EXPLANATORY NOTES

Medicines and Medical Devices Act 2021

Chapter 3

£11.50

MEDICINES AND MEDICAL DEVICES ACT 2021

EXPLANATORY NOTES

What these notes do

These Explanatory Notes relate to the Medicines and Medical Devices Act 2021 which received Royal Assent on 11 February 2021 (c. 3).

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

Table of Contents

Overview of the Act

1 The Medicines and Medical Devices Act 2021 (the Act):

i. establishes a Patient Safety Commissioner, with the core duties of promoting patient safety and the importance of the patient voice in relation to the regulation of human medicines and medical devices;

ii. 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);

iii. provides information sharing gateways to enabling sharing of information with relevant persons (such as regulators and regulatory networks) outside of the UK in order to give effect to international agreements and arrangements concerning the regulation of human medicines, veterinary medicines and medical devices;

iv. provides a delegated power to establish one or more information systems in relation to medical devices;

v. provides a delegated power to establish on a legislative basis a medical device expert advisory committee; and

vi. consolidates the enforcement provisions for medical devices and introduces civil sanctions.

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 ("the ECA") which was the principal piece of domestic legislation passed by the UK Parliament which provided for EU Regulations to take direct effect in UK law and conferred a delegated power (section 2(2)) by which EU Directives and other pieces of EU legislation could be transposed into UK law through domestic regulations.

3 Section 1 of the European Union (Withdrawal) Act 2018 ("EUWA 2018") repealed the ECA on exit day (31st January 2020) but the ECA continued to have effect until the IP completion day (31st December 2021) by virtue of section 1A of the European Union (Withdrawal Agreement) 2020).

4 The European Union (Withdrawal Agreement) 2020 received Royal Assent on 24 January 2020. The Act implements the Withdrawal Agreement, as agreed between the UK 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 regime overview and delegated powers

5 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 regimes in each case. The comprehensive regimes, 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 2012 (SI 2012/1916)
- The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)
- The Veterinary Medicines Regulations 2013 (SI 2013/2033)
- The Medical Devices Regulations 2002 (SI 2002/618)

6 Each of the above sets of Regulations were made using section 2(2) of the 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) of the ECA. Updates have taken place across these Regulations to reflect changes in EU Directives and updates to the EU regulatory systems.

7 Now that the transition period has ended, section 2(2) of the ECA is no longer available for making changes to the regulatory regimes for human medicines, clinical trials of human medicines, or veterinary medicines through secondary legislation. In the absence of this delegated power, it is not possible to update the schemes except through primary legislation, even if those changes are relatively minor, or using powers in EUWA 2018 (in relation correcting deficiencies further to leaving the EU (power expires 2 years after the end of the transition period) or the NI protocol.

8 The effect of the repeal of section 2(2) of the ECA on medical devices is slightly different. This is because medical devices legislation in the UK is made jointly under section 2(2) of the ECA and section 11 of the Consumer Protection Act 1987 ("the CPA"). Whilst section 11 of the CPA is not repealed (though it is being disapplied 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 of the 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 to update much of the regulatory framework for medical devices without primary legislation.

9 Sections 2, 10 and 15 of the Act therefore provide 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 amended and supplemented. These delegated powers may only be exercised in relation to a finite list of matters specified on the face of the Act. The regulation maker have an overarching objective to satisfy before making these regulations, and as part of that assessment regard must be had to the safety and the availability of human or veterinary medicines or devices (as the case may be) and the likelihood of the UK being seen as a favorable place to develop and supply these products. Subject to two discrete exceptions. Further the regulation maker my only make regulations that may have an impact on safety if satisfied that the benefits of the proposed changes outweigh the risks. The powers may also only be exercised following public consultation.

10 For two years after the end of the transition period, section 8 of the EUWA 2018 provides a power to address deficiencies arising from leaving the EU. Whilst under section 8C of the EUWA 2018, changes may be made to the existing regulatory regimes governing human medicines, veterinary medicines, and medical devices. Such changes are limited to matters that relate to giving effect to the Northern Ireland Protocol.

Human medicines - existing regulatory regime

11 The regulatory regime for human medicines in the UK is based on the EU Human Medicines Directive[1] and is set out in the Human Medicines Regulations 2012 ("the HMRs"). The regime provides a comprehensive scheme for regulating human medicines that covers their licensing, 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 ("the MHRA") acting on behalf of the Secretary of State.

12 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.

13 As well as transposing the EU Medicines 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.

14 The Medicines (Products for Human Use) (Fees) Regulations 2016 (SI 2016/190) makes provision for the fees payable in relation to the regulation of human medicines.

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 regime

16 The regulatory regime for clinical trials in the UK is based on the EU Clinical Trials Directive[2] and is set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 ("the 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).

---

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

[2] Directive 2001/20/EC

17 The EU legislation on which the CTRs are based is due to be repealed and replaced by a new EU Regulation[3].

Veterinary medicines - existing regulatory regime

18 Veterinary medicines are regulated by the Veterinary Medicines Regulations 2013 (SI 2013/2033)[4] 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 regime

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.

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 (SI 2005/1803) apply to devices that are also consumer products.

Consolidating and expanding medical devices enforcement provisions

22 Chapter 3 of Part 4 of the Act seeks to consolidate the enforcement regime for medical devices and provides the Secretary of State with the ability (see Schedule 2) to impose civil sanctions as an alternative to criminal prosecution. Chapter 4 of Part 4 provides the Secretary of State with a new information sharing gateway.

---

[3] EU No. 536/2014

[4] Exit amendments were made to these Regulations by SI 2019/865, 676 and 2020/1461 and by S.R. 2020 No. 353.

23 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).

24 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.

25 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.

26 The Act 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 Act (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.

27 The Act 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 Act provides the Secretary of State with powers to impose a monetary penalty on a person (where the Secretary of State is satisfied beyond 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).

28 The Act 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 information. It also includes a power to share information internationally with certain persons (such as other regulators) further to international arrangements about the regulation of medical devices.

Legal background

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

Territorial extent and application

30 Section 49 sets out the territorial extent of the Act. These are the legal systems of which the Act will form part. The extent of an Act can be different from its application. Territorial application is about where an Act produces a practical effect rather than where it forms part of the law. The Act extends and applies to the whole of the UK. In addition, repeals and amendments made by the Act have the same territorial extent as the legislation that they are repealing or amending.

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

32 See the table in Annex A for a summary of the position regarding territorial extent and application.

Commentary on provisions of Bill

Part 1: Commissioner for Patient Safety

Section 1: Commissioner for Patient Safety

33 Section 1 relates to the establishment of a Patient Safety Commissioner and sets out the core duties of the Patient Safety Commissioner in relation to medicines and medical devices in England. This section of the Act should be read with Schedule 1.

34 Subsection (1) places a duty on the Secretary of State to appoint a Commissioner for Patient Safety.

35 Subsection (2) sets out that the Commissioner's core duties are to promote the safety of patients with regard to the use of medicines and medical devices; and promote the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices.

36 Subsection (3) prevents the Commissioner from being regarded as a servant or agent of the Crown or as enjoying any status, immunity or privilege of the Crown.

Part 2: Human Medicines

Chapter 1: Regulations

Section 2: Power to make regulations about human medicines

37 Section 2(1) confers a delegated power to amend or supplement the law relating to human medicines by regulations.

38 The "law relating to human medicines" is defined (in section 9) 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.

39 Any amendments to this listed legislation will be captured by this definition, meaning this definition will always include the latest version.

40 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.

41 The power is targeted in its scope because regulations made under it may only contain provision relating to the matters specified on the face of the Act at sections 3 to 7. The lists of matters specified in sections 3, 4, 5, 6 and 7 are exhaustive in each case, meaning that only regulatory changes that fall within these descriptions may be made under this power.

42 Section 2(2) places a duty on the Secretary of State or Northern Ireland department making regulations (or both if acting jointly) to have the overarching objective of safeguarding public health when making regulations using the power under section 2(1).

43 Section 2(3) provides that when considering whether regulations would contribute to the objective set out in section 2(2), the appropriate authority must at least have regard to the three factors set out at (a) to (c). These are the safety and availability of human medicines, and the likelihood of a relevant part of the UK (England, Scotland, Wales, or Northern Ireland) as being seen as a favourable place in which to carry out research relating to human medicines, to conduct clinical trials, and to manufacture or supply human medicines. Other factors may of course be relevant to any decision to exercise the delegated power.

44 Section 2(4) provides that the appropriate authority may make regulations under section 2(1) that may have an impact on the safety of human medicines only if the authority considers that the benefits of doing so outweigh the risks.

45 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.

Section 3: Manufacture, marketing and supply

46 Section 3(1) lists matters relating to the manufacture, marketing and supply of human medicines that regulations made under section 2(1) can address. The list is exhaustive.

47 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 section 2(1) and relying on section 3(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.

48 Subsection (1)(b) allows provision to be made in relation to authorisations to import human medicines. In general, regulatory rules 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 section 2(1) and relying on section 3(1)(b) could, for example, amend the requirements relating to importation that must be met by the holders of such authorisations.

49 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 section 2(1) and relying on section 3(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.

50 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.

51 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 has produced a flowchart that provides further information on the stages of the registration process.

52 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.

53 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 section 9.

54 Subsection (1)(h) allows provision to be made in relation to the recording of information about the supply of human medicines. 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). Regulations made under section 2(1) and relying on section 3(1)(h) provision could, for example, amend these requirements.

55 Subsection (1)(i) allows provision to be made in relation to notifying and reporting requirements. 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.

56 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. Existing requirements are found in Part 13 (packaging and leaflets) of the HMRs. Regulations made under section 2(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.

57 Subsection (1)(k) allows provision to be made in relation to the advertising of human medicines. Existing requirements are found at Part 14 (advertising) of the HMRs. Regulations made under section 2(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.

58 Subsection (1)(l) provides that regulations made under section 2(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.

59 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. Current requirements are 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.

60 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 section 2(1) and relying on section 3(1)(n) 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.

61 Subsection (1)(o) provides that regulations can be made about the use of human tissues or cells in relation to human medicines. Human tissues or cells are defined by regulation 5(1) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (SI 2007/1523).

Section 4: Falsified medicines

62 Section 4 sets out two matters that regulations made under section 2(1) may be used to address. The first provides that regulatory provisions may be made about the prevention of the supply of falsified medicines. The second, provides that provisions can be made about the use, retention and disclosure of information held within a possible future falsified medicine prevent system for any additional purpose to do with human medicines.

63 Falsified human medicines are defined in section 9, by reference to regulation 8 of the HMRs, as human medicines that represent falsely their identity (including packaging, naming or composition), source or provenance.

64 Subsection (2) sets out a framework for preventative measures that regulations made under subsection (1)(a) may include. Subsection (2)(a) provides what regulation made under section 2(1) and relying on clause 4(1)(a)) may include, i.e. rules around 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.

65 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.

66 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.

67 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. This duty applies to provisions made in reliance of clause 4(1)(a) and (b).

Section 5: Clinical trials

68 Section 5(1) lists matters relating to clinical trials that provisions made under section 2(1) may address.

69 Subsection (1)(a) provides that provision may be made which is corresponding or similar to the EU Clinical Trial Regulation.

70 Subsection (1)(b) provides that provision may be made about 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.

71 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 section 2(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.

72 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.

73 Subsection 1(e) allows provision to be made about 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.

Section 6: Fees, offences, powers of inspectors

74 Section 6(1) lists other matters which regulations made under section 2(1) may provide for.

75 Subsection (1)(a) allows regulations made under section 2(1) to introduce charges where they relate to functions conferred by regulations made under section 1(1), the HMRs or the Medicines for Human Use (Clinical Trials) Regulations 2004.

76 Subsection (1)(b) allows regulations made under section 2(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.

77 Subsection (1)(c) allows regulations made under section 2(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.

78 Subsection (2) provides that regulations made under section 2(1) cannot provide for any offence, whether new or existing, to be punishable with a sentence of imprisonment of more than two years.

Section 7: Emergencies

79 Section 7 allows amending and supplementary regulations to be made under section 2(1) about the relaxation of regulatory requirements relating to medicines in circumstances where there is a need to alleviate a threat of serious harm to the health of the general public or a section of the public. The Covid-19 pandemic would be an example of such circumstances.

80 By way of example, the provisions could be made to facilitate stocks of medicines to be shared between persons who do not hold wholesale dealer's 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.

81 Subsections (2) and (3) provide that the relaxing of a regulatory requirements can be made subject to conditions. Conditions may be found in regulations or a time-limited protocol 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. Conditions can be important safeguards and may need to be bespoke. The use of protocols may be the most effective means to communicate the applicable conditions to healthcare and other professions accustomed to operating within the comprehensive regulatory regime governing medicines.

Chapter 2: International Agreements: Disclosure of Information

Section 8: Disclosure of information in accordance with international agreements

82 Section 8 confers a power on the Secretary of State and the Department of Health in Northern Ireland to disclose information they hold relating to human medicines.

83 Section (2) provides that information may be disclosed to a relevant person outside the UK where it is required in order to give effect to international agreements and arrangements concerning the regulation of human medicines and the relevant authority considers that the disclosure is in the public interest.

84 Subsection (3) provides that the relevant authority may not disclose commercially sensitive information under this section unless the relevant authority considers the disclosure to be necessary and proportionate.

85 Subsection (4) sets out that, except as provided by subsections (5) and (6), any disclosure of information in accordance with this section does not breach the restrictions on disclosure at (a) and (b).

86 Subsection (5) provides a restriction requiring that identifiable patient information is only shared with the patient's consent.

87 Subsection (6) provides that nothing in this section allows disclosures of information that breach data protection legislation or are prohibited by Parts 1 to 7 or Chapter 1 of Part 9 of the Investigatory Powers Act 2016.

88 Subsection (7) makes it clear that this section does not limit the circumstances in which information may be disclosed under any other enactment or rule of law (for example under common law powers).

89 Subsection (8) provides definitions for terms used in section 8.

Chapter 3: Interpretation

Section 9: Interpretation of Part 2

90 This section provides definitions for certain terms used in Part 2.

Part 3: Veterinary Medicines

Chapter 1: Regulations

Section 10: Power to make regulations about veterinary medicines

91 Section 10(1) confers a delegated power to amend or supplement the Veterinary Medicines Regulations 2013 (SI 2013/2033) by regulations.

92 The power is targeted in its scope because regulations made under it may only contain provision relating to the matters specified on the face of the Act at sections 11 and 12. The lists of matters specified in sections 11 and 12 are exhaustive, meaning that only regulatory changes that fall within these descriptions may be made under this power.

93 Section 10(2) provides that when making regulations under section 10(1), the appropriate authority's overarching objective must be to promote one or more of the following:

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

94 Section 10(3) provides that when considering whether regulations would contribute to the objective set out in section 10(2), the appropriate authority must at least have regard to the three factors set out at paragraphs (a) to (c). These are the safety of veterinary medicines, the availability of veterinary medicines, and the likelihood of a relevant part of the UK (England, Scotland, Wales or Northern Ireland) being seen as a favourable place in which to develop, manufacture or supply veterinary medicines. Other factors may of course be relevant to any decision to exercise the delegated power.

95 Section 10(4) provides that the appropriate authority may make regulations under section 10(1) that may have an impact on the safety of veterinary medicines only if the authority considers that the benefits of doing so outweigh the risks.

96 The delegated power is conferred on the "appropriate authority" as defined in section 10(6). 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.

Section 11: Manufacture, marketing, supply and field trials

97 Subsection (1) lists matters relating to the manufacture, marketing, supply and field trials of veterinary medicines that regulations made under the power at section 10(1) can cover.

98 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 a veterinary medicine in the UK as set out in regulation 5 (manufacture of veterinary medicinal 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 Practice. This describes the minimum standard that a medicines manufacturer must meet in their production processes.

99 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 dealing authorisation. These requirements are detailed in regulation 9 of the Veterinary Medicines Regulations 2013.

100 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 section 10(1) that rely on section 11(1)(c) could, for example, amend the 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.

101 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 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. Subsection (d) combined with paragraphs (a), (b), (g), and (i) could be used to make provision in regulations under section 10 about using a medicine outside the terms of a marketing 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 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.

102 Subsection (1)(e) allows provision to be made in relation to manufacturing, importing and 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.

Example (4): Veterinary Medicines prescribing policy

Some veterinary medicines can only be supplied against a prescription issued by an appropriate practitioner. 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 professionals within the veterinary industry will evolve and certain professionals may be added to or removed from this list by amending the Regulations.

103 Subsection (1)(f) covers who can supply veterinary medicines – meaning provision could be made to add additional prescribing professions who would be given appropriately restricted prescribing rights.

104 Subsection (1)(g) covers the requirements that need to be met in relation to the supply of veterinary medicines. Current requirements are detailed in Schedule 3 of the Veterinary Medicines Regulations 2013.

105 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.

106 Subsection (1)(i) allows provision to be made about the circumstances in which veterinary medicines can be administered. This could include provision about circumstances in which veterinary medicines may be administered under the Cascade.

107 Subsection (1)(j) allows provision to be made in relation to notification and reporting requirements. 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.

108 Subsection (1)(k) allows provision to be made in relation to the labelling and packaging of veterinary medicines.

Example (5): Labels 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.

109 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 section 10(1) and relying on this provision could, for example, provide for the inclusion of a detailed definition of advertising to provide clarity to industry and improve compliance with the Regulations.

110 Subsection (1)(m) allows provision to be made in relation to animal test certificates granted under 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 medicine.

111 Subsection (2) provides that regulations may make corresponding or similar provision to EU Regulations 2019/4 and 2019/6, as the appropriate authority sees fit.

Section 12: Fees, offences, powers of inspectors, costs

112 Subsection (1) lists further matters that regulations made under the power at section 10(1) can cover.

113 Subsection (1)(a) allows regulations made under section 10(1) to introduce or amend charges where they relate to functions conferred by regulations made under section 10(1) of the Act or by the Veterinary Medicines Regulations 2013.

114 Subsection (1)(b) allows regulations made under section 10(1) to make the breach of requirements or prohibitions introduced by the regulations a criminal offence. Subsection (2) provides that those regulations may not provide for a criminal offence to carry a sentence of imprisonment of more than two years.

115 Subsection (1)(c) allows regulations made under section 10(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 regulations 34 (powers of entry) and 35 (powers of an inspector) of the Veterinary Medicines Regulations 2013.

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

117 Subsection (2) provides that regulations made under section 10(1) cannot provide for any offence, whether new or existing, to be punishable with a sentence of imprisonment of more than two years.

118 Subsection (3) provides that a power of entry conferred by regulations relying on subsection (1)(c) must not include a 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 or supply of veterinary medicines under a veterinary medicines provision.

119 Subsection (4) defines "veterinary medicines provision" as meaning provision in regulations made under section 10(1) or the Veterinary Medicines Regulations 2013.

Chapter 2: International Agreements: Disclosure of Information

Section 13: Disclosure of information in accordance with international agreements

120 Section 13 confers a power on the Secretary of State and the Department of Agriculture, Environment and Rural Affairs in Northern Ireland to disclose information they hold relating to veterinary medicines.

121 Subsection (2) provides that information may be disclosed to a relevant person outside the UK where it is required in order to give effect to an international agreement or arrangement concerning the regulation of veterinary medicines and the relevant authority considers that the disclosure is in the public interest.

122 Subsection (3) provides that the relevant authority may not disclose commercially sensitive information under this section unless the relevant authority considers the disclosure to be necessary and proportionate.

123 Subsection (4) sets out that, except as provided by subsection (5), a disclosure of information in accordance with this section does not breach the restrictions on disclosure at (a) and (b).

124 Subsection (5) provides that nothing in this section allows disclosures of information that breach data protection legislation or are prohibited by Parts 1 to 7 or Chapter 1 of Part 9 of the Investigatory Powers Act 2016.

125 Subsection (6) makes it clear that this section does not limit the circumstances in which information may be disclosed under any other enactment or rule of law (for example under common law powers).

126 Subsection (7) provides definitions for terms used in section 13.

Chapter 3: Interpretation etc

Section 14: Interpretation of Part 3 and supplementary provision

127 Section 14 provides definitions for certain terms used in Part 3 of the Act. This section 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 4: Medical Devices

Chapter 1: Regulations: General

Section 15: Power to make regulations about medical devices

128 Section 15(1) confers a delegated power to amend or supplement the Medical Devices Regulations 2002 (MDR).

129 The power is targeted in its scope because regulations made under section 15(1) may only contain provision relating to the matters specified on the face of the Act at sections 16, 17 and 18. The lists of matters specified in sections 16 to 18 are exhaustive, meaning that only regulatory changes that fall within these descriptions may be made under this power.

130 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 and in practice it would be the Secretary of State for Health and Social Care exercising this power.

131 Section 15(2) places a duty on the Secretary of State to have the overarching objective of safeguarding public health when making regulations using the power under section 15(1).

132 Section 15(3) provides that when considering whether regulations would contribute to this objective, the Secretary of State must at least have regard to the three factors listed in (a) to (c). These are: the safety of medical devices, the availability of medical devices and the likelihood of the UK being seen as a favourable place in which to carry out research relating to medical devices, develop medical devices, and manufacture or supply medical devices. Other factors may of course be relevant to any decision to exercise the delegated power.

133 Section 15(4) provides that the Secretary of State may make regulations under section 15(1) that may have an impact on the safety of medical devices only if the authority considers that the benefits of doing so outweigh the risks.

Section 16: Manufacture, marketing and supply

134 Section 16 lists matters relating to the marketing of medical devices that regulations made under section 16(1) can cover. This list is exhaustive.

135 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 market, supplied put into service. 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.

136 Subsection (1)(b) allows provision to be made in relation to the assessment of whether requirements are met.

137 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.

138 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 manufacturer them (for instance, the requirement to maintain a quality management system).

139 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.

140 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

New registration requirements are being phased in for medical devices. As a result, if you place certain medical devices on the market, then from a certain date you, your appointed UK responsible person (or, if you are placing devices on the NI market, and have a NI based authorised representative, your authorised representative) must register with the MHRA. These requirements differ depending on the class of device being placed on the market, and whether or not the device is being placed on the GB or NI market.

141 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.

142 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.

143 Subsection (2) relates to what provisions may be included in regulations made under section 15(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.

Section 17: Fees, information, offences

144 Section 17 lists further matters relating to medical devices that regulations made under section 15(1) can cover. This list is exhaustive.

145 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 section 15(1) or a provision of the MDRs, including the function of charging fees by a person appointed under regulations made in reliance on section 16(1)(c).

Example (7): Fees

The MHRA currently requires fees to be paid:

- by any person registering certain 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.

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.

146 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).

147 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 section 16(1)(c).

148 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 3 to this Bill.

149 Subsection (2) provides a definition for "medical devices provision" (that is, a provision in regulations made under the power at section 15(1) or a provision in the MDR).

Section 18: Emergencies

150 Section 18 allows amending and supplementary regulations to be made under section 15(1) about the relaxation of regulatory requirements in circumstances where there is a need to protect the public from a threat of serious harm to health. The Covid-19 pandemic would be an example of such circumstances.

151 By way of example, regulations made in reliance on section 18 could allow for certain devices to be supplied notwithstanding that an assessment of compliance with a requirement has not yet taken place. Subsections (2) and (3) provide that the relaxing of a regulatory requirement could be made subject to conditions. Conditions may be found in regulatory provisions or a time-limited protocol that is published by the Secretary of State. Conditions can be important safeguards and may need to be bespoke. The use of protocols may be the most effective means to communicate the applicable conditions to healthcare and other professions accustomed to operating within the comprehensive regulatory regime governing medical devices.

Chapter 2: Regulations: Information Systems, Advisory Committee

Section 19: Information Systems

152 Section 19 confers a delegated power on the Secretary of State to make regulations providing for a database of information in relation to medical devices to be established and managed by the Health and Social Care Information Centre. The Health and Social Care Information Centre is also known as NHS Digital.

153 Subsection (1) provides that regulations may be made about the establishment and operation by the Health and Social Care Information Centre ("the Information Centre") of one or more information systems. The power is restricted to purposes relating to monitoring and taking action to ensure: the safety and performance, including the clinical effectiveness, of medical devices; the safety of patients, and; the use of advances in technology to improve the safety and performance of medical devices.

154 Subsection (2) outlines the type of provisions that may be made by regulations. This is a non-exhaustive list. Provisions may be about the type of information that could be gathered, the requirements on the provision of that information, the rules around the use or disclosure of that data and the requirements that may be placed on "the Information Centre" in exercising of its functions under the regulations.

155 Subsection (3) sets out additional information that provisions relying on subsection (2)(b) could include.

156 Subsection (3)(a) provides that provisions may be made requiring specified persons or descriptions of persons providing services, or exercising any powers or duties, relating to medical devices, to provide specified information to the Information Centre.

157 Subsection (3)(b) provides that regulations may specify the time and manner in which the information required must be provided.

158 Subsection (3)(c) provides that regulations may enable the Information Centre to determine the manner and timing of information required from specified persons or descriptions of persons providing services, or exercising any powers or duties, relating to medical devices. Provisions

may enable the Information Centre to specify the description of the information, the purposes for which the information is to be gathered and specify any other information the Information Centre considers it needs to fulfil its functions.

159 Subsection (3)(d) provides that regulations may describe any procedural steps the Information Centre must follow when requiring a person to provide information.

160 Subsection (3)(e) provides that regulations may specify how required information is recorded or retained.

161 Subsection (3)(f) provides that regulations may include enforcement requirements in relation to regulations may under section 19(1).

162 Subsection (5) provides examples of the type of information that could be required to be provided under the power in subsections (2)(a), (3)(a) and (3)(c)(i). The list is not exhaustive.

163 Subsection (6) provides non-exhaustive examples of the possible provisions that may be included in the regulations on the use and disclosure of information held within the information system (subsection (2)(c)). These include the analysis of that information (whether alone or linked with other information), the publication of it, the disclosure of it to specified persons or descriptions of persons or for specified purposes, and on the use or further disclosure by any person to whom information has been disclosed under the regulations.

Section 20: Advisory Committee

164 Section 20 provides the Secretary of State with a power to make regulations creating a statutory committee to advise on matters relating to medical devices. Further, Section 20 lists the matters relating to establishing an advisory committee that the regulations may cover.

165 Subsection (1) enables regulations to be made to establish a committee to advise the Secretary of State on matters relating to medical devices.

166 Subsections (2)(a) to (d) enable regulations to make, among other things, provisions about membership of the committee, establishment of sub-committees by the committee and matters which the committee may or must consider. It also allows the regulations to make provisions for co-operation between the committee and the Commission on Human Medicines and other bodies with medical devices expertise. The Commission on Human Medicines is a statutory committee which advises Ministers on the safety, efficacy and quality of medicinal products.

167 Subsection (3) sets out a non-exhaustive list of matters in respect of which regulations under 2(a) may make provision. Subsection 3(a) sets out that provisions made under 2(a) relating to membership of the committee may include numbers of members, their appointment and the circumstances in which they cease to be members. Subsection 3(b) allows provisions made under subsection 2(a) to include requirements for the independence of members from the Secretary of State. Subsection 3(c) allows for provisions to be made for payment of remuneration and allowances to committee members.

Chapter 3: Enforcement

168 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.

169 "Enforcement authority" is defined in section 42(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 2002/618) (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(1) 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.

Section 21: Compliance notices

170 Section 21 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 under section 17(2)). If the person reasonably suspected of non-compliance is a manufacturer based overseas, the notice could also be issued to their UK responsible person or, if the device has been placed on the NI market and the overseas manufacturer has designated an authorised representative based in NI, that authorised representative.

171 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.

172 Subsection (3) is self-explanatory.

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

174 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.

Section 22: Suspension notices

175 This section 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.

176 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. This list is exhaustive.

177 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.

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

179 Subsection (5) is self-explanatory.

Section 23: Safety notices

180 This section 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.

181 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.

182 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.

183 Subsection (4) provides that a requirement to recall a device (further to reliance on section 23(3)(b)) can only be imposed on a person if there is no alternative requirement available which could sufficiently protect health and safety.

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

185 Subsection (6) is self-explanatory.

186 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 considers 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.

Section 24: Information notices

187 This section gives the enforcement authority the power to issue a notice requiring a person to disclose or produce information (an information notice). A 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.

188 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.

189 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 section 24(2)(a)) must be provided.

190 Subsection (4) provides that the time specified for the production of the records (under section 24(2)(b)) must be at least 28 days after the day on which the notice is served.

191 Subsection (5) provides that information notices can be varied or revoked.

Section 25: Applications to set notices aside etc

192 This section 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.

193 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 section 42 (2)).

194 Subsection (2) provides that the same application may also be made by person who has received an information notice.

195 Subsection (3) states that such applications must be made within 28 days, starting from the day the notice was served, or varied.

196 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.

197 Subsection (5) explains that the court can vary a compliance notice so as not to apply in relation to a medical devices provision (as defined under section 17(2)). 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.

198 Subsection (6) states that the court can vary a suspension notice if it is satisfied that the time period of suspension is too long.

199 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.

200 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.

201 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 section 27 (see below for appeal process).

Section 26: Compensation

202 Section 26 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.

203 The application for compensation can be made at the same time as an application to set the notice aside or vary it.

Section 27: Further appeals

204 This section explains the appeals process relating to enforcement notices.

205 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.

206 As set out in section 42, 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.

207 Subsection (2) provides that any appeal made under subsection (1) must be made within 28 days, starting on the day the relevant decision was made.

208 Subsection (3) provides that the appropriate appeals court may make any order it considers appropriate.

Section 28: Offences

209 Section 28 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.

210 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.

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

> ### Example (10): Section 281(5) of the Criminal Justice Act 2003
> Section 281(5) 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.

Section 29: Defence of due diligence

212 Section 29 provides there is a defence of due diligence available to persons charged with an offence under section 28. Due diligence is where a person takes all reasonable steps to avoid committing an offence.

213 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 replaced 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 of the proceedings.

214 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.

215 Subsection (5) explains how references in this section apply to Scotland. This includes setting out that a reference to "the hearing of the proceedings" is to be read as a reference to "the trial diet" in Scotland.

Section 30: Offences by bodies corporate

216 This section provides that where an offence under section 28 has been committed by a corporate body or a Scottish partnership and has been proved to 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.

217 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.

Section 31: Civil Sanctions

218 This section explains that Schedule 2 outlines the civil sanctions that will be applicable to anyone committing an offence in relation to medical devices.

Section 32: Forfeiture of medical devices

219 This section 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 under section 17(2)). 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).

220 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 section 32. 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).

221 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.

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

223 Subsection (8) defines "appropriate time" for the purposes of this section.

224 Subsection (9) defines what "entitled to a device" means.

Section 33: Appeals against forfeiture decisions

225 This section outlines the appeal processes applicable to forfeiture orders.

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

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

228 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).

229 Subsection (7) sets out the definition of persons "entitled to a device".

Section 34: Recovery of expenses of enforcement

230 Section 34 outlines the process by which the enforcement authority can apply to the court to recover the expenses incurred by its enforcement activities.

231 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 28, 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.

232 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.

Section 35: Recall of medical device by enforcement authority

233 This section concerns the recalling of medical devices by the enforcement authority.

234 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.

235 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.

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

Section 36: Power of officer of Revenue and Customs to detain medical devices

237 Section 36 outlines the power of a customs officer in relation to detaining medical devices.

238 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.

239 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 4 of this Act, a medical devices provision (as defined in section 17(2) – see explanation above), or Schedule 5 of the Consumer Rights Act 2015 (investigatory powers).

240 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.

241 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.

Section 37: Offence of obstructing an officer of Revenue and Customs

242 Subsection (1) provides that it is an offence to obstruct a customs officer (as described above in section 36) from undertaking their duties.

243 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.

244 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 281(5) of the Criminal Justice Act 2003 is commenced.

Section 38: Civil proceedings

245 This section provides that breach of an obligation contained in a medical devices provision (as defined in section 17(2) – see explanation above) is actionable as a breach of statutory duty.

246 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 4: Disclosure of Information and Consequential etc Provision

Section 39: Disclosure of information

247 Section 39 concerns the disclosure of information and applies in relation to information the Secretary of State holds regarding medical devices.

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

249 Subsection (3) provides that 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 a function or provide a service in relation to medical devices.

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

251 Subsection (5) provides the Secretary of State with the power to disclose information to a relevant person outside of the UK the disclosure is required to give effect to an international agreement or arrangement concerning the regulation of medical devices, and the Secretary of State considers that the disclosure is in the public interest.

252 Subsection (6) provides that no identifiable patient information can be disclosed under the power in subsection (5) without the consent of the individual to whom the information relates.

253 Subsection (7) provides that commercially sensitive information may only be disclosed for the purposes set out in subsections (2), (3), (4) or (5), 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.

254 Subsection (8) provides that information disclosed in reliance on subsection (3) or (4), must not be used or further disclosed by the recipient for any purpose other than the purpose for which it was originally disclosed. The two exceptions set out in (a) and (b) are, firstly if the use or further disclosure is with the agreement of the Secretary of State and for a purpose in subsection (3) or (4); and secondly, if the use or further disclosure is in accordance with an enactment or order of a court or tribunal.

255 Subsection (9) provides that, except as provided by subsection (10) (see below), a disclosure of information under this power does not contravene on obligation of confidence owed by the person making the disclosure or any other restriction on the disclosure of information.

256 Subsection (10) provides that nothing in this section 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.

257 Subsection (11) makes it clear that this section does not limit the circumstances in which information may be disclosed under any other enactment or rule of law (for example under common law powers).

258 Subsection (12) provides definitions of terms used in section 39.

Section 40: Offence relating to information

259 Section 40 outlines the offences that are related to information disclosure.

260 Subsection (1) provides that a person commits an offence if they use or further disclose information in a manner that breaches subsections (8) of section 39.

261 Subsection (2) provides that a person commits an offence if they were disclosed information under regulations made under section 19 (Information systems) and then use or disclose that information in contravention of those regulations.

262 Subsection (3) outlines the maximum penalties for these offences. 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.

263 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 281(5) of the Criminal Justice Act 2003 is commenced.

Section 41: Consequential and supplementary provisions

264 Section 41 outlines the consequential and supplementary amendments made by this Act. These amendments are outlined in subsections (1) to (7).

265 Subsection (8) is self-explanatory.

266 Subsection (9) introduces Schedule 3, which provides that it is an offence to breach various provisions in the MDR.

Chapter 5: Interpretation of Part 4

Section 42: Interpretation of Part 4

267 This section provides definitions of words and phrases used in Part 4 of this Act.

Part 5: Regulations under Parts 1, 2, 3 and 4

Section 43: Power to make consequential etc provision

268 This section makes further provision about the regulation-making powers in Parts 1, 2, 3 and 4, apart from paragraph 9 of Schedule 2. It provides that regulations made under these powers may make:

a. consequential, supplementary, incidental, transitional, transitory or saving provision;

b. different provision for different purposes and different areas;

c. provision creating exceptions or limited in application to specified cases.

Section 44: Scope of powers of Northern Ireland departments

269 This section provides that provision may not be made in regulations under section 2(1) (human medicines) and section 10(1) (veterinary medicines 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 provision, if contained in an Act of the Northern Ireland Assembly, would be within the Assembly's competence, and would not require consent from the Secretary of State.

270 The Northern Ireland Assembly is a devolved legislature and cannot legislate on matters that are outside its legislative competence.

Section 45: Consultation

271 This section sets out the consultation requirements that must be met before regulations are made under Parts 1, 2, 3 and 4 of the Act.

272 Subsection (1) creates a duty to carry out a public consultation. It provides that before regulations are made under Parts 1, 2, 3 and 4, public consultation must take place. The duty is placed on the "relevant authority" which is defined in subsection (6).

273 Subsection (2) creates a duty to consult the Welsh Ministers, the Scottish Ministers, the Department of Health in Northern Ireland, and any other persons as the Secretary of State considers appropriate before making regulations under section 19(1) about the establishment and operation of information systems in relation to medical devices. Section 19(1) provides a power to make UK-wide regulations establishing UK-wide information systems. Given those information systems will use information from healthcare providers throughout the UK for purposes that relate to both devolved and reserved matters, it is appropriate in this particular situation that the Secretary of State consults the devolved administrations when making regulations under this section.

274 Subsection (3) provides that a summary of the relevant authority's assessment of the matters mentioned in sections 2, 11 and 17 must be included in the consultation document ahead of making any regulations under sections 2(1), 11(1) or 17(1). For example, this means that if the Secretary of State proposed policy changes that would require regulations under section 2, the consultation document must include a summary of the Secretary of State's assessment of the matters in section 2, which includes whether proposed regulatory changes would contribute to the objective of safeguarding public health and if proposed changes may have an impact on the safety of medicines, an initial assessment of whether the benefits of those regulations would outweigh the risks.

275 Subsection (4) provides that the consultation duty does not apply in relation to regulations made in reliance on section 7 or section 18 (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 regulations contain a declaration that they are required urgently due to an imminent risk of serious harm to health.

276 Subsection (5) provides that consultation carried out before the Act is passed may satisfy the duty to consult.

277 Subsection (6) provides a definition for the term "relevant authority" as used in section 45.

Section 46: Reporting requirements

278 Section 46 sets out reporting requirements in relation to the operation of certain regulations made under this Act.

279 Subsection (1) requires the relevant authority to lay a report before the appropriate legislature on the operation of any regulations made under sections 2(1), 10(1), 15(1) and 19(1) that were in force during the reporting period. The report must be laid as soon as reasonably practicable after the end of each reporting period. This means that the Northern Ireland department must lay a report before the Northern Ireland Assembly on any regulations they have made (whether alone or jointly with the Secretary of State) under sections 2(1) and 10(1) that were in force at any time during the two-year reporting period. The Secretary of State must lay a report before Parliament on any regulations the Secretary of State has made under sections 2(1) and 10(1) (whether alone or jointly with a Northern Ireland Department) and under sections 15(1) and 19(1) that were in force at any time during the two-year reporting period.

280 Subsection (2) provides that when preparing this report, the relevant authority must consult with whomever they consider appropriate.

281 Subsection (3) sets out what must be included in the report.

282 Subsection (4) provides that the reporting period is two years. This means that a report will be due every two years. The first reporting period start afters on the day the first set of regulations subject to the reporting requirement come into force.

283 Subsection (5) sets out definitions of terms "relevant authority" and "appropriate legislature" as used in section 49.

Section 47: Procedure

284 This section provides that when the powers to make regulations in Parts 1 to 4 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 sections 2 and 10 will be exercisable by statutory rule.

285 Subsection (3) refers to a table that sets out the procedure for making regulations under Parts 1 to 4. For the vast majority of regulations made under the Bill the applicable procedure is the draft affirmative procedure. The exceptions to this are Regulations that only contain provision made in reliance on sections 6(1)(a), 12(1)(a), 17(1)(a), or paragraph 9 of Schedule 2; these are subject to the negative procedure. Regulations containing provision made in reliance on sections 7 and 18 are subject to the made affirmative procedure where the regulations contain a declaration that the person making them considers that they need to be made urgently to protect the public from an imminent risk of serious harm to health. Without that declaration, those regulations are subject to the draft affirmative procedure. The table provides that Regulations containing provision made in reliance on any other provision of Parts 1 to 4 are subject to the draft affirmative procedure. This would include for example regulations made under sections 1, 19 and 20, and regulations made under section 2 that rely on sections 3 to 5, 6(1)(b) or (c).

286 Subsection (4) provides that provision that may be made in regulations subject to the negative procedure may be included in regulations subject to the draft affirmative procedure. For example, regulatory changes made under section 15 relying on section 17(1)(a) (that on its own would be subject to the negative procedure), may be made in regulations containing provision relying on another section, for example section 16 – in this situation such a set of Regulations are subject to the draft affirmative procedure.

287 Subsection (5) sets out the negative procedure.

288 Subsection (6) sets out the draft affirmative procedure.

289 Subsection (7) sets out the made affirmative procedure.

290 Subsections (8) and (9) detail how to calculate the periods of 40 days referred to the made affirmative procedure (in subsection (7)).

291 Subsection (10) provides that if as a result of subsection (7) regulations cease to have effect at the end of the period of 40 days, that does not invalidate anything previously done under those regulations and it does not prevent new regulations being made.

Part 6: Report on operation of medicines and medical devices legislation

Section 48: Report on operation of medicines and medical devices legislation

292 Section 48 sets out the requirement for the Secretary of State to publish a report on the operation of medicines and medical devices legislation after 5 years of the Bill passing, as set out in subsection (1) and (5).

293 Subsection (2) sets out what the report must cover.

294 Subsection (3) and (4) provides that the Secretary of State must acknowledge any report on medicines and medical devices legislation prepared by relevant parliamentary committees, and that this report must be laid before Parliament.

295 Subsection (5) provides definition for terms used in section 48.

Part 7: Extent, commencement and short title

Section 49: Extent

296 This section provides that the Act is UK wide in that it extends to England and Wales, Scotland and Northern Ireland.

Section 50: Commencement

297 Subsection (1) lists the provisions in this Act that come into force on the day the Act is passed.

298 Subsection (2) lists the provisions that come into force two months after Royal Assent.

299 Subsection (3) provides that certain medical devices provisions in this Act (Chapters 3 and 4 of Part 4) come into force on the day or days specified by the Secretary of State in regulations.

300 Subsection (4) provides that regulations made in reliance on sections 7 or 18 that come into force within two months of the Act being passed, may only be made if those regulations contain a declaration that the person (or persons) making them considers that they need to be made urgently to protect the public from an imminent risk of serious harm to health.

Section 51: Transitional etc provision in connection with commencement

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

302 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 2 and 3 as far as they relate to Northern Ireland.

303 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.

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

305 Subsection (6) defines what is meant by "relevant Northern Ireland department".

Section 52: Short title

306 The short title of this Act is the Medicines and Medical Devices Act 2021.

Schedules

Schedule 1: Further Provision about the Commissioner for Patient Safety

Principles relating to core duties

307 Paragraph 1(1) places a duty on the Commissioner to prepare and publish a set of principles to govern the way in which the Commissioner will carry out their core duties.

308 Paragraph 1(2) allows the Commissioner to revise these principles and requires any revised versions to be published.

309 Paragraph 1(3) sets out that the Commissioner must carry out a public consultation when preparing or revising the principles.

Involvement of patients

310 Paragraph 2(1) requires the Commissioner to take reasonable steps to involve patients in the discharge of their core duties.

311 Paragraph 2(2)(a) requires the Commissioner to take reasonable steps to ensure that patients are aware of the Commissioner's core duties and of how they may communicate with the Commissioner.

312 Paragraph 2(2)(b) requires the Commissioner to take reasonable steps to consult patients on matters which the Commissioner proposes to consider in the discharge of their core duties.

Supplementary functions and information

313 Paragraph 3(1) sets out the supplementary functions the Commissioner may exercise for the purposes of carrying out their core duties. These include making reports or recommendations to relevant persons; consulting patients and appropriate persons; as well as requesting information from and sharing information with, relevant persons.

314 Paragraph 3(2) provides that a relevant person to whom a report or recommendation is made must provide a response within such period as the Commissioner may reasonably require.

315 Paragraph 3(3) sets out that a relevant person must, so far as reasonably practicable, comply with a request for information within such period as the Commissioner may reasonably require.

316 Paragraph 3(4) outlines that nothing in Schedule 1 authorises a disclosure of information which contravenes data protection legislation. 'Data protection legislation' has the meaning given by section 3(9) of the Data Protection Act 2018.

317 Paragraph 3(5) provides definitions. It outlines that in paragraph 3 "relevant person" means a person who exercises functions of a public nature in England in relation to medicines and medical devices; and any other person who, in the course of providing health care, provides services relating to medicines or medical devices in relation to England.

Individual cases

318 Paragraph 4(1) prevents the Commissioner from exercising functions in relation to an individual case.

319 Paragraph 4(2) provides that this does not prevent the Commissioner considering individual cases and drawing conclusions about them for the purpose of, or in the context of, considering a general issue.

Amendments to primary legislation

320 Paragraph 5 makes various amendments to primary legislation relating to the Commissioner for Patient Safety.

321 Paragraph 5(1) amends Schedule 1 to the Public Records Act 1958 to include the Commissioner for Patient Safety. This provides for the Commissioner's records to be regarded as public records.

322 Paragraph 5(2) amends Schedule 1 to the House of Commons Disqualification Act 1975. The effect is that the Commissioner cannot also be a Member of Parliament.

323 Paragraph 5(3) amends Schedule 1 to the Freedom of Information Act 2000 to bring the Commissioner within the Act's definition of a "public authority". This makes the Commissioner subject to relevant provisions of that Act.

324 Paragraph 5(4) amends section 71 of the National Health Service Act 2006 (schemes for meeting losses and liabilities etc. of certain health service bodies). This means that the Commissioner will be eligible to participate in indemnity schemes established under that section. This does not mean that the Commissioner will automatically be a member of any such scheme.

325 Paragraph 5(5) amends Schedule 19 to the Equality Act 2010 (authorities subject to the public sector equality duty) to include the Commissioner.

Regulations about appointment and operation

326 Paragraph 6(1) provides a power for the Secretary of State to make provision in regulations about the appointment and operation of the Commissioner for Patient Safety.

327 Paragraph 6(2) sets out a list of matters regulations may (among other things) contain provision for and about. These include the Commissioner's terms of office; the provision of financial or other assistance, including staff, accommodation, equipment or other facilities for the Commissioner; and the appointment of a board to provide advice to the Commissioner.

Schedule 2: Medical Devices: Civil Sanctions

Part 1: Monetary Penalties

Imposition of monetary penalty

328 Schedule 2 outlines how the new civil sanctions regime for medical devices will operate. Part 1 relates to monetary penalties.

329 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 section 28 of this Act 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 3 to the Act and explained below). The amount payable is determined by the Secretary of State.

Notices, representations and appeals etc

330 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.

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

332 Paragraph 2(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.

333 Paragraph 2(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

334 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

335 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

336 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 section 28 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.

337 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

338 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

339 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

340 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

341 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 2 ("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

342 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

343 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

344 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. Sub-paragraph (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

345 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.

346 Sub-paragraph (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.

347 Sub-paragraph (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.

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

349 Sub-paragraph (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.

350 Sub-paragraph (6) outlines who the Secretary of State must consult with before publishing any new or revised guidance.

351 Sub-paragraph (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

352 Paragraph 14 provides that consultation on either supplementary regulations made under section 45 (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

353 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.

354 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

355 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.

356 Sub-paragraphs (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

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

Schedule 3: Offences of breaching provisions in the Medical Devices Regulations 2002

Part 1: Offence

358 Paragraph 1 inserts various regulations into the MDR.

60A Offence of breaching certain provisions

359 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 3.

360 Paragraph 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.

361 Paragraph 3 sets out the limitation period that applies in relation to the offence, which is the earlier of:

a. the end of the period of one year beginning with the day on which evidence which the prosecutor thinks is sufficient to justify a prosecution comes to the knowledge of the prosecutor; and

b. the end of the period of three years beginning with the day on which the offence was committed.

362 Paragraph 4 outlines that a certificate outlining the date on which the evidence came to the prosecutor's knowledge and that is signed by the prosecutor is to be considered conclusive evidence that the evidence referred to above has come to the prosecutor's knowledge.

363 Paragraph 5 outlines that the maximum 51 weeks imprisoned outlined in paragraph (2)(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

364 This insertion sets out the defences available.

365 Paragraph (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.

366 Paragraphs (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.

367 Paragraph (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 paragraph 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.

368 Paragraph (5) provides that in the application of regulation 60B to Scotland, references to the defendant are to be read as references to the accused and references to "the hearing of the proceedings" are to be read as "the trial diet".

60C Offences by bodies corporate

369 This insertion covers the offences committed by bodies corporate.

370 Paragraph (1) applies to offences committed by a body corporate.

371 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".

372 Paragraphs (2) to (4) set out the definition for "officer".

Part 2: Provisions

373 This Part inserts a Schedule into the Medicines Devices Regulations 2002 which sets out which provisions it is an offence to breach.

Commencement

374 Commencement is provided for in section 50. Section 50(1) sets out which sections of the Act will commence on the day the Act is passed, and these relate to the operation of the emergency provisions. Section 50(2) sets out the sections that will come into force two months after Royal Assent. Section 50(3) provides that Chapters 3 and 4 of Part 4 will be commenced by regulations made by the Secretary of State.

Related documents

375 The following documents are relevant to the Act and can be read at the locations stated below:

- The Life Sciences Sector Deal
- Medicines and Medical Devices Bill: Overarching documents
- The Medicines and Medical Devices Bill Delegated Powers Memorandum
- Supplementary Delegated Powers Memorandum

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?
Part 1 (including Schedule 1)	Yes	No	No	No
Part 2	Yes	Yes	Yes	Yes
Part 3	Yes	Yes	Yes	Yes
Part 4 (including Schedules 2 and 3)	Yes	Yes	Yes	Yes
Part 5	Yes	Yes	Yes	Yes
Part 6	Yes	Yes	Yes	Yes
Part 7	Yes	Yes	Yes	Yes

Annex B – Hansard References

376 The following table sets out the dates and Hansard references for each stage of the Act's passage through Parliament.

Stage	Date	Hansard Reference
House of Commons		
Introduction	13 February 2020	No debate
Second Reading	02 March 2020	Vol. 672 Col. 659
Public Bill Committee	08 June 2020 08 June 2020 10 June 2020	First Sitting Col. 1 Second Sitting Col. 29 Third Reading Col. 53
Report and Third Reading	23 June 2020	Vol. 677 Col. 1219
House of Lords		
Introduction	24 June 2020	Vol. 804
Second Reading	02 September 2020	Vol. 804 Col. 371
Grand Committee	19 October 2020 26 October 2020 28 October 2020 04 November 2020 11 November 2020 17 November 2020 19 November 2020	First Sitting Vol. 806 Col. 316GC Second Sitting Vol. 807 Col. 2GC Third Sitting Vol. 807 Col. 118GC Fourth Sitting Vol. 807 Col. 308GC Fifth Sitting Vol. 807 Col. 444GC Sixth Sitting Vol. 807 Col. 622GC Seventh Sitting Vol. 807 Col. 716GC
Report	12 January 2021 14 January 2021	First Sitting Vol. 809 Col. 614 Second Sitting Vol. 809 Col. 892
Third Reading	21 January 2021	Third Reading Vol. 809 Col. 1281
Commons Consideration of Lords Amendments	27 January 2021	Vol. 688 Col. 485
Royal Assent	11 February 2021	House of Lords Vol. 810 House of Commons Vol. 689 Col. 504

Annex C – Progress of Bill Table

377 This Annex shows how each section and Schedule of the Act was numbered during the passage of the Bill through Parliament.

Section of the Act	Bill as Introduced in the Commons	Bill as amended in Committee in the Commons	Bill as introduced in the Lords	Bill as amended in Committee in the Lords	Bill as amended on Report in the Lords
Section 1					Clause 1
Section 2	Clause 1	Clause 1	Clause 1	Clause 1	Clause 2
Section 3	Clause 2	Clause 2	Clause 2	Clause 2	Clause 3
Section 4	Clause 3	Clause 3	Clause 3	Clause 3	Clause 4
Section 5	Clause 4	Clause 4	Clause 4	Clause 4	Clause 5
Section 6	Clause 5	Clause 5	Clause 5	Clause 5	Clause 6
Section 7	Clause 6	Clause 6	Clause 6	Clause 6	Clause 7
Section 8					Clause 8
Section 9	Clause 7	Clause 7	Clause 7	Clause 7	Clause 10
Section 10	Clause 8	Clause 8	Clause 8	Clause 9	Clause 11
Section 11	Clause 9	Clause 9	Clause 9	Clause 10	Clause 12
Section 12	Clause 10	Clause 10	Clause 10	Clause 11	Clause 13
Section 13				Clause 12	Clause 14
Section 14	Clause 11	Clause 11	Clause 11	Clause 13	Clause 16
Section 15	Clause 12	Clause 12	Clause 12	Clause 14	Clause 17
Section 16	Clause 13	Clause 13	Clause 13	Clause 15	Clause 18
Section 17	Clause 14	Clause 14	Clause 14	Clause 16	Clause 19
Section 18	Clause 15	Clause 15	Clause 15	Clause 17	Clause 20
Section 19			Clause 16	Clause 18	Clause 21
Section 20					Clause 22
Section 21	Clause 16	Clause 16	Clause 17	Clause 19	Clause 23
Section 22	Clause 17	Clause 17	Clause 18	Clause 20	Clause 24
Section 23	Clause 18	Clause 18	Clause 19	Clause 21	Clause 25
Section 24	Clause 19	Clause 19	Clause 20	Clause 22	Clause 26
Section 25	Clause 20	Clause 20	Clause 21	Clause 23	Clause 27
Section 26	Clause 21	Clause 21	Clause 22	Clause 24	Clause 28
Section 27	Clause 22	Clause 22	Clause 23	Clause 25	Clause 29
Section 28	Clause 23	Clause 23	Clause 24	Clause 26	Clause 30
Section 29	Clause 24	Clause 24	Clause 25	Clause 27	Clause 31
Section 30	Clause 25	Clause 25	Clause 26	Clause 28	Clause 32
Section 31	Clause 26	Clause 26	Clause 27	Clause 29	Clause 33

Section of the Act	Bill as Introduced in the Commons	Bill as amended in Committee in the Commons	Bill as introduced in the Lords	Bill as amended in Committee in the Lords	Bill as amended on Report in the Lords
Section 32	Clause 27	Clause 27	Clause 28	Clause 30	Clause 34
Section 33	Clause 28	Clause 28	Clause 29	Clause 31	Clause 35
Section 34	Clause 29	Clause 29	Clause 30	Clause 32	Clause 36
Section 35	Clause 30	Clause 30	Clause 31	Clause 33	Clause 37
Section 36	Clause 31	Clause 31	Clause 32	Clause 34	Clause 38
Section 37	Clause 32	Clause 32	Clause 33	Clause 35	Clause 39
Section 38	Clause 33	Clause 33	Clause 34	Clause 36	Clause 40
Section 39	Clause 34	Clause 34	Clause 35	Clause 37	Clause 41
Section 40	Clause 35	Clause 35	Clause 36	Clause 38	Clause 42
Section 41	Clause 36	Clause 36	Clause 37	Clause 39	Clause 43
Section 42	Clause 37	Clause 37	Clause 38	Clause 40	Clause 45
Section 43	Clause 38	Clause 38	Clause 39	Clause 41	Clause 46
Section 44	Clause 39	Clause 39	Clause 40	Clause 42	Clause 47
Section 45	Clause 40	Clause 40	Clause 41	Clause 43	Clause 48
Section 46				Clause 44	Clause 49
Section 47	Clause 41	Clause 41	Clause 42	Clause 45	Clause 50
Section 48					
Section 49	Clause 42	Clause 42	Clause 43	Clause 46	Clause 51
Section 50	Clause 43	Clause 43	Clause 44	Clause 47	Clause 52
Section 51	Clause 44	Clause 44	Clause 45	Clause 48	Clause 53
Section 52	Clause 45	Clause 45	Clause 46	Clause 49	Clause 54
Schedule 1					Schedule 1
Schedule 2	Schedule 1	Schedule 1	Schedule 1	Schedule 1	Schedule 2
Schedule 3	Schedule 2	Schedule 2	Schedule 2	Schedule 2	Schedule 3

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, Controller of Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.

tso
a Williams Lea company

Published by TSO (The Stationery Office), a Williams Lea company, and available from:

Online
www.tsoshop.co.uk

Mail, Telephone, Fax & E-mail
TSO
PO Box 29, Norwich, NR3 1GN
Telephone orders/General enquiries: 0333 202 5070
Fax orders: 0333 202 5080
E-mail: customer.services@tso.co.uk
Textphone: 0333 202 5077

TSO@Blackwell and other Accredited Agents

ISBN 978-0-10-560232-3

9 780105 602323