

MEDICINES AND MEDICAL DEVICES BILL

EXPLANATORY NOTES

What these notes do

These Explanatory Notes relate to the Medicines and Medical Devices Bill as introduced in the House of Commons on 13 February 2020 (Bill 90).

- These Explanatory Notes have been prepared by the Department of Health and Social Care in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by Parliament.
- These Explanatory Notes explain what each part of the Bill will mean in practice; provide background information on the development of policy; and provide additional information on how the Bill will affect existing legislation in this area.
- These Explanatory Notes might best be read alongside the Bill. They are not, and are not intended to be, a comprehensive description of the Bill.

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Overview of the Bill

- 1 The Medicines and Medical Devices Bill (The Bill) does three things: (i) introduces targeted delegated powers in the fields of human medicines, veterinary medicines and medical devices to enable the existing regulatory frameworks to be updated following the United Kingdom's (UK) departure from the European Union (EU); (ii) consolidates the enforcement provisions for medical devices and introduces sanctions; and (iii) provides an information gateway to enable the sharing of information held by the Secretary of State about medical devices, for example to warn members of the public about safety concerns.

Policy background

Exiting the EU

- 2 On 1 January 1973 the UK joined the European Economic Community, which has since evolved to become today's EU. As a condition of EU membership, the UK was required to give effect to EU law in the UK. This was achieved through the European Communities Act 1972 (ECA) which provided for EU Regulations to take direct effect in UK law and conferred a delegated power (section 2(2) ECA) by which EU Directives and other pieces of EU legislation could be transposed

into UK law through domestic regulations.

- 3 On 17 December 2015 the European Union Referendum Act 2015 received Royal Assent. The Act made provision for holding a referendum in the UK and Gibraltar on whether the UK should remain a member of the EU.
- 4 The referendum was held on 23 June 2016 and a majority voted to leave the EU. The European Union (Notification of Withdrawal) Act 2017 received Royal Assent on 16 March 2017. On 29 March 2017, the Prime Minister gave notification of the withdrawal of the UK from the EU under article 50(2) of the Treaty on the European Union.
- 5 On 26 June 2018 the European Union (Withdrawal) Act 2018 received Royal Assent. Via operation of section 1 of that Act section 2(2) ECA will be repealed.
- 6 On 19 December 2019, the European Union (Withdrawal Agreement) Bill was introduced to Parliament. It received Royal Assent on 24 January 2020. The Act implements the

Withdrawal Agreement, as agreed between the United Kingdom and the EU. The Act provides that new pieces of directly applicable EU law that are introduced during the transition period will continue to apply automatically within the UK, in line with Part 4 of the Withdrawal Agreement. It also inserted section 1A into the European Union (Withdrawal) Act 2018 to save and amend the ECA so that it continues to have effect in domestic law, as amended, during the transition period.

Existing regulatory framework overview and delegated powers

7 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 each of these fields (taking clinical trials separately from the other regulatory aspects of human medicines) and created comprehensive regulatory frameworks in each case. The comprehensive frameworks, informed through the negotiation process by the UK Government, are established in EU legislation and have primarily been implemented in the UK by the following legislation:

- [The Human Medicines Regulations](#)

2012¹

- The Medicines for Human Use (Clinical Trials) Regulations 2004²
- The Veterinary Medicines Regulations 2013³
- The Medical Devices Regulations 2002⁴

8 Each of the above sets of Regulations were made using the delegated power at section 2(2) ECA. The same delegated power has been used on a regular basis to update each set of regulations, for example, the Human Medicines Regulations 2012 have been updated 11 times using section 2(2) ECA since their inception. Updates have taken place across these Regulations to reflect changes in EU Directives and updates to the EU regulatory frameworks.

9 After the end of the transition period, section

¹ S.I 2012 No. 1916

² S.I 2004 No. 1031

³ S.I 2013 No. 2033

⁴ S.I 2002 No. 618

2(2) ECA will no longer be available to update the regulatory schemes for human medicines, clinical trials of human medicines, or veterinary medicines through secondary legislation. In the absence of section 2(2) ECA, it will not be possible to update the schemes except through primary legislation, even where those changes relate to minor details in the existing regulatory frameworks.

10 The effect of the repeal of section 2(2) ECA on medical devices is slightly different. This is because medical devices legislation in the UK is made jointly under section 2(2) ECA and section 11 of the Consumer Protection Act 1987 (CPA). Whilst section 11 CPA is not being repealed (though it is being dis-applied with respect to medical devices – see below) it cannot be relied on exclusively to update the regulatory framework for medical devices. This is because it only allows for provision to be made for the purpose of securing that devices are “safe”, that is, that they do not create a risk of death or personal injury. This means that many aspects of the regulatory scheme cannot be updated using section 11 CPA, such as most technical requirements (particularly for lower risk devices), and obligations on manufacturers and others in the supply chain.

This means that it will not be possible after the end of the transition period to update much of the regulatory framework for medical devices without primary legislation.

11 Parts 1 to 3 of the Bill therefore create critical, but targeted delegated powers which enable specific features of the regulatory regimes for human medicines, clinical trials of human medicines, veterinary medicines and medical devices to be updated. The delegated powers may only be exercised in relation to a finite list of matters specified on the face of the Bill and only after consideration has been given to the safety and the availability of human or veterinary medicines or devices (as the case may be) and the attractiveness of the UK as a place to develop and supply these products. Subject to two discrete exceptions, the powers may also only be exercised following consultation.

Human Medicines - Existing regulatory framework

12 The regulatory framework for human medicines in the UK is based on the [EU](#)

[Human Medicines Directive](#)⁵ and is set out in the Human Medicine Regulations 2012 (HMRs). The framework provides a comprehensive scheme for regulating human medicines that covers their licencing, manufacture, importing, brokering, labelling, distribution, advertising and pharmacovigilance (safety monitoring), amongst other things. The scheme is overseen by the UK licensing authority which consists of the Secretary of State (for Health and Social Care) and the Minister of Health in Northern Ireland. In practice, the scheme is overseen by the Medicines and Healthcare products Regulatory Agency (MHRA) acting on behalf of the Secretary of State.

13 The MHRA is an executive agency of the Department of Health and Social Care. It operates as a trading fund which means that it has a degree of financial autonomy but it does not have a separate legal personality from the Department.

14 As well as transposing the EU Medicines

⁵ Directive 2001/83/EC on the Community Code relating to medicinal products for human use

Directive into UK law, the HMRs contain some provisions on matters that relate to human medicines, but which fall outside EU competence and hence are a matter of national policy. In particular the HMRs create a framework around the supply of human medicines to the patient, for example who may prescribe prescription-only medicines, who may supply them and the circumstances in which non-prescription medicines may be supplied, including in all cases multiple exceptions.

15 The Medicines Act 1968 (c.67) also contains some national provision that relates to human medicines. It contains the provisions that regulate pharmacies and pharmacists in relation to supplying human medicines which is also a matter that falls outside EU competence.

Clinical Trials of human medicines - Existing regulatory framework

16 The regulatory framework for clinical trials in the UK is based on the [EU Clinical Trials](#)

[Directive](#)⁶ and is set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 (CTRs). The framework provides a scheme for regulating clinical trials of medicines involving humans that covers the authorisation of clinical trials, their ethical approval, the conduct of the trial including adherence to good clinical practice, the reporting of adverse events and breaches of the authorisation, the manufacture and importation of the medicinal products involved in the trial and their labelling. The regulatory system is again overseen by the UK licensing authority operating through the MHRA (as described in paragraphs 11 and 12).

17 The EU legislation on which the CTRs are based is due to be repealed and replaced by [a new EU Regulation](#)⁷. Whilst this EU Regulation is in force, it is not expected to apply in the EU until after the end of the transition period meaning it will not form part of retained EU law⁸.

⁶ Directive 2001/20/EC

⁷ EU No. 536/2014

⁸ It will apply 6 months after publication of a notice by the European Commission in the Official Journal of the European Union.

Veterinary Medicines - Existing regulatory framework

18 Veterinary medicines are currently regulated by the Veterinary Medicines Regulations 2013 (SI 2013/2033) which implement various pieces of EU legislation. These regulations help ensure animal welfare, and protect the safety of treated animals, people handling the medicines, consumers of produce from treated animals, and the environment. They do this by regulating the authorisation, manufacture, classification, distribution and administration of veterinary medicinal products.

Medical Devices - Existing regulatory framework

19 A medical device is an instrument, apparatus, appliance, software, material or other article that is used in the prevention, diagnosis or treatment of illness or disease, the alleviation of / compensation for a handicap or injury or the replacement of a physiological process or the control of conception. Some types of medical device, known as in-vitro diagnostic medical devices (IVDs) are also used to conduct in-vitro

diagnostic tests. These are tests done on samples such as blood or tissue that have been taken from the human body. In-vitro diagnostics can detect diseases or other conditions and be used to monitor a person's overall health. With limited exceptions devices placed on the EU market must bear a CE mark - a mark to prove that a product has been assessed and meets required performance, safety, health and environmental protection standards.

20 The MHRA, acting on behalf of the Secretary of State (as described in paragraphs 11 and 12) is the designated competent authority that regulates compliance with and enforces the law on medical devices in the UK. It has a range of investigatory and enforcement powers to ensure device safety, quality and performance. It is also responsible for the post market surveillance and vigilance of medical devices on the UK market, working with Competent Authorities across the EU on safety considerations including where the device has not been certified by a UK Notified Body.

21 Medical devices are regulated in the UK by the Medical Devices Regulations 2002 (SI

2002/618). These regulations provide definitions for medical devices (including IVDs), and place obligations on manufacturers to ensure that medical devices are safe and fit for their intended purpose. Some aspects of the [General Product Safety Regulations 2005](#)⁹ apply to devices that are also consumer products.

22 The new EU Regulation on Medical Devices (Regulation (EU) 2017/745) which covers all general medical devices (including active implantable devices) will apply across the EU and in the UK from the 26 May 2020 following a three year transition period. The new EU Regulations on In Vitro Medical Devices (IVDR) (Regulation (EU) 2017/746) has a transition period of five years and will fully apply in EU member states from 26 May 2022. The aim of both of the new EU Regulations is to address inherent weaknesses in the existing Directives as well as drive increased patient safety and confidence in the system of conformity assessment. As the UK will not be a Member

⁹ SI 2005 No 1803

State of the EU it will need to make its own decisions about the future regulation of IVDs using the powers proposed in this Bill.

Consolidating and expanding medical devices enforcement provisions

23 Chapter 2 of Part 3 of the Bill seeks to consolidate the enforcement regime for medical devices and provides the Secretary of State with the ability (see Schedule 1) to impose civil sanctions as an alternative to criminal prosecution. Chapter 3 provides the Secretary of State with a new information sharing gateway.

24 Currently, the Secretary of State's powers to enforce compliance with medical device regulation can be found in numerous pieces of legislation, including the Medical Devices Regulations 2002 (SI 2002/618), the Consumer Protection Act 1987 (c. 43), the Consumer Rights Act 2015 (c. 15) and the General Product Safety Regulations 2005 (SI 2005/1803).

25 The structure of these legislative powers

does not enable the MHRA to operate efficiently or provide clarity to UK and international manufacturers on the operation of its enforcement regime. For instance, currently, the Secretary of State has enforcement powers to restrict the supply of devices in both the Medical Devices Regulations 2002 and the CPA (see regulation 63 (restriction notices) of the Medical Devices Regulations 2002 and sections 13 (Prohibition notices and notices to warn) and 14 (suspension notices) of the CPA), and it is not clear in what circumstances each power should be used.

26 The link to the CPA also means that the sanction for failing to comply with medical device regulations is the general offence of breaching safety regulations contained in section 12 (Offences against the safety regulations) of the CPA. This offence contains four “limbs” and determining whether or not a failure to comply with a provision of the Medical Devices Regulations 2002 is an offence involves an analysis of whether the provision fits within any of the “limbs”. This creates uncertainty for both the Secretary of State and industry.

27 The Bill seeks to remedy this uncertainty by creating a clearer consolidated enforcement regime. The key features of this new regime are:

- a. the disapplication of the CPA, and amendments to the Medical Devices Regulations 2002, so that powers to issue enforcement notices are contained solely in this Bill (meaning that they are more specific to medical devices); and
- b. the creation of a bespoke criminal offence, which clarifies which contraventions of the Medical Devices Regulations 2002 could result in prosecutions (note: this does not criminalise new behaviour but for the most part reflects the existing position under section 12 of the CPA in a more transparent and focussed manner). This offence will retain the existing maximum penalties under section 12 of the CPA.

28 The Bill also introduces new powers to impose civil sanctions on those who have breached the Medical Devices Regulations 2002, as an alternative to criminal prosecution. In particular, the Bill provides the Secretary of

State with powers to impose a monetary penalty on a person (where the Secretary of State is satisfied beyond a reasonable doubt that the person has committed an offence) and accept an enforcement undertaking (where the Secretary of State has reasonable grounds to suspect a person has committed an offence and that person offers the undertaking).

29 The Bill also provides the Secretary of State with new powers to share information it holds about medical devices in limited circumstances. These include a power to share medical device information with the public where necessitated by safety concerns and a power to share information with persons providing services or exercising functions in relation to medical devices. Such powers are subject to data protection legislation, and also to provisions which place restrictions on the disclosure of commercially sensitive

Legal background

30 The relevant legal background is explained in the policy background section of these notes.

Territorial extent and application

31 Clause 42 sets out the territorial extent of the Bill. These are the legal systems of which the Bill will form part. The extent of a Bill can be different from its application. Territorial application is about where a Bill produces a practical effect rather than where it forms part of the law. The Bill extends and applies to the whole of the UK. In addition, repeals and amendments made by the Bill have the same territorial extent as the legislation that they are repealing or amending.

32 There is a convention that Westminster will not normally legislate with regard to matters that are within the legislative competence of the Scottish Parliament, the National Assembly for Wales or the Northern Ireland Assembly without the consent of the legislature concerned.

33 The matters to which the provisions of the Bill relate are not within the legislative competence of the Scottish Parliament or the National Assembly for Wales, and accordingly no legislative consent motion is being sought from those legislatures in relation to any provision of the Bill. If there are amendments relating to matters within the legislative

competence of the Scottish Parliament, or the National Assembly for Wales, the consent of the relevant devolved legislature(s) will be sought for the amendments.

34 Parts 1 and 2 of the Bill relate to matters that are within the legislative competence of the Northern Ireland Assembly. Parts 4 and 5 make further provision in relation to the powers in Parts 1 and 2, and confer a power to make transitional, transitory or saving provision on the relevant Northern Ireland departments. Accordingly, a legislative consent motion is being sought from the Northern Ireland Assembly in respect of those Parts.

35 See the table in Annex A for a summary of the position regarding territorial extent and application. The table also summarises the position regarding legislative consent motion.

Commentary on provisions of Bill

Part 1: Human Medicines

Clause 1: Power to make regulations about human medicines

36 Clause 1(1) confers a delegated power to amend or supplement the law relating to human medicines by regulations.

37 The “law relating to human medicines” is defined (in clause 7) to include four pieces of legislation only, namely:

- the Human Medicines Regulations 2012 which provides the comprehensive regulatory structure under which human medicines are regulated;
- the Medicines for Human Use (Clinical Trials) Regulations 2004 which regulate trials of human medicines involving humans;
- the Medicines Act 1968 (specified provisions only) which regulates pharmacies; and
- the Medicines (Products for Human Use) (Fees) Regulations 2016.

- 38 Any amendments to this listed legislation will be captured by this definition, meaning this definition will always include the latest version.
- 39 The power only allows for the existing legislative regime to be amended or supplemented. This means the power will be used to build on what is already there.
- 40 The power is further restricted because regulations made under it may only contain provisions relating to the matters specified on the face of the Bill at clauses 2 to 6. The lists of matters specified in clauses 2, 3, 4, 5 and 6 are exhaustive in each case, meaning that no other matters may be legislated for using this power.
- 41 Clause 1(2) places a duty on the person or Northern Ireland department making regulations in exercise of the delegated power (or both acting jointly) to consider three factors before doing so. These factors are set out at (a) to (c) and relate to the safety and availability of human medicines and maintaining the attractiveness of the relevant part of the UK (England, Scotland, Wales or Northern Ireland) as a place to market human medicines and carry out clinical trials.
- 42 The delegated power is conferred on the “appropriate authority”. In relation to England, Scotland and Wales, the “appropriate

authority” is the Secretary of State. “Secretary of State” is defined in the Interpretation Act 1978 (c.30) to mean any Secretary of State but in practice it would be the Secretary of State for Health and Social Care exercising this power. In relation to Northern Ireland, the “appropriate authority” is the Department of Health in Northern Ireland acting alone, or the Secretary of State and the Department of Health in Northern Ireland acting jointly.

Clause 2: Manufacture, marketing and supply

43 Clause 2(1) lists matters relating to the manufacture, marketing and supply of human medicines that regulations made under clause 1(1) can address. The list is exhaustive.

44 Subsection (1)(a) allows provision to be made in relation to manufacturing authorisations. As a general rule, a manufacturing authorisation is required by any person manufacturing human medicine in the UK as set out in regulation 17 (manufacturing of medicinal products) of the Human Medicines Regulations 2012 (HMRs). Regulations made under clause 1(1) and relying on clause 2(1)(a) could, for example, amend the application process for applying for such an authorisation, add to the requirements that must be met by the holder of a manufacturing authorisation or

amend the exceptions to the requirement for a manufacturing authorisation.

45 Subsection (1)(b) allows provision to be made in relation to authorisations to import human medicines. In general, regulations are in place to secure supply chains for medicines entering the UK. A manufacturer's licence is required in order to import medicines into the UK from outside the EEA, as set out in regulation 17 of the HMRs. A wholesale dealer's licence is required in order to import unlicensed medicines from within the EEA, as set out in regulation 167(7) of the HMRs. Regulations made under clause 1(1) and relying on clause 2(1)(b) could, for example, amend the requirements relating to importation that must be met by the holders of such authorisations.

46 Subsection (1)(c) allows provision to be made in relation to wholesale dealing authorisations. Generally, a wholesale dealing authorisation is required by any person supplying medicines by way of wholesale dealing in the UK. This is governed by regulation 18 (wholesale dealing in medicinal products) of the HMRs. Wholesale dealers are the middle-persons in the supply chain moving products from manufacturers to the persons who will actually supply the product to

its end user. Usually wholesale dealers are distribution companies but not necessarily - if a hospital supplies a medicine to another hospital then that is also an example of wholesale dealing and will need an authorisation unless an exception applies. Regulations made under clause 1(1) and relying on clause 2(1)(c) provision could, for example, amend the application process for applying for such an authorisation, add to the requirements that must be met by the holder of a wholesale dealing authorisation or amend the exceptions to the requirement for a wholesale dealing authorisation.

47 Subsection (1)(d) allows provision to be made in relation to marketing authorisations. As a general rule, a marketing authorisation is required by any person who wishes to place a medicine on the UK market. This is governed by Part 4 (requirement for authorisation) of the HMRs. Regulations made under this provision could, for example, amend the application process for applying for such an authorisation, add to the requirements that must be met by the holder of the authorisation or amend the exceptions to the requirement for a marketing authorisation.

48 Subsection (1)(e) allows provision to be made in relation to the importation, distribution

and manufacture of active pharmaceutical substances. These are the raw ingredients used to make finished medicines and give a medicine its therapeutic effect. Chapter 4 of Part 3 of the HMRs requires any person who imports, manufactures, or distributes an active substance to register with the MHRA. The MHRA have produced a [flowchart](#) that provides further information on the stages of the registration process.

- 49 Subsection (1)(f) allows provision to be made in relation to the brokering of medicines. Brokering of medicinal products consists of negotiating independently and on behalf of another legal or natural person in relation to the sale or purchase of medicinal products. Under Chapter 3 of Part 3 of the HMRs brokers have to register with the MHRA. As part of this they must have a permanent address in the UK and comply with the guidelines on good distribution practice (GDP), insofar as those guidelines apply to brokers.
- 50 Subsection (1)(g) provides that regulatory provisions may be made in relation to the registration of the premises of a pharmacy business. “Pharmacy business” is defined at clause 7.
- 51 Subsection (1)(h) allows provision to be made in relation to the recording of information

about the supply of human medicines. Existing regulations under regulation 253 of the HMRs currently require, with some exceptions, a pharmacy to keep records in respect of the sale or supply of prescription only medicines (POMs).

52 Subsection (1)(i) allows provision to be made in relation to notifying and reporting. This would include requirements relating to the reporting of adverse reactions to medicines which are used to ensure that emerging risks in connection with a medicine are identified and acted upon as early as possible.

53 Subsection (1)(j) allows provision to be made in relation to the labelling and packaging of human medicines as well as the patient information leaflets (PILs) that accompany them. The existing requirements can be found in Part 13 (packaging and leaflets) of the HMRs. Regulations made under clause 1(1) and relying on this provision could update the existing requirements to allow further for the provision of information online and/or through other emerging media platforms or they could be used to create new requirements to address gaps identified in the provision of information, for example to require that patient information leaflets are included in both boxes where a pharmacist splits a product between

two patients.

Example (1): Labelling and Leafletting

The labelling and leafletting of medicines in the UK are currently regulated by Part 13 (Packaging and Leaflets) of the HMRs. MHRA approves all packaging and labelling information for medicines sold in the UK including the information that must be provided. Medicines must include a patient information leaflet (PIL) if the label does not contain all the necessary information. It is essential for certain medicines that they are dispensed together with a PIL and other risk minimisation materials. An example of how this power may be used could be to make provision imposing an obligation on the holders of marketing authorisations for medicinal products, to make available the information which must be included in the package leaflet associated with such product, at all times in electronic format.

54 Subsection (1)(k) allows provision to be made in relation to the advertising of human

medicines. The existing requirements can be found at Part 14 (advertising) of the HMRs. Regulations made under clause 1(1) and relying on the provision could, for example, allow some of the information that must appear in adverts to healthcare professionals to be provided via a web link rather than included in the advert's small print.

55 Subsection (1)(l) provides that regulations made under clause 1(1) may make provision relating to the registration of persons who sell human medicines over the internet. Currently Part 12A (sale of medicines to the public at a distance) of the HMRs requires persons who sell medicinal products to the public over the internet to notify the licensing authority and comply with certain requirements. This power could, for example, be used to introduce a national scheme to replace the EU scheme.

56 Subsection (1)(m) provides that regulatory provision may be made in relation to the requirements that need to be met for a prescription to be valid. The current requirements can be found in regulations 217 to 219A in Part 12 (Dealing with Medicinal Products) of the HMRs. Regulations made relying on subsection (1)(m) could, for example, amend the particulars that must be included in a prescription or the types of

prescriptions that can be sent electronically.

57 Subsection (1)(n) provides that amendments may be made to provisions in the general rules on who can supply human medicines and from where they can be supplied. The rules are set out in subsection (2) and include regulations 214 (sale or supply of prescription only medicines), 215 (prescribing and administration by supplementary prescribers), 220 (sale or supply of medicinal products not subject for general sale), 221 (sale or supply of medicinal products subject for general sale) and 249 (restrictions on persons to be supplied with medical products) of the HMRs. These provide that prescription only medicines (POMs) can only be supplied in accordance with a prescription and set out who can issue prescriptions. They also set out that medicinal products that are not subject to general sale (POMs and pharmacy medicines) must be supplied from a registered pharmacy, while general sale medicines need to be supplied from premises that can be closed off to exclude the public. Finally, they restrict who can be supplied with medicinal products by way of wholesale dealing. There are multiple exemptions from these rules set out in Chapter 3, Part 12 of the HMRs and the associated Schedules. An example of an existing

exemption is one that enables Royal National Lifeboat Institution (RNLI) first aiders to supply prescription only medicines in the course of their work for the RNLI when needed to treat the injured. Another exemption allows schools to obtain asthma inhalers and to supply them in an emergency to pupils who are known to suffer from asthma. Regulations made under clause 1(1) and relying on clause 2(1)(i) could, for example, be used to allow additional healthcare professionals to be given appropriately restricted prescribing rights or to amend the exemptions to the requirement for a prescription.

Example (2): Prescribing Policy

Some medicines are available to patients where they are given a prescription by an appropriate practitioner. An appropriate practitioner can either be an independent prescriber (someone able to prescribe medicines under their own initiative), or a supplementary prescriber (someone able to prescribe medicines in accordance with a pre-agreed care plan that has been drawn up between a doctor and their patient).

Part 12, Chapter 2 of the HMRs sets out

which groups of healthcare professionals are regarded as having the appropriate qualifications to make prescribing decisions and such groups are granted the responsibility to prescribe, either generally or in a defined set of circumstances. Over time the roles of staff within the health service will evolve and using this proposed power, certain professionals will be added to this list by amending the HMRs.

Clause 3: Falsified medicines

58 Clause 3 lists matters relating to two things that regulations made under clause 1(1) can address. One being the prevention of the supply of falsified medicines, and the other, enabling any information that is collected for the purpose of the prevention of the supply of falsified medicines to be used, retained and disclosed for any purpose to do with human medicines.

59 Falsified human medicines are defined in clause 7, by reference to regulation 8 of the HMRs, as human medicines that represent falsely their identity (including packaging,

naming or composition), source or provenance.

60 Subsection (2) sets out a framework for preventative measures that regulations made under subsection (1)(a) may include. (2)(a) provides for the inclusion of unique identifiers and anti-tamper devices on packs of authorised human medicines in order to allow the identity and authenticity of individual packs to be verified.

61 Subsection (2)(b) allows provision to be made for checks to be carried out relating to these packs and ensuring all medicines in scope include a unique identifier and anti-tamper device.

62 Subsection (2)(c) provides that provision can be made in relation to the infrastructure, systems and processes around these checks, including who should set up, pay for and maintain any necessary systems.

63 Subsection (3) sets out a duty to have regard to the importance of ensuring that information that is collected for the purpose of the prevention of the supply of falsified medicines is retained securely.

Clause 4: Clinical trials

64 Clause 4(1) lists matters relating to clinical trials that regulations made under clause 1(1)

may address. The list is exhaustive.

65 Subsection (1)(a) provides the means for provision to be made which is corresponding or similar to the EU Clinical Trial Regulations, if the Government were to choose to do so. Whilst this EU Regulation is in force, it is not expected to apply in the EU until after the end of the Transition Period meaning it will not form part of retained EU law.

66 Subsection (1)(b) allows provision to be made in relation to the authorisation and ethical approval of clinical trials. This is governed by Part 3 (authorisation for clinical trials and ethics committee opinion) of the Medicines for Human Use (Clinical Trials) Regulations 2004. Regulations made under this provision could, for example, amend the application process for applying for such an authorisation.

67 Subsection (1)(c) allows provision to be made about the notification and reporting requirements that apply to clinical trials. Parts 4 (conduct of clinical trials) and 5 (pharmacovigilance) of the Medicines for Human Use (Clinical Trials) Regulations 2004 impose various obligations on trial sponsors and investigators responsible for the conduct of the trial to notify adverse events and safety measures to the UK licensing authority.

Regulations made under clause 1(1) and relying on this provision could, for example, update the existing requirements in order to make them more proportionate for trials that are considered to carry low levels of risk.

68 Subsection (1)(d) allows amendments to be made to the requirements that must be satisfied before a trial is started. This could include either amending or removing existing requirements for some or all trials to ensure they remain proportionate or adding new requirements to ensure that trials continue to be conducted to high standards that maximise participant safety.

69 Subsection 1(e) allows provision to be made in relation to the conduct of clinical trials. Part 4 (good clinical practice and the conduct of clinical trials) of the Medicines for Human Use (Clinical Trials) Regulations 2004 requires, amongst other things, that clinical trials in the UK must be conducted in accordance with the conditions and principles of good clinical practice set out in Schedule 1 of those Regulations. Regulations made relying on this provision could amend and update these standards that clinical trials must comply with.

Clause 5: Fees, offences, powers of inspectors

70 Clause 5(1) lists other matters which

regulations made under clause 1(1) may provide for.

71 Subsection (1)(a) allows regulations made under clause 1(1) to introduce charges where they relate to functions conferred by regulations made under clause 1(1), the HMRs or the Medicines for Human Use (Clinical Trials) Regulations 2004.

72 Subsection (1)(b) allows regulations made under clause 1(1) to make the breach of requirements or prohibitions introduced by the regulations a criminal offence. These criminal offences may carry a maximum of two years imprisonment.

73 Subsection (1)(c) allows regulations made under clause 1(1) to apply the existing powers of entry and inspection in human medicines legislation to new prohibitions and requirements introduced by the regulations. The powers of entry and inspection may be applied with modifications. The existing powers in human medicines legislation are at Part 8 (Miscellaneous and Supplementary Provisions) of the Medicines Act 1968, Part 16 (Enforcement) of the HMRs, and the Medicines for Human Use (Clinical Trials) Regulations 2004.

Clause 6: Emergencies

74 Clause 6 allows regulations to be made

under clause 1(1) that relate to the emergency supply of human medicines.

75 Subsections (1), (2) and (3) allow for the relaxing of certain regulatory requirements relating to medicines in order to alleviate a threat of serious harm to the health of the general public or a section of the public. For example, the regulations could allow stocks of medicines to be shared between persons who do not hold wholesale dealers authorisations, such as doctors surgeries, for quicker distribution within the community or it could allow for larger packs of pills to be split into smaller packs where necessary in an emergency by persons who do not hold the correct authorisation to do so and who are not otherwise exempt from the requirement to hold such an authorisation before doing so.

76 In some cases, in order to ensure that public health is not compromised the relaxing of a regulatory requirement will be subject to a time limited protocol being complied with that is published by the Secretary of State and the Department of Health in Northern Ireland. For example, the regulations could allow for the supply of medicines without a prescription, or otherwise than from a registered pharmacy, in circumstances that pose a serious risk to human health provided the supply is in

accordance with a protocol that sets out specific conditions, such as the medicinal products which may be supplied or the criteria under which a person is to be eligible for treatment.

Clause 7: Interpretation of Part 1

77 This clause provides definitions for certain terms used in Part 1.

Part 2: Veterinary Medicines

Clause 8: Power to make regulations about veterinary medicines

78 Clause 8(1) confers a delegated power to amend or supplement the Veterinary Medicines Regulations 2013 (S.I. 2013/2033) by regulations.

79 The power is further restricted because regulations made under it may only contain provision relating to the matters specified on the face of the Bill at clauses 9 and 10. The lists of matters specified in clauses 9 and 10 are exhaustive, meaning that no other matters may be legislated using this power.

80 The delegated power is conferred on the “appropriate authority” as defined in clause 8(4). In relation to England, Scotland and Wales, the “appropriate authority” is the Secretary of State. “Secretary of State” is defined in the Interpretation Act 1978 to mean

any Secretary of State but in practice it would be the Secretary of State for Environment, Food and Rural Affairs exercising this power. In relation to Northern Ireland, the “appropriate authority” is the Department of Agriculture, Environment and Rural Affairs in Northern Ireland acting alone, or the Secretary of State and the Department of Agriculture, Environment and Rural Affairs in Northern Ireland acting jointly.

81 Clause 8(2) places a duty on the person or Northern Ireland department making regulations in exercise of the delegated power (or both acting jointly) to have regard to three factors before doing so. These factors are set out at paragraphs (a) to (c) and relate to the safety of veterinary medicines, the availability of veterinary medicines and maintaining the attractiveness of the relevant part of the UK as a place to develop and supply veterinary medicines.

Clause 9: Manufacture, marketing, supply and field trials

82 Subsection (1) lists matters relating to the supply of veterinary medicines that regulations made under the power at clause 8(1) can cover. The list is exhaustive.

83 Subsection (1)(a) allows provision to be made in relation to manufacturing

authorisations for veterinary medicines. As a general rule, a manufacturing authorisation is required by any person manufacturing veterinary medicine in the UK as set out in regulation 5 (Manufacture of veterinary medical products) of the Veterinary Medicines Regulations 2013. If someone wishes to manufacture an authorised veterinary medicine, they must obtain a manufacturing authorisation and comply with Good Manufacturing Practice¹⁰. This describes the minimum standard that a medicines manufacturer must meet in their production processes.

84 Subsection (1)(b) allows provision to be made in relation to authorisations to import veterinary medicines. In general, regulations are in place to secure supply chains for veterinary medicines entering the UK. In respect of most veterinary medicines, in order to import those medicines into the UK, one or more authorisations are required, for example a wholesale dealer's authorisation. These requirements are detailed in regulation 9 of the Veterinary Medicines Regulations 2013.

¹⁰ <https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice>

85 Subsection (1)(c) allows provision to be made in relation to wholesale dealing authorisations. Generally, a wholesale dealing authorisation is required by any person supplying medicines by way of wholesale dealing in the UK as set out in regulation 13 (Wholesale dealing) of the Veterinary Medicines Regulations 2013. Wholesale dealers are the middle-persons in the supply chain moving products from manufacturers to the persons who will actually supply the product to its end user. Regulations made under clause 8(1) that rely on this provision could, for example, amend the application process for applying for such an authorisation, add to the requirements that must be met by the holder of a wholesale dealing authorisation or amend the exceptions to the requirement for a wholesale dealing authorisation.

86 Subsection (1)(d) allows provision to be made in relation to marketing authorisations for veterinary medicines. As a general rule, a marketing authorisation is required by any person who wishes to place a medicine on the UK market for sale and supply as set out in regulation 4 (placing a veterinary medicinal product on the market) of the Veterinary Medicines Regulations 2013. An authorised product will have an authorisation number preceded by the symbol “Vm” on its product

literature. This offers users a clear guarantee that the product has been assessed and approved in accordance with the instructions on the product literature. This subsection combined with subsections (a), (b) and (g) could be used to make provision about using an authorised medicine outside the terms of its authorisation if there is clinical need and benefit (the Cascade).

Example (3): The Cascade

If there is no suitable veterinary medicine authorised in the UK to treat a condition in a species, a vet can treat an animal under his or her care in accordance with the Cascade.

The Cascade is provided for in the current veterinary medicines EU Directive (2001/82 as amended) and is included in Schedule 4 (Administration of a Veterinary Medicinal Product Outside the Terms of a Marketing Authorisation) of the Veterinary Medicines Regulations 2013.

An authorisation sets out the indication(s), species, recommended dosage, methods of administration, and contra-indications (e.g. do not use in pregnant animals). Therefore, in accordance with the Cascade, a

medicinal product can be used to treat a disease outside of its authorisation or to treat a different species from that which it is authorised for. For example, vets can prescribe Gabapentin, a human medicine, for use in animals to treat chronic pain, particularly of neuropathic origin, as there is no equivalent veterinary medicine.

87 Subsection (1)(e) allows provision to be made in relation to manufacturing, importing or distributing active substances. Active substances are the raw ingredients used to make veterinary medicines which give the finished product its therapeutic effect. The quality of the active substance is critical to assure the safety, quality and efficacy of the finished veterinary medicine. Regulations relying on this provision could be made, for example, to provide for a registration scheme for importers, manufacturers and distributors of active substances.

88 Subsection (1)(f) covers who can supply veterinary medicines – meaning provision could be made allowing additional healthcare professionals to be given appropriately restricted prescribing rights.

Example (4): Veterinary Medicines prescribing policy

Some veterinary medicines are available to patients under a prescription issued by an appropriate practitioner. Regarding veterinary medicines, an appropriate practitioner can be a Vet, a Pharmacist, or a Suitably Qualified Person (SQP). An SQP is a legal category of professionally qualified persons who are entitled to prescribe and/or supply certain veterinary medicines.

The Veterinary Medicines Regulations 2013 set out which groups of professionals have the appropriate qualifications to prescribe and sets out which categories of authorised veterinary medicines they are qualified and registered to prescribe or supply.

The distribution categories for authorised medicines are:

- Prescription Only Medicine – Veterinarian (POM-V)
- Prescription Only Medicine – Veterinarian, Pharmacist, SQP (POM-VPS)
- Non-Food Animal – Veterinarian, Pharmacist, SQP (NFA-VPS)

- Authorised Veterinary Medicine – General Sales List (AVM-GSL)

Over time the roles of staff within the veterinary industry will evolve and certain professionals may be added to or removed from this list by amending the Regulations.

89 Subsection (1)(g) covers the requirements that need to be met in relation to the supply of

veterinary medicines. These requirements are detailed in Schedule 3 of the Veterinary Medicines Regulations 2013. Regulations made under clause 8(1) that rely on this provision could, for example, amend the provisions relating to the sale, supply and administration of veterinary medicines.

90 Subsection (1)(h) covers the registration or accreditation of persons who sell veterinary medicines over the internet. This could include mandating registration and registration being conditional on specified requirements being met. Currently the Veterinary Medicines Directorate (an executive agency of the Department for Environment, Food and Rural Affairs that aims to protect animal health, public health and the environment) operates a voluntary scheme that accredits UK-based retailers.

91 Subsection (1)(i) allows provision to be made to the circumstances in which veterinary medicines can be administered. This could include prohibiting the administration of substances or medicines that would be considered to adversely affect public health or consumer safety.

92 Subsection (1)(j) allows provision to be made in relation to notifying and reporting. This would include requirements relating to the

reporting of adverse reactions to veterinary medicines which are used to ensure that emerging risks in connection with a medicine are identified and acted upon as early as possible.

93 Subsection (1)(k) allows provision to be made in relation to the labelling and packaging of veterinary medicines. Regulations made under this provision could update the existing requirements to create new requirements to address gaps identified in the provision of information.

Example (5): Label and pictograms

The Veterinary Medicines Regulations 2013 includes requirements for the labelling of authorised veterinary medicines. An example of a change that could be made is the introduction of pictograms (standardised pictorial symbols for a word or phrase) to replace or supplement some of the written labelling requirements.

94 Subsection (1)(l) allows provision to be made in relation to the advertising of veterinary medicines. The existing requirements can be found in Regulations 10, 11 and 12 of the Veterinary Medicines Regulations 2013. Regulations made under clause 8(1) and relying on the provision could, for example,

allow an inclusion of a definition of advertising to provide clarity to industry and improve compliance with the Regulations.

95 Subsection (1)(m) allows provision to be made in relation to animal test certificates. This is under the circumstances set out in [Paragraph 9 of Schedule 4 to the Veterinary Medicines Regulations 2013](#). An animal test certificate is required to carry out a veterinary field trial of a veterinary medicine¹¹.

96 Subsection (2) provides the means for making corresponding or similar provision to the new EU Regulations as the UK sees fit.

Clause 10: Fees, offences, powers of inspectors, costs

97 Subsection (1) lists further matters that regulations made under the power at clause 8(1) can cover.

98 Subsection (1)(a) allows regulations made under clause 8(1) to introduce or amend charges where they relate to functions conferred by regulations made under clause 8(1) of the Bill or the Veterinary Medicines Regulations 2013.

¹¹ <https://www.gov.uk/guidance/animal-test-certificates>

99 Subsection (1)(b) allows regulations made under clause 8(1) to make the breach of requirements or prohibitions introduced by the regulations a criminal offence. These criminal offences may carry a maximum of two years imprisonment. This power can create offences only for failing to comply with the provisions set out in regulations made under clause 8(1).

100 Subsection (1)(c) allows regulations made under clause 8(1) to apply the existing powers of entry and inspection in veterinary medicines legislation to new prohibitions and requirements introduced by the regulations. The powers of entry and inspection may be applied with modifications. The existing powers in veterinary medicines legislation are at regulation 34 (powers of entry) of the Veterinary Medicines Regulations 2013.

101 Subsection (1)(d) allows provision to be made in relation to recovering costs which are incurred as a result of administration in issuing improvement notices (which are issued when an inspector believes any person is not complying with the Veterinary Medicines Regulations 2013) and issuing seizure notices (which are issued to the person appearing to be in charge of the veterinary product to be seized).

102 Subsection (2) provides that a power of

entry conferred by subsection (1)(c) must not include power of entry in respect of premises used wholly or mainly as a private dwelling unless those premises, or any part of them, are approved, registered or authorised for the sale of veterinary medicines under a veterinary medicines provision.

103 Subsection (3) defines “veterinary medicines provision” as meaning a regulation made under clause 8(1) or the Veterinary Medicines Regulations 2013.

Clause 11: Interpretation of Part 2 and supplementary provision

104 Clause 11 provides definitions for certain terms used in Part 2 of the Bill. This clause also includes a supplementary provision to update an outdated reference to “the Veterinary Medicines Regulations 2011” to now include the new “Veterinary Medicines Regulations 2013” [in section 2, subsection \(8\)\(d\) of the Animals \(Scientific Procedures\) Act 1986.](#)

Part 3: Medical Devices

Chapter 1: Regulations

Clause 12: Power to make regulations about medical devices

- 105 Clause 12(1) confers a delegated power to amend or supplement the Medical Devices Regulations 2002 (MDR).
- 106 The power is further restricted because regulations made under clause 12(1) may only contain provisions relating to the matters specified on the face of the Bill at clauses 13, 14 and 15. The lists of matters specified in clauses 13 to 15 are exhaustive, meaning that no other matters may be legislated for using this power.
- 107 The delegated power is exercisable by the Secretary of State. “Secretary of State” is defined in the Interpretation Act 1978 to mean any Secretary of State but in practice it would be the Secretary of State for Health and Social Care exercising this power.
- 108 Clause 12(2) places a duty on the Secretary of State to consider three factors before making regulations under clause 12(1). These factors are set out at (a) to (c) and are: the safety of medical devices, the availability of medical devices and the attractiveness of the UK as a place to develop and supply medical devices.

Clause 13: Manufacture, marketing and supply

- 109 Clause 13 lists matters relating to the marketing of medical devices that regulations made under clause 12(1) can cover. This list is

exhaustive.

- 110 Subsection (1)(a) allows provision to be made in relation to the requirements that must be met before a medical device can be placed on the UK market, put into service or supplied in the UK. This includes the characteristics of medical devices such as materials, design, manufacture and packaging, and the requirements for those involved in the marketing and supply of devices, including (but not limited to) the manufacturer.
- 111 Subsection (1)(b) allows provision to be made in relation to the assessment of whether requirements are met.
- 112 Subsection (1) (c) allows provision to be made in relation to who may carry out such assessments, including provision allowing for the appointment of a specified person or persons, UK-based or not, to assess and certify medical devices and assess whether they meet all relevant requirements and confirm they have been met.
- 113 Subsection (1)(d), (e) and (f) cover the assessment of requirements and confirmation that requirements are met. For example, assessments of whether or not requirements have been met, and to what standard, as well as which persons (in addition to those appointed under 1(c)) can confirm that such

requirements are met. Subsection 1(e) relates to the making of declarations that requirements are met. These requirements could include specific technical requirements relating to devices, as well as requirements placed on those who manufacture them (for instance, the requirement to maintain a quality management system).

114 Subsection (1)(g) allows provision to be made in relation to the packaging and labelling of medical devices as well as the information and instructions that accompany them. Regulations made relying on this provision could, for instance, specify what information should be included on the label and / or packaging of a device, and specify what should be included in instructions for use that accompany the device.

115 Subsection (1)(h) covers registration of devices, their manufacturers or suppliers, including what information must be entered in a register. The power could be used to, by regulations, provide that information entered on a register be made available to the public.

Example (6): Registration of Devices

Currently if you place certain medical devices on the EU market you or your designated authorised representative must register with the competent

authority (national health regulator) in the EU state where you have an office or place of business. In the UK, the MHRA is the competent authority for the registration of medical devices. The MHRA will only register manufacturers or authorised representatives that have a place of business in the UK and that are placing the lowest risk devices on the UK market.

116 Subsection (1)(i) allows provision to be made in relation to the investigation and evaluation of the safety, performance and clinical effectiveness of medical devices.

117 Subsection (1)(j) allows provision to be made in relation to surveillance, that is, the monitoring of the medical devices market to ensure that devices comply with regulatory requirements.

118 Subsection (2) relates to what provisions may be included in regulations made under clause 12(1) and relying on subsection (1)(a). It provides that provisions concerning relevant requirements, may, among other things, refer to international agreements or standards for marketing or supplying medical devices.

Clause 14: Fees, information, offences

119 Clause 14 lists further matters relating to medical devices that regulations made under clause 12(1) can cover. This list is exhaustive.

120 Subsection (1)(a) allows for regulations to be made about fees in respect of functions conferred by a medical device provision. A medical device provision is, a provision of regulations made under clause 12(1) or a provision of the MDRs, including the function of charging fees by a person appointed under regulations made in reliance on clause 13(1)(c).

Example (7): Fees

The MHRA currently requires fees to be paid:

- by any manufacturer registering certain devices such as class I or custom-made devices, IVDs and those who sterilise devices (£100 per registration) with the MHRA.
- by manufacturers of all classes of devices for clinical investigations in the UK. These fees vary by class of device.
- by Notified Bodies for the work involved in monitoring them.

- to issue a Certificate of Free Sale that supports the export of products outside of the EEA.

All fees charged by MHRA, other than fees for Certificate of Free Sale, are standardised within the MDR and operate on a cost-recovery basis.

- 121 Subsection (1)(b) allows provision to be made about the recording of information in relation to the safety and efficacy of medical devices (including information as to whether or not devices comply with applicable relevant requirements).
- 122 Subsection (1)(c) allows provision to be made permitting or requiring the information referred to in subsection (1)(b) to be disclosed to the Secretary of State or to persons appointed under clause 13(1)(c).
- 123 Subsection (1)(d) provides the Secretary of State with the ability to amend the list of regulations set out in the schedule to the MDR (offences of breaching provisions in the MDR), which is inserted by Schedule 2 to this Bill.
- 124 Subsection (2) provides a definition for “medical devices provision” (that is, a provision in regulations made under the power at clause 12(1) or a provision in the MDR).

Clause 15: Emergencies

125 Clause 15 allows regulations to be made under clause 12(1) that relate to the supply of medical devices in emergencies.

126 Subsections (1) to (3) allows for the relaxing of certain regulatory requirements in circumstances where there is a threat of serious harm to health. For example, the regulations could allow for certain devices to be supplied notwithstanding that assessment of confirmation with a requirement has not yet taken place. In some cases, in order to ensure that public health is not compromised the relaxing of a regulatory requirement could be made subject to a protocol being complied with.

Chapter 2: Enforcement

127 This Chapter sets out a new, consolidated enforcement regime for medical devices. The Chapter confers powers on the enforcement authority to issue enforcement notices in certain circumstances, in order to achieve compliance with the medical devices regulatory framework, and to address health and safety risks posed by non-compliant devices.

128 “Enforcement authority” is defined in

clause 37(2). In relation to all medical devices, this is the Secretary of State, and in relation to devices that are consumer products, it also means a local weights and measures authority in Great Britain/district council in Northern Ireland.

Example (8): Enforcement

The Medical Devices Regulations 2002 (SI 2002 No 618) (MDR) are currently safety regulations under section 11 of the Consumer Protection Act 1987. As such, the Secretary of State has a duty to enforce these breaches under section 27 of that Act (as applied by regulation 61(2) of the MDR). This means that the Secretary of State can investigate any business activity that is covered by the MDR using the powers of entry set out in Schedule 5 (investigatory powers etc) to the Consumer Rights Act 2015 (see paragraphs 3, 9(1)(a) and 10 of Schedule 5 to the Consumer Rights Act 2015). The Consumer Protection Act 1987 also contains powers of entry which are very similar in nature to those contained in Schedule 5. In the majority of circumstances, the MHRA aims to provide high level

guidance on how manufacturers can comply with the MDR and what they need to do to ensure that they are not putting members of public at risk unnecessarily.

However, it has various powers to drive compliance, restrict market access or prosecute where required.

These various powers are currently spread across the MDR, Consumer Protection Act 1987 and the General Product Safety Regulations 2005. The interplay between the enforcement powers (and the powers of entry outlined above) contained in different legislation is complex and unclear. Consolidating powers will significantly improve MHRA's ability promote and support industry compliance. It will also provide industry with clarity and certainty regarding legal obligations. Further, it will enable MHRA to take swift and effective enforcement action only when circumstances warrant it.

Enforcement notices

Clause 16: Compliance notices

These Explanatory Notes relate to the Medicines and Medical Devices Bill as introduced in the House of Commons on 13 February 2020 (Bill 90)

129 Clause 16 gives the “enforcement authority” the power to issue a compliance notice on a person involved in marketing or supplying a medical device. This means that a compliance notice can be served on any actor in the supply chain. This kind of notice can only be issued where the relevant person is reasonably suspected of not complying with a medical devices provision (as defined in clause 14(2) – see explanation above). If the person reasonably suspected of non-compliance is a manufacturer, the notice can also be issued to their representative (i.e., a person designated by an overseas manufacturer to represent them in the UK).

130 A compliance notice must –

- a. identify the relevant medical devices provision with which the person is suspected not to be complying,
- b. explain the grounds for suspicion of non-compliance,
- c. require the person to comply with the relevant provision within a specified time period,
- d. require the person to provide evidence of compliance to the enforcement authority within a specified time period,

e. require the person to take other necessary measures to ensure compliance that may be specified, within a specified period.

131 Subsection (3) is self-explanatory.

132 Subsection (4) provides that the enforcement authority may vary or revoke a compliance notice.

133 Subsection (5) provides that if the person mentioned in subsection (1) is a manufacturer, this notice can either be served on them, or their representative (or both).

Example (9): Definition of Manufacturer

A manufacturer is defined in regulation 2 of the MDR and means –

(a) as the person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party; or

(b) any other person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their

intended purpose as a device with a view to their being placed on the market under his own name, apart from a person who assembles or adapts devices already on the market to their intended purpose for an individual patient.

Clause 17: Suspension notices

134 This clause gives the enforcement authority the power to issue a “suspension notice” suspending the availability of a medical device, if this is considered necessary in order to protect health and safety.

135 Under subsection (2) the enforcement authority may serve a suspension notice on any person, meaning it can be served on any actor involved in the supply chain. A suspension notice may prohibit the person from doing any of the activities listed in this subsection, including supplying the device or offering it for supply, without the consent of the enforcement authority.

136 Subsection (3) sets out what information the suspension notice must include. The notice must set out the grounds on which the enforcement authority considers the suspension necessary and the length of time

of the suspension.

137 Subsection (4) states that this time period cannot be more than 6 months from the date the notice was served.

138 Subsection (5) is self-explanatory.

Clause 18: Safety notices

139 This clause gives the enforcement authority the powers to issue a safety notice to any person, meaning it can be served on any actor in the supply chain. A safety notice will impose prohibitions or requirements on a person that the enforcement authority deems necessary, in order to protect health and safety.

140 Subsection (2) lists activities that a person may be prohibited from carrying out in relation to a device except with the enforcement authority's consent. This list is illustrative.

141 Subsection (3) sets out further examples of the requirements that may be imposed by the enforcement authority in a safety notice.

These are:

- a. A requirement to publish a warning about the medical device, including the format of such a warning. The exact form of this warning will vary from case to case but should be specified in the safety notice.

b. A requirement for the person to recall the device (that is, organise the return of it) from where it has been supplied, or work with the enforcement authority to recall the device.

142 Subsection (4) provides that a requirement to recall a device (further to reliance on clause 18(3)(b)) can only be imposed on a person if there is no alternative requirement available which could sufficiently protect health and safety.

143 Subsection (5) provides that the notice must include the reasons as to why it has been served.

144 Subsection (6) is self-explanatory.

145 In accordance with subsection (7) the enforcement authority may only issue a safety notice if it has given the person the opportunity to make representations as to why the notice should not be issued. However, if the enforcement authority feels there is an urgent need to issue the notice, as set out in subsection (8), it may issue a notice without first having given the person opportunity to make representations.

Clause 19: Information notices

146 This clause gives the enforcement

authority the power to issue a notice requiring a person to disclose or produce information (an information notice). applies notice may be issued if the enforcement authority believes a person can provide information that the enforcement authority needs in order to decide whether to issue or revoke a compliance notice, a suspension notice, or issue, revoke or vary a safety notice.

147 This notice requires the person to provide the information requested within a specified time period or produce any records that have been requested at a time and place specified in the notice and allows a person authorised by the enforcement notice to take copies of these records at the same time and place specified.

148 Subsection (3) provides that the person has a time period of at least 28 days (beginning with the date the notice is served) within which information (under clause 19(2)(a)) must be provided.

149 Subsection (4) provides that the time specified for the production of the records (under clause 19(2)(b)) must be at least 28 days after the day on which the notice is served.

150 Subsection (5) - information notices can be varied or revoked.

Clause 20: Applications to set notices aside etc

- 151 This clause provides that any person who has an interest in a medical device that is the subject of a compliance, suspension or safety notice is able to apply to an appropriate court to set the notice aside or vary it.
- 152 An “appropriate lower court” is defined as a magistrate’s court in England and Wales, the sheriff in Scotland, and a court of summary jurisdiction in Northern Ireland (see clause 37 (2)).
- 153 Subsection (2) provides that the same application may also be made by person who have received an information notice.
- 154 Subsection (3) states that such applications must be made within 28 days, starting from the day the notice was served, or varied.
- 155 Subsection (4) provides a list of circumstances where the appropriate court can set aside a compliance, suspension, safety or information notice. This list is self-explanatory.
- 156 Subsection (5) explains that the court can vary a compliance notice so as not to apply in relation to a medical devices provision. It may do this if it is satisfied that the person on whom the notice has been served has complied with that medical devices provision.

- 157 Subsection (6) states that the court can vary a suspension notice if it is satisfied that the time period of suspension is too long.
- 158 Similarly, subsection (7) explains the court can vary a safety notice if it is satisfied that the prohibition or requirement it contains is not necessary for the protection of health or safety.
- 159 Subsection (8) explains that the court can vary an information notice if the person who received the notice does not have that information or those records requested.
- 160 Subsection (9) states that an order of the appropriate court that varies or sets aside a compliance, suspension, safety or information notice can be delayed pending the outcome of any appeal under clause 22 (see below for appeal process).

Clause 21: Compensation

- 161 Clause 21 provides that if the court varies or sets aside a notice (compliance, suspension or safety), then the affected person can apply to the appropriate lower court for compensation for loss or damage caused by the notice. This compensation is to be paid by the enforcement authority.
- 162 The application for compensation can be made at the same time as an application to set the notice aside or vary it.

Clause 22: Further appeals

- 163 This clause explains the appeals process relating to enforcement notices.
- 164 Subsection (1) provides that a person affected by a decision of the appropriate lower court in relation to an application to vary or revoke a notice can appeal against this decision to the appropriate appeals court.
- 165 As set out in Clause 37, an “appropriate appeals court” is defined as the Crown Court in England and Wales, the Sheriff Appeal Court in Scotland, and a county court in Northern Ireland.
- 166 Subsection (2) provides that any appeal made under sub-clause (1) must be made within 28 days, starting on the day the relevant decision was made.
- 167 Subsection (3) provides that the appropriate appeals court may make any order it considers appropriate.

Offences

Clause 23: Offences

- 168 Clause 23 sets out the offence provisions in relation to enforcement notices. Subsection (1) provides that the breach of any of the

enforcement notices (a compliance notice, suspension notice, safety notice and information notice) is an offence.

169 Subsection (2) outlines the convictions a person may receive if guilty of an offence. These are:

a. As a result of a summary conviction in England and Wales, which is an offence that is only triable in a magistrates court, and is often summarised without the need for trial, a person can be imprisoned for up to 51 weeks, receive a fine, or both.

b. As a result of a summary conviction in Scotland or Northern Ireland, a person can be imprisoned for up to 6 months, or receive a fine not exceeding £5,000 (level 5 of the standard scale), or both. A level 5 on the standard scale references the scale of fines for summary offences as outlined in the Criminal Justice Act 1982.

170 Subsection (3) outlines that the maximum 51 weeks imprisoned outlined in (3)(a) is to be read as 6 months if the offence is committed before section 154(1) of the Criminal Justice Act 2003 is commenced.

Example (10): 154(1) of the Criminal Justice Act 2003

Section 154 of the Criminal Justice Act 2003, yet to be commenced, provides for an increase in magistrates' sentencing powers so as to enable them to impose custodial sentences of up to and including 12 months for one offence.

The increase was originally intended to accompany a new sentence called 'custody plus' which has not been implemented.

Clause 24: Defence of due diligence

171 Clause 24 provides there is a defence of due diligence available to persons charged with an offence under clause 23. Due diligence is where a person takes all reasonable steps to avoid committing an offence.

172 Subsection (2) and (3) provide that a person cannot, as part of a due diligence defence, claim that the offence was due to either another person's action/default or to reliance placed on information provided by another person, unless they have first notified the prosecutor (unless they are allowed to do so by the court). That notification must

include any information the defendant has that may assist in identifying the other person. The notification must be served at least 7 days before the hearing.

173 Subsection (4) provides that the defendant cannot use the defence of due diligence by claiming they relied on information provided by another person unless they can prove it was reasonable to rely on it. In proving this, the defendant must have regard to the steps taken to verify the information, and if there was any reason to disbelieve the information.

174 Subsection (5) is self-explanatory.

Clause 25: Offences by bodies corporate

175 This clause provides that where an offence under section 23 has been committed by a corporate body or a Scottish partnership and has been proved to²³ have been committed with the consent or knowledge of the “officer”, or due to negligence of the “officer”, then the officer has committed an offence.

176 Subsections (2) to (4) set out the definition for the “officer” as used in relation to a body corporate, “director” in relation to a body corporate, and “officer” in relation to a Scottish partnership.

Civil Sanctions

Clause 26: Civil Sanctions

177 This clause explains that Schedule 1 outlines the civil sanctions that will be applicable to anyone committing an offence in relation to medical devices.

Forfeiture

Clause 27: Forfeiture of medical devices

178 This clause gives the enforcement authority the power to apply to the appropriate lower court for a “forfeiture order” for a medical device if there has been a breach of a medical devices provision (as defined in clause 14(3)). Under a forfeiture order the enforcement authority may seize the relevant devices, mentioned in the terms of that order. An order will be issued by the court if they agree there has been such a breach, as set out in subsection (2).

179 Subsection (3) provides that the enforcement authority must make effort to let those likely to be affected by the order know that it is applying for a forfeiture order. This includes the person from whom the device is seized or any other person entitled to the device (as defined in subsection (9)). This definition also applies to clause 28. Such persons may appear at the court hearing or write to the court with any issues in relation to the order, as set out in subsection (4).

180 Subsection (5) provides that the appropriate court can decide when the order is to commence and should include this information in the forfeiture order – and specify the order is not to take place before the appropriate time.

181 Subsections (6) and (7) are self-explanatory.

182 Subsection (8) defines “appropriate time” for the purposes of this clause.

183 Subsection (9) defines what “entitled to a device” means.

Clause 28: Appeals against forfeiture decisions

184 This clause outlines the appeal processes applicable to forfeiture orders.

185 Subsections (1) and (2) are self-explanatory.

186 Subsection (4) provides that any appeal must be made within 28 days, starting on the day the relevant decision (made or refused) was made.

187 Subsections (5) provides that the appropriate appeals court can make whatever decision it considers appropriate. However, if the appeal against the forfeiture order is allowed the court must order the return of the device to the entitled person, as set out in subsection (6).

188 Subsection (7) sets out the definition of persons “entitled to a device”.

Recovery of expenses of enforcement

Clause 29: Recovery of expenses of enforcement

189 Clause 29 outlines the process by which the enforcement authority can apply to the court to recover the expenses incurred by its enforcement activities.

190 Subsection (1) provides that order for recovery of enforcement expenses may be made if a court has convicted a person of an offence (either under section 23, or under regulation 60A of the MDR). It may also be made if a court makes a forfeiture order in relation to a medical device.

191 Subsection (2) provides that the court can order the person who has been convicted of the offence, or the person from whom the device has been seized, to reimburse the relevant enforcement authority for any costs incurred by the seizure of the relevant device or relating to compliance with the forfeiture order.

Recall of medical device by enforcement authority

Clause 30: Recall of medical device by enforcement authority

192 This clause concerns the recalling of

medical devices by the enforcement authority.

193 Subsection (1) provides that this section applies, in circumstances where a device has already been made available to the public, and where the enforcement authority considers it necessary to restrict the availability of a particular medical device to protect health and safety.

194 Subsection (2) provides that the enforcement authority can organise the return of the relevant device. This can be done whether or not a safety notice has been issued that requires the organisation/cooperation in organising the recall of the device.

195 Subsection (3) outlines that recall by an enforcement authority under subsection (2) should be a last resort.

Power of officer of Revenue and Customs to detain medical device

Clause 31: Power of officer of Revenue and Customs to detain medical devices

196 Clause 31 outlines the power of a customs officer in relation to detaining medical devices.

197 A “customs officer” is defined in the Customs and Excise Management Act 1979 as a person commissioned by the Commissioners for Her Majesty’s Revenue and Customs.

198 Subsection (1) provides that a customs office can seize a medical device and detain it for up to two days maximum in order for an enforcement authority to exercise a function it has under Part 3 of this Act, a medical devices provision (as defined in clause 14(3) – see explanation above), or Schedule 5 of the Consumer Rights Act 2015 (investigatory powers).

199 Subsection (2) provides that the seized device must be investigated during the time period it is detained, and this must be done under the direction of the Commissioners for her Majesty's Revenue and Customs.

200 Subsection (3) further explains the reference to two days in subsection (1). This means 48 hours from the time the device was seized, but this does not include weekends, Christmas Day, Good Friday, or other bank holidays relevant to where the goods are seized.

Clause 32: Offence of obstructing an officer of Revenue and Customs

201 Subsection (1) provides that it is an offence to obstruct a customs officer (as described above in clause 31) from undertaking their duties.

202 Subsection (2) outlines the convictions a person may receive if guilty of an offence. These are:

- a. As a result of a summary conviction in England and Wales, which is an offence that is only triable in a magistrates court, and is often summarised without the need for trial, a person can be imprisoned for up to 51 weeks, receive a fine, or both.
- b. As a result of a summary conviction in Scotland or Northern Ireland, a person can be imprisoned for up to 6 months, or receive a fine not exceeding £5,000 (level 5 on the standard scale), or both. A level 5 on the standard scale references the scale of fines for summary offences as outlined in the Criminal Justice Act 1982.

203 Subsection (3) outlines that the maximum 51 weeks imprisoned outlined in (2)(a) is to be read as 6 months if the offence is committed before section 154(1) of the Criminal Justice Act 2003 is commenced.

Civil Proceedings

Clause 33: Civil proceedings

204 This clause provides that breach of an obligation contained in a medical devices provision (as defined in clause 14(3) – see explanation above) is actionable as a breach of statutory duty.

205 This is subject to any provision that contradicts this in a medical devices provision, and any defences that apply to a breach of statutory duty.

Chapter 3: Disclosure of Information and Consequential etc Provision

Clause 34: Disclosure of information

206 Clause 34 concerns the disclosure of information and applies in relation to information the Secretary of State holds regarding medical devices.

207 Clause 34(2) provides that the Secretary of State may disclose information in order to warn the public about safety concerns relating to a device.

208 Subsection (3) provides that such information held by the Secretary of State may be disclosed to a person who provides services or exercises functions in relation to medical devices, in order to allow either the Secretary of State, or another person, to exercise function a function or provide a

service in relation to medical devices.

209 Subsection (4) provides that the Secretary of State may disclose information for the purposes of certain legal proceedings.

210 Subsection (5) provides that personal or commercially sensitive information may only be disclosed for the purposes set out in subsections (2), (3) or (4), if the Secretary of State considers that disclosure is necessary, and that the disclosure of such information is a proportionate way of achieving one of the listed purposes.

211 Subsection (6) provides that any non-public facing information disclosed must not be used for any purpose other than the purpose for which it was originally disclosed and must not be disclosed further without the agreement from the Secretary of State and for purposes other than the purposes for which it was originally disclosed.

212 Subsection (7) provides that, except as provided by subsection (8) (see below), a disclosure of information under this power does not contravene an obligation of confidence owed by the person making the disclosure or any other restriction on the disclosure of information.

213 Subsection (8) provides that nothing in this

clause allows disclosures of information that breach data protection legislation (subject to the powers conferred by this section) or are prohibited by Parts 1 to 7 or Chapter 1 of Part 9 of the [Investigatory Powers Act 2016](#).

214 Subsection (9) provides definitions of terms used in clause 34.

Clause 35: Offence relating to information

215 Clause 35 outlines the offences that are related to information disclosure.

216 Subsection (1) provides that a person commits an offence if they use or further disclose information in a manner that breaches subsections (6) of clause 34.

217 Subsection (2) outlines the maximum penalties for this offence. These are:

- a. As a result of a summary conviction in England and Wales, which is an offence that is only triable in a magistrates court, a person can be imprisoned for up to 51 weeks, receive a fine, or both.
- b. As a result of a summary conviction in Scotland or Northern Ireland, a person can be imprisoned for up to 6 months, or receive a fine not exceeding £5,000 (level 5 on the standard scale), or both. A level 5

on the standard scale references the scale of fines for summary offences as outlined in the Criminal Justice Act 1982.

218 Subsection (3) outlines that the maximum 51 weeks imprisoned outlined in (2)(a) is to be read as 6 months if the offence is committed before section 154(1) of the Criminal Justice Act 2003 is commenced.

Consequential amendments

Clause 36: Consequential and supplementary provisions

219 Clause 36 outlines the consequential and supplementary amendments made by this Bill. These amendments are outlined in subsections (1) to (7).

220 Subsection (8) is self-explanatory.

221 Subsection (9) introduces Schedule 2, which provides that it is an offence to breach various provisions in the MDR.

Chapter 4: Interpretation of Part 3

Clause 37: Interpretation of Part 3

222 This clause provides definitions and interpretations of words and phrases used in Part 3 of this Bill.

Part 4: Regulations under Parts 1, 2 and 3

Clause 38: Power to make consequential etc provision

223 This clause makes further provisions about the regulation-making powers in clauses 1 (human medicines), 8 (veterinary medicines), and 12 (medical devices). It provides that these regulations may make:

- a. consequential, supplementary, incidental, transitional, transitory or saving provisions;
- b. different provision for different purposes and different areas;
- c. provision creating exceptions or limited in application to specified cases.

Clause 39: Scope of powers of Northern Ireland departments

224 This clause provides that regulations made under clause 1(1) (human medicines) and clause 8(1) (veterinary medicines) may not be made by a Northern Ireland Department (Department of Health in Northern Ireland and the Department of Agriculture, Environment and Rural Affairs in Northern Ireland) acting

alone unless the relevant provisions, if contained in an Act of the Northern Ireland Assembly, would be within its competence, and would not require consent from the Secretary of State.

225 The Northern Ireland Assembly is a devolved legislature and cannot legislate on issues that are outside its ‘legislative competence’.

Clause 40: Consultation

226 This clause sets out the consultation requirements that must be met before regulations are made under clauses 1(1), 8(1) or 12(1) or under paragraph 9 of Schedule 1.

227 Subsection (1) creates a duty to consult. It provides that before regulations are made under clauses 1(1), 8(1) or 12(1) or under paragraph 9 of Schedule 1 consultation with such persons as considered appropriate must take place. The duty is placed on the “appropriate authority” which is defined in subsection (4).

228 Subsection (2) sets out exceptions to the duty to consult. It provides that the duty does not apply in relation to regulations made under clause 6 or clause 15 (which can dis-apply provisions relating to human medicines and medical devices respectively where there is a risk of serious harm to health), provided the

regulation is required urgently due to an actual or imminent threat of serious harm to human health.

229 Subsection (3) provides that consultation carried out before the Bill is passed may satisfy the duty to consult.

Clause 41: Procedure

230 This clause provides that when the powers to make regulations under clauses 1(1), 8(1) and 12(1), and paragraph 9 of Schedule 1 (supplementary regulations) are exercised by the Secretary of State alone or acting jointly with a Northern Ireland department, they are to be exercised by statutory instrument. If exercised by a Northern Ireland department alone, the powers in clauses 1 and 8 will be exercisable by statutory rule.

231 Subsection (3) provides that statutory instruments made by the Secretary of State under clauses 1(1), 8(1) and 12(1) are subject to the affirmative resolution procedure meaning they have to be laid before and approved by each House of Parliament. The exceptions to this are found in subsections (6) and (9) that sets out when the negative resolution procedure applies.

232 Subsection (4) provides that regulations made by a Northern Ireland department acting alone are subject to the affirmative resolution

procedure meaning they have to be laid before and approved by the Northern Ireland Assembly. The exceptions to this are found in subsections (7) and (9) that sets out when the negative resolution procedure applies.

233 Subsection (5) provides the procedure that applies in relation to a statutory instrument of the Secretary of State and a Northern Ireland department acting jointly.

234 Subsections (6) and (7) are self-explanatory.

235 Subsection (9) sets out the limited circumstances in which the negative resolution procedure applies. Those circumstances are where regulations contain only provision made in reliance on the following provisions:

- a. The labelling and packaging of human medicines – clause 2(1)(j)
- b. The advertising of human medicines – clause 2(1)(k)
- c. Prohibitions in the supply provisions for human medicines – clause 2(1)(n)
- d. The charging of fees in relation to human medicines – clause 5(1)(a)
- e. Emergency powers in relation to human medicines – clause 6 (where regulations contain a declaration that they need to be made urgently)

- f. Who can supply veterinary medicines – clause 9(1)(f)
- g. The labelling and packaging of veterinary medicines – clause 9(1)(k)
- h. The advertising of veterinary medicines – clause 9(1)(l)
- i. The charging of fees in relation to veterinary medicines – clause 10(1)(a)
- j. Charging of fees in relation to medical devices – clause 14(1)(a)
- k. Emergency powers in relation to medical devices – clause 15 (where regulations contain a declaration that they need to be made urgently).

236 Subsection (10) provides that regulations made under paragraph 9 of Schedule 1 are subject to the negative resolution procedure.

Part 5: Extent, commencement and short title

Clause 42: Extent

237 This clause provides that the Bill is UK wide in that it extends to England and Wales, Scotland and Northern Ireland.

Clause 43: Commencement

238 Subsection (1) lists the provisions in this Bill that come into force the day the Bill is passed.

239 The majority of clauses come into force two months after Royal Assent, and these are listed in subsection (2).

240 Subsection (3) provides that certain medical devices provisions in this Bill (Chapters 2 and 3 of Part 3) come into force on the day or days specified by the Secretary of State in regulations.

241 Subsection (4) provides that regulations made in reliance on clauses 6 or 15 that come into force within two months of the Bill being passed, may only be made if those regulations contain a declaration that the person (or persons) making it considers that they need to be made urgently to protect the public from an imminent risk of serious harm to health.

Clause 44: Transitional etc provision in connection with commencement

242 Subsection (1) gives the Secretary of State the power to make transitional, transitory or saving provision in connection with the commencement of this Bill. The exception to this is in relation to provisions that could be made by the relevant Northern Ireland department (as defined in subsection (4)).

243 Subsection (2) gives the relevant Northern Ireland department the power to make

transitional, transitory or saving provisions related to the coming into force of Parts 1 and 2 as far as they relate to Northern Ireland.

244 Subsection (3) provides that no provision may be made by the relevant Northern Ireland department in reliance on subsection (2) above, if such a provision would if it were contained in an Act be outside the legislative competence of the Northern Ireland Assembly or require the consent of the Secretary of State.

245 Subsection (5) provides that regulations made by a Northern Ireland department are to be made by statutory rule.

246 Subsection (6) defines what is meant by “relevant Northern Ireland department”.

Clause 45: Short title

247 Once passed, the short title of this Bill will be the Medicines and Medical Devices Act 2020.

Schedules

Schedule 1: Medical Devices: Civil Sanctions

Part 1: Monetary Penalties

Imposition of monetary penalty

248 Schedule 1 outlines how the new civil sanctions regime for medical devices will operate. Part 1 relates to monetary penalties.

249 Paragraph 1 provides that the Secretary of State may impose a monetary penalty on a person who he is satisfied beyond a reasonable doubt has committed an offence under clause 23 of this Bill or regulation 60A of the MDR (that is, the offence of breaching a provision listed in the last Schedule to the MDR, inserted by Schedule 2 to the Bill and explained below). The amount payable is determined by the Secretary of State.

Notices, representations and appeals etc

250 Paragraph 2 provides that the Secretary of State must notify a person on whom he is planning to impose a monetary penalty before doing so. That notice must give the person the opportunity to discharge their liability by paying less than, or an equal amount to, the penalty. The person will then also have the opportunity to write to, or object to the Secretary of State regarding the penalty. Following this, the Secretary of State must then decide whether or not to proceed with the penalty.

251 Paragraph 2, subsection 5 provides that the Secretary of State cannot issue a monetary penalty if he is no longer satisfied with the reasons for doing so.

252 Paragraph 2, subsection 6, sets out the circumstances in which the person who has

been issued with the penalty may appeal. Any such appeal is to the First Tier Tribunal. The First Tier Tribunal is made up of 7 chambers which settles legal disputes and is structured around particular areas of law.

253 Paragraph 2, subsection 8 provides that the Tribunal must allow the appeal if the appellant claims they did not commit an offence, unless they believe beyond reasonable doubt that they did. This is the same standard of proof as required by a criminal offence.

Information to be included in notices under paragraph 2

254 Paragraph 3 sets out what must be included in the notice provided by the Secretary of State to the person(s) he is considering imposing a monetary penalty on.

Monetary penalties: criminal proceedings and conviction

255 Paragraph 4 provides that a person may not be subject to any criminal proceedings in relation to the conduct that has led to the imposition of the monetary penalty if they have paid the penalty, or before the allowed time between the notice and paying the penalty.

Part 2: Enforcement Undertakings

256 Part 2 outlines “enforcement undertakings”. These provisions allow a

person to offer to take certain action within a specified time as a result of the Secretary of State suspecting (on reasonable grounds) that they have committed an offence under clause 23 or under regulation 60A of the MDR. The action taken can either be to ensure the offence does not occur again, or as set out in the supplementary regulations. The Secretary of State has the power to accept an enforcement undertaking.

257 Paragraph 5(2) provides that the person cannot be convicted of an offence, or subject to a monetary penalty, in relation to the action that led to the offer of the enforcement undertaking, unless they have failed to comply with the undertaking.

Part 3: Enforcement Costs Recovery Notices

Imposition of enforcement costs recovery notices

258 Paragraph 6 provides that the Secretary of State has the right to issue a notice to the person on whom a monetary penalty has been imposed in order to recoup the costs of issuing the penalty. These costs include administration costs, investigation costs, and the costs of obtaining expert advice (including, but not limited to, legal advice).

Information to be included in enforcement

costs recovery notices

259 Paragraph 7 outlines what must be included in an enforcement costs recovery notice. It states that the person who received an enforcement costs recovery notice can ask the Secretary of State for a detailed breakdown of costs.

Appeals

260 Paragraph 8 sets out the grounds on which a person on whom an enforcement costs recovery notice has been served can appeal. An appeal is to the First Tier Tribunal.

Part 4: Power to Make Supplementary Provision etc by Regulations

Supplementary regulations: general

261 Paragraph 9 gives the Secretary of State the power to make regulations, as set out in paragraphs 10 to 12, to supplement the civil sanctions regime set out in Schedule 1 (“supplementary regulations”). The Secretary of State may also make consequential, incidental, transitional, transitory or saving regulations using this power. Paragraph 9(2) provides that regulations under this power may make different provision for different purposes, different provision for different areas and/or provision for all cases to which the power applies, or for specified cases or descriptions

of cases.

Monetary penalties and costs

262 Paragraph 10 provides that supplementary regulations can make certain provision in relation to monetary penalties, specifically provisions relating to early payment discounts, interest on payments or other financial payments as a result of late payments (this may not exceed the total cost of the penalty), and enforcement. Provisions relating to enforcement can include provision for the recovery of the costs and/or penalties as civil debt and also under a court order.

Enforcement undertakings

263 Paragraph 11 sets out the matters relating to enforcement undertakings that can be set out in supplementary regulations, being:

- a. how a person can enter into an undertaking;
- b. the terms of an undertaking;
- c. when/how the Secretary of State can publish an undertaking
- d. variation of an undertaking;
- e. what constitutes compliance with an undertaking;
- f. how the Secretary of State can monitor

- compliance;
- g. how the Secretary of State can issue a certification of compliance for the undertaking;
- h. the ability to appeal against the Secretary of State's decision to refuse certification of compliance;
- i. provision that where a person has given inaccurate, misleading or incomplete information in relation to an undertaking, that person is to be regarded as non-compliant;
- j. provision that where an enforcement undertaking has only been partly complied with, the partial compliance should be taken into account when considering imposing any sanctions to be imposed on that person.

Appeals

264 Paragraph 12 provides that supplementary regulations may make provision with respect to the appeals process in relation to the imposition of a requirement or the service of a notice under the civil sanctions provisions. Subparagraph (2) provides that supplementary regulations may confer powers on the tribunal

to which the appeal can be made, including to withdraw/confirm the requirement/notice, to take certain steps or to require that the decision be reconsidered by the Secretary of State.

Part 5: General and Supplemental **Guidance as to enforcement**

265 Paragraph 13 requires the Secretary of State to prepare and publish guidance with regard to enforcement and civil sanctions. More specifically, this guidance must cover the sanctions that may be imposed if a person commits an offence, the action the Secretary of State may take, and the circumstances in which action is likely to be taken.

266 Subsection (2) provides that the guidance must include information on the circumstances when, and the manner in which, the Secretary of State will impose a monetary penalty.

267 Subsection (3) similarly provides the guidance must include information on the Secretary of State's powers to issue an enforcement costs recovery notice, and relevant information alongside this.

268 Similarly, subsection (4) provides that guidance must provide further information on the Secretary of State's power to accept an enforcement undertaking.

269 Subsection (5) provides that the Secretary of State can revise the guidance published under this paragraph where it is appropriate to do so and must then publish the revised guidance.

270 Subsection (6) outlines who the Secretary of State must consult with before publishing any new or revised guidance.

271 Subsection (7) provides that the Secretary of State must have regard to the guidance whilst exercising any of the powers outlined in this Schedule.

Pre-commencement consultation

272 Paragraph 14 provides that consultation on either supplementary regulations made under Clause 40 (consultation), or guidance made under Paragraph 13, that takes place before the Schedule comes into force, will satisfy the requirement to consult.

Reports on use of civil sanctions

273 Paragraph 15 provides that the Secretary of State must issue reports about the uses of the power in this Schedule and lists what each report must include.

274 However, the Secretary of State has discretion to refrain from including information in a report if in his opinion it would be

inappropriate to do so on the basis that including this information might be unlawful or might adversely impact a current investigation or current legal proceedings.

Disclosure of information

275 Paragraph 16 provides that any relevant information held by the police, crown prosecution service, a procurator fiscal, or the public prosecution service for Northern Ireland, may be shared with the Secretary of State for the purposes of exercising powers in this Schedule. Whether or not the information was obtained before or after the Schedule comes into force is irrelevant.

276 Subsections (3) to (6) make clear that these powers do not enable disclosure of information in contravention of data protection legislation or in contravention of the relevant provisions of the Investigatory Powers Act 2016, but that, other than these restrictions, disclosure of information under paragraph 16 will not contravene other legislative or common law restrictions on the disclosure of information.

Part 6: Interpretation

277 This paragraph gives meaning to terms used in this Schedule.

Schedule 2: Offences of breaching provisions in the Medical Devices Regulations 2002

Part 1: Offence

278 Paragraph 1 inserts various regulations into the MDR.

60A Offence of breaching certain provisions

279 This inserted regulation outlines the definition of an offence under certain circumstances. The circumstances are defined as where a person fails to comply with a requirement or breaches a prohibition contained in a provision listed in the Schedule to the MDR inserted by Schedule 2.

280 Subsection 2 sets the maximum penalties a person may be subject to if guilty of an offence. These are:

- a. As a result of a summary conviction in England and Wales, which is an offence that is only triable in a magistrates court, and is often summarised without the need for trial, a person can be imprisoned for up to 51 weeks, receive a fine, or both.
- b. As a result of a summary conviction in Scotland or Northern Ireland, a person can be imprisoned for up to 6 months, or receive a fine not exceeding £5,000, or

both. A level 5 on the standard scale references the scale of fines for summary offences as outlined in the Criminal Justice Act 1982.

281 Subsection 3 outlines that the maximum 51 weeks imprisoned outlined in subclause(3)(a) should be 6 months if the offence is committed before section 281(5) of the Criminal Justice Act 2003 is commenced.

60B Defence of due diligence

282 This insertion sets out the defences available.

283 Subsection (1) provides that a person being prosecuted for an offence under Regulation 60A can use the defence of due diligence if they can prove they took all reasonable steps to avoid committing the offence.

284 Subsections(2) and (3) provide that a person cannot, as part of their defence, claim that the offence was due to either another person's action/default or to reliance on information provided by another person, unless they have first notified the prosecutor. That notification must include any information the defendant has that may assist in identifying the

other person. The notification must be served at least 7 days before the hearing.

285 Subsection (4) states that a person cannot rely on the defence of due diligence if they are relying on information provided by another person (as set out in subsection 2(b)), unless the defendant can prove it was reasonable to rely on this information. This has to have regard to whether the defendant has reason to disbelieve the information, and steps taken to verify the information.

286 Subsection (5) provides that in the application of regulation 60B to Scotland, references to the defendant are to be read as references to the accused.

60C Offences by bodies corporate

287 This insertion covers the offences committed by bodies corporate.

288 Subsection (1) applies to offences committed by a body corporate as defined in clause 25.

289 It provides that an “officer” can also be prosecuted for committing an offence, if an offence has been committed under regulation 60A, by a body corporate (or, in the case of Scotland, a Scottish partnership) with the consent or knowledge of that “officer”, or due to negligence of the “officer”.

290 Subsections (2) to (4) set out the definition for “officer”.

Part 2: Provisions

291 This Part inserts a Schedule into the Medicines Devices Regulations 2002 which sets out which provision is an offence if breached.

Commencement

292 Commencement is provided for in clause 43. Clause 43(1) sets out which clauses of the Bill will commence on the day the Bill is passed. Clause 43(2) sets out the clauses that will come into force two months after Royal Assent. Clause 43(3) provides that Chapters 2 and 3 of Part 3 will be commenced by regulations made by the Secretary of State.

Financial implications of the Bill

293 Existing regulations which govern human medicines, veterinary medicines and medical devices will become retained EU law at the end of the transition period by virtue of the European Union (Withdrawal) Act 2018. The Bill introduces powers to enable changes to that domestic legislation to be made. There are no immediate financial implications arising from the delegated powers in the Bill. There will be economic familiarisation costs in the order of £0.7m with respect to powers on enforcement around medical devices (Part 3, Chapter 2). These may be outweighed by efficiency savings through the rationalisation of existing regulations. There are no financial or economic impacts monetised for the disclosure of information powers with respect to medical devices (Part 3, Chapter 3). Instead the changes to existing domestic legislation will be

determined by future developments in the relevant sectors as well as by the outcome of the continuing UK-EU negotiations.

Parliamentary approval for financial costs or for charges imposed

294 A money resolution is required for the Bill. Such a resolution is required where a Bill authorises or confers a power to authorise new charges on the public revenue (broadly speaking, new expenditure). In this case, clauses 1, 8 and 12 confer powers to make secondary legislation about human medicines, veterinary medicines and medical devices which could result in new charges on the public revenue.

295 A ways and means resolution is also required for the Bill. Such a resolution is required where a Bill authorises or confers a power to authorise new charges on the people (broadly speaking, new taxation or similar charges, including fees charged in relation to functions which were previously paid for using money from the public revenue). In this case, clauses 5, 10 and 14 confer powers to make provision about the charging of fees in connection with various functions previously paid for using money from the public revenue.

Compatibility with the European Convention on Human Rights

296 The Government considers that the Medicines and Medical Devices Bill is compatible with the European Convention on Human Rights (“the Convention”). A statement has been made under section 19(1)(a) of the Human Rights Act 1998 to this effect.

Equalities

297 During the passage of the European Union (Withdrawal) Act 2018 through the House of Commons, the previous Government committed to providing a statement on the impact of EU-exit primary legislation on either the Equality Act 2006 or the Equality Act 2010.

298 The Medicines and Medical Devices Bill does not amend, repeal or revoke any provision of the Equality Act 2006, the Equality Act 2010 or any subordinate legislation made under either of those Acts (the equalities legislation).

299 In relation to the policy which is given effect by the Bill, the Secretary of State for Health and Social Care has had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010.

Related documents

300 The following documents are relevant to the Bill and can be read at the stated locations:

- The Life Sciences Sector Deal

Annex A - Territorial extent and application in the United Kingdom

| Provision | Extends to E & W and applies to England? | Extends to E & W and applies to Wales? | Extends and applies to Scotland? | Extends and applies to Northern Ireland? | Legislative Consent Motion needed? |
|--------------------------------------|--|--|----------------------------------|--|------------------------------------|
| Part 1 | Yes | Yes | Yes | Yes | Yes (NI) |
| Part 2 | Yes | Yes | Yes | Yes | Yes (NI) |
| Part 3 (including Schedules 1 and 2) | Yes | Yes | Yes | Yes | No |
| Part 4 | Yes | Yes | Yes | Yes | Yes (NI) |
| Part 5 | Yes | Yes | Yes | Yes | Yes (NI) |

MEDICINES AND MEDICAL DEVICES BILL

EXPLANATORY NOTES

These Explanatory Notes relate to the Medicines and Medical Devices Bill as introduced in the House of Commons on 13 February 2020 (Bill 90).

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