

**SUPPLEMENTARY MEMORANDUM CONCERNING THE DELEGATED POWERS IN THE  
MEDICINES AND MEDICAL DEVICES BILL**

**(To be read alongside the Delegated Powers Memorandum (dated 24 June 2020))**

**SUMMARY OF AMENDMENTS TO AND ADDITIONAL DELEGATED POWERS**

*The following powers are contained in the amendments tabled by the Government on 12 October 2020 ahead of Lords Committee stages.*

| <b>POWER</b>   | <b>JUSTIFICATION FOR AMENDMENT</b>   | <b>SCRUTINY</b>   |
|--|--|---|
| Clause 1 power to make regulations about human medicines   |  | Subsequent superseding amendments are proposed via amendments to be tabled on 14 December, please see table below |
| Clauses 2(1)(j) (labelling and packaging), (k) (advertising) and (n) (prescribing)<br><br>Amendment made to what is now clause 45(3) and (6)   | Strengthens scrutiny   | Draft affirmative   |
| Clause 5 - offences  | Ensures that regulations under clause 1(1) may not provide for any offence to be punishable with a sentence of imprisonment of more than two years | Draft affirmative (unchanged)   |
| Clause 6 emergencies<br><br>Amendment made to what is now clause 45(3) and (7)   | Strengthens scrutiny   | Made affirmative  |
| [now] Clause 9 power to make regulations about veterinary medicines  |  | Subsequent superseding amendments are proposed via amendments to be tabled on 14 December, please see table below |
| [now] Clauses 10(1)(f) (supply) (k) (labelling and packaging), and (n) (advertising)<br><br>Amendment made to what is now clause 45(3) and (6) | Strengthens scrutiny   | Draft affirmative   |
| [now] Clause 11 - offences   | Ensures that regulations under clause 9(1) may not provide for any offence to be punishable with a sentence of imprisonment of more than two years | Draft affirmative (unchanged)   |

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| [now] clause 14 power to make regulations about human medicines                       |                      | Subsequent superseding amendments are proposed via amendments to be tabled on 14 December, please see table below |
| [now] Clause 17 emergencies<br><br>Amendment made to what is now clause 45(3) and (7) | Strengthens scrutiny | Made affirmative  |

***The following powers are contained in the amendments tabled by the Government on 14 December 2020 ahead of Lords Report stages.***

| <b>POWER</b>  | <b>JUSTIFICATION FOR AMENDMENT</b>   | <b>SCRUTINY</b>   |
|---|--|-------------------|
| <u>New Part A1</u> (and Schedule A1)<br>The Commissioner for Patient Safety - Regulations about appointment and operation | This forms part of the Government's response to the report of the Independent Review of Medicines and Medical Devices led by Baroness Cumberlege (IMMDSR Report) <sup>1</sup> . The amendments place a duty on the Secretary of State to appoint a Commissioner for Patient Safety. Regulations will then set out the necessary provision about the appointment and operation of the Commissioner. | Draft affirmative |
| Clause 1 power to make regulations about human medicines  | - Introduces an overarching objective for regulations that amend or supplement the law relating to human medicines to safeguard public health<br>- replaces previous reference to the 'attractiveness' of the UK to specify the kinds of activity that could make the UK likely to be a more favourable place to conduct that activity   | Unchanged         |

<sup>1</sup> First Do No Harm – *The report of the Independent Medicines and Medical Devices Safety Review*, 8 July 2020. Available here: [https://www.immidsreview.org.uk/downloads/IMMDSRReview\\_Web.pdf](https://www.immidsreview.org.uk/downloads/IMMDSRReview_Web.pdf)

|  |   |                  |
|--|---|------------------|
|  | <ul style="list-style-type: none"> <li>- introduces a benefit/risk assessment – if regulations have an impact on the safety of medicines, the authority can only make regulations if the benefits of doing so outweigh the risks</li> <li>– making clear safety is absolutely critical</li> </ul>   |                  |
| <p>Clause 9 power to make regulations about veterinary medicines</p> | <ul style="list-style-type: none"> <li>- Introduces an overarching objective for regulations that amend or supplement Veterinary Medicines Regulations 2012 to promote the health and welfare of animals, health and safety of the public, protection of the environment</li> <li>- replaces previous reference to the ‘attractiveness’ of the UK to specify the kinds of activity that could make the UK likely to be a more favourable place to conduct that activity</li> <li>- introduces a benefit/risk assessment – if regulations have an impact on the safety of veterinary medicines, the authority can only make regulations if the benefits of doing so outweigh the risks – making clear safety is absolutely critical</li> </ul> | <p>Unchanged</p> |
| <p>Clause 14 power to make regulations about medical devices</p>     | <ul style="list-style-type: none"> <li>- Introduces an overarching objective for regulations that amend or supplement the Medical Devices Regulations 2002 to safeguard public health</li> <li>- replaces previous reference to the ‘attractiveness’ of the UK to specify the kinds of activity that could make the UK likely to be a more favourable place to conduct that activity</li> <li>- introduces a benefit/risk assessment – if regulations</li> </ul>  | <p>Unchanged</p> |

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|   | <p>have an impact on the safety of medical devices, the authority can only make regulations if the benefits of doing so outweigh the risks – making clear safety is absolutely critical</p> |                          |
| <p><u>New clause</u> - Advisory Committee<br/>Power to establish and make other provision about an advisory committee for matters relating to medical devices</p> | <p>This is necessary to enhance the contribution of the existing Devices Expert Advisory Committee by placing it on a statutory footing</p>   | <p>Draft affirmative</p> |

## FURTHER ANALYSIS OF AMENDMENTS TABLED ON 12 OCTOBER 2020

### Amendments to existing delegated powers in the Bill

**a. Amendments to applicable parliamentary procedure to regulations made relying on clauses 2(1)(j), (k) and (n) and clauses 10(1)(f), (k) and (n) (advertising)**

**Power conferred on:** the “appropriate authority”

**Power exercised by:** Regulations

**Parliamentary procedure:** draft affirmative

1. Regulations made under clause 1 and relying on clauses 2(1)(j) (labelling and packaging), (k) (advertising) and (n) (prescribing), and regulations made under clause 9 and relying on clauses 10(1)(f) (supply) (k) (labelling and packaging), and (n) (advertising) are now subject to the draft affirmative procedure.
2. The Government tabled the amendments in order to increase the level of parliamentary scrutiny that regulatory changes to the relevant existing bodies of law governing human medicines and veterinary medicines will be subject to on these topics. Please see what is now clause 45(3) and (6).

**b. Amendments to clauses 5 and 11 (offences)**

**Power conferred on:** the “appropriate authority”

**Power exercised by:** Regulations

**Parliamentary procedure:** draft affirmative (unchanged)

3. In relation to the delegated powers to amend and supplement the existing bodies of legislation that govern human medicines and veterinary medicines, the amendments clarify that any corresponding changes to support enforcement may not provide for any offence to be punishable with a sentence of imprisonment of more than two years.

**c. Amendments to applicable parliamentary procedure to regulations made relying on clauses 6 and 17 (emergencies)**

**Power conferred on:** the “appropriate authority” (clause 6) and the Secretary of State (clause 17)

**Power exercised by:** Regulations

**Parliamentary procedure:** draft affirmative (unchanged) and made affirmative if accompanied by a declaration of urgency

4. Amendments provide that the made affirmative procedure applies to regulations made under clause 1, relying on clause 6 (human medicines), and under clause 14, relying on clause 17 (medical devices), when containing a declaration that the

regulation-maker considers that the regulatory changes need to be made urgently to protect the public from an imminent risk of serious harm to health.

5. The Government tabled the amendments to make these urgent regulations subject to the made affirmative procedure in order to increase the level of parliamentary scrutiny. Such regulations cease to have effect at the end of a period of 40 days unless approved by a resolution of each House within that same timeframe. Please see what is now clause 45(3) and (7).

## **FURTHER ANALYSIS OF AMENDMENTS TABLED ON 14 DECEMBER 2020**

### **d. Amendments to establish a Commissioner for Patient Safety (Part A1 and Schedule A1)**

***Power conferred on:*** Secretary of State

***Power exercised by:*** Regulations

***Parliamentary procedure:*** Draft affirmative

#### Context and Purpose

6. These amendments form part of the Government's response to the IMMDSR Report. The Review published its report on 8 July 2020, during this Bill's passage.
7. The amendments place a duty on the Secretary of State to appoint a Commissioner for Patient Safety and make provision for the Commissioner's functions. The amendments include a power to make provision in regulations for the appointment and operation of this new statutory office holder.

#### Justification for taking the power

8. The Commissioner's core duties include promoting the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices. The Commissioner will also be under a duty to involve patients in the discharge of the core duties and take reasonable steps to consult patients on the matters the Commissioner proposes to consider. Given this, it is appropriate that matters relating to the appointment and operation of the Commissioner are subject to public consultation and making this provision in regulations enables this to happen.
9. Furthermore, the Commissioner for Patient Safety is an entirely new role and making operational provision in regulations ensures that any changes can be made more easily should it become apparent that these are required once the Commissioner has started in the role.

#### Justification for the procedure

10. The Commissioner's core duties are set out on the face of the Bill and the regulations will make provision about the appointment and operation of the Commissioner. Given the Parliamentary interest in establishing a Patient Safety Commissioner and

in ensuring that the role operates effectively for the benefit of patients, it is considered that the draft affirmative procedure is the appropriate procedure for these supporting regulations.

Examples of how the power could be used

11. Paragraph 6 of Schedule A1 provides the power to make regulations about appointment and operation. Regulations about appointment could for example set out relevant criteria for appointment, including any reasons for disqualification.
12. Paragraph 6(2) sets out an illustrative list of the provision that can be made in regulations. This includes provision about terms of office, which could for example include provision about the duration of a term and termination. Regulations may also make provision about remuneration, financial assistance and the preparation of business plans.
13. Regulations may require the Commissioner to lay documents before Parliament and prepare reports. In combination this means that the regulations could for example, require the Commissioner to lay an annual report before Parliament and specify what that report should cover.
14. The appointment of a board to provide advice to the Commissioner is another matter that could be provided for in regulations. For example, regulations could provide that appointments to the expert advisory committee will be made following consultation with the Commissioner; the number of members; and criteria for appointment.

**e. Amendments to clauses 1, 9 and 14 (existing delegated powers in the Bill)**

***Power conferred on:*** the “appropriate authority” (clauses 1 and 9) and the Secretary of State (clause 14)

***Power exercised by:*** Regulations

***Parliamentary procedure:*** (unchanged)

15. Clauses 1, 9 and 14 contain substantial delegated powers that allow for amendments to be made to the existing bodies of law that govern human medicines, veterinary medicines and medical devices. In combination the amendments seek to, provide that the overarching objective in making amending regulations is to safeguard public health for human medicines and medical devices, and to ensure that regulations amending the veterinary medicines legislative regime meet one or more of the following overarching objectives to promote the health and welfare of animals; the health and safety of the public; or the protection of the environment.
16. Further, what was previously a reference to the ‘attractiveness of the United Kingdom’ will be omitted and amendments seek to make clear the kinds of activity we would hope regulatory changes could encourage within the UK.

17. The amendments add a safety 'lock' on use of the delegated powers at clauses 1, 9 and 14, so that where regulations have an impact on the safety of medicines, or medical devices, the authority can only make regulatory changes if the benefits of doing so outweigh the risks. In the context of making regulatory changes, whilst complex assessments form a necessary part of any decision, the changes make clear safety remains absolutely critical.

**f. Amendments to establish Advisory Committee on legislative basis**

**Power conferred on:** Secretary of State

**Power exercised by:** Regulations made by statutory instrument

**Parliamentary Procedure:** Draft affirmative

Context and Purpose

18. The purpose of this amendment is to place an expert advisory committee for medical devices) onto a statutory footing (the Committee). Currently, the MHRA has a Devices Expert Advisory Committee comprised of clinical experts and healthcare professionals from a range of professional bodies, and lay representatives. Its existing mandate is to provide MHRA with advice on a range of matters connected to medical devices, including clinical and scientific aspects of medical device safety; regulatory issues in the context of wider national policies and international concerns; and the implications of "real world" clinical practice for device-related policies.
19. Putting the Committee and its mandate on a statutory footing will enhance its contribution to the safety of medical devices on the market. This would also ensure parity with the medicines regime, in respect of which MHRA currently receives advice from two statutory committees established under the Human Medicines Regulations 2012, the Commission on Human Medicines (CHM) and the British Pharmacopoeia Commission (BPC). This approach is further supported by the IMMDSR Report which highlighted the need to strengthen scrutiny of medical devices, particularly with regards to post market safety and vigilance.
20. Subsection (1) of this new clause will provide the Secretary of State with a delegated power to make regulations establishing a committee to advise the Secretary of State on such matters that may be specified in the regulations. The regulations can also make other provision about the committee.
21. Subsection (2) of this clause lists the sorts of things in relation to which the regulations may make provision. This is not an exhaustive list. The matters listed include the membership of the committee; the establishment of sub-committees; matters to which the committee may or must have regard; cooperation between the committee and the CHM; and other bodies with expertise in relation to medical devices.
22. Subsection (3) of this clause provides that provision about membership of the committee can include provision about the number of members and their

appointment; requirements that members be independent from the Secretary of State; and provision about payment of remuneration and allowances to members.

#### Justification for taking the power

23. The justification for taking the power is to strengthen the ability of the Committee to provide the MHRA with advice regarding medical devices by placing it on a statutory footing, in particular in light of adjustments that may be made to the regulatory landscape in response to the IMMDSR Report.
24. In respect of other delegated powers contained in this Bill (for instance, the power contained at clause 14 (1)), we have sought to limit the matters in respect of which regulations can make provision by reference to exhaustive lists. This however is not appropriate for the delegated power contained in this clause. This is because, it is important that this delegated power enables the MHRA to be flexible and agile in ensuring the Committee works with the regulatory system to improve oversight of medical devices and their safety. Examples of how this delegated power could be used to respond to ensure this are as follows:
  - i. *Patient engagement* - The power will enable the Secretary of State to make regulations providing for membership of the Committee to include a representative from a patient advocacy group and providing that the Committee must, or may, have regard to patient views.
  - ii. *Conflicts of interest* - In its current format, the Committee has stringent measures in place to ensure the independence of its appointed members. This delegated power will enable the Secretary of State to make regulations about the appointment of members and allow the current rules surrounding appointment and independence to be strengthened and kept up to date.
  - iii. *Transparency* - This power will enable the Secretary of State to make regulations that require the Committee to communicate publicly about the advice it gives, or for the MHRA to publish information about new and emerging risks it is seeking advice on. It would also enable regulations to set out the timeframes within which the Committee should provide its advice. This would support time-bound procedures for risk-management and regulatory decision making and it is important that these can be updated as appropriate.

#### Justification for the procedure

25. The Department considers it appropriate that this regulation making power is subject to the draft affirmative procedure. Parliamentarians will no doubt want to ensure that the Department is able to strengthen oversight and decision making for medical devices in a robust manner, and it is accordingly appropriate that they have an opportunity to debate and approve any regulations made under this power.

### Example of how the power could be used

26. In addition to making provision to establish the Committee, regulations could make the following provision:
- i. Empower the Committee to make **recommendations** to MHRA. Such recommendations could include, for instance:
    - Recommendations with respect to regulatory requirements to be met by particular types of devices; and
    - Recommendations about a need for a review into a specific type of device or clinical practice using a specific type of device;
  - ii. Set out requirements relating to the Committee **membership**. Such requirements could include:
    - specific requirements to be met by prospective members;
    - requirements as to the make-up of members. For instance, there could be a requirement that one of the Committee members must be from a patient representative group;
    - detail of how long membership will last (tenure) (including the requirements for termination of tenure);
    - circumstances in which a member will be disqualified or suspended from holding office;
  - iii. Provide for the creation of a **sub-committee** (including requirements as to membership and mandate of that sub-committee) on a broad class of devices, for instance in vitro diagnostic medical devices; or on a more specific class of devices, for instance breast implants;
  - iv. Set out matters with respect to which the Committee **may or must have regard** when performing its functions. These could include, for example impacts on the patient community; and the need to ensure the safety and effectiveness of medical devices on the UK market.
  - v. Set out how the Committee might work with, exchange **information** with or otherwise **cooperate** with other committees such as CHM or other bodies that could be specified in regulations.

**Department for Health and Social Care**

**[14 December 2020]**