



Department of Health & Social Care

*From the Lord Bethell
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The Rt Hon. the Baroness Taylor of Bolton
Chair, Constitution Committee
By email: constitution@parliament.uk

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Dear Chair,

MEDICINES AND MEDICAL DEVICES BILL: GOVERNMENT RESPONSE

Thank you for the report from the Constitution Committee dated 29 July 2020, on the Medicines and Medical Devices Bill.

I have given careful consideration to concerns and recommendations raised alongside the views of the Delegated Powers and Regulatory Reform Committee and the House. As a result, I am pleased to be able to respond in this letter and 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 these amendments 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 and additional regulations subject to the draft affirmative procedure;**
 - ii. **Strengthening the statutory consultation obligation;**
 - iii. **Introducing a forward and backward looking reporting requirement;**
 - iv. **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; and**
 - v. **Clarification of the limitations around maximum penalties for criminal offences.**

Greater checks and balances in the exercise of the delegated powers at clauses 1, 9 and 14

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 Peers) that regulatory changes might seek to encourage in the UK.
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. Since the Bill’s introduction, the majority of the exercises of the Bill’s powers have been subject to the draft affirmative procedure. At Committee stage, the Government tabled amendments to subject regulations making provision about labelling and packaging, advertising and prescribing in relation to human medicines 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. I trust these amendments to allow for greater parliamentary scrutiny will be welcomed by the Committee.

Strengthening the statutory consultation obligation

9. Amendments made at Committee stage and to be made at Report stage require that a public consultation is carried out before making regulations under any of the powers in the Bill.

Importantly, in relation to regulations made under clauses 1, 9 and 14, amendments will require the consultation document to include a summary of the relevant authority's assessment of the matters mentioned above, namely the overarching objective and what factors in this assessment have been taken into account so far in the development of the proposals leading to legislative change. These amendments therefore provide greater transparency about how the powers may be exercised.

Introducing a forward and backward looking reporting requirement

10. 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 extend this important reporting requirement to the operation of regulations made under clause 18 (information systems) and place an equivalent obligation on the relevant Northern Ireland department in respect of regulations they make under clauses 1 and 9.

11. In combination, I trust the Committee will agree that the amendments above add meaningful and real constraints to the exercise of the delegated powers at clauses 1, 9 and 15 and increase transparency around their use.

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

12. 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 and 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.

13. I have heard the Committee's and the DPRRC'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 Lord's Committee stage.

14. The Committee and the DPRRC recommended that the option to set out the conditions of the disapplications in a protocol be removed. I wish to reassure the Committee that they 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.

15. 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 2012¹ 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 chain².
16. 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 protocol³ 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 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. 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.
17. 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.

Clarification of the limitations around maximum penalties for criminal offences

18. 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.
19. The majority of the regulatory regimes for human medicines, veterinary medicines and medical devices is set out in secondary legislation. 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

¹For example, regulations 174 and 247 of the Human Medicines Regulations 2012

² See regulation 19 of the Human Medicines Regulations 2012 (as amended by SI 2020/1125)

³ See new regulation 247A of the Human Medicines Regulations 2012

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.

20. At Committee stage the Government tabled an amendment to expressly make clear the limits of the powers. It is now explicit 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.

Thank you again for your report on the Medicines and Medical Devices Bill. I hope the Committee will welcome the real and positive impact of the Government amendments that have been tabled in response to its concerns.

Yours,

A handwritten signature in dark ink, appearing to read 'Bethell', written in a cursive style.

LORD BETHELL