Written Evidence Submitted to the Medicines and Medical Devices Public Bill Committee

Quigley, Muireann; McHale, Jean; Dickson, Rachael; Downey, Laura

Written evidence submitted 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 is problematic. The extremely short deadlines for amendments and the consideration of evidence at Committee stage risks inadequate scrutiny of a Bill which proposes broad changes and powers in relation to important areas of the law.
- A key concern with the Bill is that patient safety must be prioritised. We support the amendment by Alex Norris MP to remove 'attractiveness' clauses to strengthen this.
- 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. This is not addressed in the existing amendments tabled. Although the deadline for suggested amendments for parts 1 and 2 of the Bill has lapsed, we recommend new clauses to be inserted in the Bill to mitigate the potential for regulatory divergence.
- The existing regulatory regime for medical devices is complex and unwieldy. We recommend the insertion of a new Clause in part 3 of the Bill to commit the Secretary of State to introduce new primary legislation consolidating the existing regime within 2 years of the Bills Royal Assent.
- The Bill in its current form provides extensive delegate powers. These should be time limited. Alex Norris MP has introduced an amendment to Clause 1 of the Bill providing a time limit on delegated powers in relation to human medicines, however no such amendment has been tabled for parts 2 and 3 relating to veterinary medicine and medical devices respectively. We have recommended a new clause creating time limits on all three areas of delegated powers.

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.
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 part of this Bill and to the issues we highlight in this submission.

Risk of inadequate scrutiny

1. The Bill appeared on the Parliamentary agenda with little notice in February. Following its pause due to Covid-19 pandemic, the Bill has resumed with little notice and extremely tight deadlines for amendments.
2. This raises concern over the ability afforded to Members to consider the proposed provisions, conduct research, and table amendments. 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.

Patient and user safety

3. 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) and place in which to develop or supply medical devices (Part 3). However there is no definition in the Bill as to what "attractiveness" means.
4. Recent scandals, such as the DePuy metal-on-metal hips and PIP breast implants, show the need for strong regulatory oversight. Therefore 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 priority safety.
5. These concerns have been addressed by amendments tabled by Alex Norris MP in removing the "attractiveness" clauses and inserting requirements to give primary regard to safety. We encourage Members to support these changes across all parts of the Bill.

Northern Ireland and potential regulatory divergence

7. 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.
8. This issue has not been addressed by any tabled amendments and so we urge member to consider including provisions to this effect. 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.

Stream-lined legislation

9. The existing regulatory framework concerning medical devices is complex and unwieldy. 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.
- 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.
- 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).

10. 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.
11. To address this, the Bill should require the introduction of two pieces of comprehensive primary legislation dealing with medical devices. This should be done by 2022 to coincide with the need for regulatory alignment with the In Vitro Diagnostic Regulation.
12. This provides an opportunity 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.

Time-limiting delegated powers

13. The Bill confers an extensive range of delegated powers to make regulations in relation to medicine and medical devices, including in relation to manufacturing, marketing and supply; falsified medicines; clinical trials, fees, information and offences; and emergency situations.
14. 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.
15. 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.'
16. Alex Norris MP has tabled an amendment to Clause 1 to limit the use of the delegated powers in relation to medicines to two years following the date of Royal Assent. However neither he, or anyone else, has tabled a similar amendment for parts 2 and 3 relating to veterinary medicine and medical devices.
17. To address this, and to ensure that delegated powers in all three parts are time limited, we urge members to consider parallel new clauses in Parts 2 and 3, or one covering the whole Bill.