HOUSE OF LORDS

Select Committee on the Constitution

10th Report of Session 2019–21

Medicines and Medical Devices Bill

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Select Committee on the Constitution

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The Members of the Constitution Committee are:

Lord Beith
Baroness Corston
Baroness Drake
Lord Dunlop
Lord Faulks
Baroness Fookes
Lord Hennessy of Nympsfield
Lord Howarth of Newport
Lord Howell of Guildford
Lord Pannick
Lord Sherbourne of Didsbury
Baroness Taylor of Bolton (Chair)
Lord Wallace of Tankerness

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Committee staff

The current staff of the committee are Matt Korris (Clerk) and Dan Weedon (Committee Assistant). Professor Stephen Tierney and Professor Jeff King are the legal advisers to the Committee.

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Medicines and Medical Devices Bill

Introduction

1. The Medicines and Medical Devices Bill was brought to the House of Lords on 24 June 2020. Second reading is scheduled for 2 September.

2. The Bill does three main things:

   - It provides delegated powers relating to human medicines, veterinary medicines and medical devices which allow the UK and Northern Ireland governments to amend the regulatory frameworks after the end of the Brexit transition period;

   - It consolidates the enforcement provisions relating to medical devices and introduces a scheme of civil sanctions; and

   - It allows information held by the Secretary of State about medical devices to be shared (e.g. to warn the public about safety issues).

3. Human medicines, veterinary medicines, and medical devices have previously been regulated by EU law and by secondary legislation made under the European Communities Act 1972. These regulations remain part of UK law at the end of the transition period, but with the UK's departure from the EU and the repeal of the European Communities Act, the Government needs to introduce new powers to amend and supplement this regulatory regime.

Delegated powers

4. The Bill is a skeleton bill. It provides an extensive range of delegated powers to allow ministers to amend and supplement the regulatory regimes for medicines (clauses 1–7), veterinary medicines (clauses 8–11) and medical devices (clauses 12–15). It provides only scant policy detail to suggest how these powers might be exercised.

5. We have concluded previously that "Skeleton bills inhibit parliamentary scrutiny and we find it difficult to envisage any circumstances in which their use is acceptable. The Government must provide an exceptional justification for them."[1]

6. The Delegated Powers and Regulatory Reform Committee (DPPRC) has reported on the Bill. It concluded that "clauses 1, 8 and 12 contain inappropriate delegations of power". It said the Government had "failed to provide sufficient justification for … adopting a 'skeleton bill' approach" which gives ministers "very wide powers to almost completely re-write the existing regulatory regimes for human and veterinary medicines and medical devices."[2]

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1 Constitution Committee, *The Legislative Process: The Delegation of Powers* (16th Report, Session 2017–19, HL Paper 225), para 58

2 Delegated Powers and Regulatory Reform Committee, *Medicines and Medical Devices Bill* (19th Report, Session 2019–21, HL Paper 109), para 28

7. The DPRRC was particularly critical of the lack of adequate justification for the broad delegated powers in the Bill. It thought that the arguments put forward by the Government downplayed the issues and made claims about constraints on the powers that were "more apparent than real".[3] The DPPRC concluded: "In future, we will expect a more transparent approach in which a department acknowledges the breadth of the powers and seeks to fully justify it."[4]

8. We share the concerns of the Delegated Powers and Regulatory Reform Committee. We consider that the Government's claims that the powers in the Bill are "targeted"[5] and that they are analogous to those exercised under section 2(2) of the European Communities Act 1972[6] are unfounded. Ministerial powers under section 2(2) of that Act are far more constrained than those created by the Bill. They are limited to giving effect to EU obligations, rather than a freestanding mandate to legislate in the best interests of the public. The extent of parliamentary scrutiny and consultation followed under the EU law-making procedures is also more extensive that what would be mandated under this Bill.

9. **This is a skeleton bill containing extensive delegated powers, covering a range of significant policy matters, with few constraints on the extent of the regulatory changes that could be made using the powers. The Government has not provided the exceptional justification required for this skeleton approach.**

10. **We accept that regulatory regimes in policy areas such as these require frequent adjustment, and so need to be flexible, but the Government has not made a persuasive case for conferring largely unrestricted delegated powers that can be used to rewrite the existing regulatory framework.**

11. **We recognise that the existing powers to amend these complex regulatory regimes will cease to have effect on 31 December 2020 and that alternative arrangements are required. If the Government is unable to specify the principles according to which it intends to amend and supplement the existing law, the delegated powers in the Bill should be subject to sunset clauses. This would allow Parliament to scrutinise a new bill which provides sufficient detail on the policy it is being asked to approve.**

Emergency powers

12. The Bill confers emergency powers on the Government to disapply existing health medicines regulations. Clause 6 allows an "appropriate authority"[7] to make regulations disapplying certain laws on human medicines "in circumstances which give rise to a need to protect the public from a serious risk to public health." The disapplication authorised in the regulations can be subject to conditions specified in the regulations or "conditions set out in a protocol published by the public authority". No formal requirements are

3 *Ibid.*
4 *Ibid.*, para 53
5 Medicines and Medical Devices Bill, Explanatory Notes, para 9
6 HC Deb, 2 March 2020, cols 664–5
7 The Secretary of State in respect of England, Wales and Scotland. For Northern Ireland, it is the Northern Ireland Department of Health or the Department and the Secretary of State acting jointly.

set for the form, publication or dissemination of a protocol—it may simply be a document published on a website by the appropriate authority.

13. If a protocol is published, the regulations "must" provide that the appropriate authority may withdraw or amend the protocol and that the protocol shall have effect for a time period specified in the protocol. Equivalent emergency powers in respect of medical devices are in clause 15.

14. These provisions raise a range of concerns. In other bills emergency powers are time-limited and there are often requirements for periodic reviews of their use.[8] No such constraints or safeguards exist in this Bill. These powers are subject only to the negative resolution procedure and can be adjusted by the amendment of a protocol which is not subject to parliamentary scrutiny.

15. The DPRRC was critical of these provisions:

> "Allowing regulations to make the disapplication of legislation subject to conditions set out in a 'protocol' is yet another example of 'camouflaging legislation' … we consider that, where those powers are to be used to provide for legislation to be disapplied in an emergency, any conditions to which disapplication is to be subject should be set out in the regulations themselves and not in a 'protocol' which is not subject to Parliamentary scrutiny."[9]

16. **We share the concerns of the DPPRC about these emergency powers. We recommend the use of these powers should be time bound, subject to periodic review and that any conditions on the disapplication of legal provisions should be set out in regulations.**

17. We have concluded previously that the Government should seek the made-affirmative resolution procedure sparingly and only for urgent measures. Emergency powers are one such use.[10] **We recommend that the emergency powers in this Bill are subject to the made affirmative procedure, rather than the negative procedure, such that Parliament is required actively to approve them.**

Criminal offences

18. The Bill confers delegated powers to create criminal offences. Clause 5(1)(b) allows regulations under clause 1 to make provision "creating a criminal offence of failing to comply with a provision made in the regulations, but not one punishable with a sentence of imprisonment of more than two years". Clause 10(1)(b) provides likewise in relation to veterinary medicines.

19. While schedule 2 inserts a schedule to the Medical Devices Regulations 2002 containing a list of imprisonable offences, the regulation-making power in clause 14(1)(d) permits the amendment of that schedule by regulations made under clause 12. Further, the underlying regulations contain dozens

8 See, for example, the powers in the Public Health (Control of Diseases) Act 1984, the Coronavirus Act 2020 and the Corporate Insolvency and Governance Act 2020.

9 Delegated Powers and Regulatory Reform Committee, *Medicines and Medical Devices Bill* (19th Report, Session 2019–21, HL Paper 109), para 42

10 Constitution Committee, *Fast-track Legislation: Constitutional Implications and Safeguards* (15th Report, Session 2008–09, HL Paper 116), paras 134–139; Constitution Committee, *European Union (Withdrawal) Bill* (9th Report, Session 2017–19, HL Paper 69), paras 220–222; Constitution Committee, *Corporate Insolvency and Governance Bill* (7th Report, Session 2019–21, HL Paper 76), paras 33–39

of criminal offences which may be varied or amended using the powers provided in the Bill.

20. The DPRRC concluded that, "in the absence of a full justification", allowing the ingredients of new criminal offences and the penalties for existing offences to be set by delegated legislation amounted to inappropriate delegations of power.[11]

21. We have concluded previously that "the creation of criminal offences through delegated powers is constitutionally unacceptable",[12] save for exceptional circumstances. **The delegated powers to create and adjust criminal offences in this Bill are constitutionally unacceptable.**

11 Delegated Powers and Regulatory Reform Committee, *Medicines and Medical Devices Bill* (19th Report, Session 2019–21, HL Paper 109), para 31

12 Constitution Committee, *The Legislative Process: The Delegation of Powers* (16th Report, Session 2017–19, HL Paper 225), para 50; Constitution Committee, *Private International Law (Implementation of Agreements) Bill* (5th Report, Session 2019–21, HL Paper 55), para 21

APPENDIX 1: LIST OF MEMBERS AND DECLARATIONS OF INTEREST

Members

Lord Beith
Baroness Corston
Baroness Drake
Lord Dunlop
Lord Faulks
Baroness Fookes
Lord Hennessy of Nympsfield
Lord Howarth of Newport
Lord Howell of Guildford
Lord Pannick
Lord Sherbourne of Didsbury
Baroness Taylor of Bolton (Chair)
Lord Wallace of Tankerness

Declarations of interest

Lord Beith
Honorary Bencher of the Middle Temple
Baroness Corston
No relevant interests
Baroness Drake
No relevant interests
Lord Dunlop
No relevant interests
Lord Faulks
No relevant interests
Baroness Fookes
No relevant interests
Lord Hennessy of Nympsfield
No relevant interests
Lord Howarth of Newport
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Lord Howell of Guildford
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Lord Pannick
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Lord Sherbourne of Didsbury
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Baroness Taylor of Bolton (Chair)
No relevant interests
Lord Wallace of Tankerness
No relevant interests

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Professor Jeff King, University College London, and Professor Stephen Tierney, University of Edinburgh, acted as legal advisers to the Committee. They both declared no relevant interests.