

MEDICINES AND MEDICAL DEVICES BILL 2019-20

This note deals mainly with Parts 1 and 3 of the Bill



UNIVERSITY OF BIRMINGHAM

EXECUTIVE SUMMARY

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- Patient and user safety with regards to medical devices is paramount. This should be prioritised 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 existing regulatory framework for medicines and medical devices has become complex and unwieldy. Legislation which consolidates regulation on each these areas (separately) is needed. A requirement to introduce this should be included in the Bill.
 - 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. This is necessary in the short-term to facilitate alignment with those parts of EU law which are to be implemented post-transition; notably the EU Clinical Trials Regulation and the Medical Device and In Vitro Devices Regulations. However, the on-going use of delegated powers in this area should be time-limited.
- introduces much needed consolidated and expanded enforcement provisions, including criminal and civil provisions for breach of obligations relating to medical devices. Additionally, the Bill recognises the need to be responsive and flexible with regards to medicines and medical device regulation.
- However, 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.

Patient and user safety should be prioritised

The Bill contains the requirement that the Secretary of State must have regard to the safety and availability of medicines and medical devices (Parts 1 and 3), as well as the “attractiveness of the relevant part of the United Kingdom” as 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).

Introduction

The Medicines and Medical Devices Bill had its first reading in the House of Commons on 13 February 2020. The Bill proposes a legislative programme for the regulation of medicines and medical devices in the UK at the end of the EU exit transition period, currently 31 December 2020. It is imperative that the Bill provides for high standards of safety and is forward-looking so as to capture the fast pace of innovation in these areas.

Some aspects of the Bill indicate the Government is moving in the right direction. For example, the Bill in-

Whilst recognising the need for the UK to remain competitive, patient and user safety must be paramount. Recent scandals such as those concerning DePuy metal-on-metal hips and PIP breast implants, as well as those relating to Primodos, sodium valproate, and pelvic mesh (the subject of the recent Independent Medicines and Medical Devices Safety Review), have demonstrated the need for strong regulatory oversight.

Currently there is no definition in the Bill as to what constitutes “the attractiveness of the relevant part of the United Kingdom”. The attractiveness clauses

should either (a) be removed entirely from the Bill, or (b) a clear statutory definition of attractiveness should be included in the Bill, along with a further clause requiring the appropriate authority to prioritise safety whenever different elements need to be balanced.

Northern Ireland and potential regulatory divergence

In relation to medicines, the Bill refers to Northern Ireland separately from England, Wales, and Scotland. Medicines are a devolved power while 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.

The need for consolidated legislation

The existing medicines and medical device regulatory framework has over time become complex and unwieldy. 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. However, in light of the disruption caused by 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.
- The *EU Regulation on In-Vitro Diagnostic Medical Devices* (Regulation (EU) 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 unless alternative provisions are made. These amend the *Medical Devices Regulations 2002* to mirror key ele-

ments 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).

In relation to human 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 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 *EU Regulation on Clinical Trials* (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.

The Bill represents an opportunity for the Government to address the range of legislation incorporated in statutory instruments and to provide a more streamlined

legislative approach.

Time-limit the use of delegated powers

The Bill confers the Secretary for State with an extensive range of delegated powers to make regulations about medicines and medical devices. This includes: powers with regards to manufacture, marketing, and supply; falsified medicines; clinical trials; fees, information, and offences; and emergencies. In effect, this covers the majority of areas where regulation might be required.

It is important that the medicines and medical devices regulatory framework is appropriately responsive and flexible in order to take account of (a) the EU exit transition period and (b) future technological and other changes. However, delegated powers should not be used indefinitely. Doing so risks inadequate scrutiny and oversight of major regulatory objectives and changes.

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.’

To deal with this, the Bill should include a clause which time-limits the provisions in this proposed legislation and requires the Government to introduce comprehensive primary legislation.

Summary of recommendations

Parliament should:

- 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 (including veterinary medicines) and medical devices should be introduced. This will enable the successive amendments to be integrated and consolidated, making the regulatory framework more stream-lined and easier to understand.

Background research

Professor Quigley and Dr Dickson are currently working on a Wellcome Trust funded project investigating how the law should take account of (smart) medical devices. In addition to this, recently they have been researching how citizen innovation in the area of medical devices should be regulated.

Professor Jean McHale’s research is in the area of Health Law. Her recent books include *European Health Law Themes and Implications* (CUP, 2015) (with Professor Tamara Hervey) and *Principles of Medical Law* (4th ed: OUP 2017) with Professor Judith Laing. She was recently the principal investigator on a two year ESRC funded project “Health Law Outside the EU: Immediate, Intermediate, and Long-Term Impacts.”

Dr Downey is conducting research on the development and use of innovative medical devices; 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.

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