HOUSE OF LORDS

Delegated Powers and Regulatory Reform Committee

19th Report of Session 2019–21

Medicines and Medical Devices Bill

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The Delegated Powers and Regulatory Reform Committee

The Committee is appointed by the House of Lords each session and has the following terms of reference:

(i) To report whether the provisions of any bill inappropriately delegate legislative power, or whether they subject the exercise of legislative power to an inappropriate degree of parliamentary scrutiny;

(ii) To report on documents and draft orders laid before Parliament under or by virtue of:

(a) sections 14 and 18 of the Legislative and Regulatory Reform Act 2006,

(b) section 7(2) or section 19 of the Localism Act 2011, or

(c) section 5E(2) of the Fire and Rescue Services Act 2004;

and to perform, in respect of such draft orders, and in respect of subordinate provisions orders made or proposed to be made under the Regulatory Reform Act 2001, the functions performed in respect of other instruments and draft instruments by the Joint Committee on Statutory Instruments; and

(iii) To report on documents and draft orders laid before Parliament under or by virtue of:

(a) section 85 of the Northern Ireland Act 1998,

(b) section 17 of the Local Government Act 1999,

(c) section 9 of the Local Government Act 2000,

(d) section 98 of the Local Government Act 2003, or

(e) section 102 of the Local Transport Act 2008.

Membership

The members of the Delegated Powers and Regulatory Reform Committee who agreed this report are:

Baroness Andrews
Lord Blencathra (Chair)
Baroness Browning
Lord Goddard of Stockport
Lord Haselhurst
Lord Haskel
Baroness Meacher
Lord Rowlands
Lord Thurlow
Lord Tope

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Contacts for the Delegated Powers and Regulatory Reform Committee

Any query about the Committee or its work should be directed to the Clerk of Delegated Legislation, Legislation Office, House of Lords, London, SW1A 0PW. The telephone number is 020 7219 3103. The Committee's email address is hldelegatedpowers@parliament.uk.

Historical Note

In February 1992, the Select Committee on the Committee work of the House, under the chairmanship of Earl Jellicoe, noted that "in recent years there has been considerable disquiet over the problem of wide and sometimes ill-defined order-making powers which give Ministers unlimited discretion" (Session 1991–92, HL Paper 35-I, paragraph 133). The Committee recommended the establishment of a delegated powers scrutiny committee which would, it suggested, "be well suited to the revising function of the House". As a result, the Select Committee on the Scrutiny of Delegated Powers was appointed experimentally in the following session. It was established as a sessional committee from the beginning of Session 1994–95. The Committee also has responsibility for scrutinising legislative reform orders under the Legislative and Regulatory Reform Act 2006 and certain instruments made under other Acts specified in the Committee's terms of reference.

Nineteenth Report

MEDICINES AND MEDICAL DEVICES BILL

1. This Bill was passed by the House of Commons on 23 June 2020 and had its first reading in the House of Lords on 24 June 2020. The Bill is awaiting second reading.

2. The Bill contains 46 clauses and two Schedules. It:

   - creates extensive delegated powers in the fields of human medicines, veterinary medicines and medical devices, to enable the existing regulatory frameworks in those fields to be updated following the UK's departure from the European Union (EU);
   - creates a delegated power to establish one or more information systems in relation to medical devices;
   - consolidates enforcement provisions for medical devices and introduces sanctions; and
   - provides an information gateway to enable the sharing of information held by the Secretary of State about medical devices.

3. The regulation of human medicines (including clinical trials of human medicines), veterinary medicines and medical devices falls within EU competence. The EU has legislated in these fields to create comprehensive regulatory frameworks. While the UK was a member of the EU, it was a condition of our membership that we gave effect to that law in the UK. That included putting in place domestic legislation to achieve objectives set out in EU Directives (a process known as 'implementation'). The regulatory frameworks for medicines and medical devices have primarily been implemented in the UK by the following legislation:

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

4. These four sets of Regulations were made using a special delegated power in section 2(2) of the European Communities Act 1972 ("the 1972 Act"). Section 2(2) was created to give Ministers power to make secondary legislation which implements EU law in the UK. As and when the EU Directives that these Regulations implement have been updated over the years, so the Regulations themselves have been updated using the power in section 2(2). At the end of the transition period[1], the power in section 2(2) will no longer exist. The Bill creates new delegated powers which are designed to allow the regulatory frameworks to be updated by statutory instrument after the transition period ends.

1 The period agreed in the UK-EU Withdrawal Agreement during which the UK is no longer a member of the EU but continues to be subject to EU rules and remains a member of the single market and customs union.

5. The Department of Health and Social Care has provided a Delegated Powers Memorandum ("the Memorandum")[2] which runs to some 66 pages. It has also published six illustrative statutory instruments. We are grateful for the detail provided but we have concerns about the approach taken in the Memorandum. This Bill gives Ministers very broad powers indeed but, instead of acknowledging this and seeking to provide a full justification for it, the Memorandum—

   - downplays the significant differences between the existing law and what the Bill would put in its place;
   - presents a false dichotomy by suggesting that the only alternative to the extensive delegated powers in the Bill is to have every detail of the regulatory regimes in primary legislation, and
   - offers unconvincing arguments that the delegated powers in the Bill are subject to significant constraints.

   We discuss this further in paragraphs 14 to 28 below. **In future, where a Bill confers broad powers, we will expect a more transparent approach in which the department acknowledges the breadth of the powers and seeks to fully justify it.**

6. We draw the following powers to the attention of the House.

Clause 1 (power to make regulations about human medicines), clause 8 (power to make regulations about veterinary medicines) and clause 12 (power to make regulations about medical devices)

7. The first 15 clauses of the Bill consist entirely of powers to make provision by regulations:

   - clauses 1 to 7 confer powers to make regulations about human medicines;
   - clauses 8 to 11 confer powers to make regulations about veterinary medicines;
   - clauses 12 to 15 confer powers to make regulations about medical devices.

   Each of these three parts is similarly constructed. Taking human medicines as an example: clause 1 contains the power to make regulations "amending or supplementing" specified legislation, and clauses 2 to 6 specify the things that can be done under that power.

Clauses 1 to 7: human medicines

8. Clause 1 allows Ministers[3] to make regulations "amending or supplementing"—

   - sections 10 and 15, and Part 4, and section 131 of the Medicines Act 1968 ("the 1968 Act") (which make provision relating to pharmacies);

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2 Delegated Powers Memorandum, Department of Health and Social Care, dated 23 June 2020.

3 In relation to England and Wales and Scotland, the Secretary of State; in relation to Northern Ireland, the Department of Health in Northern Ireland or that Department and the Secretary of State acting jointly.

- the Human Medicines Regulations 2012;
- the Medicines for Human Use (Clinical Trials) Regulations 2004; and
- the Medicines (Products for Human Use) (Fees) Regulations 2016.

9. This is a power of significant breadth:

- it can only be exercised to make the provision specified in clauses 2 to 6, but the range of matters specified appears to cover all elements of the regulatory regime for human medicines and clinical trials that is contained in the legislation referred to above;
- the Human Medicines Regulations 2012 alone contain over 350 regulations and over 40 Schedules, and include dozens of provisions creating criminal offences punishable by imprisonment for up to two years. Those Regulations set out a comprehensive regime for the regulation of medicinal products: from authorisation, manufacture, import, distribution, sale and supply to labelling, advertising and pharmacovigilance. They also contain enforcement powers;
- the provision in the Medicines for Human Use (Clinical Trials) Regulations 2004 includes more than 25 criminal offences, all of which are punishable by imprisonment for up to two years;
- it includes power to create new criminal offences punishable by imprisonment for up to two years;
- it includes power to apply, in relation to prohibitions or requirements imposed by regulations under clause 1, powers of entry and other powers of inspectors that are set out in primary legislation (the 1968 Act);
- it includes power to make provision about clinical trials corresponding or similar to provision in the EU Clinical Trials Regulation (Regulation (EU) No 536/2014).

Clauses 8 to 11: veterinary medicines

10. Clause 8 allows Ministers[4] to make regulations "amending or supplementing" the Veterinary Medicines Regulations 2013. The 2013 Regulations make provision for the authorisation, manufacture, classification, distribution and administration of veterinary medicinal products.

11. Again, the power is of significant breadth:

- it can only be exercised to make the provision specified in clauses 9 and 10, but the range of matters specified appears to cover all elements of the regulatory regime for veterinary medicines that is contained in the 2013 Regulations;
- the provision in the 2013 Regulations includes more than 20 criminal offences, all of which are punishable by imprisonment for up to two years;

4 In relation to England and Wales and Scotland, the Secretary of State; in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs in Northern Ireland or that Department and the Secretary of State acting jointly.

- it includes power to create new criminal offences punishable by imprisonment for up to two years;
- it includes power to apply, in relation to prohibitions or requirements imposed by regulations under clause 8, powers of entry and other powers of inspectors that are set out in the 2013 Regulations;
- it includes power to make provision corresponding or similar to provision in Regulation (EU) 2019/4 (on medicated feed) and Regulation (EU) 2019/6 (on veterinary medicinal products), the latter containing some 160 articles.

Clauses 12 to 15: medical devices

12. Clause 12 allows the Secretary of State to make regulations "amending or supplementing" the Medical Devices Regulations 2002 ("the 2002 Regulations"). The 2002 Regulations make provision with respect to matters including the manufacture and marketing of medical devices and post-market surveillance and vigilance.

13. Once again, the power is of significant breadth:

- it can only be exercised to make the provision specified in clauses 13 to 15, but the range of matters specified appears to cover all elements of the regulatory regime for medical devices that is contained in the 2002 Regulations, save for those aspects relating to enforcement that are provided for in Chapter 3 of Part 3 of the Bill,[5]
- the 2002 Regulations contain over 200 regulations and 29 Schedules;
- it includes power to legislate for imprisonable offences.[6]

Justification for the delegations

(a) The need to "amend and update"

14. The main reason given in the Memorandum for taking the delegated powers in clauses 1, 8 and 12 is the need to be able to frequently "amend and update" the regulatory frameworks so that they "remain fit-for-purpose".[7]

15. The Government argue that:

- it is "not possible or appropriate to set out detailed requirements for regulatory process on the face of primary legislation";[8] and
- it would not be "practical or appropriate" for frequently-required technical changes to be made through primary legislation.[9]

We readily accept this, but the Bill leaves almost everything to be provided for in regulations. It contains no regulatory provision relating to human or veterinary medicines that can be debated here and now, and only very limited provision relating to medical devices. The Memorandum asserts

5 Chapter 3 of Part 3 contains clauses 17 to 34 inclusive.
6 See further para 29 below.
7 See paras 48, 72 and 90 of the Memorandum.
8 See para 19 of the Memorandum.
9 See paras 56, 73 and 90 of the Memorandum.

that "the approach proposed is necessary and justified"[10] but, rather than seek to provide a full justification for that approach, it instead presents a false dichotomy by suggesting that the only alternative to the approach it has taken (that is, a "skeleton" part of a Bill) is to have every detail of the regulatory regimes in primary legislation.

16. The Memorandum says nothing about why it would not be appropriate to have aspects of the regulatory regimes which are not "detail" or "technical" provided for on the face of the Bill and combined with more focused delegated powers to fill in the detail by regulations.

17. The fact that the Bill provides for most exercises of these powers to be subject to the affirmative procedure could be seen as an acknowledgment that it covers matters of great importance to patients, medical practitioners and the life science and pharmaceutical industries. However, as we have said before:

> "the affirmative procedure offers nothing like the scrutiny given to a bill. A bill typically goes through several substantive stages in each House and can be amended. An affirmative statutory instrument is unamendable during its making and is debated once in each House".[11]

(b) The Bill "replaces one set [of delegated powers] with another"

18. The second justification given for the powers in clauses 1, 8 and 12 is that the Bill simply replaces the delegated powers under which the regulations containing the existing regulatory frameworks were made with new delegated powers:

- the Memorandum states that "the regulatory regimes [for human and veterinary medicines, clinical trials and medical devices] have to date all been updated using statutory instruments",[12]

- at the Bill's Second Reading in the House of Commons, the Secretary of State said the following:

  > "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".[13]

19. It is true that almost all aspects of the existing regulatory regimes are provided for in regulations. But those regulations were made under the unique delegated power in section 2(2) of the European Communities Act 1972. The 1972 Act is the conduit by which EU law is introduced into UK domestic law and section 2(2) plays a key role in that.

20. Despite being in many respects a power of considerable breadth (it may be used to make such provision as might be made by Act of Parliament[14]), the section 2(2) power is subject to a critical constraint: it gives Ministers power

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10 See para 4 of the Memorandum.
11 34th Report, Session 2017-19, HL Paper 194, para 6 (on the Agriculture Bill).
12 See para 4 of the Memorandum.
13 HoC deb, 2 March 2020, col 664.
14 Save that Schedule 2 to the 1972 Act prevents the use of the power for taxation, retrospective provision, conferral of powers to legislate or the creation of criminal offences punishable by more than two years' imprisonment.

to make laws giving effect to EU law–not simply power to make laws that Ministers may wish to make.

21. The EU makes two kinds of laws. The first kind applies automatically. The second kind does not: a Member State is required to enact domestic legislation in order to put it into force in its territory. The process of enacting such legislation is known as 'implementation' or 'transposition'. EU Directives are EU law of the second kind: they are binding on Member States as to the objective or result to be achieved, but leave to Member State discretion the form and methods of implementation.

22. Unless and until either we left the EU—or the EU law we were required to implement in UK law changed—the contents of delegated legislation made under section 2(2) were, in effect, ring-fenced. Legal rules derived from EU law and transposed into UK law by domestic legislation were not open to domestic repeal or amendment in ways that might be inconsistent with EU law. And a UK domestic court would interpret that legislation where possible to ensure that it was compatible with EU law generally and the EU law it implemented. This has operated as a very significant constraint on the ability of Ministers to amend that delegated legislation: they are not able to frustrate rights established by EU Directives and given effect to by implementing domestic legislation.

23. The powers in clauses 1, 8 and 12 of the Bill are very different: they would give Ministers free rein to amend the regulatory regimes for human medicines, veterinary medicines and medical devices as they see fit. By leaving almost everything about those regulatory regimes to be provided for by Ministers in regulations under the new powers–and little or nothing to be settled under the fuller scrutiny given to Bill provisions–the Bill could be seen as effecting a significant transfer of powers from the EU to Ministers, bypassing Parliament.

Constraints on the exercise of the powers

24. The Government claim in the Memorandum that the delegated powers in clauses 1, 8 and 12 are "deliberately constrained in several significant ways".[15]

25. It is true that most exercises of these powers would be subject to the affirmative procedure, and the consultation requirement imposed by clause 41 of the Bill is to be welcomed (it applies to any regulations under clause 1, 8 or 12, save for urgently made emergency regulations[16]).

26. However, other constraints seem more apparent than real:

- the Memorandum emphasises that these powers "can only be exercised to make provision about the finite list of matters specified on the face of the Bill".[17] This is true but it is questionable whether it is a meaningful restriction that can reasonably be described as imposing "strict limits"[18] or a "safeguard".[19] The "finite list" appears to cover all aspects of the regulatory regimes for human and veterinary medicines that is contained in the legislation that may be amended by regulations under

15 See para 2 of the Memorandum.
16 See clause 6 (emergencies) and clause 15 (emergencies).
17 See para 2 of the Memorandum.
18 See paras 49 and 69 of the Memorandum.
19 See para 20 of the Memorandum.

the new powers–and almost every element of the regulatory regime for medical devices that is contained in the 2002 Regulations;

- it is claimed that the powers "may only be used to amend or supplement the existing regulatory frameworks"[20] and "can only be used to build on the existing frameworks".[21] But there appears to be nothing to prevent the powers being used to almost completely re-write those frameworks;

- it is stated that the power in clause 1 "may only amend or supplement … sections 10, 15, and 131 and Part 4 of the Medicines Act 1968" ,[22] but this is a significant Henry VIII power which would allow regulations to re-write the whole of Part 4 of the 1968 Act (which contains some 33 sections);

- the powers may only be exercised after consideration has been given to the following three factors:

(a) "the safety of [human medicines/veterinary medicines/medical devices]";

(b) "the availability of [human medicines/veterinary medicines/medical devices]"; and

(c) "the attractiveness of … the UK as a place in which to [conduct clinical trials or supply human medicines/develop or supply veterinary medicines/develop or supply medical devices]".

However, it is not clear to what extent these are meaningful constraints. It might be considered that these are matters that any responsible Minister could be expected to take into account. Crucially, the extent to which these factors might constrain the exercise of the powers would depend entirely on the weight that a Minister chose to attach to each factor—and the provision says nothing about the relative weight to be attached to each factor.

27. It is claimed that the Bill "represents a significant increase in the scrutiny that Parliament will have over the regulatory regimes".[23] It is true that—

- delegated legislation made under section 2(2) of the 1972 Act may be subject to the affirmative or the negative procedure (Ministers have a choice), and changes have been made to the regulatory regimes in question by delegated legislation under section 2(2) that was subject to the negative procedure; and

- most exercises of the new powers would be subject to the affirmative procedure.

However, as explained above, there are other, more fundamental, differences between the section 2(2) power and the delegated powers in this Bill. These raise questions about whether there are aspects of the regulatory regimes that the Bill leaves to be provided for in regulations (albeit subject to the affirmative procedure) which may be considered sufficiently important to merit inclusion on the face of the Bill, where they would be subject to much greater Parliamentary scrutiny.

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20 See para 9 of the Memorandum.
21 See paras 46, 66 and 82 of the Memorandum.
22 See para 46 of the Memorandum.
23 See para 4 of the Memorandum.

28. **We consider that clauses 1, 8 and 12 contain inappropriate delegations of power:**

(a) the Government have failed to provide sufficient justification for this part of the Bill adopting a "skeleton bill" approach, with Ministers given very wide powers to almost completely re-write the existing regulatory regimes for human and veterinary medicines and medical devices;

(b) instead of seeking to justify taking such broad powers—

- **the Government downplay them by suggesting that they are like-for-like replacements for the existing power in section 2(2) of the 1972 Act but, for the reasons given in paragraphs 19 to 23 above, this is not the case. The section 2(2) power is subject to a very significant built-in constraint: it is a mechanism for transposing into UK law EU rules on medicines and medical devices that the UK is required to follow. The new powers are subject to no such constraint: they would give Ministers free rein to legislate in those areas;**

- **the Government claim that the new powers are constrained in significant ways but, for the reasons given in paragraphs 26 and 27 above, we consider those constraints to be more apparent than real.**

Clauses 1 and 5(1)(b) (human medicines: criminal offences), clauses 8 and 10(1)(b) (veterinary medicines: criminal offences) and clauses 12 and 14(1)(d) (medical devices: criminal offences)

29. The Bill gives Ministers powers to create and modify imprisonable offences by statutory instrument:

- regulations under clause 1 may create a criminal offence of failing to comply with a provision made in such regulations, punishable by imprisonment for up to two years (see clause 5(1)(b) of the Bill);

- regulations under clause 8 may create a criminal offence of failing to comply with a provision made in such regulations, punishable by imprisonment for up to two years (see clause 10(1)(b) of the Bill);

- regulations under clauses 1 and 8 may also amend the dozens of offence-creating provisions in the existing regulations;

- regulations under clause 12 may create new criminal offences relating to medical devices, punishable by imprisonment for up to one year. Schedule 2 to the Bill inserts a new regulation 60A and a new Schedule into the 2002 Regulations. It is a criminal offence—punishable by imprisonment for up to one year—to breach any of the provisions in the 2002 Regulations that are listed in the new Schedule. Clause 14(1)(d) of the Bill provides that regulations under clause 12 may amend the new Schedule.

30. The powers conferred give rise to two concerns:

- first, we have previously expressed the view that we expect a compelling justification for the ingredients of a criminal offence to be set by

delegated legislation. The powers in clauses 1, 8 and 12 would allow Ministers to create completely new criminal offences—and make changes to the ingredients of existing offences—yet the Memorandum does not appear to contain any justification at all for this;

- second, we have also said that, where the penalty for a criminal offence may be set by delegated legislation, we would expect the maximum penalty to be included on the face of the Bill, save in exceptional circumstances. The Bill does (in clauses 5(1)(b) and 10(1)(b)) limit the maximum penalty for offences "created" by regulations under clauses 1 and 8 (to 2 years' imprisonment), but it is unclear whether this limit also applies to the many existing medicines offences which could be modified by regulations under clause 1 or 8. The Memorandum does not appear to shed any light on this.

31. **We consider that, in the absence of a full justification—**

(a) **in allowing the ingredients of criminal offences to be set by delegated legislation, clauses 1, 8 and 12 contain inappropriate delegations of power;**

(b) **if clauses 1 and 8 would allow the penalties for existing offences to be set by delegated legislation without anything on the face of the Bill to limit the maximum penalties, this is an inappropriate delegation of power. We recommend that the House press the Minister to explain.**

Clauses 1 and 6 (human medicines: emergencies) and clauses 12 and 15 (medical devices: emergencies)

32. Clause 6 provides that regulations under clause 1 may make provision about the disapplication of any provision in—

- regulations under clause 1;
- the Human Medicines Regulations 2012; or
- the Medicines for Human Use (Clinical Trials) Regulations 2004.

It provides that such provision may be disapplied "in circumstances which give rise to a need to protect the public from a risk of serious harm to health".

33. Clause 15 makes equivalent provision for the disapplication of any provision in—

- regulations under clause 12; or
- the Medical Devices Regulations 2002.

34. The affirmative procedure applies to regulations made in reliance on clause 6 or clause 15. However, there is an exception: clause 42[24] provides that, where any such regulations need to be made "urgently to protect the public from an imminent risk of serious harm to health", the negative procedure applies instead.

24 See subsections (6), (7), (8) and (9)(a)(iii) and (vii).

35. The Government's justification for departing from the affirmative procedure in urgent cases is as follows:

> "It is appropriate for regulations made in these circumstances to be subject to the negative resolution so that they can come into force immediately and provide an efficient means of addressing an imminent serious public health risk. We 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".[25]

36. In our 14th Report of Session 2019–21, we drew attention to examples in the Corporate Insolvency and Governance Bill of powers otherwise subject to the affirmative procedure being made subject to the negative procedure in urgent cases. The justification for that was also based on the need to act quickly. We explained that this did not take account of the fact that the "made affirmative" procedure is as expeditious as the negative procedure:

> "Under this procedure, the instrument is able to come into force as soon as it is made, but it will automatically cease to have effect if it is not approved by both Houses within a specified period of time. The period specified for approval is usually 28 days or 40 days, subject to extension for periods of dissolution, prorogation or adjournment for more than four days.
>
> Regulations under the "made affirmative" procedure can be made and laid as expeditiously as regulations subject to the negative procedure. They can also be laid during a parliamentary recess, unlike draft affirmative instruments. By way of example, the main coronavirus regulations (SI 2020/350) have restricted civil liberty in a way that no other legislation has done in peacetime. They were made in considerable haste and during a parliamentary recess, and yet were still subject to the "made affirmative" procedure".[26]

37. **We are wholly dissatisfied by departments repeatedly arguing for powers otherwise subject to the affirmative procedure to be subject to the negative procedure where there is a need to act quickly, and seeking to justify this without acknowledging the existence of the made affirmative procedure. Departments are very well aware of that procedure and we can only conclude that their failure to mention it is a device to try to minimise Parliamentary scrutiny. In future, where a department seeks to justify powers that are otherwise subject to the affirmative procedure being subject to the negative procedure in urgent cases, we will expect them to explain why the made affirmative procedure should not apply.**

38. **Even accepting the appropriateness of the delegation of powers in clauses 1 and 12, if the affirmative procedure provides the appropriate level of Parliamentary scrutiny for regulations made in reliance on clauses 6 or 15 in non-urgent cases then, in the absence of cogent reasons for the negative procedure to apply in urgent cases, we take the view that the made affirmative procedure should apply in urgent cases.**

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25 See para 62 of the Memorandum (in relation to clause 6). Para 94 contains essentially the same justification in relation to clause 15.

26 14th Report, Session 2019–21, HL Paper 74, paras 22 and 23.

39. Clauses 6(2) and 15(2) both provide that any disapplication of regulatory provisions may be subject to conditions set out in regulations, or to conditions that are not set out in legislation at all but in a "protocol" published by Ministers[27]. Any such "protocol" would not be subject to Parliamentary scrutiny. The Memorandum contains no explanation or justification for this.

40. On a number of occasions, we have drawn the attention of the House to provision in Bills which enables Ministers to make what are, in effect, legally enforceable rules under the radar of the Parliamentary scrutiny that is afforded to primary and secondary legislation. For example, in Session 2017–19, we reported on the Ivory Bill and the Mental Health Units (Use of Force) Bill. Although dealing with entirely different subjects, we noted that they each included "a striking procedural similarity", namely that they each contained a delegated power enabling the Secretary of State to issue guidance which was, in effect, mandatory. We sought an assurance from the Government that they would not continue this practice of "camouflaging legislation as guidance".[28] In reply, the Rt Hon. Baroness Evans of Bowes Park, Leader of the House of Lords, said:

> "As you will be aware, it is Government policy that guidance should not be used to circumvent the usual way of regulating a matter. If the policy is to create rules that must be followed, the Government accepts that this should be achieved using regulations subject to parliamentary scrutiny and not guidance."[29]

41. In our report on the European Union (Withdrawal) Bill,[30] we referred to provision on the statutory duty of the Queen's printer in relation to the publication of retained EU law and noted that the Bill would allow the scope of the duty to be amended not by statutory instrument but by a direction. We said: "Amending the law by direction–with no statutory instrument and no parliamentary procedure–is highly unusual" and "sets an ominous precedent".[31] In our report on the Taxation (Cross-border Trade) Bill,[32] we drew attention to the inclusion of "the radical concept of making law by "public notice"". We said: "For Ministers and others to make law by "public notice", without any recourse to Parliament, is highly unusual and such provisions should attract strict surveillance by Parliament. The Statute of Proclamations 1539 gave proclamations the force of statute law. Although it was repealed in 1547 after the death of Henry VIII, it now enjoys a limited revival under the veil of Ministers and HMRC making law by "public notice"."[33]

42. **Allowing regulations to make the disapplication of legislation subject to conditions set out in a "protocol" is yet another example of "camouflaging legislation". Even accepting the appropriateness of the delegations of power in clauses 1 and 12, 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**

27 The Secretary of State (or, in the case of regulations made in reliance on clause 6 which relate to Northern Ireland, the Department of Health in Northern Ireland or that Department and the Secretary of State acting jointly).
28 31st Report, Session 2017–19, HL Paper 177, para 4.
29 35th Report, Session 2017–19, HL Paper 202, Appx 1.
30 12th Report, Session 2017–19, HL Paper 73.
31 See para 49 of that Report.
32 11th Report, Session 2017–19, HL Paper 65.
33 See para 25 of that Report.

subject should be set out in the regulations themselves and not in a "protocol" which is not subject to Parliamentary scrutiny.

Clauses 1 and 2(1)(n) (prohibitions relating to the supply of human medicines)

43. Clause 2(1)(n) provides that regulations under clause 1 may make provision about prohibitions relating to the supply of human medicines[34]. Clause 42(9) of the Bill provides for such regulations to be subject to the negative procedure. The explanation given for this in the Memorandum is as follows:

> "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".[35]

44. We find this an unconvincing explanation. It isn't clear why consultation with relevant professional bodies lessens the requirement for scrutiny in Parliament. Indeed, if proposed changes are sufficiently important for there to be extensive consideration and scrutiny by professional bodies, this supports requiring the higher level of scrutiny in Parliament that the affirmative procedure affords. Furthermore, the prohibitions to which clause 2(1)(n) applies are sufficiently important that breach of them is a criminal offence (punishable, in the case of 4 of the 5 prohibitions, by imprisonment for up to two years).

45. **Even accepting the appropriateness of the delegation of powers in clause 1, we take the view that the affirmative procedure should apply. The consultation requirement imposed by clause 41 of the Bill is to be welcomed but we are concerned at consultation being presented as a substitute for Parliamentary scrutiny. On the contrary, if the exercise of the power is of sufficient importance to merit extensive consultation, it is of sufficient importance to warrant the higher level of Parliamentary scrutiny which the affirmative procedure affords.**

Clauses 8 and 9(1)(f) (supply of veterinary medicines)

46. Clause 9(1)(f) provides that regulations under clause 8 may make provision about the categories of person who may supply veterinary medicines. Clause 42(9) of the Bill provides for such regulations to be subject to the negative procedure. The explanation given for this in the Memorandum is as follows:

> "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".[36]

47. We find this unconvincing for the same reasons we gave in paragraphs 44 and 45 above in relation to the power in clause 1 to make provision about prohibitions relating to the supply of human medicines.

48. **Even accepting the appropriateness of the delegation of power in clause 8, we take the view that the affirmative procedure should apply. If the**

34 The prohibitions in question are those in the provisions in the Human Medicines Regulations 2012 that are specified in clause 2(2).
35 See para 63 of the Memorandum.
36 See para 80 of the Memorandum.

exercise of the power is of sufficient importance to merit extensive consultation, it is of sufficient importance to warrant the higher level of Parliamentary scrutiny which the affirmative procedure affords.

Clause 16 (information systems)

49. Under clause 16, the Secretary of State may make regulations about the establishment and operation of "information systems" for purposes relating to the safety and effectiveness of medical devices. Such systems are to be operated by the Health and Social Care Information Centre (HSCIC), which is a body established under section 252 of the Health and Social Care Act 2012. The Memorandum explains that the purpose of the power is "to enable information on medical devices to be obtained, analysed, used and disseminated by the HSCIC".[37] The affirmative procedure applies to regulations under clause 16.

50. Again, the Government have chosen to create a framework for future regulatory changes by statutory instrument rather than substantive legislative changes that can be debated here and now. Rather like the justifications given for the powers in clauses 1, 8 and 12, the Memorandum states that the power allows any information system to be "updated".[38]

51. We consider this to be an inadequate explanation. It may well be appropriate to take powers which would allow aspects of an information system to be provided for in delegated legislation but the Government has not explained why the Bill provides for every aspect to be provided for in regulations. The powers conferred include, significantly, power to take any of the provision that is made in clauses 17 to 34 of the Bill (about enforcement in relation to the marketing or supply of a medical device) and apply that provision to requirements imposed by regulations in relation to information systems[39]. Indeed, the Government acknowledge that, "the subject matter is new … there are a number of potential stakeholders with an interest and … any future changes could be of significant interest to Parliament".[40]

52. **We have doubts about the justification provided for the delegation and take the view that, unless the Government can fully justify it, the delegation is inappropriately wide.**

Conclusion

53. **We are deeply concerned not only by the Government's failure to provide sufficient justification for the adoption of a "skeleton bill" approach—which would give Ministers sweeping powers to almost completely re-write the existing regulatory regimes for medicines and medical devices—but also by their failure to acknowledge the breadth of the powers that the Bill would confer. 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.**

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37 See para 97 of the Memorandum.
38 See para 99 of the Memorandum.
39 See clause 16(7) of the Bill.
40 See para 100 of the Memorandum.

APPENDIX 1: MEMBERS' INTERESTS

Committee Members' registered interests may be examined in the online Register of Lords' Interests at https://www.parliament.uk/hlregister. The Register may also be inspected in the Parliamentary Archives.

For the business taken at the meeting on 15 July 2020 Members declared no interests.

Attendance

The meeting was attended by Baroness Andrews, Lord Blencathra, Baroness Browning, Lord Goddard of Stockport, Lord Haslehurst, Lord Haskel, Baroness Meacher, Lord Rowlands, Lord Thurlow and Lord Tope.