to matters that sit within the legislative competence of the Northern Ireland Assembly. The Explanatory Notes to the Bill state that "a legislative consent motion is being sought from the Northern Ireland Assembly in respect of those Parts."[252] **Clause 39** defines the scope of the powers in relation to Northern Ireland while **Clause 41** sets out the procedure for making regulations under section 1(1), 8(1),12(1) or paragraph 9 of Schedule 1. Subsections 3 and 4 of Clause 41 provide for the affirmative procedure in each House of Parliament, and in the Northern Ireland Assembly respectively.

6.2 Consultation

Before exercising the delegated powers under Clauses 1(1), 8(1) and 12(1) and paragraph 9 of Schedule 1, **Clause 40** sets out a statutory requirement to consult with appropriate persons. Exceptions to this requirement are set out in subsection 2, which lists the following as instances where the duty to consult does not apply:

> where regulations contain only provision made in reliance on clause 6(1) (disapplication of provisions relating to human medicines where there is a risk of serious harm to health), or clause 15(1) (disapplication of provisions relating to medical devices where there is a risk of serious harm to health) and if they contain a declaration that they need to be made urgently.[253]

[252] HM Government, Medicines and Medical Devices Bill: Explanatory Notes, February 2020, p11
[253] Medicines and Medical Devices Bill: Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, February 2020, p 9

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