MEDICINES AND MEDICAL DEVICES BILL

EXPLANATORY NOTES ON LORDS AMENDMENTS

What these notes do

1 These Explanatory Notes relate to the Lords Amendments to the Medicines and Medical Devices Bill as brought from the House of Lords on 21 January 2021 (Bill 242).

2 These Explanatory Notes have been prepared by the Department of Health and Social Care in order to assist the reader of the Bill and the Lords amendments, and to help inform debate on the Lords amendments. They do not form part of the Bill and have not been endorsed by Parliament.

3 These Explanatory Notes, like the Lords amendments themselves, refer to HL 116, the Bill as first printed for the Lords.

4 These Explanatory Notes need to be read in conjunction with the Lords amendments and the text of the Bill. They are not, and are not meant to be, a comprehensive description of the Lords amendments.

5 Lords Amendments 1, 4 to 7, 9 to 11, 15 to 22, 26 to 29, 31 to 39, 41 to 48 and 51 to 55 were tabled in the name of the Minister.

6 Lords Amendments 2, 13 and 24 were tabled by Baroness Thornton, and were opposed by the Government.

7 Lords Amendments 3, 14, 25, 30, 49 and 50 were tabled by Lord Sharkey, and were opposed by the Government.

8 Lords Amendments 12, 23 and 40 were tabled by Lord Patel, and were opposed by the Government.

9 Lords Amendment 8 was tabled by Lord Hunt of Kings Heath and was supported by the Government.

10 In the following Commentary, an asterisk(*) appears in the heading of any paragraph that deals with a non-Government amendment.

Commentary on Lords amendments

Lords Amendments to Before Clause 1

Lords Amendment 1

11 Lords Amendment 1 would introduce a new clause before clause 1 and set out the establishment and core duties of the Patient Safety Commissioner in relation to medicines and medical devices in England. Subsection (1) would place a duty on the Secretary of State to appoint a Commissioner for Patient Safety. Subsection (2) sets out that the Commissioner's core duties would be to promote the safety of patients with regard to the use of medicines and medical devices; and promote the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices. Subsection (3) would prevent the Commissioner from being regarded as a servant or agent of the Crown or as enjoying any status, immunity or privilege of the Crown. This new clause should be read with the new Schedule inserted by Lords Amendment 54.

Lords Amendments to Clause 1: Power to make regulations about human medicines

Lords Amendment 2*

12 Lords Amendment 2 would provide a sunset period for Part 1 (human medicines). The delegated powers in Part 1 may be exercisable for a period of only three years, beginning with the day the Bill receives Royal Assent.

Lords Amendment 3*

13 Lords Amendment 3 would amend clause 1 and require regulations made under clause 1(1) to be subject to the super-affirmative procedure.

Lords Amendments 4 and 5

14 Lords Amendment 4 would require that when making regulations under clause 1(1), the appropriate authority's overarching objective must be safeguarding public health.

15 Lords Amendment 5 would require that when considering whether regulations contribute to the overarching objective of safeguarding public health, the appropriate authority must have regard to the three considerations set out in subsection (2)(a), (b) and (c).

Lords Amendments 6

16 Lords Amendment 6 would make clear that when considering the overarching public health objective, the appropriate authority must have regard to the likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to:

- carry out research relating to human medicines;
- conduct clinical trials;
- manufacture or supply human medicines.

Lords Amendment 7

17 Lords Amendment 7 would provide that the appropriate authority may make regulations under clause 1(1) that may have an impact on the safety of human medicines only if the authority considers that the benefits of doing so outweigh the risks.

Lords Amendments to Clause 2: Manufacture, marketing and supply

Lords Amendment 8*

18 Lords Amendment 8 would amend clause 2(1) to insert new subsection (o). This subsection would allow regulations under clause 1 to make provision about the use of human tissues or cells in relation to human medicines.

Lords Amendments to Clause 5: Fees, offences, power of inspectors

Lords Amendment 9 and 10

19 Lords Amendments 9 and 10 would ensure that regulations made under clause 1 cannot provide for any offence, whether new or existing, to be punishable with a sentence of imprisonment of more than two years.

Lords Amendments after Clause 6

Lords Amendment 11

20 Lords Amendment 11 would confer a power on the Secretary of State and the Department of Health in Northern Ireland to disclose information relating to human medicines with relevant persons (such as regulators and regulatory networks) outside of the United Kingdom in order to give effect to an international agreements and arrangements concerning the regulation of human medicines. Lords Amendment 11 would also provide a distinct and closed list of the relevant persons outside the United Kingdom with whom information may be disclosed under the clause, which includes governments of other countries and their regulators as well as international organisations exercising functions relating to human medicines. The amendment would not limit the circumstances in which information may be disclosed under any other enactment or rule of law.

21 The amendment would also provide that disclosing information to a person outside the UK in order to give effect to an international agreement or arrangement concerning the regulation of human medicine is possible provided this was for pharmacovigilance, or 'in the public interest'.

Lords Amendment 12*

22 Lords Amendment 12 would introduce a new clause that would require the Secretary of State to publish draft consolidated legislation on human medicines within three years of the Bill achieving Royal Assent.

Lords Amendments to Clause 8: Power to make regulations about veterinary medicines

Lords Amendment 13*

23 Lords Amendment 13 would provide a sunset period for Part 2 (veterinary medicines). The delegated powers in Part 2 may be exercisable for a period of only three years, beginning with the day the Bill receives Royal Assent.

Lords Amendment 14*

24 Lords Amendment 14 would amend clause 8 and require regulations made under clause 8(1) to be subject to the super-affirmative procedure.

Lords Amendments 15 to 17

25 Amendment 15 would mean that when making regulations under clause 8(1), the appropriate authority's overarching objective must to be promote one or more of the following:

- the health and welfare of animals;
- the health and safety of the public;
- the protection of the environment.

26 Lords Amendments 16 and 17 would provide that the appropriate authority must have regard to the three considerations set out in subsection (2)(a), (b) and (c) in terms of their contribution to the overarching objective.

Lords Amendment 18

27 Lords Amendment 18 would make clear that the appropriate authority must have regard to the likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to:

- develop veterinary medicines;
- manufacture or supply veterinary medicines.

Lords Amendment 19

28 Lords Amendment 19 would provide that the appropriate authority may make regulations under clause 8(1) that may have an impact on the safety of veterinary medicines only if the authority considers that the benefits of doing so outweigh the risks.

Lords Amendments to Clause 10: fees, offences, power of inspectors, costs

Lords Amendment 20 and 21

29 Lords Amendments 20 and 21 would ensure that regulations made under clause 8 cannot provide for any offence, whether new or existing, to be punishable with a sentence of imprisonment of more than two years.

Lords Amendments after Clause 10

Lords Amendment 22

30 Lords Amendment 22 would confer a power on the Secretary of State and the Department of Agriculture, Environment and Rural Affairs in Northern Ireland to disclose information relating to veterinary medicines with relevant persons (such as regulators and regulatory networks) outside of the United Kingdom in order to give effect to an international agreements and arrangements concerning the regulation of veterinary medicines. This amendment would also make a change to provide for sharing only with a "relevant person" outside the United Kingdom, as opposed to any person. Lords Amendment 22 would provide a distinct and closed list of such relevant persons to whom information may be disclosed

under the clause, which includes governments of other countries and their regulators as well as international organisations exercising functions relating to veterinary medicines. The amendment would not limit the circumstances in which information may be disclosed under any other enactment or rule of law.

31 Lords Amendment 22 would also provide that disclosing information to a person outside the UK in order to give effect to an international agreement or arrangement concerning the regulation of veterinary medicines is possible, provided this was for pharmacovigilance, or 'in the public interest'.

Lords Amendment 23*

32 Lords Amendment 23 would introduce a new clause relating that would require the Secretary of State to publish this draft consolidated legislation concerning the regulation of veterinary medicines within three years of the Bill achieving Royal Assent.

Lords Amendments to Clause 12: Power to make regulations about medical devices

Lords Amendment 24*

33 Lords Amendment 24 would provide a sunset period for Part 3, chapter 1 of the Bill (medical devices: regulation general). The delegated powers may be exercisable only for a period of three years, beginning with the day the Bill receives Royal Assent.

Lords Amendment 25*

34 Lords Amendment 25 would amend clause 12 and require regulations made under clause 12(1) to be subject to the super-affirmative procedure.

Lords Amendments 26 and 27

35 Lords Amendments 26 would mean that when making regulations under clause 12(1), the overarching objective is safeguarding public health.

36 Lords Amendments 27 would ensure that when considering the overarching objective, the appropriate authority must have regard to the three considerations set out in paragraphs (2)(a), (b) and (c).

Lords Amendment 28

37 Lords Amendment 28 would make clear that the appropriate authority must have regard to the likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to:

- carry out research relating to medical devices;
- develop medical devices;
- manufacture or supply medical devices.

Lords Amendment 29

38 Lords Amendment 29 would provide that the appropriate authority may make regulations under clause 12(1) that may have an impact on the safety of medical devices only if the authority considers that the benefits of doing so outweigh the risks.

Lords Amendments to Clause 16

Lords Amendment 30*

39 Lords Amendment 30 would amend clause 16 and require regulations made under clause 16(1) to be subject to the super-affirmative procedure.

Lord Amendments after Clause 16

Lords Amendment 31

40 Lords Amendment 31 would introduce a new clause to provide the Secretary of State with a power to make regulations creating a committee to advise on matters relating to medical devices. Further, the new clause would list the matters relating to establishing an advisory committee that the regulations may make provision about. Paragraphs 2(a) to (c) would allow the regulations to make, among other things, provision about membership of the committee, establishment of sub-committees by the committee and matters which the committee may or must consider. Paragraph 2(d) would allow the regulations to make provision about co-operation between the committee and the Commission on Human Medicines and other bodies with medical devices expertise. The Commission on Human Medicines is a statutory committee which advises Ministers on the safety, efficacy and quality of medicinal products. Subsection 3 sets out a non-exhaustive list of matters relating to the committee's membership that regulations may make provision about, including numbers of members; their appointment, independence, and remuneration; and the circumstances in which they cease to be members.

Lords Amendments to Clause 35: Disclosure of information

Lords Amendment 32

41 Lords Amendment 32 would provide the Secretary of State with the power to disclose information in connection with medical devices to a relevant person outside of the United Kingdom where the disclosure is required to give effect to an international agreement or arrangement concerning the regulation of medical devices. This provision would ensure that no patient identifiable information can be disclosed without the consent of the individual to whom the information relates. These amendments also would specify that patient information is based on data which can relate to the physical, mental health or condition of a patient, including their diagnosis and the treatment which they receive.

42 Lords Amendment 32 would also provide that disclosing information to a person outside the UK in order to give effect to an international agreement or arrangement concerning in the regulation of medical devices is possible provided it was for pharmacovigilance, or ‘in the public interest’.

Lords Amendment 33 to 36 and 39.

43 Lords Amendments 33 to 35 and 39 are consequential amendments to Lords Amendment 32.

44 Lords Amendment 36 would make it clear that clause 35 would not limit the circumstances in which information may be disclosed under any other enactment or rule of law.

Lords Amendment 37 and 38

45 Lords Amendments 37 and 38 would provide definitions of "relevant person" and "patient information". These amendments would include amendments to define a “relevant person” in order to restrict the persons with whom information may be disclosed for the purpose of

giving effect to international agreements or arrangements concerning the regulation of medical devices. As such a relevant person could be for example; an international regulator, a person acting on behalf of a government or an international organisation that function to provide services relating to medical devices.

Lords Amendments after Clause 37

Lords Amendment 40*

46 Lords Amendment 40 would require the Secretary of State to publish draft consolidated legislation concerning the regulation of medical devices within three years of the Bill achieving Royal Assent.

Lords Amendments to Clause 39: Powers to make consequential etc provision

Lords Amendment 41 and 42

47 Lords Amendments 41 and 42 are consequential amendments relating to the introduction of a Patient Safety Commissioner by Lords Amendment 1. The amendments would enable regulations under the power inserted by those provisions to make consequential and other connected provision.

Lords Amendments to Clause 41: Consultation

Lords Amendment 43 and 45

48 Lords Amendments 43 and 45 are consequential amendments. They would update clause 41 on consultation to include the new clauses we would introduce, such as the Patient Safety Commissioner.

Lords Amendment 44

49 Lords Amendment 44 would require the relevant authority to carry out a public consultation before making regulations under any provision of parts 1, 2 and 3 of the Bill. Subsection (2) would provide that before making regulations under clause 16(1), the medical devices information system, the appropriate authority must consult the devolved administrations. Subsection (4) would provide that the relevant authority must set out in the consultation document, its assessment of the three considerations as set out in clauses 1, 8 and 12.

Lords Amendments after Clause 41

Lords Amendment 46

50 Lords Amendment 46 would insert a new clause after clause 41 introducing a reporting requirement. This new clause would require the Secretary of State to lay a report on the operations of any regulation made using the powers in this Bill under clauses 1(1), 8(1) and 12(1). Subsection (3) of this amendment sets out what must be included in the report. The reporting period is every two years, initially starting after one of the specified delegated powers is exercised and every two years after that. The amendment would also require the Secretary of State to consult whomever they deem appropriate when preparing this report.

Lords Amendments to Clause 42: Procedure

Lords Amendment 47

51 Lords Amendment 47 is consequential on the Lords amendment inserting a new clause before clause 1 relating to the Commissioner for Patient Safety.

Lords Amendment 48

52 Lords Amendment 48 would provide for urgent regulations made in reliance on clauses 6 and 15 (emergencies) to be subject to the made affirmative procedure rather than the negative procedure.

Lords Amendments after Clause 42 (procedure)

Lords Amendment 49 and 50*

53 Lords Amendments 49 and 50 would introduce new clauses after clause 42. These set out the super-affirmative procedure that would apply to the majority of the delegated powers in the Bill. Amendment 49 sets out the detail of the super-affirmative procedure that would apply when the delegated power is exercised by the Secretary of State. Amendment 50 sets out the detail of the super-affirmative procedure if the delegated power is exercised by a Northern Ireland department.

Lords Amendments to Clause 44: Commencement

Lords Amendment 51 to 53

54 Lords Amendments 51 to 53 would all be consequential amendments relating to changes made at Lords Report. Lords Amendment 51 would commence the definition of "human medicines provision" from the day on which the Bill is passed. Lords Amendment 52 would provide for the new Part introduced before clause 1 on a Commissioner for Patient Safety coming into force two months after the Act is passed. Lords Amendment 53 would provide that the new clause inserted after clause 16 would come into force two months after the Bill is passed.

Lords Amendments before Schedule 1

Lords Amendment 54

55 Lords Amendment 54 would insert a new schedule that sets out further provision with regard to the Patient Safety Commissioner established by Lords Amendment 1 inserted before clause 1.

56 Paragraph 1(1) would place a duty on the Commissioner to prepare and publish a set of principles to govern the way in which the Commissioner will carry out their core duties. Paragraph 1(2) would allow the Commissioner to revise these principles and ensure any revised versions will be published. Paragraph 1(3) would set out that the Commissioner must publicly consult when preparing or revising the principles.

Involvement of patients

57 Paragraph 2(1) would require the Commissioner to take reasonable steps to involve patients in the discharge of their duties. Paragraph 2(2)(a) would require the Commissioner to take reasonable steps to ensure that patients are aware of the Commissioner's core duties and of how they may communicate with the Commissioner. Paragraph 2(2)(b) would require the

Commissioner to take reasonable steps to consult patients on matters which the Commissioner proposes to consider in the discharge of their core duties.

Supplementary functions and information

58 Paragraph 3(1) would set out the supplementary functions the Commissioner may exercise for the purposes of carrying out their core duties. These include making a report or recommendation to a relevant person; consulting patients and appropriate persons; as well as requesting information from and sharing information with, relevant persons. Sub-paragraph (5) would explain that in paragraph 3 "relevant person" means a person who exercises functions of a public nature in England in relation to medicines and medical devices; and any other person who, in the course of providing health care, provides services relating to medicines or medical devices in relation to England. Paragraph 3(2) would provide that a relevant person to whom a report or recommendation is made must provide a response within such period as the Commissioner may reasonably require. Paragraph 3(3) would set out that a relevant person must, so far as reasonably practicable, comply with such a request for information within such period as the Commissioner may reasonably require. Paragraph 3(4) would outline that nothing in the new Schedule would authorise a disclosure of information which contravenes data protection legislation. 'Data protection legislation' has the meaning given by section 3(9) of the Data Protection Act 2018.

Individual cases

59 Paragraph 4(1) would prevent the Commissioner from exercising functions in relation to an individual case. However, paragraph 4(2) would provide that this does not prevent the Commissioner considering individual cases and drawing conclusions about them for the purpose of, or in the context of, considering a general issue.

Amendments to primary legislation

60 Paragraph 5 would make various amendments to primary legislation relating to the Commissioner for Patient Safety. Paragraph 5(1) amends Schedule 1 to the Public Records Act 1958 to include the Commissioner for Patient Safety. This would provide for the Commissioner's records to be regarded as public records. Paragraph 5(2) would amend Schedule 1 to the House of Commons Disqualification Act 1975. The effect would be that the Commissioner cannot also be a Member of Parliament. Paragraph 5(3) would amend Schedule 1 to the Freedom of Information Act 2000 to bring the Commissioner within the Act's definition of a "public authority". This amendment would make the Commissioner subject to relevant provisions of that Act. Paragraph 5(4) would amend section 71 of the National Health Service Act 2006 (schemes for meeting losses and liabilities etc. of certain health service bodies). This would mean that the Commissioner will be eligible to participate in indemnity schemes established under that section. This would not mean that the Commissioner will automatically be a member of any such scheme. Paragraph 5(5) would amend Schedule 19 to the Equality Act 2010 (authorities subject to the public sector equality duty) to include the Commissioner.

Regulations about appointment and operation

61 Paragraph 6(1) would provide a power for the Secretary of State to make provision in regulations about the appointment and operation of the Commissioner for Patient Safety. Paragraph 6(2) sets out a list of matters regulations may (among other things) contain provision for and about. These would include the Commissioner's terms of office; the provision of financial or other assistance, including staff, accommodation, equipment or other

facilities for the Commissioner; and the appointment of a board to provide advice to the Commissioner.

Lords Amendments to Schedule 2

Lords Amendment 55

62 Lords Amendment 55 would ensure that prosecutions for an offence under new regulation 60A of the Medical Devices Regulations 2002 can be brought before the earlier of one year from the prosecutor thinking there was sufficient evidence to justify a prosecution or three years of the commission of the offence, as is currently the case with regard to equivalent offences under section 12 of the Consumer Protection Act 1987.

Lords Amendments to the Title

63 This amendment would add a limb to the long title to make reference to the new provision about the establishment of a Commissioner for Patient Safety.

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