

HOUSE OF LORDS

Delegated Powers and Regulatory Reform
Committee

33rd Report of Session 2019–21

Medicines and Medical Devices Bill: Government Response

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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](#)

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[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 hlddelegatedpowers@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.

Thirty Third Report

MEDICINES AND MEDICAL DEVICES BILL: GOVERNMENT RESPONSE

1. We considered this Bill in our 19th Report of this Session.¹ The Government have now responded by way of a letter from Lord Bethell, Parliamentary Under Secretary of State at the Department of Health and Social Care. The response is printed at Appendix 1.

1 [19th Report](#), Session 2019-21 (HL Paper 109).

APPENDIX 1: MEDICINES AND MEDICAL DEVICES BILL: GOVERNMENT RESPONSE

Letter from Lord Bethell, Parliamentary Under Secretary of State at the Department of Health and Social Care, to the Rt Hon. Lord Blencathra, Chair of the Delegated Powers and Regulatory Reform Committee

I am writing in response to the recommendations made in the Delegated Powers and Regulatory Reform Committee's report of 22 July 2020 on the Medicines and Medical Devices Bill.

I am grateful for the Committee's scrutiny of this Bill and I have given careful consideration to its concerns and recommendations alongside the views of the House. As a result, I am pleased to be able to take the opportunity to set out below the Government amendments tabled on 12 October ahead of Committee and on 14 December ahead of Report stage. I hope that you will agree with me that these amendments appropriately address the concerns raised and will be welcomed by the Committee.

1. The following are intended to respond to concerns raised by the Committee and refers to clause numbers in the Bill as amended in Grand Committee:
 - i. Greater checks and balances in the exercise of the delegated powers at clauses 1, 9 and 14, including the introduction of an overarching focus on safety;**
 - ii. Strengthening the statutory consultation obligation;**
 - iii. Introducing a forward and backward-looking reporting requirement;**
 - iv. Clarification of the limitations around maximum penalties for criminal offences;**
 - v. Emergency Regulations (that disapply existing regulatory provisions when accompanied by the declaration that the changes are needed to protect the public from an imminent risk of serious harm to health) to be made subject to the made affirmative procedure;**
 - vi. Additional regulations (for example those with provisions about persons who may supply veterinary medicines) to be subject to the draft affirmative procedure; and**
 - vii. Strengthening the oversight of regulations establishing information systems (clause 18).**

Greater checks and balances in the exercise of the delegated powers at clauses 1, 9 and 14; Strengthening the statutory consultation obligation; and introducing a forward- and backward-looking reporting requirement

2. Clauses 1, 9 and 14 provide broad powers to amend and supplement the existing bodies of law that regulate human medicines, veterinary medicines and medical devices respectively. These central delegated powers that provide the means to make changes to the existing bodies of law governing human medicines, veterinary medicines and medical devices, after the end of the transitional period, necessarily reflect the span of these important regulatory regimes from manufacturing to supply. The Government has

listened carefully inside and outside the House to concerns raised about the breadth of the powers and considered how the powers might be constrained whilst providing a means by which the Government remains able to respond to safety concerns and maintain the effective regulation these vital products.

3. The legislation that governs medicines and devices is itself necessarily comprehensive and whilst we have taken care to ensure the delegated powers relate to amendments and supplementary provision, at Committee stage in the House of Lords, Government amendments were made to clauses 1, 9 and 14. These provided that regulations could only be made under these clauses if the person making the regulations is satisfied that they would promote the health and safety of the public, or in the case of veterinary medicines, the regulations would promote the health and safety of the public; the health and welfare of animals; or the protection of the environment.
4. Whilst the positive impact of these amendments was recognised by Peers, the Government heard the further requests to see these constraints formulated differently and further elevate the consideration that must be given to the safety of medicines and medical devices before regulations are made. In response, the Government tabled further amendments to these clauses on 14 December to be debated at Report Stage.
5. The tabled amendments will replace clauses 1(2), 9(2) and 14(2) to introduce the requirement that the overarching objective of making regulations must be to safeguard public health for human medicines and medical devices. And for veterinary medicines, the overarching objective must be to promote the health and welfare of animals; the health and safety of the public; or the protection of the environment. Safety has always been an inherent part of the existing regulatory regimes and with these amendments we have sought to strengthen this further as part of any changes to the law, enabled by these powers under the Bill.
6. What was previously a reference to “attractiveness” as a factor that regard must be had to when making regulations, has been replaced with expanded-upon activities (as put forward by Noble Lords during Committee consideration) that regulatory changes might seek to encourage in the UK. It is hoped the Committee also welcomes this further clarity.
7. In addition, amendments tabled on 14 December introduce a new sub-clause to clauses 1, 9 and 14 to add a further constraint that will apply if regulatory changes have an impact on the safety of human medicines, veterinary medicines and medical devices. The effect is that regulations that may impact on the safety of these products can only be made under clauses 1, 9 and 14 if it is considered that the benefits of doing so outweigh the risks. This further strengthening check on the use of these delegated powers provides more openness around the decision-making process.
8. I was pleased to see that the Committee welcomed the consultation requirement introduced by clause 43 of the Bill. To build on this important provision and increase transparency, amendments made at Committee stage and to be made at Report stage require that a public consultation is carried out. Importantly, amendments also insert the requirement that the consultation document includes a summary of the relevant authority’s initial assessment of the matters mentioned above how the overarching objective has been taken into account and what factors in this assessment have been

taken into account so far in the development of the proposals leading to legislative change.

9. Amendments at Committee stage also inserted a reporting requirement (clause 44) on the operation of regulations made under clauses 1, 9 and 14. The Secretary of State must consult on the preparation of the report and the report must contain a summary of any concerns or proposals raised during that consultation and the Secretary of State's response, including any plans to make further regulations under those clauses. The report will be laid before Parliament and provide an opportunity for further scrutiny of both regulations already made and plans for future regulations. This mechanism for a forward look, and the opportunity it seeks to provide for debate and discussion, is an additional check on the exercise of these crucial powers. Amendments have been tabled ahead of Report to also place this important reporting obligation on the relevant Northern Ireland department at Northern Ireland's request.
10. In combination, the amendments add meaningful and real constraints to the exercise of these delegated powers and increase transparency around their use.

Clarification of the limitations around maximum penalties for criminal offences

11. I am grateful for the Committee's expert assessment as to how the powers could be used to amend existing criminal offences. It is vital that our regulatory regimes are enforceable and criminal offences are a critical part of the enforcement regime, deterring potentially harmful activity and providing a means to take punitive measures against those whose actions put people at risk.
12. As updates are made to the existing comprehensive regulatory regimes to safeguard public health, it is imperative that any corresponding offences remain extant and new offences can be created when new requirements are introduced. For existing offences, by amending a regulatory requirement, the breach of which is a criminal offence, it may mean that the ingredients of that offence have indirectly been amended. It cannot be the case that the exercise of powers to make regulatory updates, risks rendering the requirements unenforceable. In such circumstances the update would be nugatory and compromise both the efficacy and coherence of these important regulatory regimes. Similarly, the powers in clauses 1 and 9 will enable the regimes to be supplemented to regulate new types of medicines and innovative practice. Regulations to ensure the safety of cutting-edge practice needs to be as enforceable as the existing regulations that ensure the safety of long-standing practices. It remains critical to the integrity of the existing regulatory systems.
13. Having carefully considered the concerns raised that the powers could be used to increase the maximum penalties for existing offences, at Committee stage the Government tabled an amendment to expressly make clear the limits of the powers. Whilst the Bill already made explicit provision preventing the creation of offences punishable with a sentence of more than two years imprisonment, our amendments have made it clear on the face of the Bill that regulations may not provide for any offence, new or existing, to be punishable with a sentence of more than two years imprisonment. These

regulations will be subject to the draft affirmative procedure. I trust that this amendment has provided the Committee with the assurance it was seeking.

Clauses 1 and 6 (human medicines: emergencies) and clauses 14 and 17 (medical devices: emergencies)

14. The powers to make provision in regulations to respond to risks of serious harm to health are some of the most important in the Bill. They can be used proactively or reactively; the intention is that where possible and appropriate, as much provision as is foreseeable will be made in regulations before the risk arises, allowing time for public consultation and Parliamentary scrutiny of draft regulations that seek to disapply provisions in an emergency.
15. I have heard the Committee's recommendation that regulations accompanied with a declaration that they need to be made urgently to protect the public from an imminent risk of serious harm to health, should be subject to the made affirmative procedure. Amendments to this effect were made at Lords' Committee stage.
16. The Committee recommended that the option to set out the conditions of the disapplications in a protocol be removed. I wish to reassure the Committee that protocols are not an attempt to camouflage legislation, but they are essential to ensure the Government and importantly stakeholders on the ground can respond quickly and effectively to protect the public from a risk of serious harm to health. Protocols will not work in isolation — they may only be used if provided for by secondary legislation. Medicines and devices are highly regulated areas, and where disapplication of any of the regulatory provision is considered, it is vital that conditions are put in place to ensure matters such as safety. They would be time-limited to provide flexibility and administrative detail, tailored to the professional audience that requires it and in language which they are familiar with.
17. By way of example, in October 2020, the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (SI 2020/1125) were made under section 2 of the European Communities Act 1972 to enable the roll-out of Covid-19 vaccination programmes. These regulations made amendments to existing disapplications in the Human Medicines Regulations 2012² and made provision for new disapplications that are required to respond to the current pandemic. For example, the regulations provided an exemption from the need for a wholesale dealer's licence to allow for the swift and safe transfer of Covid-19 vaccines in response to patient need by NHS providers and providers of armed forces medical services at the end of the medicines supply chain³. This disapplication was made subject to conditions that were set out in the 2020 Regulations. The Regulations also introduced a new type of national immunisation protocol⁴ to allow those who are registered healthcare professionals who do not normally vaccinate, and people who are not registered health care professionals, to safely administer a licensed or temporarily authorised COVID-19 or influenza vaccine. That disapplication is an example of where the conditions are set out both in regulations and by reference to a protocol, which under that regulation must be approved by the Secretary of State, the Scottish Ministers, the Welsh Ministers or the Minister of Health in Northern Ireland. That protocol will be written

2 For example, regulations 174 and 247 of the Human Medicines Regulations 2012.

3 See regulation 19 of the Human Medicines Regulations 2012 (as amended by SI 2020/1125).

4 See new regulation 247A of the Human Medicines Regulations 2012.

similarly to patient group directions, which are well-known to the healthcare workforce and are used, for example, as part of the annual national influenza immunisation programme. The use of a protocol will provide the flexibility to define the training and competence requirement of vaccinators, and the clinical considerations they must follow — details that will need to be written and updated as vaccines for Covid-19 are authorised for supply, and not details that it would be appropriate to set out in legislation, or indeed practical to set out in made affirmative SIs every time an update is required.

18. As explained, the Human Medicines Regulations 2012 already provided certain disapplications for supplying medicines during or in anticipation of a disease becoming pandemic but the current pandemic required further provision to be made. That further provision was provided by the 2020 Regulations in the form of additional disapplications that are subject to conditions set out in the regulations and where appropriate in a protocol. It is vital that the Medicines and Medical Devices Bill provides a power to enable such provision to continue be made so that the Government and the MHRA can respond quickly and effectively to emergency circumstances that require the public to be protected from a risk of serious harm to health.
19. It is the Government's view that these powers are justified, necessary and proportionate in the important context of emergencies and the Government has been transparent with Parliament about its potential use.

Parliamentary procedure—additional regulations to be subject to the draft affirmative procedure

20. Since the Bill's introduction, the majority of the exercises of the Bill's powers have been subject to the affirmative procedure. I have heard the Committee's concerns that regulations made under clause 1, relying on clause 2(1)(n), and regulations made under clause 9, relying on clause 10(1)(f) should be subject to the draft affirmative procedure and accordingly tabled amendments at Committee stage to subject these regulations to greater Parliamentary scrutiny. I also reflected on the Chair, Lord Blencathra's speech at Second Reading that the Bill was "all to be filled in with negative secondary legislation" and tabled amendments to see further exercises of the powers subject to the draft affirmative procedure. The result is that regulations making provision about labelling and packaging, advertising and prescribing in relation to human medicines will be subject to the draft affirmative procedure. And in relation to amendments to the Veterinary Medicines Regulations 2012, where provisions are about supply, labelling and packaging and advertising, regulations will also be subject to the draft affirmative procedure.

Clause 18 (Information Systems)

21. Clause 18 provides a power to make provision about the establishment and operation of information systems. It provides that these are information systems that will be operated by the Health and Social Information Centre (NHS Digital) and sets out three distinct purposes that the systems may relate to.
22. The Government's view is that regulations to be made under the draft affirmative procedure are an appropriate and necessary means to meet the need for more clinical data to be gathered by the UK's healthcare services about the safety of both medical devices and the clinical interventions required for those devices.

23. In addition to the justification given in the Supplementary Memorandum (17 June 2020), we would ask the Committee to bear in mind that, for this to be a successful UK wide information system, it will require extensive engagement and close working with the devolved administrations and other groups of stakeholders.
24. Indeed, there has already been extensive engagement with the devolved administrations to date both at official and Ministerial level. This has enabled future working arrangements to be agreed that will include various working groups, workshops, and regular four nations Ministerial meetings. These arrangements and the public consultation will inform both the administrative and governance arrangements for the information system, and also matters concerning information-sharing and access to the system, which will need to be provided for in legislation. It would simply not be possible or appropriate to conduct this engagement in a meaningful way by reference to more extensive provisions of primary legislation being debated in Parliament.
25. Amendments the Government tabled on 14 December will extend the reporting requirements at clause 44 to regulations made under clause 18. This means that the Secretary of State will need to report on the operation of those regulations and consult on the preparation of that report. That will include consulting the devolved administrations and the report will need to contain a summary of any concerns and proposals raised, and the Secretary's response to the same, including any plans to make further regulations under clause 18. This reporting requirement therefore provides Parliament with another opportunity to review how the powers have been exercised and gives Parliament notice of plans to make further regulations in response to any concerns or proposals raised.
26. In these circumstances and given the potential benefits that effective information systems could bring for patients, it is the government's view that Clause 18 is an appropriate delegation.

Thank you again for these recommendations and I trust this letter has addressed your points of concern with the Bill. I look forward to discussing in more detail at Report.

6 January 2021

APPENDIX 2: 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.