Memorandum submitted to the House of Lords Delegated Powers Committee

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Written evidence submitted to the House of Lords Delegated Powers Committee by Professor Muireann Quigley, Professor Jean McHale, Dr Rachael Dickson, and Dr Laura Downey at the University of Birmingham

Executive Summary

- The sudden reappearance of Medicines and Medical Devices Bill on the parliamentary agenda in the House of Commons was problematic. The extremely short deadlines for amendments and the consideration of evidence at Committee stage, and the speed with which the Bill passed through the House once re-introduced, has risked inadequate scrutiny of a Bill which proposes broad changes and powers in relation to important areas of the law.
- The House of Lords now has the opportunity to ensure that the Bill receives adequate and detailed scrutiny, and we urge Members to take this.
- The Bill in its current form provides for extensive delegated powers in major policy areas. These should be time-limited. We suggest sunset clauses regarding the powers contained in the Bill.
- The existing regulatory regime for medicines and medical devices has become complex and unwieldy. Primary legislation which consolidates regulation on each these areas is needed. A requirement to introduce this should be included in the Bill.
- With respect to the previous two points, we recommend new sunset clauses creating time limits on all three areas of delegated powers. This should also be accompanied by requirements for new primary legislation covering (1) medicines and veterinary medicines and (2) medical devices.
- A key concern with the Bill is patient safety. This must be prioritised, including in situations where there are competing considerations such as "attractiveness of the UK" as to the conduct of clinical trials and supply of medicines and medical devices.
- The Bill refers to Northern Ireland separately from the rest of the UK in relation to medicines. Medicines are a devolved issue for Northern Ireland which means there may be potential for future regulatory divergence between Northern Ireland and the rest of the UK. We recommend new clauses to be inserted in the Bill to mitigate the potential for regulatory divergence.

Introduction

1. Professor Quigley and Dr Dickson are currently working on a Wellcome Trust funded project investigating how the law should take account of and regulate (smart) medical devices.
2. Professor McHale carries out research in the area of health law and recently was the principal investigator on a two-year ESRC funded project on health law outside the EU.
3. Dr Downey is conducting research on the development and use of innovative medical devices and, in particular, software as medical devices. She is also working on issues relating to the Bill as part of an ESRC funded Impact Acceleration Award.
4. The Medicines and Medical Devices Bill confers on the Secretary of State an extensive range of powers to make regulations pertaining to medicines, clinical trials, and medical

devices. As such, the potential for the Secretary of State to make changes to important areas of law and public policy is wide-ranging and far-reaching.

5. It is, therefore, essential that adequate scrutiny is given to the different parts of the Bill and to the issues we highlight in this submission.

Risk of inadequate scrutiny

6. The Bill appeared on the Parliamentary agenda with little notice in February 2020. Following its pause due to the Covid-19 pandemic, the Bill resumed in June 2020 with little notice and extremely tight deadlines for amendments.

7. As a result, the ability afforded to Members of the House of Commons to consider the proposed provisions, conduct research, and table amendments was limited. As such, there is real risk of inadequate scrutiny on a very important set of areas that are, individually and collectively, subject to complex regulation.

8. The House of Lords now has the opportunity to ensure that the Bill receives adequate and detailed scrutiny, and we urge Members to take this.

Time-limiting delegated powers

9. The Bill confers an extensive range of delegated powers to make regulations in relation to medicines and medical devices, including in relation to manufacturing, marketing and supply; falsified medicines; clinical trials, fees, information and offences; and emergency situations.

10. As noted in the House of Commons Library briefing paper (Number CBP-8699), 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."

11. However, whilst delegated powers may be needed to ensure responsiveness to deal with the EU exit transition period and to meet the challenges of technological change, they should not be used indefinitely or relied on to implement matters of policy.

12. A recent report of the House of Lords Select Committee on the Constitution (The Legislative Process: The Delegation of Powers) recommended that whilst delegated powers are appropriate 'to make provision for minor and technical matters . . ., [i]t is essential that primary legislation is used to legislate for policy and other major objectives.'

13. The risk of delegations that provide significant flexibility is that policy is *amended* by secondary legislation and not merely *implemented.* As uncertainty continues with regards the UK's future relationship with the EU in the areas covered in the Bill, this risk may be exacerbated.

14. Further, the constitutionality of seeking delegated powers when substantive policy decisions have not been taken was questioned by the Committee. Given the disruption to regular Government work due to Covid-19, particularly in the Department of Health and

Social Care, and the rushed approach to passing the Bill, we are concerned the Bill could give rise to problems in the future.

15. The Committee held that both Bills and Statutory Instruments should be sufficiently clear so that guidance need not be relied upon to interpret the legislation. The lack of detail in the Bill in its current form could lead to uncertainty amongst stakeholders as to their obligations. Any guidance published *ex post facto* would not undergo the same Parliamentary scrutiny as the Bill, which is problematic.

16. The Committee advises that the publication of draft statutory instruments alongside Bills assists proper scrutiny and indicates how any delegated powers could be used. The Government has not provided any such drafts in relation to the current Bill.

17. To address this, and to ensure that delegated powers in all three parts are time-limited, we urge members to consider new clauses in Parts 1, 2, and 3. These can be found in the appendix at the end of this document.

Patient and user safety

18. The Bill states that the appropriate authority must have regard to the "attractiveness of the relevant part of the United Kingdom" as a place in which to conduct clinical trials or supply medicines (Part 1), develop or supply veterinary medicines (Part 2), and develop or supply medical devices (Part 3). However, there is no definition in the Bill as to what "attractiveness" means.

19. The Independent Medicines and Medical Devices Safety Review (Cumberlege Review), published on 8 July 2020, focused on safety issues with just 3 three medical interventions: Primodos, sodium valproate, and pelvic mesh. Along with these, other recent scandals, such as those relating to DePuy metal-on-metal hips and PIP breast implants, show the need for strong regulatory oversight.

20. Patient safety must be prioritised, including in situations where there are competing considerations such as "attractiveness of the UK" as to the conduct of clinical trials and supply of medicines and medical devices.

21. To address this, the attractiveness clauses should either be removed or a statutory definition of attractiveness should be included, along with a further provision that the appropriate authority should always prioritise safety. Suggested amendments can be found in the appendix at the end of this document.

Northern Ireland and potential regulatory divergence

22. In relation to medicines, the Bill refers to Northern Ireland separately from England, Wales, and Scotland. Medicines are a devolved power, whilst medical devices are not. Clauses 1(3) and 1(4) confer the power to enact separate regulations with regards to Northern Ireland, with the prospect of a separate weighing of the 'attractiveness' criterion. This raises the important question of whether in the future, without the

requirement to implement EU law, there could be heightened regulatory divergence between Northern Ireland and the rest of the UK in the area of medicines regulation.

23. The situation regarding regulatory alignment/divergence in Northern Ireland is politically charged and so the Bill must explicitly deal with these issues to avoid future uncertainty.

24. Suggested amendments to deal with this can be found in the appendix at the end of this document.

Stream-lined legislation

25. The existing regulatory framework concerning medicines and medical devices is complex and unwieldy.

26. In relation to medical devices it consists of:

- The *Medical Devices Regulations 2002 (SI/2002/618)*, implementing three different EU Directives (Directive 90/385/EEC, Directive 93/42/EEC, and Directive 98/79/EEC).

In addition:

- The *EU Regulation on Medical Devices (Regulation (EU) 2017/745)* was to be fully implemented by 26 May 2020, and thus automatically part of UK-wide law. However, in light of the disruption caused the pandemic, the EU have delayed this until the 26 May 2021. As a result, it will not automatically become part of UK law during the EU exit transition period. There is a need for the UK to remain aligned with these to facilitate both high safety standards and trade.
- The *EU Regulation on In-Vitro Diagnostic Medical Devices 2017/746* will not be fully implemented until 26 May 2022 and so will not automatically become part of UK law during the EU exit transition period. There is a need for the UK to remain aligned with these to facilitate both high safety standards and trade.
- The *Medical Devices (Amendment etc.) (EU Exit) Regulations 2019* come into force at the end of the EU exit transition period. These amend the Medical Devices Regulations 2002 to mirror key elements contained in *EU Regulation on Medical Devices 2017/745* and the *EU Regulation on In-Vitro Diagnostic Medical Devices 2017/746* (in order to maintain good regulatory alignment between the UK and EU, as well as between different parts of the UK's own regulatory framework).
- The *Medical Devices (Amendment etc.) (EU Exit) Regulations 2019* make a vast and complex set of amendments to the *Medical Devices Regulations 2002*. This would then be coupled with this Bill and any new regulations made as a result of new powers conferred.

27. In relation to medicines, relevant legislation includes:

- The *Medicines Act 1968* which covers many aspects of both human and veterinary medicines. Over the years this has been amended (and partially repealed) several times by both primary and secondary legislation, most comprehensively by the *Human Medicines Regulations 2012*.

- The *Human Medicines Regulations 2012* consolidates previous primary legislation and statutory instruments governing human medicines. It also implements EU Directive 2010/84 which relates to pharmacovigilance.
- The *Medicines for Human Use (Clinical Trials) Regulations 2004 (SI/2004/1031)*, which implements *EU Clinical Trials Directive (Directive 2001/20/EC)*, and relates to good clinical practice in the conduct of clinical trials on medicinal products for human use.
- The *Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (SI/2019/744)* come into force at the end of the EU transition period. These will enable continued alignment with the Directive. Although there will be elements of this as with other areas of pharmaceuticals and devices which cannot be achieved without a specific agreement with the EU; e.g. access to EU systems for the notification of serious adverse reactions to pharmaceuticals.
- The *Clinical Trials Regulation* (*Regulation (EU) No 536/2014)* was due to be implemented during the transition period. However, implementation by the EU has now been postponed until 2021. There is a need for the UK to remain aligned with this to facilitate continued clinical trials standards and cross-border research.

28. Just this snapshot (which is not the full picture) demonstrates the complexity of the law as it stands. The risk under the new Bill is that these areas become even more opaque and difficult to navigate. It is essential that stakeholders can easily and clearly determine their obligations under the law.
29. The Bill provides an opportunity to mandate a more streamlined legislative approach; something which would be of benefit to all stakeholders, including industry and businesses.
30. It is an opportunity to make provision for the UK to consolidate its legislative framework in this area and provide clarity for regulatory bodies, device manufacturers and marketers, and, importantly, patients and users.
31. To address this, the Bill should require the introduction of two separate pieces comprehensive primary legislation. The first dealing with medicines and veterinary medicines and the second dealing with medical devices.

Appendix
Suggested Amendments

1. Time limits on delegated powers

To move the following Clause—

"Time limits on delegated powers

(1) Sections 1, 8, and 12 of this Act, and the powers they confer therein, shall be revoked on the date that is X years following Royal Assent.

Or

To move the following Clause—

"Expiry

(1) This Act expires at the end of the period of X years following Royal Assent.

These amendments would ensure that the delegated powers are time limited to X years following Royal Assent for all delegated powers conferred by the Bill.

2. Attractiveness

1. Suggested amendment to Part 1 of the Bill:

Clause 1, page 1, lines 9 and 10, remove sub-section 2(c)

Or

Clause 1, page 1, line 11, at end insert—
'(3) In subsection (2), "attractiveness" means—

(a) suitable to facilitate the supply and demand of medicinal products and/or related services, and/or

(b) favourable to the establishment of research, design, and/or manufacture of medicinal products and/or related services

(4) In making regulations under subsection (1), paragraph 2(a) relating to the safety of human medicines must always be prioritised above paragraph 2(b) relating to availability and 2(c) relating to attractiveness.

2. Suggested amendment to Part 2 of the Bill:

Clause 8, page 5, line 18 and 19, leave out sub-section 8(c)

Or

Clause 8, page 5, line 19, at end insert—
'(3) In subsection (2), "attractiveness" means—

(a) suitable to facilitate the supply and demand of veterinary medicine products and/or related services, and/or
(b) favourable to the establishment of research, design, and/or manufacture of veterinary medicine products and/or related services

(4) In making regulations under section (1), paragraph 2(a) relating to the safety of veterinary medicines must always be prioritised above paragraph 2(b) relating to availability and 2(c) relating to attractiveness.

3. Suggested amendment to Part 3 of the Bill:

Clause 12, page 7, lines 26 and 27, leave out sub-section 12(c)

Or

Clause 12, page 7, lines 26 and 27, at end insert—
'(3) In subsection (2), "attractiveness" means—
(a) suitable to facilitate the supply and demand of medical devices and/or related services, and/or
(b) favourable to the establishment of research, design, and/or manufacture of medical devices and/or related services

(4) In making regulations under subsection (1), paragraph 2(a) relating to the safety of medical devices must always be prioritised above paragraph 2(b) relating to availability and 2(c) relating to attractiveness.

These amendments would ensure that patient safety is a priority.

3. Northern Ireland and regulatory divergence

To move the following Clause—

"Northern Ireland and regulatory divergence

(1) The Secretary of State is required to make an annual report to Parliament on potential areas of regulatory divergence; and
(2) Where the Secretary of State has identified areas of potential regulatory divergence between Northern Ireland and the rest of the UK, plans to mitigate such divergence should be put before Parliament.

This amendment would create a specific commitment of the Secretary of State to report on regulatory divergence with a plan for mitigation of such divergence.

Or

To move the following Clause—

"Northern Ireland and regulatory divergence

(1) The Secretary of State must work together with the appropriate authority in Northern Ireland to minimise the potential for regulatory divergence.

This amendment would create a more general requirement for the Secretary of State to cooperate with the appropriate authority in Northern Ireland to minimise regulatory divergence.

4. Stream-lined legislation

To move the following Clause—

"Requirement for consolidated legislation

(1) The Secretary of State is required to introduce to Parliament new primary legislation consolidating the existing regulatory regime as it applies to Medicines and Veterinary Medicines by the date X years following Royal Assent.

This amendment would commit the Secretary of State to introducing new, consolidated legislation.

To move the following Clause—

"Requirement for consolidated legislation

(2) The Secretary of State is required to introduce to Parliament new primary legislation consolidating the existing regulatory regime as it applies to Medical Devices by the date X years following Royal Assent.

This amendment would commit the Secretary of State to introducing new, consolidated legislation.