MEDICINES AND MEDICAL DEVICES BILL

Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee

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A. INTRODUCTION

1. This memorandum has been prepared for the Delegated Powers and Regulatory Reform Committee to assist with its scrutiny of the Medicines and Medical Devices Bill ("the Bill"). The Bill was introduced in the House of Commons on 13 February 2020. This memorandum identifies the provisions of the Bill that confer powers to make delegated legislation. It explains in each case why the power has been taken and explains the nature of, and the reason for, the procedure selected.

2. The Bill contains four regulation-making powers that are deliberately constrained in several significant ways. Most importantly, the powers can only be exercised to make provision about the finite list of matters specified on the face of the Bill. The Bill also contains a power to issue guidance and three standard powers in relation to commencement and making transitional and savings provision.

3. It is important to underline that many of the provisions outlined in this document are technical in nature. They are however, vital in terms of ensuring in future years that the Government can respond to changes in innovation; public health challenges; and global developments in medicines, as appropriate, within the clearly defined parameters set out in this document.

4. The Department has carefully considered the nature of the powers in the Bill in relation to identified policy opportunities and legislative requirements on medicines and medical devices regulation after leaving the EU. We have reached the view that the approach proposed is necessary and justified. The Bill's provisions strike an important balance between the need for robust parliamentary scrutiny, and the critical need to be able to make the frequently required and typically expert-reviewed updates. This balance has been achieved by applying the affirmative parliamentary procedure to the majority of uses of the powers. The Bill, thereby represents a significant increase in the scrutiny that Parliament will have over the regulatory regimes for medicines and medical devices because the choice of procedure will be removed; the regulatory regimes have to date all been

updated using statutory instruments subject to the negative procedure under section 2(2) of the European Communities Act 1972 (ECA).

5. Human and veterinary medicines and medical devices are regulated through existing well-established legislation – these primarily being the Human Medicines Regulations 2012, the Medicines for Human Use (Clinical Trials) Regulations 2004, the Medicines Act 1968, the Medicines (Products for Human Use) (Fees) Regulations 2016, the Veterinary Medicines Regulations 2013 and the Medical Devices Regulations 2002. Regulations made using delegated powers in Parts 1 to 3 of the Bill will be limited to amending or supplementing these existing pieces of legislation.

6. In order to deliver community pharmacy reform, the power in clause 1 includes a limited use to make amendments to parts of the Medicines Act 1968 through regulations. The proposed reforms would require complex amendments to the Medicines Act 1968, which could be made using these powers. In line with the statutory consultation requirement, there will be consultation on these reforms before they are reflected in legislation. The constraint on the exercise of this power is that regulations may only make changes to the sections of the primary legislation specified on the face of the Bill.

7. The power in Schedule 1 to make supplementary regulations is similarly constrained to provision that supplements, is consequential on, or incidental to provision made by that Schedule; or provision that is transitional, transitory or saving in relation to earlier supplementary regulations. And it is important to note that in making regulations under the Bill, there is a statutory requirement for consultation that will support Parliamentary consideration of the regulations.

B. PURPOSE AND EFFECT OF THE BILL

8. The UK's ability to amend the regulatory regimes for human and veterinary medicines, clinical trials and medical devices is derived primarily from the powers contained in section 2(2) of the ECA. This is because, while the UK was a member of the EU, the regulatory regime for these areas fell within the competence of EU legislation, which has been implemented into UK law by means of statutory instruments made under section 2(2) ECA.

9. Section 1 of the European Union (Withdrawal) Act 2018 (EUWA) repealed the ECA on exit day. Section 1 of the EU (Withdrawal Agreement) Act 2020 saves and repurposes section 2(2) ECA for use during the Transition Period. As a result of the repeal of section 2(2) ECA, the delegated power previously used to update the regulatory regimes for human medicines (including the regime for clinical trials of human medicines), veterinary medicines and medical devices will no longer be available after the end of the Transition Period. It is important that we introduce appropriate legislation so that we can update our domestic regulatory regimes to keep abreast with scientific and technical progress, and to make necessary changes to those regimes arising out of public health concerns or developments, amongst other things. This Bill will ensure that appropriate powers are in place to enable the regimes to continue to evolve, be updated and not stagnate. Whilst changes are usually technical in nature, they are often

important in terms of access to medicines, public health and the competitiveness of the UK.

10. The powers in this Bill will enable the UK to maintain an effective regulatory regime for medicines (both human and veterinary), clinical trials, and medical devices after the end of the Transition Period. The delegated powers may only be used to amend or supplement the existing regulatory framework in relation to the specific matters specified on the face of the Bill.

11. As regards who may exercise the delegated powers, In Parts 1 (human medicines) and 2 (veterinary medicines) it is the "appropriate authority". This means the Secretary of State in relation to Great Britain and the relevant Northern Ireland Department in relation to Northern Ireland or both. In relation to medical devices, delegated powers will be exercised by the Secretary of State (of Health and Social Care) on a UK wide basis.

12. In exercising the delegated powers regard must be had to patient safety, availability of human and veterinary medicines and medical devices, and the attractiveness of the relevant part of the UK as a place in which to conduct clinical trials or supply medicines or supply and develop medical devices. This ensures the uses of the power will align with the Government's overarching ambition that the UK should have a world-leading and dynamic system for the regulation of medicines and medical devices. Striking the right balance between these aims and safety and availability will ensure that safe, innovative medicines and medical devices will be available on the UK market at a point that is equivalent to or earlier than other leading health systems, thus improving patient health outcomes.

13. In certain circumstances, regulations under the Bill could be used to ensure UK legislation remains consistent with internationally accepted standards, such as those presented on good clinical practice by the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[1] and those set by the International Organization for Standardisation (ISO) on medical devices.

Life Sciences Sector Deal

14. To place the legislation in broader context, the Government has been implementing a bold vision for the future of UK life sciences through two ambitious sector deals. Both deals worked to implement the Life Sciences Industrial Strategy through extensive collaboration between Government and the sector, working together strategically to deliver joint strategic commitments, to invest in and grow the UK's life sciences sector.

15. This Bill supports the commitments laid out in the Life Sciences Sector deals and the NHS Long-Term Plan by taking delegated powers that take into account making the UK a more attractive regulatory environment to conduct clinical trials, and supply, develop and manufacture medicines. The Bill also supports the Government's vision, enshrined in the second Life Sciences Sector Deal, for the Medicines and Healthcare products Regulatory Agency (MHRA) (an executive agency of the Department of Health and Social Care responsible for the regulation

[1] For more information go to: https://www.ich.org/home.html

of medicines, clinical trials, and medical devices) to be a forward-thinking regulator. This means taking approaches to regulation that can maintain a swift response to scientific advice, ensuring that the Department can effectively manage regulatory routes suitable for the authorisation of innovative types of medical products.

16. By taking delegated powers in this Bill in this focussed way, the Government aims to ensure that companies want to do business in the UK and continue to bring the best new human medicines, advanced therapies and devices to UK patients early, compared to other world-leading health systems. When exercising relevant powers in this Bill, the Government will work in close collaboration with stakeholders to develop a clear regulatory pathway for clinical trials, medicines and medical devices, to promote patient access and safety. Hence the requirement for statutory consultation which will be introduced as part of this Bill.

Powers for Ministers in Devolved Administrations

17. The subject matter of human and veterinary medicines (including clinical trials of human medicines) is reserved in relation to Scotland and Wales but is transferred in relation to Northern Ireland. The Bill reflects this by conferring delegated powers on the "appropriate authority". In relation to England, Scotland and Wales the "appropriate authority" is the Secretary of State. In relation to Northern Ireland the "appropriate authority" is the relevant Northern Ireland Department acting alone, or the Secretary of State and the relevant Northern Ireland Department acting jointly. For human medicines the relevant Northern Ireland Department is the Department of Health and for veterinary medicines is the Department of Agriculture, Environment and Rural Affairs.

18. The subject matter of medical devices is reserved in relation to Scotland, Wales or Northern Ireland. The Bill reflects this by conferring the delegated powers relating to medical devices on the Secretary of State in relation to the whole of the UK.

Purposes of delegated powers

19. Best regulatory practice, together with technical and scientific progress, means that the medicines and medical devices landscape is regularly evolving in ways that require a proportionate and effective regulatory response. For instance, product innovation means that medical devices are growing more complex, technologically intelligent, customisable and miniaturised. For medicines, horizon scanning activities have noted: the evolution of big data; precision medicine; novel manufacturing; novel clinical trials design; and developments in synthetic biology as relevant innovations impacting on regulatory systems. These are common challenges for all international regulatory regimes, and there will be an expectation that every Government is able to keep pace with these evolving technologies where they require regulatory management. Whilst we have a comprehensive regulatory framework in our existing secondary legislation, it is vital that we have the powers to enable the UK to continue to evolve as a credible regulator of medicines and devices in the context of this landscape, so as to avoid consequent harm to health outcomes or the economy.

20. It is important that we retain the ability to make changes, most of which are highly technical provisions, so as not to inadvertently create a regulatory barrier to health

service or product innovation changes that could not have been anticipated at the point that detailed processes were laid down. The Human Medicines Regulations 2012 have been updated eleven times since being made to adapt to these sorts of changes. Similarly, the Medical Devices Regulations 2002 have been updated nine times since being made. For precisely this reason, we have considered it not possible or appropriate to set out detailed requirements for regulatory process on the face of primary legislation. Without a regulatory updating power, all these changes would require further primary legislation for each change and would have significant implications for the UK's ability to manage the regulation of medicines and medical devices safely and efficiently. To this end, Parts 1 to 3 of the Bill contain three targeted delegated powers. The Department considered extremely carefully both the overall scope and particular nature of each of these powers. Our priority has been to balance the need for powers that allow us to respond promptly to changes in the medicines and medical devices landscape and the need for effective Parliamentary oversight.

21. The delegated powers are in the Bill so as to retain the essential flexibility on technological developments, improve medicines' accessibility, undertake limited de-regulatory measures that may impede the sector in their delivery of the above objectives or to account for continuously emerging expert scientific recommendations. These recommendations may indicate a need for technical enhancements to the existing framework to better preserve patient safety. We have one specific aspect of the power intended to apply in the case of unexpected events posing serious risk to public health, where temporary actions have to be taken so as to enable very swift regulatory response tailored to the resolution of the immediate threat of harm to health. As a safeguard to ensure that the powers are only used to update the current frameworks, and the framework created by the Bill, they have been limited on the face of the Bill so that they may only be exercised to amend or supplement the existing regulatory regimes: namely to amend, or add to, the pre-existing legislation or to supplement the provision made in Schedule 1 to the Bill relating to civil sanctions in relation to the commission of offences to do with medical devices.

22. **The existing medicines legislation that may be supplemented or amended by regulations made under clause 1 is: The Human Medicines Regulations 2012 (S.I. 2012/1916) ("HMRs"), The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031) ("CTRs"); the Medicines (Products for Human Use) (Fees) Regulations 2016 (S.I.2016/190); and sections 10 and 15, and Part 4, and section 131 of the Medicines Act 1968 (1968 c. 67).**

23. The HMRs came into force in 2012 and consolidated existing domestic legislation regulating the authorisation, sale and supply of medicinal products for human use. Prior to the HMRs, legislation had comprised of various Acts of Parliament and many statutory instruments. To simplify medicines legislation and improve accessibility, the HMRs consolidated the regulatory framework in a rationalised form. They provide a comprehensive framework for regulating human medicines that amongst other things covers their licensing, manufacture, import, labelling, brokering, distribution, advertising and ongoing monitoring of the safety and efficacy of medicines once they are on the market (known as pharmacovigilance). They also regulate who can prescribe, supply and administer specific medicines in both general circumstances and specific situations which require a response, such as epidemics. Furthermore, the HMRs

regulate homeopathic and herbal medicines, and deal with borderline substances.

24. Having the ability to update the HMRs will prevent the medicines regime from stagnating over time and ensure that it remains fit-for-purpose and able to protect patient safety in a regularly evolving public health environment. This Bill will support the Government's priorities for patient safety, for example, through the regulation of labelling and leafletting of medicines, and important measures to prevent falsified medicines from entering the medicines supply chain.

25. The CTRs set out a comprehensive framework for regulating clinical trials of human medicines. The CTRs ensure that before a clinical trial of a new medicine can begin, the MHRA, acting on behalf of the UK licensing authority, must review and authorise it. The CTRs also cover, amongst other things, the ethical approval of trials, their conduct (including adherence to good clinical practice), pharmacovigilance and the manufacturing, import and labelling of the medicines.

26. Having the ability to update the CTRs will maintain high levels of patient safety by ensuring the safe conduct of trials and improving patient health outcomes. This is to ensure the UK is a preferred location for the trial of innovative medicines, with a regime that can evolve to move with best practice and scientific and technical innovation. There will also be further progression of commitments laid out in the Life Sciences Strategy[2] allowing the UK to maintain an internationally competitive clinical trials infrastructure for the emerging class of advanced therapies and precision medicines. The new EU Clinical Trials Regulation is in force but is unlikely to fully apply in the EU until after the end of the Transition Period. This Regulation would further integrate clinical trial processes and requirements. The power in the Bill will allow the Government to deliver the same effects as certain elements of the new EU regulations on clinical trials, in upcoming UK clinical trials legislation, if it is deemed that this will help ensure we maintain a world-leading approach to clinical trials.

27. Where a comprehensive framework is put in place through primary legislation, it is appropriate to take secondary powers to implement the detail and enable updating. The comprehensive framework for human medicines has evolved through the development of EU legislation and has been implemented into domestic legislation using section 2(2) ECA. No such general power exists for updating - nor was it needed whilst section 2(2) remained extant.

28. The HMRs and CTRs will need amending and updating frequently. The HMRs have been amended using the delegated power at section 2(2) ECA at least once every year since they came into force. In 2017 the HMRs were amended using section 2(2) ECA to allow schools in the UK to buy adrenaline auto-injector devices (known as AAIs) without a prescription to use in an emergency on children who are at risk of a severe allergic reaction but whose own device is not available or not working. This could be because their AAI(s) are broken, or out-of-date. Another example is the inclusion of EU-led changes including more robust provisions on pharmacovigilance in 2013, and provisions on cross-border/mutual recognition of prescriptions in 2014. In 2006 we updated the

[2] Key commitments for the Life Sciences Sector deal - https://www.gov.uk/government/publications/life-sciences-sector-deal/life-sciences-sector-deal-2-2018#key-commitments.

CTRs using section 2(2) ECA to add a requirement to report serious breaches of good clinical practice and the trial protocol to the UK licensing authority. A serious breach is something that affects safety of the trial subjects and/or the integrity of the trial data. The implementation of this amendment allowed oversight of important issues that affected UK trial subjects.

29. **The Veterinary Medicines Regulations 2013 (S.I. 2013/2033) ("VMR"):** The VMR allow us to ensure animal welfare, and protect the safety of treated animals, the people handling the medicines, the consumers of produce from treated animals and the environment. More specifically, they cover the marketing, manufacturing and supply of veterinary medicines in the UK, and relevant exemptions to prescribing. They also cover wholesale dealing and enforcement and offences provisions relating to veterinary medicines.

30. Having the ability to update the VMR will keep UK legislation up to date and in line with future international advances and developments for veterinary medicines. The power will also be used to ensure that veterinary medicines are being used in accordance with their authorisation. The regulation of veterinary medicines is technical and there will be a need for the UK to develop and evolve with international scientific and technical standards, and regulatory needs.

31. The power in Part 2 is needed so that the regulatory scheme for veterinary medicines, the domestic legislation for which is currently made entirely under section 2(2) ECA, can be updated. This will be exercised only by amending or supplementing the VMR so that they remain current after the end of the Transition Period, once the existing power to amend the regulations in the ECA, is no longer available.

32. **The Medical Devices Regulations 2002 (S.I. 2002/618) ("MDRs")**: A medical device is defined in the MDRs as 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. A wide range of items, from plasters to pacemakers, fall within this definition.

33. Some types of medical device, called in vitro diagnostic medical devices (IVDs), are used to conduct in-vitro diagnostic testing. In vitro diagnostic tests are carried out 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.

34. The MDRs cover each stage of getting a medical device to market and the continued monitoring of the safety and performance of medical devices once they are on the market. In particular, the MDRs cover a wide range of provisions relating to scope and definition; classification; safety and performance requirements; conformity assessment; requirements that need to be met by conformity assessment bodies; post-market surveillance and vigilance; enforcement powers and fees; and exemptions. The MDRs also place obligations on manufacturers to ensure that medical devices, including IVDs, are safe and fit for their intended purpose.

35. Currently, medical devices are regulated in the UK by the MDRs and the General Product Safety Regulations 2005 (S.I. 2005/1803). The MDRs provide definitions for medical devices and IVDs, and also place obligations on manufacturers to ensure that medical devices and IVDs are safe and fit for their intended purpose.

36. The new EU Regulation on Medical Devices (Regulation (EU) 2017/745) which covers active implantable medical devices, will fully apply across the EU and in the UK after an agreed transition period ending on 26 May 2020. The new EU Regulation on In Vitro Medical Devices (IVDR) (Regulation (EU) 2017/746) has a transition period of five years and will fully apply in the EU from 26 May 2022. Together these EU regulations will replace and consolidate all previous EU Directives on medical devices. The aim of both of the new EU Regulations is to address inherent weaknesses in the existing Directives as well as drive increased patient safety and confidence in the end to end system of conformity assessment.

37. Having the ability to update the MDRs will support the Government to deliver on its commitments in the Life Sciences Strategy and continue to be a world leader in the sector of medical devices. The medical devices sector is at the forefront of innovation in the UK, and this Bill will provide us with powers to update and improve systems and processes.

38. These powers are needed so that the regulatory scheme for medical devices, which was created and kept up to date using section 2(2) ECA, can be altered. Part 3 of, and Schedule 1 to the Bill consolidates the enforcement regime for medical devices, and also provides the Secretary of State with the ability to impose civil sanctions as an alternative to criminal prosecution of offences. The powers in Part 3 and Schedule 1 will mean that the medical devices regulatory scheme and corresponding enforcement provisions remain current and fit-for-purpose after the UK has left the EU.

39. Whilst it may have been possible for some updating and amending to be progressed using the power in section 11 of the Consumer Protection Act 1987 (CPA), this would have been more limited and less certain than a power tailored specifically to medical devices. The CPA only covers a subset of medical devices because regulations under section 11 of the CPA can only be made for the purpose of securing that goods are “safe”. “Safe” is defined in section 19 CPA as goods which pose no risk (or a risk that is reduced to a minimum) of death or personal injury. “Unsafe” is to be construed accordingly. Accordingly, this power is not applicable to all medical devices, particularly those that are considered “low risk”, and so which are unlikely to pose a risk of death or personal injury. Furthermore, a device may fail to comply with some requirements of the MDRs, but this does not necessarily mean that it would be considered to be “unsafe”. This inadequacy is currently acknowledged in regulation 61(7) and (8) of the MDRs which provide that the power to issue a prohibition notice contained in section 13 of the CPA in relation to unsafe goods is expanded to allow for such a notice to be issued on “non-conforming” devices. A key policy objective behind the Bill is therefore to have sufficient powers to amend the regulatory regime for all medical devices in the absence of the section 2(2) ECA power and given the weaknesses in scope and application of existing powers under the CPA.

40. Whilst the regulatory system aims to ensure that the risks to patients of medical devices are minimised, no medical device is risk-free. Recent concerns raised through journalistic investigations about medical device regulation show the need for the regulatory system to be able to rapidly respond to effect targeted system updates in the interest of product safety where this is identified as critical. Examples of recent concerns on the safety of medical devices include the review of the use of vaginal mesh for Stress Urinary Incontinence being led by the Independent Medicines and Medical Devices Safety Review; the Panorama investigation into system weakness in EU Notified Body conformity assessment of medical devices (November 2019); product specific concerns raised by EU competent authorities, as also referenced in a Dispatches investigation, into the use of certain brands of breast implants (May 2019).

41. This need for regulatory improvements could equally be driven in the future by new reviews or by needs identified within the healthcare system in response to critical incidents or patient safety concerns. This could include a need for regulatory changes as a consequence of improvements in and an expansion of the cross-organisational assessment of devices.

42. Failure to have this legislative capacity could restrict the UK's ability to continue to lead innovation in technology and life sciences as it is committed to doing, whilst ensuring compliance with the highest possible product safety standards.

43. Overall, the Government's view is that the Bill will allow Parliament to have the right level of scrutiny over the medicines and medical devices regime as the majority of the regulation-making powers in this Bill will be subject to the affirmative resolution procedure, as explained further below in the analysis of delegated powers by clause.

Consultation requirements

44. Before exercising these delegated powers, there is a statutory requirement to consult, as set out in clause 40 in relation to the powers in clauses 1(1), 8(1) and 12(1) and paragraph 9 of Schedule 1. The only exception to this requirement is where regulations contain only provision made in reliance on clause 6(1) (disapplication of provisions relating to human medicines where there is a risk of serious harm to health), or clause 15(1) (disapplication of provisions relating to medical devices where there is a risk of serious harm to health) and if they contain a declaration that they need to be made urgently. This will enable the power to be exercised urgently to protect the public from an imminent threat of serious harm to health, when there may not be time for consultation.

45. Even in the absence of a statutory requirement to consult, the Department of Health and Social Care and the Department for Environment, Food and Rural Affairs have always chosen to consult on proposed regulations relating to the regulation of medicines (human and veterinary respectively) and medical devices. The Departments recognise the importance of consulting with industry and stakeholders during the legislative process and meaningful engagement has always formed part of the legislative process for medicines and medical devices.

C. SUMMARY OF THE DELEGATED POWERS

POWER	JUSTIFICATION	SCRUTINY
Clause 1: power to make regulations about human medicines	The human medicines regulatory regime is ever-changing and requires technical changes in order to keep up to date. These are changes we cannot predict in advance and therefore would not be practical or appropriate for these amendments to be made through primary legislation each time an update is required. Delegated powers will give the UK the ability to keep pace with advances and adapt and improve its human medicines regulatory regime accordingly.	Affirmative, with the exception of: a) clause 2(1)(j) - the labelling and packaging of human medicines b) clause 2(1)(k) - advertising human medicines c) clause 2(1)(n) - prohibitions in the supply provisions for human medicines d) clause 5(1)(a) - the charging of fees in relation to human medicines e) clause 6 - emergency powers in relation to human medicines, where they contain a declaration that they need to be made urgently.
Clause 8: power to make regulations about veterinary medicines	The regulation of veterinary medicines is technical and there will be a need for the UK to develop and evolve with international scientific and technical standards, and regulatory needs. Delegated powers to amend the secondary legislation regulating veterinary medicines, provides an appropriate and efficient means by which to make these technical updates as and when they are required to maintain a safe and robust regulatory regime.	Affirmative, with the exception of: a) clause 9(1)(f) - who can supply veterinary medicines b) clause 9(1)(k) - the labelling and packaging of veterinary medicines c) clause 9(1)(l) – the advertising of veterinary medicines d) clause 10(1)(a) - charging of fees.

Clause 12: power to make regulations about medical devices	The medical devices regulatory regime is ever-changing and requires technical changes in order to keep it up to date. These are changes we cannot predict in advance and therefore would not be practical or appropriate for these amendments to be made through primary legislation each time an update is required. Delegated powers will give us the ability to adapt, improve and keep pace with the medical devices regulatory regime.	Affirmative, with the exception of: a) clause 14(1)(a) – charging of fees b) clause 15 - supply etc of medical devices in emergencies, where they contain a declaration that they need to be made urgently.
Clause 43(3): power for the Secretary of State to bring chapters 2 and 3 of Part 3 of the Bill into force on an appointed day or days	The delegation of this power is necessary for the following reasons: - in relation to the civil penalty provisions, the Government intends to publish guidance and consult on the supplementary regulations. The Government, therefore, considers it necessary to commence these provisions, after such actions are taken; - in relation to the disclosure of information provisions in Chapter 3, it will not be appropriate or necessary to commence these provisions until after the end of the Transition Period because there is currently EU legislation governing the same subject matter.	Nil.

Clause 44: Transitional provision etc. in connection with commencement.	This is a standard power to make transitional or saving provision in connection with the commencement of the Bill.	None
Paragraph 9 of Schedule 1: supplementing the new civil sanctions regime for medical devices	This will ensure that the new civil sanctions regime can be supplemented with more detailed provision setting out procedural steps and relevant appeals processes, so that it functions appropriately and can be updated accordingly. This will also enable changes to be made to the operation of the civil sanction regime where necessary, for instance provisions for the payment of interest in respect of late payment may need to be adjusted.	Negative
Paragraph 13 of Schedule 1: Guidance as to enforcement	This will enable the Government to provide greater clarity around the civil sanctions regime, by setting out in greater detail the circumstances in which the Secretary of State will pursue different civil sanctions. The guidance will also cover topics such as how the Secretary of State will use the power to impose a monetary penalty (including guidance surrounding the amount of a monetary penalty and rights of representation and appeal) and the power to issue an enforcement costs recovery notice (including when such a notice may not be	None

	served, and rights of representation and appeal). Such guidance must also include greater detail about how the Secretary of State will use the power to accept an enforcement undertaking. This could include, for instance, the process for making an offer of an enforcement undertaking, the form such an offer should take and the circumstances in which one is likely to be accepted.	

D. ANALYSIS OF DELEGATED POWERS BY CLAUSE

46. As described above, the delegated powers in this Bill are split into human medicines (which includes falsified medicines and clinical trials), medical devices, and veterinary medicines. For all three policy areas, the overriding principles for exercising the powers are the same - enhancing patient safety, improving the availability of medicines and medical devices, and maintaining the attractiveness of the UK regulatory environment.

Clause 1: Power to make regulations in relation to human medicines

Power conferred on: the appropriate authority. This is the Secretary of State in relation to England, Wales and Scotland. In relation to Northern Ireland, this is the Northern Ireland Department of Health in Northern Ireland acting alone, or the Department of Health in Northern Ireland and the Secretary of State acting jointly.

Power exercised by: Regulations made by statutory instrument

Parliamentary procedure: Affirmative. With the exception of regulations made in reliance on the following which are subject to the negative procedure:

- Clause 2(1)(j) - the labelling and packaging of human medicines
- Clause 2(1)(k) - advertising human medicines
- Clause 2(1)(n) - prohibitions in the supply provisions for human medicines
- Clause 5(1)(a) - the charging of fees in relation to human medicines
- Clause 6 - emergency powers in relation to human medicines, where a declaration is made that the regulations need to be made urgently.

Context and Purpose

47. Clause 1 provides for a delegated power in connection with human medicines. The power is limited in two ways. Firstly, regulations made under the delegated power may only contain provisions of the sort listed in clauses 2 to 6 (see below). Secondly, regulations made under the power may only amend or supplement the HMRs, the CTRs, the Medicines (Products for Human Use) (Fees) Regulations 2016 and sections 10,15 and 131 and Part 4 of the Medicines Act 1968 (which cover pharmacies). This means that the power can only be used to build on the existing frameworks for these regulatory regimes.

48. In addition, clause 1 requires that the power may only be exercised after regard has been had to safety, the availability of human medicines and the attractiveness of the relevant part of the UK as a place in which to conduct clinical trials and supply human medicines.

49. The purpose of the power is to enable us to amend and update the existing regulatory frameworks in human medicines legislation in order that they remain fit-for-purpose.

Clause 2: Manufacture, marketing and supply

50. This clause lists the areas relating to the manufacture, marketing and supply of human medicines about which provision can be made in regulations made under the power in clause 1. The list is exhaustive and so provides strict limits on the areas of supply that can be amended or updated under the clause 1 power. The areas listed are:

    a) authorisations to manufacture human medicines,
    b) authorisations to import human medicines,
    c) authorisations to distribute human medicines by way of wholesale dealing,
    d) marketing authorisations,
    e) manufacturing, importing or distributing active substances,
    f) brokering in relation to human medicines
    g) the registration of the premises of pharmacy businesses,
    h) the recording of information about the supply of human medicines
    i) notification and reporting requirements in relation to human medicines that have been placed on the market,
    j) the labelling and packaging of human medicines or the information that must be supplied with them or made available in relation to them,
    k) advertising with regard to human medicines,
    l) the registration of persons who supply or offer to supply human medicines by means of the internet,
    m) the requirements that must be met in relation to a prescription, or
    n) prohibitions in the provisions mentioned in subsection (2).

Clause 3: Falsified Medicines

51. This clause lists the areas relating to the prevention of falsified medicines for which provision can be made in regulations made under the power in clause. The areas listed are:

    a) the prevention of the supply of falsified human medicines, which may include provision relating to unique identifiers on packs of medicinal products, and anti-tamper devices;
    b) the use, retention and disclosure, for any purpose to do with human medicines, of information collected for the purpose of preventing the supply of falsified human medicines.

Clause 4: Clinical Trials

52. This clause lists the areas relating to clinical trials for which provision can be made in regulations made under the power in clause 1. The list is exhaustive and so provides strict limits on the areas relating to clinical trials that can be amended or updated under the clause 1 power. The areas listed are:

    a) provision corresponding or similar to provision in the EU Clinical Trials Regulation (Regulation 536/2014),
    b) about authorisations concerning clinical trials in the United Kingdom, including applications for an assessment of the ethics of a proposed clinical trial,
    c) about notification and reporting requirements in relation to clinical trials,

d) about requirements that must be met before a clinical trial may be carried out, or
e) relating to the conduct of clinical trials.

Clause 5: Fees, offences, power of inspectors

53. Clause 5(1) lists further supplementary matters that may be provided for in regulations made under clause 1. Again, the list is exhaustive. The matters listed are:

a) about the charging of fees in connection with the exercise of a function conferred by a human medicines provision (that is a provision in the HMRs, the CTRs or regulations made under clause 1),
b) creating a criminal offence of failing to comply with a provision made in the regulations, but not one punishable with a sentence of imprisonment of more than two years, or
c) applying relevant powers of entry or other powers of inspectors with or without modification in relation to a prohibition or requirement in provision made in the regulations.

Clause 6: Emergencies

54. This clause provides that regulations made under the power in clause 1 can provide for the disapplication of a human medicines provision (again, this being provision in the HMRs, the CTRs and regulations made under clause 1) in circumstances which give rise to a need to protect the public from a risk of serious harm to health. Regulations relying on this clause can provide for the disapplication to be subject to:

a) conditions set out in the regulations;
b) conditions set out in a protocol published by the appropriate authority.

55. Where regulations provide that the appropriate authority may publish a protocol setting out conditions, the regulations must provide —

a) that the appropriate authority may withdraw or amend the protocol, and
b) that the protocol is to have effect only for a period of time specified in the protocol.

<u>Justification for taking the power</u>

56. The overall justification for this power is to ensure that the regulatory scheme for human medicines can be updated and amended over years to come in order to (i) maintain acceptable levels of safety for patients; (ii) maximise the accessibility of human medicines; and (iii) keep the UK as an attractive place to develop and market human medicines so as to retain its strong life sciences sector. This is reflected in clause 1(2) which imposes a duty to consider each of these factors prior to exercising the power. Without this power, the regulatory scheme for human medicines will stagnate over time because the context in which the scheme operates does not stand still: science advances, new and better ways of doing things are developed often using new technologies; better safeguards are identified which can support de-regulation and new threats to human health

emerge. The regulatory scheme needs to be updated to address all these and other changes in order to ensure that it functions optimally in the UK.

57. The human medicines regulatory regime is ever-changing and requires frequent, technical changes in order to keep it up to date. These are changes we cannot predict in advance and therefore would not be practical or appropriate for these amendments to be made through primary legislation each time they are required. Delegated powers will give the UK the ability to keep pace with advances and adapt and improve its human medicines regulatory regime accordingly.

58. Each limb of the clause 1 power as set out in the lists in clauses 2 to 6 has been included because the Department has identified the need to amend that area with a specific policy objective in mind. We hope it reassures the Committee that no aspect of the power has been taken on a "just in case" basis and without a clear reason behind it.

59. Annex A looks at each limb of the power in turn explaining the specific use of that limb of the power that the Department has identified. In several cases the Department has also prepared illustrative SIs to show how regulations made under the power implementing the change might look. These have been published here on gov.uk.[3]

Justification for the procedure

60. For the most part, it is considered that the human medicines power in this Bill should be subject to the affirmative procedure. The power is to amend or supplement the existing law relating to human medicines, although we note that previous amendments have been made under the negative procedure using section 2(2) ECA. Given that there may be parliamentary interest in the Government's future intentions in the individual policy areas, such as a falsified medicines scheme, or developments in the regulation of online sales of human medicines, the Department's view is that it is right that Parliament has the opportunity to debate and approve any regulations brought forward by means of the affirmative procedure, where there may be innovation in current approaches.

61. Regulations made under clause 1 concerning the labelling, and packaging of human medicines, will be subject to the negative resolution procedure. The existing labelling and packaging provisions are detailed, technical requirements contained in a number of regulations and schedules in the HMRs. The labelling and packaging provisions of Part 13 of the HMRs, and their associated schedules, impose detailed requirements as to the information that must appear on the immediate and outer packaging and in patient information leaflets for medicinal products. For example, regulation 257 of the HMRs requires the information specified in Part 1 of Schedule 24 to appear on the outer and immediate packaging. That Part of the Schedule lists 18 requirements, including the name of the product, its strength and pharmaceutical form, whether it is intended for babies, children or adults etc. Examples of previous amendments include adding a requirement to have the name of the medicine in Braille on the packaging; adding specified warning statements for paracetamol regarding overdose; and a

[3] Medicines and Medical Devices Bill: Overarching documents - https://www.gov.uk/government/publications/medicines-and-medical-devices-bill-overarching-documents

requirement for child resistant packaging for certain medicines – these last two examples in particular were made following consultation with the Commission of Human Medicines, which advises ministers on the safety, efficacy and quality of medicinal products. We therefore, suggest that the negative procedure will provide Parliament with the appropriate form of oversight of changes to requirements of this kind that would not take up unnecessary parliamentary time.

62. Similarly, regulations made concerning the advertising of human medicines will also be subject to the negative resolution procedure. The existing provisions in the HMRs include detailed and specific requirements for advertising to the public, advertising to health professionals and advertising to children. For example, regulation 294 of the HMRs provides that a related advertisement may not be published unless it contains particulars set out in Schedule 30 – in which there are nine particulars to consider. A previous amendment to the advertising provisions in the HMRs was for example, in 2014, the requirement to include essential information (the 'small print') in advertisements to healthcare professionals was simplified for over-the-counter medicines. At the same time, provisions were made to ensure that digital advertisements could link to the essential information, rather than requiring the text to be included in the advertisement.

63. The negative resolution procedure also applies to regulations relating to the supply of human medicines in emergencies (in reliance on clause 6), where those regulations contain a declaration that the person making the regulations considers that they need to be made urgently to protect the public from an imminent risk of serious harm to health. These regulations would disapply a relevant human medicine provision (as defined above) in circumstances that give rise to a need to protect the public from a risk of serious harm to health. It is appropriate for regulations made in these circumstances to be subject to the negative resolution so that they can come into force immediately and provide an efficient means of addressing an imminent serious public health risk. We expect that such regulations would only need to be in place for a very short period of time, potentially shorter than it would take to schedule and hold debates, which is another reason why the negative procedure is most appropriate for these urgent regulations. Where these regulations do not contain a declaration about their urgency, they will be subject to the affirmative procedure.

64. The Department also proposes that regulations about prohibitions in specific parts of the HMRs relating to the supply of human medicines should be subject to the negative resolution procedure. This is because proposals to make changes to existing provisions, or to introduce new provisions enabling the supply, administration or prescribing of medicines are made to reflect shifts in best practice following extensive consideration and scrutiny by the relevant professional bodies. These types of amendments to the HMRs have been made frequently in recent years by way of regulations made under section 2(2) ECA, which are subject to the negative procedure.

65. This is also the case for the charging of fees in relation to human medicines provisions. In the Department's view, the negative procedure is appropriate for these regulations. The charging of fees is quite technical in nature and the power is limited to charging fees in connection with the exercise of a function conferred by a human medicines provision (which does not include a provision in the Medicines Act 1968). The negative procedure for these regulations also mirrors

the procedure for making regulations in relation to fees under section 1 of the Medicines Act 1971. The appropriate authority would be required to consult before making these regulations.

66. As above, clause 40 requires the appropriate authority to consult such persons as they consider appropriate before making regulations under clause 1, except for regulations made in reliance on clause 6 (supply of human medicines in emergencies) where they contain a declaration as to their urgency. Furthermore, before laying regulations under clause 1 that amend or revoke secondary legislation made under section 2(2) ECA, the Secretary of State will need to make and publish a statement as to why there are good reasons for the amendment or revocation (see paragraph 15 of Schedule 8 to the EU (Withdrawal) Act 2018).

Clause 8: Regulations relating to Veterinary Medicines

Power conferred on: The appropriate authority. This is the Secretary of State for Environment, Food and Rural Affairs in relation to England, Wales and Scotland. In relation to Northern Ireland, it is the Department of Agriculture, Environment and Rural Affairs in Northern Ireland acting alone, or the Department of Agriculture, Environment and Rural Affairs in Northern Ireland and the Secretary of State acting jointly.

Power exercised by: Regulations made by statutory instrument

Parliamentary Procedure: Affirmative. With the exception of regulations made in reliance on:

- clause 9(1)(f) - who can supply veterinary medicines
- clause 9(1)(k) - the labelling and packaging of veterinary medicines
- clause 9(1)(l) – the advertising of veterinary medicines
- clause 10(1)(a) - charging of fees.

Context and Purpose

67. Clause 8 provides a delegated power in connection with veterinary medicines. The power is significantly limited in two ways. Firstly, regulations made under the delegated power may only contain provisions of the sort listed in clauses 9 and 10. Secondly, regulations made under the power may only amend or supplement the VMR. This means that the power can only be used to build on the existing framework for this regulatory regime.

68. In addition, clause 8 requires that the power may only be exercised after the appropriate authority has had regard to factors relating to safety, the availability of veterinary medicines and the attractiveness of the UK as a place in which to develop and supply veterinary medicines.

69. Veterinary medicines are currently regulated by the VMR (made under section 2(2) of the ECA), which help ensure animal welfare and protect the safety of treated animals, people handling the medicines, consumers of produce from treated animals and the environment.

Clause 9: Marketing, marketing, supply and field trials

70. This clause lists the areas relating to the manufacture, marketing, and supply of veterinary medicines, including field trials, for which provision can be made in regulations made under the power in clause 8. The list is exhaustive and so provides strict limits on the areas of supply that can be amended or supplemented under the clause 8 power. The areas listed are:

    a) authorisations to manufacture veterinary medicines,
    b) authorisations to import veterinary medicines,
    c) authorisations to distribute veterinary medicines by way of wholesale dealing,
    d) marketing authorisations,
    e) marketing, importing or distributing active substances,
    f) the categories of person who may supply veterinary medicines,
    g) requirements that must be met in relation to the supply of veterinary medicines,
    h) the registration of persons who supply or offer to supply veterinary medicines by means of the internet,
    i) the circumstances in which veterinary medicines may be administered,
    j) notification and reporting requirements in relation to veterinary medicines (or things purporting to be veterinary medicines) that have been placed on the market,
    k) the labelling and packaging of veterinary medicines or the information that must be supplied with them or made available in relation to them,
    l) advertising with regard to veterinary medicines, or,
    m) animal test certificates granted under the Veterinary Medicines Regulations 2013 (S.I. 2013/2033) for research purposes.

Clause 10: fees, offences, power of inspectors

71. Clause 10(1) lists further supplementary matters that may be provided for in regulations made under clause 8. Again, the list is exhaustive. The matters listed are:

    a) about the charging of fees in connection with the exercise of a function conferred by a veterinary medicines provision,
    b) creating a criminal offence of breaching a prohibition or failing to comply with a requirement in provision made in the regulations, but not one punishable with a sentence of imprisonment of more than two years,
    c) applying powers of entry or other powers of an inspector in the Veterinary Medicines Regulations 2013 (S.I. 2013/2033) with or without modification in relation to a prohibition or requirement in provision made in regulations under clause 8(1),
    d) the recovery of costs incurred in the administration of improvement notices or seizure notices under the Veterinary Medicines Regulations 2013 (see regulations 38 and 41).

<u>Justification for taking the power</u>

72. This power ensures that the regulatory scheme for veterinary medicines can be updated and amended in order to (i) maintain acceptable levels of safety for animals and the environment; (ii) maximise the accessibility of veterinary

medicines; and (iii) keep the UK as an attractive place to develop and market veterinary medicines so as to retain its strong life sciences sector. This is reflected in clause 8(2) which imposes a duty on the appropriate authority to consider each of these factors prior to exercising the power.

73. The purpose of the power is to enable us to amend and supplement the existing regulatory framework in veterinary medicines legislation in order that it remains fit-for-purpose as UK domestic policy needs arise.

74. The veterinary medicines regulatory regime is frequently changing. It requires amendments to be made in order to keep up to date with changes in international scientific standards. These are changes we cannot predict in advance and therefore it would not be practical or appropriate for these amendments to be made through future primary legislation each time they are required. If the changes had to be made in primary legislation, this would mean the UK would fall behind other countries in adopting new international standards, as the process for introducing new primary legislation would be too slow. This would disadvantage UK companies.

75. The changes to the veterinary medicines regulatory regime are technical in nature and it is therefore considered that making these changes in secondary legislation, most of which will be subject to the affirmative procedure, will be a more appropriate use of Parliamentary time.

76. Delegated powers will give the UK the ability to keep pace with advances and adapt and improve its veterinary medicines regulatory regime accordingly.

77. Annex A looks at each limb of the power in turn explaining the specific use of that limb of the power that the Department has identified.

Justification for the procedure

78. Although the subject-matter of this power is technical, and small changes will be necessary from time to time, we believe that this power for the most part, should still be subject to the affirmative resolution procedure in order to ensure appropriate scrutiny is applied.

79. Included in this power is a provision for the labelling and packaging of veterinary medicines, which we would propose is subject to the negative resolution procedure. The existing labelling and packaging provisions are detailed, technical requirements included in the VMR. The labelling and packaging provisions in Schedule 1 of the VMR include detailed requirements for the information that must appear on the immediate, outer packaging and in package leaflets for veterinary medicines. The labelling requirements in Schedule 2 of the VMR include detailed requirements for the information that must appear on autogenous vaccines, blood bank products, equine stem cell products and extemporaneous products. For example, the VMR requires the information specified in Schedule 1 paragraph 48 to appear on the immediate packaging. This paragraph of the Schedule lists twenty-three requirements that must appear on the labelling including the name of the product, its strength and pharmaceutical form, the species it is authorised for, etc. Examples of previous amendments include adding labelling requirements for equine stem cell centre authorisation holders for the products they

manufacture. We therefore suggest that the negative procedure will provide Parliament with the appropriate level of oversight on changes to labelling and packaging requirements; this would also not take up unnecessary parliamentary time.

80. Similarly, regulations made concerning the advertising of veterinary medicines will also be subject to the negative resolution procedure. The existing advertising provisions in the VMR are detailed in regulations 10 and 11 and include detailed and specific requirements for advertising to prescribers of veterinary medicines, advertising to the public and advertising to professional keepers of animals. For example, regulation 11 of the VMR provides for the restrictions on advertising to particular audiences, depending on the distribution category of the medicine. There are four distribution categories, with five different audience groups to consider. An example of a previous amendment was a restriction on the advertising of certain prescription medicines to owners and keepers of horses. A further example of a previous amendment was the introduction of a restriction on advertising antimicrobial medicines to professional keepers of animals.

81. The Department also proposes that the provision for categories of persons who may supply veterinary medicines should be subject to the negative resolution procedure. This is because any proposals to make changes to existing powers or to introduce new powers for veterinary professionals to supply, administer or prescribe medicines will be subject to extensive consideration and scrutiny by professional bodies.

82. This is also the case for the charging of fees in relation to veterinary medicines provisions. In the Department's view, the negative procedure would be appropriate for these regulations. The charging of fees is technical in nature and the Bill sets out the functions in respect of which the appropriate authority could be permitted to charge. The appropriate authority would also be required to consult before making these regulations.

Clause 12: Power to make regulations for Medical Devices

Power conferred on: The Secretary of State

Power exercised by: Regulations made by statutory instrument

Parliamentary procedure: Affirmative. With the exception of regulations made in reliance on:

- clause 14(1)(a) – charging of fees
- clause 15 - supply etc of medical devices in emergencies, where a declaration is made that the regulations need to be made urgently.

Context and Purpose

83. Clause 12 provides a delegated power in connection with medical devices. As with the delegated power for human medicines (outlined above), the power is limited in two ways. First, regulations made under the delegated power may only

contain provisions of the sort listed in clauses 13 to 15. Clauses 13 to 15 are outlined below. Secondly, regulations made under the power may only amend or supplement the MDRs, meaning that the power can only be used to build on the existing framework for the regulation of medical devices.

84. In addition, clause 12(2) requires that the power may only be exercised after regard has been had to factors relating to safety, the availability of medical devices and the attractiveness of the UK as a place in which to develop and supply them.

Clause 13 – Manufacture, marketing and supply

85. This clause lists the areas relating to manufacture, marketing and supply of medical devices for which provision can be made in regulations under clause 12. The list is exhaustive and so limits what aspects of the regulatory regime can be amended or supplemented under the clause 12 power. These aspects are as follows:

a) requirements that must be met in relation to medical devices in order for them to be marketed, put into service or otherwise supplied ("relevant requirements"), including—
    i. requirements in terms of design, manufacture, composition or other characteristics of the devices, or
    ii. requirements imposed on persons involved in marketing or supplying the devices.

b) assessments of whether relevant requirements are met in relation to medical devices,
c) who may carry out such assessments, including provision about the appointment of one or more persons (whether or not established in the United Kingdom) who meet criteria set out in the regulations—
    i. to assess whether relevant requirements are met, and
    ii. if appropriate, to confirm that they are,

d) treating confirmation that relevant requirements are met given by one or more persons who are not appointed under provision made in reliance on paragraph (c) in the same way as confirmation given by a person who is so appointed,
e) the making of declarations confirming that relevant requirements are met,
f) requirements that medical devices carry evidence that relevant requirements are met, including evidence that confirmation has been given as mentioned in paragraph (c) or (d),
g) the packaging of medical devices, and information, labelling or instructions to be supplied on, with or in relation to them,
h) one or more registers of medical devices, their manufacturers or their suppliers, including provision—
    i. conferring functions relating to establishing and maintaining a register,
    ii. requiring information in relation to a medical device to be entered in a register and
    iii. permitting or requiring some or all of that information to be entered in a register to be made publicly available,

i) investigations into or evaluations of the safety or performance, including the clinical effectiveness, of medical devices, or
j) surveillance of the market in medical devices.

Clause 14 – Fees, information, offences

86. Clause 14 lists other areas relevant to the regulation of medical devices for which provision can be made under the power in clause 12. Again, this list is exhaustive.

a) about the charging of fees in connection with the exercise of a function conferred by a medical devices provision, including the charging of fees by a person appointed under provision made in reliance on clause 13(1)(c),
b) about the recording of information regarding the safety and efficacy of medical devices, including the extent to which relevant requirements that apply in relation to the devices are met,
c) permitting or requiring such information to be disclosed to the Secretary of State or to a person appointed under provision made in reliance on clause 13(1)(c), or
d) amending the Schedule to the Medical Devices Regulations 2002 (S.I. 2002/618) inserted by Schedule 2 to this Act (list of regulations breach of which is an offence under regulation 60A).

87. In particular, clause 14(d) provides the Secretary of State with a power to amend the list of regulations contained in the last Schedule to the Medical Devices Regulations 2002 (a list of regulations which, if breached, constitute a criminal offence under Regulation 60A). Regulation 60A and this Schedule are inserted by Schedule 2 to the Bill. This is discussed further in Annex A.

Clause 15 – Emergencies

88. This clause provides that regulations made under the power in clause 12 can provide for the disapplication of a medical devices provision (this being the Medical Devices Regulations 2002 or regulations made under clause 12(1)) in circumstances which give rise to a need to protect the public from a risk of serious harm to health. Regulations can provide for the disapplication to be subject to:

a) conditions set out in the regulations;
b) conditions set out in a protocol published by the Secretary of State

89. Where regulations provide that the Secretary of State may publish a protocol setting out conditions, the regulations must provide —

a) that the Secretary of State may withdraw or amend the protocol, and
b) that the protocol is to have effect only for a period of time specified in the protocol.

<u>Justification for taking the power</u>

90. The power in clause 12 is necessary to ensure that the regulatory scheme for medical devices can be updated and amended over years to come in order to (i) maintain acceptable levels of safety for the public; (ii) maximise the accessibility of medical devices; and (iii) keep the UK as an attractive place to develop and market medical devices so as to retain its strong life sciences sector. This is reflected in clause 12(2) which imposes a duty to consider each of these factors prior to exercising the power.

91. The medical devices regulatory regime is ever-changing and therefore requires frequent, technical changes in order to keep it up to date. These are changes we cannot predict in advance and therefore it would not be practical or appropriate for these amendments to be made through future primary legislation. Delegated powers will give us the ability to keep pace with advances and adapt and improve the medical devices regulatory regime accordingly.

92. Without this power, the Secretary of State will be unable to ensure that the UK regulatory regime for medical devices evolves with scientific advances. New technologies will lead to new types of medical device and it is key to both public safety and the functioning of the UK life sciences sector that the Secretary of State is able to adequately regulate these. New threats to human health may arise, which would also necessitate changes to the regulatory regime for medical devices.

93. This delegated power is further required so that the regulatory scheme for medical devices, which was made principally under s. 2(2) of the ECA can be altered for the purpose of either amending or supplementing that scheme so that it remains current after the UK has left the EU.

Justification for the procedure

94. With the exception of regulations made solely in reliance on clause 14(1)(a) or clause 15 (where a declaration is made as to urgency), the regulations made under clause 12 are subject to the affirmative procedure. It is to be noted that previous amendments have been made under the negative procedure using section 2(2) ECA; however, we consider that the affirmative procedure is appropriate for most uses of this power, given that it could be used to make significant changes to the medical devices regime (within the limitations of the power set out above). The affirmative procedure will accordingly, give Parliament the opportunity to debate and approve the new regulations before they are made.

95. It is appropriate that regulations made only in reliance on clause 15 (supply etc. of medical devices in emergencies) be subject to the negative resolution procedure when a declaration is made that the Secretary of State considers they need to be made urgently to protect the public from an imminent risk of serious harm to health. In these circumstances, we need to be able to make the regulations as quickly as possible to respond to a public health emergency with appropriate provision in relation to medical devices. The negative resolution procedure will enable regulations to be made and brought into force immediately if the regulations were required to protect the public in an emergency. We also expect that such regulations would only need to be in place for a very short period of time, potentially shorter than it would take to schedule and hold debates, which is another reason why the negative procedure is most appropriate for these urgent

regulations. Where these regulations do not contain a declaration about their urgency, they will be subject to the affirmative procedure.

96. The negative resolution procedure is also appropriate for regulations made in relation to the charging of fees under clause 14(1)(a). Any amendments or supplementary provision made is likely to be minor updates, and therefore the negative resolution procedure would provide Parliament with the appropriate form of oversight that would not unnecessarily take up Parliamentary time. Also, provision about the charging of fees is limited to fees in connection with the exercise of a function conferred by a medical devices provision and the Secretary of State would be required to consult before making any regulations.

97. Annex A sets out in further detail the matters in relation to which provision can be made under this power.

Clause 43(3) – Commencement of Chapters 2 and 3 of Part 3

Power conferred on: The Secretary of State

Power exercised by: Regulations made by statutory instrument

Parliamentary Procedure: No procedure

Context and Purpose

98. This is a standard power to bring Chapters 2 and 3 of Part 3 of the Bill (which is concerned with medical devices) into force by commencement regulations. These chapters of the Bill concern enforcement, disclosure of information, and consequential provision in relation to medical devices.

Justification for taking the power

99. These chapters of the Bill may not need to be commenced as early as others and this power will therefore enable the Secretary of State to bring these chapters into force at the appropriate time. In particular:

- in relation to the civil penalty provisions in Chapter 2, the Government intends to publish guidance and consult on the supplementary regulations that may be made under paragraph 9 of Schedule 1. The Government, therefore, intends to commence these provisions, after such actions have been taken;

- in relation to the disclosure of information provisions in Chapter 3, it will not be appropriate or necessary to commence these provisions until after the end of the Transition Period because there is currently EU legislation governing the same subject matter.

Justification for the procedure

100. As is usual with commencement powers, regulations providing for the coming into force of these chapters of the Bill are not subject to any parliamentary procedure. Parliament has approved the principle of the provisions to be

commenced by enacting them; commencement by regulations simply enables the provisions to be brought into force at the appropriate time.

Clause 44 – Transitional etc provision in connection with commencement

Power conferred on: The Secretary of State and the relevant Northern Ireland Department.

Power exercised by: Regulations made by statutory instrument and statutory rule

Parliamentary Procedure: None

Context and Purpose

101. This is a standard power to make transitional or saving provision in connection with the coming into force of this Bill. In so far as the transitional or saving provision is in connection with the commencement of Part 1 or 2 of the Bill in relation to Northern Ireland, the regulations may be made by the relevant Northern Ireland department. The relevant Northern Ireland department is the Department of Health in Northern Ireland in relation to Part 1, and the Department of Agriculture, Environment and Rural Affairs in relation to Part 2 of the Bill.

Justification for taking the power

102. The power to make transitional or saving provision is often needed when bringing legislative provisions into force. It will enable a smooth commencement of, and transition to, the provision made by this Bill.

Justification for the procedure

103. This power is subject to no procedure. It is common practice for this type of power not to be subject to any parliamentary procedure.

Paragraph 9 of Schedule 1 - Supplementing new civil sanctions regime for medical devices

Power conferred on: The Secretary of State

Power exercised by: Regulations

Parliamentary Procedure: Negative procedure

Context and Purpose

104. Paragraph 9(1) of Schedule 1 provides for a delegated power to make regulations that supplement the new civil sanctions regime for medical devices. The new civil sanctions regime is contained in Schedule 1 to the Bill. It allows the Secretary of State to do the following:

a) where satisfied beyond reasonable doubt that a person has committed an offence, impose a monetary penalty on that person;

b) where the Secretary of State has reasonable grounds to suspect that a person has committed an offence, accept an enforcement undertaking from that person; and
c) where a person has been served with a monetary penalty, serve an enforcement costs recovery notice on that person.

105. The civil sanctions regime includes appeal rights (to the First-Tier Tribunal) (see paragraph 8 of Schedule 1).

Paragraph 9

106. The delegated power contained in paragraph 9(1) of Schedule 1 allows for provision to be made in relation to the following, for the purpose of supplementing the regime, as set out in paragraphs 10 to 12:

a) Monetary penalties and costs, in particular provision for early payment discounts, payment of interest / late payment and provision for enforcement;
b) Enforcement undertakings, in particular provision:

i. for the procedure for entering into, and the terms of, an undertaking,
ii. its publication
iii. variation
iv. circumstances denoting compliance;
v. monitoring of compliance;
vi. certification that an undertaking has been complied with and provision for appeals regarding any refusal to provide such certification;
vii. regarding inaccurate or misleading information in relation to an undertaking;
viii. regarding part-compliance,

a) Appeals, in particular:

i. Provisions suspending any requirement or notice pending the outcome of the appeal,
ii. Provision as to the powers of the tribunal to which the appeal is made.

<u>Justification for taking the power</u>

107. This targeted delegated power will ensure that the new civil sanctions regime can be supplemented where necessary, so that it functions appropriately. In providing the Secretary of State with an alternative to criminal prosecution, the new civil sanctions regime will promote product safety and the UK's strong life sciences sector.

<u>Justification for the procedure</u>

108. In our view, it is appropriate for this narrow power to be subject to the negative resolution procedure, on the basis that the framework of the regime is for the most part set out on the face of the Bill in Schedule 1. As explained above, regulations would merely supplement this regime, for example by adding procedural details, and would only do so in relation to the matters listed. It is also worth noting that the Secretary of State is required to consult persons it considers appropriate before making these regulations (see clause 40). Accordingly, the negative resolution procedure provides the correct level of Parliamentary oversight.

Paragraph 13 of Schedule 1 – Duty to issue guidance about new civil sanctions regime for medical devices

Power conferred on: Secretary of State

Power exercisable by: Statutory guidance

Parliamentary procedure: None

Context and purpose

109. As outlined above, Schedule 1 to this Bill establishes a new civil sanctions regime for medical devices, giving the Secretary of State the power to impose monetary penalties and enforcement costs recovery notices, and the power to accept enforcement undertakings, in the circumstances explained above. As explained above, paragraph 9 of Schedule 1 provides the Secretary of State with a delegated power to make regulations supplementing this regime. Paragraph 13 places a duty on the Secretary of State to issue guidance about the exercise of those powers contained in this Schedule.

Justification for the power

110. The purpose of this guidance is to aid policy implementation by supplementing the legal framework provided for in Schedule 1 to this Bill (and as may be supplemented by supplementary regulations made under the delegated power in paragraph 9 of the Schedule, explained above).

111. This statutory guidance will clarify how the Secretary of State will use the power to impose monetary penalties and enforcement costs recovery notices and the power to accept enforcement undertakings.

112. In particular, the guidance will:

- with respect to monetary penalties, provide information on the following
  - the circumstances where a penalty may not be imposed;
  - the amount of a penalty, including matters that the Secretary of State may take into account when determining this;
  - how liability for a penalty can be discharged;
  - rights to make representations, objections and appeals,

- with respect to enforcement costs recovery notice, provide information on the following

- when such a notice may not be served;
- the amount a person may be required to pay, including matters that the Secretary of State may take into account when determining this;
- how liability can be discharged;
- rights to make representations, objections and appeals,

- with respect to enforcement undertakings, set out further information about how this power will be used.

113. The obligation to publish revised guidance as appropriate will enable the Secretary of State to ensure that the new regime is fit-for-purpose and update it where necessary.

Justification for the procedure

114. This guidance is not subject to any parliamentary procedure, but it will be prepared and revised in consultation with the Welsh Ministers, the Scottish Ministers and the Department of Health in Northern Ireland, together with any other persons that the Secretary of State considers appropriate.

115. Annex A sets out in further detail the matters in relation to which provision can be made under this power.

Department Name Department of Health and Social Care
Date: 12th February 2020

Annex A: How the powers in the Medicines and Medical Devices Bill could be used

HUMAN MEDICINES

1. The list of matters in clauses 2 to 6 indicate the potential uses of the delegated power in clause 1. Below we go through each limb of the power as set out in clauses 2 to 6 line by line explaining how the Department envisages using each limb. The Committee should note that examples of how the power could be used are illustrative, not least because the use of the power will be subject to a statutory consultation requirement.

Clause 2: Manufacture, marketing and supply

(1)(a) authorisations to manufacture human medicines

2. This limb of the power relates to the licence needed by manufacturers of human medicines in the UK, including the application process and the information required to be sent to the appropriate authority as part of monitoring the licence. In the UK a person may not manufacture human medicines without a licence.

3. Each licensed manufacturer is required to have a highly skilled "qualified person" (QP) who quality assures the manufactured medicines prior to release onto the market. Manufacturing facilities are listed on the licence and inspected prior to approval. The manufacturing facilities are usually in place for decades, with different products manufactured in the same facility.

4. For short shelf life products there may not be time for a QP to perform the regulatory checks before the product has expired. Alternative systems of 'assurance' are required to replace traditional end of process checks, particularly if the process is scaled up to manufacture bigger batches.

5. A revised approach to regulation of the 'distributed manufacturing' model is required to ensure regulatory oversight and quality assurance requirements that protect public health and avoid regulatory complexity that risks barriers to patient access to medicines. This limb of the power will enable appropriate changes to be made to the current scheme (set out in regulation 17 of HMRs) for this purpose.

6. The Medicines and Healthcare products Regulatory Agency (MHRA - an executive agency of the Department of Health and Social Care responsible for the regulation of medicines, clinical trials, and medical devices) is already exploring regulatory options that facilitate a distributed manufacturing model. For example, it is considering a model which would allow the holder of a manufacturing licence to use a centralised control centre to deliver a quality system for specific products, including a QP that oversees multiple sites of distributed manufacture such as theatres and hospital clinics.

7. If this example were to be pursued the sort of changes we would need to make by regulations to the existing legislation are:

    a) Define a central "control site" where a manufacturing authorisation would be required, with a QP;

    b) Exempt the distributed manufacturing sites from holding their own manufacturing authorisation and QP provided that they were named on the distributed manufacturer's list, attached to the control centre manufacturing licence;

c) Exempt products manufactured under agreed protocols at these distributed sites from the need for prospective QP certification;

d) Extend existing powers to inspect and enforce to cover new requirements (with possible addition to inspection powers to address new needs).

8. This limb of the power could also allow provision to be made amending or supplementing the requirements around the manufacture of investigational medicinal products (IMPs) for clinical trials. Innovations in healthcare are moving towards personalised medicines, which need to be manufactured close to the patient in a clinic or hospital, and medicinal products with ultra-short shelf lives such as medical gases, cell-based and biological therapies. The manufacturing model requires a traditional manufacturers licence, a highly skilled 'qualified person' to oversee activities and regulatory inspections. As uptake of personalised and short life medicines increases the traditional manufacturing model will become less feasible for IMPs and create significant regulatory and cost burden. This is especially the case where clinical trials often have continuous change in adding and removing trial sites, as trial recruitment changes.

9. We could use this limb of the power to adapt the current manufacturing model for IMPs to facilitate the 'distributed manufacturing' model, where IMPs need to be manufactured across multiple clinic/hospital/theatre-based manufacturing facilities. This will allow us to ensure regulatory oversight and quality assurance requirements that protects public health but avoids regulatory complexity that risks barriers to patient access. This would require us to amend the existing legislation for example, to define a central "control site" where a manufacturing authorisation would be required with a QP; exempt distributed manufacturing sites from holding their own manufacturing authorisation and QP provided that they were named on the distributed manufacturers list attached to the central control centre manufacturing authorisation; and extend existing powers to inspect and enforce to cover new requirements.

<u>(1)(b) authorisations to import human medicines</u>

10. This limb of the power relates to the licence required to import human medicines into the UK. Currently, a manufacturer's licence is required in order to import medicines into the UK from outside the EEA.

11. One of the requirements of the licence is to have a highly skilled "qualified person" who is responsible for certifying that medicines imported from a non-EEA State have been tested and checked to ensure the quality of the product.

12. In the event that changes were made to the manufacturing requirements, we would want to be able to make corresponding changes to the importation requirements. Otherwise, any divergence has the potential to result in the need for separate authorisations for manufacture and importation, which would lead to increased burdens on companies that carry out both activities.

13. Another example of how the power might be used could be to change the type of licence required for different types of import. For example, to allow importers to hold a wholesale dealer's licence, rather than a manufacturer's licence, when importing products from companies that are based outside the EEA where the medicines are already physically in the EEA. This would help reduce burdens on importers, as there are higher costs associated with holding and maintaining a manufacturer's licence compared to a wholesale dealer's licence. Therefore, this could enhance UK competitiveness by reducing costs associated with maintaining the type of licence required for this activity.

(1)(c) authorisations to distribute human medicines by way of wholesale dealing

14. This limb allows the appropriate authority to amend and update the existing provisions on wholesale dealer's licences, including the application process and the information required to be sent to the appropriate authority as part of monitoring the licence.

15. To sell or supply medicines to anyone other than the patient using the medicine, a wholesaler licence is required. This is also known as a wholesale dealer licence or wholesale distribution authorisation. This licence allows the wholesale dealer to sell, supply, offer for sale or supply pharmacy, prescription only, traditional herbal and General Sales List medicines wholesale.

16. Without this power we would lose the ability to amend the conditions of a UK wholesale dealer's licence. For example, amending requirements to provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the medicinal products under the licence as are necessary in light of emerging safety concerns, innovative new techniques and technologies, in order to maintain the quality of, and ensure proper distribution of the medicinal products.

(1)(d) marketing authorisations

17. This limb would allow amendments and updates to be made to the provisions on marketing authorisations, including the application process. As a general rule, a marketing authorisation is required by any person who wishes to place a medicine on the UK market as set out in regulation 46 of the HMRs. Keeping these provisions up to date will help to ensure the UK remains an attractive place for the pharmaceutical industry to bring to market new and established medicinal products, and that UK patients are not disadvantaged by having to wait for new, innovative or generic medicinal products. Provision made under this limb of the power could include provision about when these authorisations are not required.

18. We already have some specific examples as to how we might amend the marketing authorisation provisions using this limb of the power.

19. The first example is the offer of additional statutory rewards or incentives for certain types of application for a marketing authorisation. This would be to encourage new medicines to continue to come to the UK market in a timely fashion.

20. More specifically, we could incentivise through the offer of additional or favourable data and/or market exclusivity periods. These periods are currently fixed in the HMRs (for example, see regulations 51 and 53, which currently cross-refer to periods of protection in Article 10 of Directive 2001/83), and so to introduce incentives that require changes to exclusivity periods would require amendments to legislation.

21. A second example of where we can use this power is to simplify submissions for some application types, for example in relation to generic medicines and medicines in well-established use. We would consider amending regulation 50 of, and Schedule 8 to, the HMRs, which set out requirements in relation to the material that must accompany a marketing authorisation application.

(1)(e) manufacturing, importing or distributing active substances

22. This limb of the power relates to the importation, distribution and manufacture of active pharmaceutical substances. These are the substances used in the manufacture of medicinal products that are intended to give the medicine its therapeutic effect.

23. Any person who imports, manufactures or distributes an active substance is required to register with the licensing authority and comply with good manufacturing and distribution practice for active substances.

24. The quality of the active substance is critical to the quality and safety of the finished medicinal product and active substances that do not comply with the applicable requirements pose serious risks to public health. Therefore, the ability to amend and update regulations in relation to the manufacture, importation and distribution of active substances is necessary to protect public health.

25. Contamination in the active substance can carry over into the finished medicinal product if there is not adequate control. As demonstrated in the recent precautionary recall of certain 'sartan' medicines and Ranitidine, where the finished medicinal products were found to be contaminated with nitrosamine due to issues with the active substance. Once the investigation into this incident has concluded, we may need to make legislative changes to the requirements for active substances to prevent similar incidents occurring in the future. For example, to bring in more stringent testing or audit requirements.

26. This power would ensure that UK regulations can be amended to react quickly in response to emerging public health risks resulting from issues in relation to active substances.

27. Legislation could be updated to ensure production operations continue to be conducted in a manner that will prevent contamination of starting materials and active substances with other materials or in the manufacture of a finished medicine. Additionally, legislative updates could continue to enable precautions to be taken to avoid contamination when starting materials and active substances are handled, either before or after purification.

28. Regulatory updates could take place to ensure continued effective procedures around the sampling, examination and/or testing. For example additional testing at specific points after sourcing or conducting a manufacturing activity where there is potential for contamination and ensuring quarantine if necessary where a failure is identified. In addition, measures could require more robust audit requirements particularly where contamination of the materials poses the greatest risk.

29. Similarly, legislative changes could update the requirements around cleaning procedures for equipment to be validated and cleaning validation to be directed to situations or process steps where contamination or carryover of materials poses the greatest risk to give greater assurance. This could include measures to ensure testing of material following the manufacture of the first batch for known contaminants.

<u>(1)(f) brokering in relation to human medicines</u>

30. This limb of the power relates to the brokering of medicines. Brokering consists of negotiating independently and on behalf of another legal or natural person in relation to the sale or purchase of medicinal products. Brokers of medicinal products have to register with the MHRA and comply with the guidelines on good distribution practice (GDP), insofar as those guidelines apply to brokers.

31. Brokers interact with wholesalers and play an active role in the supply chain for medicines. Therefore, the ability to make future changes to UK legislation regarding broker registrations and obligations will be necessary to secure the medicines supply

chain and ensure the UK remains an attractive place to market medicines. This could include changes to the application process or the information that brokers need to provide as part of their registration.

32. In addition, should any new industry practices arise that risk supply chain infiltration with falsified medicines, it could be necessary to amend the definition of brokering to provide greater clarity in respect of the activities this captures. For example, having more than one broker operating in a chain between the original seller and the destined buyer, could result in opportunities for falsified medicines to enter the supply chain. To reduce this risk, we could use this power to restrict such activities.

33. Brokers are already required to inform the licensing authority of medicinal products which the broker identifies as, suspects to be, or has reasonable grounds for knowing or suspecting to be, falsified. To further identify risks to the supply chain, we could also extend this obligation to report a person who has approached the broker and who the broker identifies as operating without any appropriate licence or registration under their bona fide checks.

(1)(g) the registration of the premises of retail pharmacy businesses

34. Reliance on this provision, combined with others in the Bill, can be used to help deliver community pharmacy reform. In recent years, there has been an increase in 'hub and spoke' dispensing arrangements, where a retail pharmacy (notionally at the end of a spoke), takes in prescriptions, sends them off to the 'hub' pharmacy (which takes in prescriptions from a number of 'spoke' pharmacies), and the 'hub' then does any preparation or assembly activities that are needed as part of the dispensing process. The medicines that are ready for supply to the patient may then be sent back to the 'spoke' for that supply, or possibly sent directly to the patient via a home delivery service. At the moment, this is only possible if both "hub" and "spoke" are part of the same legal business (see section 10(1)(a) of the Medicines Act 1968).

35. These sorts of arrangements allow pharmacies to make savings by way of economies of scale and the use of new technologies and automation. For example, if the patient's medicines are to be supplied in a 'Multiple Dosage System' (MDS) – such as a tray with indents that has a number of medicines in each indent representing all the medicines that a patient is to take at a particular time on a particular day – if production of that MDS can be automated, significant cash savings can potentially be made, and there is also evidence that automation can bring significant safety benefits for patients.

36. However, such is the cost of setting up 'hubs', a significant number of 'spokes' are required before savings can be made. Larger retail chains are currently at a competitive advantage over the smaller retail chains, able to make use of the hub and spoke arrangements. This is because of the restriction in section 10 of the Medicines Act 1968 that effectively prevents separate legal businesses from grouping together in such a way to make a 'hub' viable.

37. Section 10 is an exemption for pharmacists from requirements that relate to authorisations to manufacture human medicines and to marketing authorisations, and it is possible to use powers relating to those requirements to remove that restriction. As a consequence we would need to ensure that a 'hub' is appropriately regulated, which it is anticipated to be done by ensuring that both 'hub' and 'spoke' pharmacies must be a registered pharmacy under Part IV of the Medicines Act 1968, including those that do not make the final sale/supply to the patient. Consequentially, it may be appropriate to make changes to ensure that the premises registration arrangements in Part IV function appropriately for those registered premises that do not make the final sale/supply.

38. The intention behind the package of changes as a whole would be to introduce a 'level playing field' so that smaller businesses can benefit from the same economies of scale as larger businesses.

(1)(h) the recording of information about the supply of human medicines

39. This limb of the power would allow us to make amendments to the current regulations surrounding the recording of information about the supply of human medicines. For example, currently a person conducting a retail pharmacy business is required to record the name, quantity, pharmaceutical form and strength of the prescription only medicines (POMs) that they sell or supply, as well as the name and address of the person for whom the prescription only medicine was prescribed. We could use this power to require the unique identifier that is included on packs of POMs under the EU Falsified Medicines Directive (FMD) to be recorded by pharmacies alongside the other information they already record. This would enable the identification of medicines down to pack level. Being able to identify the specific pack that was given to a particular patient, as opposed to just the type of product supplied could deliver valuable public health benefits.

40. Currently, if there is an issue with a particular batch of medicine checks can be made against the pharmacy's records to see who has received that type of product. But without being able to identify which customer received which pack, the pharmacy would have to contact everyone who has received the product in question. Recording the pack-level identifier would enable the pharmacy to identify and target their communications only to those customers who received the affected packs. This has the potential to reduce the time taken to contact affected patients and would ensure that other patients are not contacted unnecessarily.

(1)(i) notification and reporting requirements in relation to human medicines that have been placed on the market

41. This limb could be used to amend and update the reporting and notification requirements for medicines on the UK market under Part 11 of the HMRs. These requirements state that the licensing authority must take all appropriate measures to encourage the reporting to it of suspected adverse reactions and to facilitate reporting through the provision of alternative reporting formats in addition to web-based formats. This is in order to improve pharmacovigilance in the UK.

42. We could use this power to amend these provisions in order to make the reporting requirements more risk-proportionate and reduce unnecessary burden. For example, in the future we could use this limb to remove any duplicative measures. Keeping this provision up to date will help to ensure the UK remains an attractive place for the pharmaceutical industry to bring to market new and established medicinal products, and that the UK is a less burdensome place to market medicines. This limb ties in with the overarching duty to have regard to patient safety under clause 1(2)(b) and we will of course be required to consult on any future changes under clause 40 of this Bill.

(1)(j) the labelling and packaging of human medicines or the information that must be supplied with them or made available in relation to them

43. This limb allows amendments and updates to be made to the provisions setting out the labelling and packaging requirements for human medicines and the information that must accompany them (often currently in the form of a patient information leaflet (PIL)). Ensuring that medicines are clearly identifiable and the essential information for patients is easily accessible is an important factor in ensuring patient safety. This limb could be

used to modernise the current labelling and packaging requirements of human medicines in order to make the UK a more attractive place to market medicines.

44. An example of a change is in the way information is shared. Currently, delivery of the statutory PIL is in hard copy, in or on the package, and this is enshrined in the HMRs. Advances in technology and patient preference mean that whilst paper versions of the statutory information continue to play an important role, they would ideally no longer be the only required route. This will support the many patients who would prefer to access safety and health-related information from manufacturers on-line and via smart phone technology. An illustrative SI[4] - *The Human Medicines (Amendment) (Electronic Package Leaflets) Regulations 2020* - demonstrating how this proposal might be implemented can be found published on gov.uk.

45. A further example of how we would use this limb is in relation to "white box"/"split box" dispensing. The HMRs exempt "white box" dispensed products from the requirement to be supplied with a PIL. "White box" dispensing occurs where a pharmacist splits a pack of medicines prior to dispensing to fulfil an order in a prescription, for example, by splitting a packet of 24 pills so as to give a patient the 12 pills they have been prescribed. The exemption arises because dispensing in pharmacy boxes is regarded as "assembly" under regulation 8 HMRs; and regulation 4 HMRs provides that the packaging and leaflet requirements in Chapter 1 of Part 13 HMRs do not apply in these circumstances.

46. We consider it important to retain flexibility to require that certain medicines be dispensed together with a PIL and other risk minimisation materials, so we would consider amending the relevant provisions to ensure that relevant information accompanies specified "white box" dispensed products in certain circumstances. We may exercise this power in relation to a specific medicine, a class of medicines or all medicines. This ties in to our overarching duty of ensuring patient safety by making essential information for patients easily accessible.

(1)(k) advertising with regard to human medicines

47. This limb allows the provisions that govern the advertising of human medicines to be amended and updated. The current medicines regulatory model requires certain information to be included in advertisements for medicines. The powers would be used to enable innovation in both the information provided and the way in which it is delivered.

48. We have a particular amendment already in mind that could be made under this power. Regulation 294(2) of the HMRs sets out requirements in relation to adverts aimed at those who prescribe, dispense or supply medicines. In particular, it contains a general rule that written adverts must contain the information set out at paragraphs 1 to 8 of Schedule 30 to the HMRs. In 2014, an exception to the general rule was created through the insertion of regulation 294(2A) and (2B) (inserted by regulation 24 of SI 2014/1878). This exemption allows adverts for Pharmacy only and General Sale List medicines to provide the information set out at paragraphs 1 (authorisation number), 7 (adverse reactions, contra-indications, dosage, method of administration etc) and 8 (costs) of Schedule 30 through a web link rather than having to incorporate the information into the advert. This recognised that the information was readily available online and that online information was as likely to be read as the 'small print' of an

[4] The Human Medicines (Amendment) (Electronic Package Leaflets) Regulations 2020 - https://www.gov.uk/government/publications/medicines-and-medical-devices-bill-overarching-documents

advert. We could make regulations under this limb of the power to extend this exemption to adverts for Prescription Only Medicines.

(1)(l) the registration of persons who supply or offer to supply human medicines by means of the internet

49. This limb would allow the introduction of a registration scheme for online sellers of medicines. Currently, under Article 85c of the EU Medicines Directive, which was transposed into the HMRs by insertion of a new Part 12A in 2015, online suppliers of medicinal products must register with the national competent authority for the Member State in which they are established, comply with certain requirements and display a logo on their website to indicate that they are authorised to sell medicines online. This is in order to assist patients to choose a reputable online pharmacy and stay safe.

50. We could use this limb of the power to introduce a national scheme to replace the EU scheme which may not be available to the UK at the end of the Transition Period. This is because the logo which the scheme currently asks online pharmacies to display is under copyright to the EU and so the UK cannot continue with that scheme without EU permission.

51. It is envisaged that the replacement national scheme will retain some aspects of the EU scheme but will need to be adapted in order to meet the needs of the UK. A new scheme is likely to require registration and mandate the display of a UK logo at a minimum. If the UK opted for an enhanced scheme registration this would be likely to manifest itself through the introduction of additional conditions and requirements of registration.

52. How a UK scheme might be inserted into the HMRs using this limb of the power is set out in an illustrative SI [5] -*The Human Medicines (Amendment) (Sale at a Distance) Regulations 2020* – published on gov.uk.

(1)(m) the requirements that must be met in relation to a prescription

53. Regulation 214 of the HMRs sets out the general rule that medicinal products categorised as "prescription only" may only be supplied in accordance with a prescription given by an appropriate practitioner. The general requirements for a prescription are then set out at regulations 217 to 220. The general requirements in regulation 217 (and 218 for prescriptions given by an EEA health professional) include requirements for prescriptions to be "signed in ink" and "written in ink". However, these general requirements are subject to the provisions on electronic prescriptions set out at regulation 219 and 219A (see regulation 217(8)(b) and 218(8)).

54. The provisions set out at regulation 219 apply to all prescriptions given by an appropriate practitioner, other than an EEA health professional, save those that relate to medicinal products specified in Schedule 1 to the Misuse of Drugs Regulations 2001 or Schedule 1 to the Misuse of Drugs Regulations (Northern Ireland) 2002. Regulation 219A applies to prescriptions given by an EEA health professional save those that relate to medicinal products specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations 2001 or Schedule 1,2 or 3 to the Misuse of Drugs Regulations (Northern Ireland) 2002. The effect of regulations 219 and 219A is to allow the prescriptions to which they apply to be created and sent to the dispensing pharmacy electronically.

[5] The Human Medicines (Amendment) (Sale at a Distance) Regulations 2020 - https://www.gov.uk/government/publications/medicines-and-medical-devices-bill-overarching-documents

55. We would like to be able to amend regulation 219 and 219A of the HMRs to restrict further, both on a temporary or permanent basis, the types of prescriptions or medicinal products to which either regulation applies. Additionally, we could use this limb to amend the conditions in regulations 219 and 219A or introduce additional conditions for the electronic prescriptions of certain medicinal products. For example, expanding the products that require an electronic prescription to be sent via the electronic prescription service managed by the Health and Social Care Information Centre (see regulation 219(4)(c)(ii) which currently applies to prescriptions for products specified in Schedule 2 or 3 to the Misuse of Drugs Regulations). This is to address a concern that the over-prescribing or improper prescribing of certain medicinal products is exacerbated by the availability of electronic prescriptions (which under GMC guidelines can be provided online without a face to face consultation). Examples of such products include antibiotics (overprescribing) and opiates (improper prescribing).

56. This is the sort of detailed change that we believe is suitable for a delegated power.

<u>(1)(n) prohibitions in the provisions mentioned in subsection (2)</u>

57. These provisions all set out general rules relating to the supply of human medicines specifically:

- that the sale or supply of POMs must be in accordance with a prescription issued by an appropriate practitioner: reg 214 and Schedule 13 HMRs;
- the prescribing and administration of POMs by supplementary prescribers: reg 215 and Schedule 14 HMRs;
- that human medicines not subject to general sale must be supplied from a registered pharmacy: reg 220
- that medicinal products subject to general sale must be supplied from lockable premises: reg 221 and Schedule 15
- that medicinal products can only be sold by way of wholesale dealing to certain persons: reg 249 and Schedule 22.

58. “POMs” refer to prescription only medicines. “P” refers to Pharmacy medicines i.e. medicines that do not require a prescription but may only be supplied from a registered pharmacy. “GSL” refers to the General Sale List medicines which are widely available.

59. All these general rules are subject to exemptions which are set out in Chapter 3 of Part 12 of the HMRs and the associated Schedules often in lengthy tables. These provide exemptions from legislative restrictions to allow healthcare professionals and others to supply and administer particular medicines directly to patients in the course of their professional practice.

60. For example, exemptions permit certain medicines listed in legislation to be sold, supplied and/or administered to patients by certain health professional groups without using a prescription. Another example enables the supply of medicines in accordance with Patient Group Directions – a legal framework that allows some registered health professionals to supply and/or administer specified medicines to a pre-defined group of patients, without them having to see a prescriber. The use of exemptions to supply and administer medicines will allow healthcare professionals and other appropriate persons to deliver prevention, treatment and maintenance of health effectively and efficiently. This will ensure that patients receive the best care, first time and in the right place. The use of exemptions also has the potential to further improve patient safety by creating clearer lines of responsibility for decisions made regarding medicines.

61. We would use this limb to expand the role of healthcare professionals, subject to expert recommendation, concerning who can supply, administer and prescribe medicines in line with healthcare needs. This would further advance the Department's policy aim of getting medicines to patients at the first safe point of need.

62. A specific example of how we might use this limb of the power is to create a further exemption to the general rule in regulation 214 that prescription only medicines may only be supplied under a prescription so that dental hygienists and dental therapists can supply and administer certain medicinal products in the course of their professional practice. This example has been set out in an illustrative SI[6] - *Human Medicines (Amendment) (Exemption for Supply by Dental Hygienists and Dental Therapists) Regulations 2020* – published on gov.uk.

Clause 3: Falsified medicines

(1)(a) the prevention of the supply of falsified human medicines

63. This limb could be used to make provision combatting falsified medicines entering the supply chain in order to keep UK patients safe. The term "falsified medicinal product" refers to a product which falsely represents some aspect of itself e.g. its composition or who manufactured it.

64. The EU introduced legislation to combat falsified medicinal products through the Falsified Medicines Directive (2011/62/EU) which amended the main EU Medicines Directive (2001/83/EC). A key part of the scheme was the introduction of an EU Delegated Regulation (EU/2016/161) which introduced the 'safety features' scheme (the "Safety Features Regulation"). This is an end-to-end verification scheme that requires each pack of medicines to carry a unique identifier in the form of a 2D data matrix barcode and tamper-evident packaging. The unique identifier is scanned at various points along the supply chain, allowing for the verification of the authenticity and the identification of an individual pack of a medicinal product. At the point that the product is supplied to the patient, the person supplying must remove it from the system.

65. The Safety Features Regulation came into force on 9 February 2019 taking direct effect in the UK. Its implementation in the UK was supported by amendments made to the HMRs by the Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62).

66. The Government has committed to evaluating the options for a future UK falsified medicines framework and would intend to use this power to this effect. Engagement has begun with stakeholders concerning the key objectives and functions of a replacement scheme, and to that end clause 3(2) sets out an illustrative list of the provisions that may be made in reliance on clause 3(1)(a).

(1)(b) the use, retention and disclosure of information collected for the purpose of preventing the supply of falsified human medicines

67. This limb relates to the use of information collected for the purpose of preventing the supply of falsified medicines. The core use of this power would be to ensure that the information collected under 1(a) could also be used for other purposes not related to the prevention of falsified medicines.

[6] Human Medicines (Amendment) (Exemption for Supply by Dental Hygienists and Dental Therapists) Regulations 2020 - https://www.gov.uk/government/publications/medicines-and-medical-devices-bill-overarching-documents.

68. The body managing the falsified medicine system will need to access and use data held on the system to:

    - supervise the functioning of the system itself to ensure it is operating correctly; and
    - where appropriate, to thoroughly investigate instances of falsified medicines both to identify impact on patients, route through the supply chain and prevent any further impacts, for example sharing information with other countries or other regulators.

69. Currently under the EU scheme information held on the system can also be used for the purposes of reimbursement, pharmacovigilance and pharmacoepidemiology.

70. In addition to the above there may be other circumstances where we would want to be able to use the data for public interest purposes, to ensure that the scheme delivers the most benefits for the UK and for patients. For example, the information in the falsified medicines system could be useful in the event of a product recall to help quickly identify affected packs or to help manage supply shortages and ensure availability of medicines.

71. Information about the supply of medicines through the supply chain can be commercially sensitive and therefore subsection 3 requires the appropriate authority to have regard to the importance of ensuring that information is retained securely when making regulations under subsection 1.

Clause 4: Clinical Trials

(1)(a) corresponding or similar to provision in the EU Clinical Trials Regulation

72. This limb allows us to make provisions corresponding or similar to those in the EU Clinical Trial Regulation (Regulation EU No 536/2014) (the EU CTR).

73. Whilst the EU CTR is in force, it is not expected to apply until after the end of the Transition Period[7] meaning it will not form part of retained EU law. The power in the Bill will allow the Government to deliver the same effects as certain elements of the new EU regulations on clinical trials, in upcoming UK clinical trials legislation, if it is deemed that this will help ensure we maintain a world-leading approach to clinical trials.

(1)(b) for or relating to authorisations concerning clinical trials in the United Kingdom, including applications regarding the ethics of a proposed clinical trial

74. This limb would allow amendments and updates to be made to the provisions on clinical trial authorisations and ethical approval of clinical trials. Keeping the systems for authorisations and their applications as up to date as possible will help to ensure that the UK remains a competitive place for the pharmaceutical industry to develop and market new and established medicinal products, and that UK patients are not disadvantaged by having to wait for new, innovative or repurposed medicinal products.

75. For example, we could use this limb of the power to amend the statutory timelines for assessing applications for clinical trial authorisations. The maximum number of days that can be taken to complete an assessment is set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 (CTRs) (and reflects EU law). The UK has always felt that it could assess considerably faster than these statutory maximums, and this limb of the provision would allow the statutory maximum to be reduced demonstrating the UK commitment to fast assessment of applications.

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

76. We may also wish to use this power to modernise the application process for the ethical review of clinical trials. Currently, for example, Part 1 of Schedule 3 to the CTRs states that ethics committees should receive a copy of the script for advertising contained in a video or audio cassette. Ideally this should now be done online.

(1)(c) about notification and reporting requirements in relation to clinical trials

77. This limb of the power allows provision to be made amending and updating the notification and reporting requirements in the CTRs. The CTRs impose various obligations on trial sponsors (as defined in regulation 3) and investigators (as defined in regulation 2) to notify or report various events to the UK licensing authority.

78. Regulation 29A of the CTRs requires the sponsor to notify serious breaches; regulation 30 requires a sponsor to notify any urgent safety measures taken; regulation 32 requires an investigator to report serious adverse events; regulation 33 requires a sponsor to report any suspected unexpected serious adverse reactions and regulation 35 requires sponsors to produce an annual safety report. These requirements apply to all trials regulated under the CTRs.

79. We could use this power to amend the notification and reporting requirements in the CTRs, in particular to make them more risk-proportionate, so as to reduce unnecessary burden on sponsors and investigators.

80. An example of how we could do this is in relation to trials that are considered to carry low levels of risk, such as academic trials involving a single product already in common usage, such as paracetamol. For those trials, it is thought the requirement to produce an annual safety report is disproportionate and could be removed. We could possibly remove the requirement for serious adverse events to be individually listed annually and instead produce an annual safety summary. Thirdly, we could limit the requirement to only report adverse events that produced new information. These decisions will of course be subject to wider consultation with stakeholders, as set out in clause 40.

81. An illustrative SI[8] has been published - *The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2020* - showing how the power could be used to:

    a) limit the requirement for investigators to report all serious adverse events so that they are instead only required to report serious adverse reactions that are linked to the administration of the medicinal product;

    b) remove the duplicate requirement to report suspected unexpected serious adverse reactions which occur during the course of a clinical trial to the relevant ethics committee when this is already reported to the licensing authority; and

    c) limit the requirement for sponsors of low risk trials to provide the licensing authority and the relevant ethics committees with a list of all the suspected serious adverse reactions which have occurred during a year so that they are only required to provide a list of the serious adverse reactions which are not consistent with the information set out in the summary of product characteristics.

(1)(d) about requirements that must be met before a clinical trial may be carried out

[8]The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2020 - https://www.gov.uk/government/publications/medicines-and-medical-devices-bill-overarching-documents

82. This limb could be used to amend the requirements that must be satisfied before a trial is started. This could involve amending or removing existing requirements for some or all trials to ensure they remain proportionate to risk and adding other new requirements to ensure that trials continue to be conducted to high standards and in a way that maximises participant safety.

83. An example of how this limb of the power may be used is in relation to ensuring that the health care professionals (HCP) conducting the trials are fit to do so. In particular, we would consider introducing a requirement to confirm that any other trials being conducted by the HCP are being conducted to a satisfactory standard (and if not that the shortcomings are addressed) prior to starting the new trial.

(1)(e) relating to the conduct of clinical trials.

84. This limb allows amendments and updates relating to all aspects of how a trial is conducted, and in particular to the principles of good clinical practice that must be adhered to.

85. The principles of good clinical practice are set down at an international level by the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[9]. These principles are enshrined in Schedule 1 of the CTRs. In the event that ICH were to update their principles, the UK would be able to amend its provision and avoid the risk of being considered to conduct trials to outdated standards. Being able to update and amend the principles of good clinical practice is essential to ensure the trials conducted in the UK remain creditable and accepted worldwide; and to ensure that UK trial participants can be confident that trials are conducted to high standards.

Clause 5: Fees, offences, powers of inspectors

(1)(a) for or relating to the charging of fees in connection with the exercise of a function conferred by a relevant provision

86. This limb of the power covers the introduction of new charges in relation to functions introduced under the power at clause 1(1) as well as the amendment of existing fees relating to functions conferred under the HMRs or CTRs (see the definition of 'relevant provision' in clause 5(3)). This limb cannot be used to create or impose taxation.

87. The UK regulator of human medicines (including clinical trials of human medicines) is the MHRA. The MHRA is self-funding for the purpose of medicine regulation and the costs of its work must be off-set by the fees it charges. It is therefore important that fees can be introduced in relation to functions carried out by the MHRA. Medicines regulation is funded entirely from industry fees. In setting its fees the MHRA takes account of the principles set out in HM Treasury's Managing Public Money.

(1)(b) creating a criminal offence of failing to comply with a provision made in the regulations, but not one punishable with a sentence of imprisonment of more than two years

88. This limb of the power allows for the creation of a criminal offence with a maximum period of imprisonment of 2 years, in relation to new requirements or prohibitions introduced in regulations made under the clause 1(1) power.

89. We would need to have the ability to create criminal sanctions in order to deter individuals from breaching any of these provisions, and to introduce punitive measures

[9] For more information go to: https://www.ich.org/home.html

for those who do breach the provisions. We also require these sanctions in order to remain consistent with the existing regime, which already imposes criminal sanctions for certain breaches.

(1)(c) applying relevant powers of entry and inspection with or without modification in relation to a prohibition or requirement imposed by provision made in the regulations

90. This limb allows the application of the existing entry and inspection powers to new prohibitions and requirements introduced by regulations made under the clause 1(1) power. Existing inspection powers can be found in Part 8 of the CTRs, Part 16 of the HMRs, and in Part 8 of the Medicines Act 1968. The existing powers may be applied with or without modifications.

91. It is important that the existing powers of entry and inspection may be applied to new elements of the regulatory scheme to ensure that compliance with those new elements can be enforced.

92. An example of where we would potentially like to apply the existing powers of entry and inspection is in relation to any new requirement made in regulations under clause 2(1)(l) for online sellers of medicines to register.

Clause 6: Emergencies

(1) Regulations under section 1(1) may make provision about the disapplication of a human medicines provision in circumstances which give rise to a need to protect the public from a risk of serious harm to health.

(2) regulations made in reliance on subsection (1) may provide for the disapplication to be subject to –

(a) conditions set out in the regulations

(b) conditions set out in a protocol published by an appropriate authority

(3) where regulations made in reliance on subsection (1) provide that an appropriate authority may publish a protocol setting out conditions, the regulations must provide –

(a) that the appropriate authority may withdraw or amend the protocol and

(b) that the protocol is to have effect only for a period of time specified in the protocol

93. This limb allows actions to be taken to alleviate supply issues during public health emergencies such as a pandemic or a nuclear explosion. During such times there is often unprecedented pressure on both the stocks of the necessary medicines and supply chains' ability to distribute them quickly and efficiently to those that need them. Under this limb, regulations can be made which identify the provisions that can be disapplied in order to alleviate supply issues and best manage an emergency that gives rise to a risk of serious harm to health.

94. The power could be used pre-emptively or reactively. Pre-emptively would mean making provision in anticipation of a future crisis and these provisions would become active when specified conditions are met. Reactively would mean making provision to deal with a situation that has arisen with the provision to take immediate effect.

95. The HMRs already contain some pre-emptive provisions to assist in the event of various forms of public health emergency.

96. Regulation 174 of the HMRs disapplies the prohibition on supplying medicines without a marketing authorisation where the supply is authorised on a temporary basis by the licensing authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation, which may cause harm to human beings.

97. Regulation 247 of the HMRs disapplies the requirements set out in regulations 214, 220 and 221 which limit the circumstances in which prescription, pharmacy and over- the-counter medicines respectively may be supplied. The exemption is triggered where two conditions are met: (a) that there is a pandemic or risk of pandemic that poses a serious risk to human health; and (b) that the supply is in accordance with a protocol approved by an NHS body or Ministers.

98. Regulation 247 only applies where there is a serious risk to human health arising from a pandemic disease outbreak, and therefore may not cover a localised outbreak of disease or a serious risk to human health arising out of a non-disease issue, such as a nuclear explosion, irrespective of the serious risk to human health.

99. Our expectation is that this power would be used pre-emptively. One of the uses of this limb of the power that we anticipate would be to introduce a similar provision to regulation 247 that applies to a wider range of events where there is a threat of serious harm to public health. We have published an illustrative SI[10] - *The Human Medicines (Amendment) (Exemption for Supply in Response to Spread of Pathogenic Agents etc) Regulations 2020* – on gov.uk, to set out how such a change would look.

100. We also may need to use the power to respond reactively to a specific pressure on the supply chain that arises during a public health emergency and that has not been anticipated in advance. Until an emergency unfolds it is often difficult to predict where the supply chain might break down. The problems could be importing, manufacture, distribution or dispensing to the public. For example, it is possible that due to a pandemic a section of the supply chain are particularly incapacitated. If this section were the distributors, we could consider partially disapplying the requirement for distributors to hold licenses to allow other specified groups of people to do some of the distribution - such as hospital to hospital distribution which would normally require a licence. As mentioned above, another example might be where a particular medicine was not reaching the public fast enough and so requirements around dispensing would be disapplied to allow local authorities to supply the medicine to the public. These examples are entirely hypothetical and for illustrative purposes but give a flavour of the consideration that this limb of the power might be used to address. Any decision to relax a requirement would not be taken lightly and, although it would need to be implemented at pace, full consideration would be given to the safety considerations as required by clause 1(2).

101. Where provisions are disapplied under this limb of the power, there is the option of introducing a protocol which applies in place of the disapplied requirements in order to ensure minimum acceptable standards of public safety are preserved. The protocol would only have effect for the period of time specified in the protocol.

VETERINARY MEDICINES

[10] The Human Medicines (Amendment) (Exemption for Supply in Response to Spread of Pathogenic Agents etc) - https://www.gov.uk/government/publications/medicines-and-medical-devices-bill-overarching-documents

102. The list of matters in clauses 9 and 10 are a detailed breakdown of how the power in clause 8(1) may be used, by reference to subject matter. To provide the Committee with further information, we set out below what each matter covers and give examples of what provision might be made in relation to each matter.

Clause 9 – Manufacture, marketing, supply and field trials

(1)(a) authorisations to manufacture veterinary medicines

103. This limb relates to the licenses required in order to manufacture veterinary medicines in the UK.

104. The VMR currently set out the requirement that all manufacturers of veterinary medicines must be inspected on a risk-based inspection schedule. This includes manufacturers of authorised products as well as other products that are permitted under the regulations. The inspection of manufacturers ensures that veterinary medicines are consistently produced and controlled in accordance with quality standards appropriate to their intended use. This power would allow us to introduce authorisation requirements for manufacturers that are currently unregulated, for example active pharmaceutical ingredient manufacturing sites and those sites that manufacture canine and feline stem cells.

(1)(b) authorisations to import veterinary medicines

105. This limb relates to the licences required in order to import veterinary medicines.

106. The VMR currently set out the requirements for import of authorised medicines in regulation 9. An example of how this power could be exercised is by allowing veterinary nurse prescribers to import authorised medicines.

107. To ensure medicines continue to be accessible for animal owners, we could allow veterinary nurses to import and prescribe authorised medicines. Animal owners could benefit from reduced consultation costs and quicker access to medicines if the import and prescribing restrictions for veterinary medicines were widened to include veterinary nurses.

(1)(c) authorisations to distribute veterinary medicines by way of wholesale dealing

108. This limb would cover amendments to the requirements for those companies that wholesale supply veterinary medicines.

109. An example of an amendment that could be made under this power is changing the requirements for good distribution practice (GDP) of veterinary medicines. For example, we may wish to change the requirements to cover new and novel products which may have new storage and distribution requirements. This would maintain the quality of the distribution chain for veterinary medicines and ensure they are stored appropriately and safely.

(1)(d) marketing authorisations

110. One example of the use of this power would be the offer of additional statutory rewards or incentives for certain types of application. This would be to ensure that new medicines continue to come to the UK market in a timely fashion. Although we would not wish to limit the nature of the statutory incentives we can offer in the future, one idea is to incentivise through the offer of a reduction in the data requirements of medicines for minor species such as alpacas. The generation of data for applications for marketing authorisations is the most expensive part of developing a new veterinary medicine,

therefore offering a reduced data package requirement would make the UK an attractive place to authorise new or novel veterinary medicines for minor species.

111. A second example would be the offer of additional or favourable data exclusivity periods. Companies can apply for a generic authorisation by referring to parts of a data package submitted for a previously authorised veterinary medicine, which is referred to as the reference product. Currently, the reference product must have been authorised for at least 10 years, before the generic product can be placed on the market. This period is referred to as the data protection period. These periods are fixed currently by Paragraphs 11 and 12 of Schedule 1 to the VMR and so to introduce incentives that relate to changes to data protection periods would require legislation.

112. A third example is simplification of regulatory submissions for some application types, for example generic medicines and those in well-established use. The requirements for the data supplied with an application for a marketing authorisation are set out in Paragraph 2 of Schedule 2 to the VMR and Annex I to the EU Veterinary Medicines Directive (2001/82/EC). Some of the data may be omitted in certain cases, such as generics which refer to the data of existing products and products in well-established use which may refer to published literature. Whilst there are no specific examples in mind, it is possible that other derogations from the full application requirements could be introduced in future.

113. This limb combined with (a), (b) and (g) could be used to make provision about using a licensed medicine outside the terms of its license if there is clinical need and benefit.

114. 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 – which is where a medicinal product can be used to treat a disease outside of its authorisation or to treat a different species from that it is authorised for. The Cascade is set out in the EU Veterinary Medicines Directive (2001/82/EC) and is included in Schedule 4 to the VMR.

115. An authorisation sets out the indication(s), species, recommended dosage, methods of administration, and contra-indications (for example, do not use in pregnant animals). The Cascade would mean using a medicinal product to treat a disease for which it is not authorised (‘indicated’) or to treat a different species from that for which it is authorised. 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.

116. As the Cascade is set out in legislation, this clause in combination with the others cited will allow changes to its provisions, for example, to introduce restrictions on companies that try to encourage or facilitate inappropriate use of the Cascade by vets.

<u>(1)(e) marketing, importing or distributing active substances</u>

117. This limb relates to securing the supply chain for active substances that are used in veterinary medicines.

118. This limb will allow us to make provisions corresponding or similar to the EU regulation on veterinary medicinal products (Regulation EU No 2019/6) where it is desirable from a UK policy perspective. The regulation includes a requirement for importers,

manufacturers and distributors of active substances in the UK to register their activity and comply with good manufacturing practice or good distribution practice.

119. We may initially use this power to include a similar registration scheme within the VMR. A future use of this power could be updating the requirements following changes to either good manufacturing practice or good distribution practice.

(1)(f) the categories of person who may supply veterinary medicines, and

(1)(g) the requirements that must be met in relation to the supply of veterinary medicines

120. These limbs relate to the administering and the supply of veterinary medicines, and requirements for prescription-only medicines to be supplied.

121. Regulation 7 of and Schedule 3 to the VMR (classification and supply, wholesale dealers and sheep dip) address the sale and supply of veterinary medicines. These are partly matters within national competence but the provisions in Schedule 3 have been made and amended using section 2(2)(b) ECA because they relate to the UK's EU obligations for veterinary medicines.

122. They set out, amongst other things, the rules for vets, pharmacists and Suitably Qualified Persons ("SQPs") on which categories of authorised veterinary medicines they are qualified and registered to prescribe or supply.

123. 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)

124. We would use this power to update regulation 7 and the associated Schedule 3 to the VMRs to update the provisions relating to the sale, supply and administration of veterinary medicines with new prescribing practices. The Government may wish to use this power to update these requirements to allow, for example, veterinary nurses to prescribe certain categories of medicines. This reflects the Government's desire to make medicines as accessible as possible whilst not compromising animal safety or the safety of the person administering the medicine.

(1)(h) the registration or accreditation of persons who supply or offer to supply veterinary medicines by means of the internet,

125. The VMD (Veterinary Medicines Directorate – which is responsible for the promotion of animal health and welfare by assuring the safety, quality and efficacy of veterinary medicines) has a voluntary, free scheme for the accreditation of online retailers of veterinary medicines (Accredited Internet Retailer Scheme – AIRS). Most of the accreditation criteria are existing legal requirements for selling veterinary medicines, which are set out in Schedule 3 to the VMR. There are some additional criteria, such as having links to the seller's professional body's website on the website so that customers can verify the seller's details.

126. We would use the powers to make this accreditation scheme mandatory for all UK internet retailers. This will provide further assurance for UK customers and prevent customers unwittingly buying illegal medicines from sites purporting to be UK-based.

127. We plan to charge fees for this scheme on a cost-recovery basis. The VMD is required to recover its costs from fees and charges according to the principles laid down in HM Treasury's document 'Managing Public Money'. Fees will be set at a level designed to ensure that they cover the cost of managing the accreditation scheme without cross-subsidy between activities or industry sectors. All proposed fees will be subject to public consultation.

128. The power will also allow us to enforce such a scheme with appropriate sanctions, to include the ability to suspend or revoke an online supplier's registration as well as the extension of existing inspection powers and criminal offences in the VMR to cover any new scheme.

(1)(i) the circumstances in which a veterinary medicine can be administered

129. This would allow regulations to be made which would prohibit the administration of substances that would be considered to adversely affect public health or consumer safety. For example, we could use this power to restrict the circumstances in which active substances that are persistent, bio-accumulative and toxic (PBT) can be administered.

130. PBT substances are concerning because of their persistence, their ability to accumulate in living organisms and their toxicity. Due to the combination of these properties they pose serious concerns for the environment and human health if used in food-producing species. We could use this power to restrict the administration of PBT substances to animals that will not enter the food chain.

(1)(j) notification and reporting requirements in relation to veterinary medicines that have been placed on the market

131. This limb would cover amendments to the reporting and notification requirements for marketed medicines under the VMR. We would use this power to amend these provisions in order to make reporting requirements more proportionate and reduce unnecessary burden. For example, we could use this power to make changes to the process by which companies report any suspected adverse events to veterinary medicines to the VMD.

(1)(k) the labelling and packaging of veterinary medicines or the information that must be supplied with them or made available in relation to them

132. This limb allows us to make provisions about the labelling of veterinary medicines and the information that must be supplied with them in order to best inform vets, prescribers and animal owners. The VMR include requirements for the labelling of authorised veterinary medicines.

133. One example of where we could exercise this power is to introduce pictograms (standardised pictorial symbols for a word or phrase) to replace some of the written labelling requirements. This would simplify the process and improve animal safety.

(1)(l) advertising with regard to veterinary medicines.

134. This limb allows us to make provisions about the advertising of veterinary medicines and allows the provisions that govern the advertising of veterinary medicines to be amended and updated. The VMR currently includes restrictions on advertising in regulations 10 and 11.

135. An example of how we could exercise this power is by including a definition of advertising within the VMR. The current VMR does not provide a definition of advertising and therefore the VMD has issued guidance to set out what the VMD considers to be advertising. Including a definition in the VMR will provide clarity to industry, make it easier for companies to comply with the legislation and provide a legal definition for enforcement purposes.

(1)(m) animal test certificates granted under the Veterinary Medicines Regulations 2013 (S.I 2013/2033) for research purposes

136. An Animal Test Certificate is required to carry out a veterinary field trial of a medicine. These trials are used to evaluate the safety and/or efficacy of a medicine under conditions of field use and will usually be conducted in client owned animals.

137. It is important for the UK to retain its position as a leading destination for veterinary clinical field trials. Many companies currently prioritise the UK as one of the key places to launch new veterinary medicines. In order to maintain this, the regulatory framework must remain fit-for-purpose.

138. One example of how we could use this power is introducing reduced data requirements for applications for animal test certificates for exotic or minor species. Companies must provide supporting data with their applications; for example, data to support the safety of the test product after administration to the target species. The reduction in data requirements may encourage more companies to carry out trials in the UK which could result in more medicines becoming available for these species. Simplified data requirements for minor species would provide a clearer set of requirements for industry and ensure that our systems compare favourably to other countries.

(2) Regulations under clause 8(1) may make provision corresponding or similar to provision in the relevant EU Regulations

139. This limb allows us to make provisions corresponding and similar to provision in two EU Veterinary Medicines Regulations (Regulation (EU) 2019/6, and Regulation (EU) 2019/4) where it is beneficial to the UK.

140. The EU Regulations are in force but will not apply until after the end of the Transition Period meaning they will not form part of retained EU law. This limb provides the means for making corresponding and similar provision to elements found the new EU Regulations as the UK sees fit.

141. To accompany the Bill and its supporting documents during their passage through Parliament, we have published an illustrative SI [11] which primarily illustrates some of the changes we intend to make using the Bill power.

Clause 10 - Fees, offences, powers of inspectors

(1)(a) about the charging of fees in connection with the exercise of a function conferred by a veterinary medicines provision

142. As a cost recovery agency, the VMD is required to recover its costs from the industry. This is achieved through charges for applications and inspections etc. For example, when introducing application processes for the registration of websites for online retail

[11]The Veterinary Medicines (Amendment) Regulations 2020 - https://www.gov.uk/government/publications/medicines-and-medical-devices-bill-overarching-documents

supply, and applications for the registration of active substances, we would propose to introduce fees to recover the costs of considering these applications.

(1)(b) creating a criminal offence of failing to comply with a requirement in provision made in the regulations, but not one punishable with a sentence of imprisonment of more than two years

143. This limb covers the creation of a criminal offence with a maximum period of imprisonment of 2 years, in relation to new requirements or prohibitions introduced under the power.

144. An example of how this power could be exercised, would be the creation of an offence for failing to comply with the new mandatory accreditation scheme for internet retailers. The power will allow us to enforce such a scheme with appropriate sanctions. This would include the extension of existing inspection powers and criminal offences in the VMR to cover this new scheme to ensure a level playing field for all online retailers.

(1)(c) applying powers of entry or inspection in the Veterinary Medicines Regulations 2013 with or without modification in relation to prohibition or requirement in provision made in regulations under section 8(1)

145. This matter relates to the powers of entry required for veterinary medicines. As with human medicines, the regulation-making power would allow (if exercised) the application of existing powers of entry and inspection, with or without modification, to new prohibitions or requirements introduced under the regulations.

146. An example of how this power could be exercised would be the application of powers of entry to new manufacturer categories that we plan to introduce using the powers in 9 1(a), for example, sites that manufacture active pharmaceutical ingredients and sites that manufacture canine and feline stem cells. As these are new manufacturer categories, the existing powers of entry in the VMR would not currently cover these sites.

(1)(d) the recovery of costs incurred in the administration of improvement notices or seizure notices under the Veterinary Medicines Regulations 2013

147. As a cost recovery agency, the VMD is required to recover its costs from industry. This is achieved through charges for applications and inspections etc. The power to recover costs incurred when issuing formal compliance notices will provide a deterrent to companies and will help ensure compliance with the Regulations.

MEDICAL DEVICES

148. The list of matters in clauses 13, 14 and 15 are a detailed breakdown of how the power in clause 12(1) may be used, by reference to subject matter. To provide the Committee with further information, we set out below what each matter covers and give examples of what provision might be made in relation to each matter.

Clause 13 – Manufacture, marketing and supply

(1)(a) requirements that must be met in relation to medical devices in order for them to be marketed, put into service or otherwise supplied ("relevant requirements"), including—

i. requirements in terms of design, manufacture, composition or other characteristics of the devices, or

ii. requirements imposed on persons involved in marketing or supplying the devices,

Requirements relating to devices

149. This power will enable the Secretary of State to update the requirements that must be met by medical devices in order for them to be placed on the market / further supplied in the UK. These could include, for instance, requirements relating to their composition in terms of materials, design, and manufacture, as well as specific evidence (including clinical evidence) for their safety, performance and clinical effectiveness.

150. This power could be used to amend device requirements in response to public health matters, such as, for instance, on the recommendation of the Independent Medicines and Medical Devices Safety Review.

151. The power could also be used to enable recognition of international standards for medical devices, for example where required as part of international trading arrangements with third country partners and/or as part of any negotiated future relationship with the European Union (see clause 13(2)).

152. This power will be relevant to updating the regulatory regime so that it is better placed to address new medical device technology, such as robotics and forms of artificial intelligence. For instance, the power could be used to create a set of bespoke requirements and standards for these types of medical device, which do not necessarily fit neatly within the existing framework. A more bespoke part of the regime for these devices could support public health and encourage innovation within the UK's life sciences sector.

153. Use of the power in this context might entail:

a) amending or replacing the 'general safety and performance requirements' for medical devices;

b) specifying detailed safety and performance requirements covering matters including:

i. what substances can be present in devices such as substances that are carcinogenic, mutogenic or toxic to reproduction;

ii. what steps must be taken to eliminate or reduce, as far as possible, the risks from microbial contamination and in particular sterilisation methods;

iii. the interaction of devices with the environment in which they are used;

iv. the reduction of exposure to radiation;

v. the nature of the power supply for active devices.

154. The current requirements in each of these areas are set out in the MDRs, but these are all areas where scientific and technical advances may require the updating or reshaping of the regulatory requirements. Such re-shaping could also be required as a consequence of decisions yet to be made on post-EU Exit conformity assessment of devices entering the UK system, including as part of future relations with the EU and with wider trading partners.

Requirements relating to persons marketing or supplying medical devices

155. This power would enable the Secretary of State to update obligations imposed on economic actors in the medical device supply chain, including manufacturers, suppliers, distributors, importers and persons representing manufacturers based outside the UK.

156. This power could be used to amend or replace current requirements (which in general refer only to manufacturers and their representatives) so that appropriate obligations are imposed on them and on a wider range of economic operators including:

a) so far as manufacturers are concerned, detailed requirements as to information which must be kept available for the Secretary of State (for instance, incident data in relation to medical devices);

b) the steps manufacturers must take where they either know or suspect problems have or might have occurred with a device;

c) the duties of importers in respect of defective or falsified devices and in relation to storage and transport of devices;

d) the obligations of distributors to ensure that particular requirements are met before supplying a device.

157. These obligations need to be kept up to date particularly in circumstances where there are new trading arrangements with the EU or wider partners or where experience shows that these requirements are not having the desired effect and need to be strengthened in the interests of protecting patient safety and/or patient confidence.

(1)(b) assessments of whether relevant requirements are met in relation to medical devices

158. This subsection relates to a power to specify how an assessment of whether relevant requirements are met is to take place. In the current framework, established in the MDRs this process is referred to as a "conformity assessment".

159. Notified bodies / conformity assessment bodies currently carry out conformity assessment procedures for most devices, depending on their classification. Devices are currently classified according to risk, with the lowest risk devices (for instance, plasters) classified as Class I devices, and the highest risk devices (for instance, pacemakers) classified as Class III devices. Directives 93/42/EEC, 90/385/EEC and 98/79/EC contain rules relating to risk classification. While Class I devices do not require notified body involvement in conformity assessment procedures, devices falling into Class IIa, Class IIb and Class III are all required to undergo conformity assessment procedures with notified body oversight.

160. These conformity assessment procedures are currently outlined in the Annexes to Directives 93/42/EEC, 90/385/EEC and 98/79/EC and are reflected in the MDRs. As noted above, these Directives are in the process of being replaced by EU Regulations 2017/745 and 2017/746, which contain new classification rules and new requirements for conformity assessment procedures.

161. Notified bodies / conformity assessment bodies are third parties who are designated to perform this role under the Directives. UK notified bodies are designated pursuant to Part V of the MDRs, which currently reflect the requirements of the Directives.

162. In order to support compliance with the medical devices regime and protect public health we would want to specify and set the requirements for these conformity assessments and relevant parties conducting those assessments prior to access to the UK market. This could include variation to the system to deliver on agreed change to

support new international trading relationships and/or the negotiated relationship with the European Union.

163. These powers could accordingly be used to revise requirements for the carrying out of conformity assessment procedures. Specific examples of how this power might be used include to:

a) alter how assessments of quality management systems are carried out;

b) alter details of whether and if so how such bodies should carry out surveillance to ensure that the manufacturer is continuing to comply with the quality management system;

c) alter requirements for the assessment of technical documentation;

d) specify the procedures which must be followed in relation to devices which incorporate tissues or cells of human origin or which incorporate medicinal products;

e) specify any specific requirements for the assessment of software and artificial intelligence.

(1)(c) who may carry out such assessments, including provision about the appointment of one or more persons (whether or not established in the United Kingdom) who meet criteria set out in the regulations—

a. to assess whether relevant requirements are met in relation to medical devices, and

b. if appropriate, confirm that they are.

164. This work is currently done by third party conformity assessment bodies, known in the EU as notified bodies. At the end of the Transition Period, UK notified bodies may lose their EU wide status depending on the nature of any agreement reached with the EU during the Transition Period. In these circumstances the Secretary of State would need a power to ensure this function can be undertaken by a UK-based set of bodies.

165. This power will therefore enable regulations to:

a) appoint persons (who might be similar to the existing notified bodies or differently constituted) to carry out conformity assessments of medical devices; such persons would determine whether devices meet the general performance and safety requirements (or essential requirements);

b) specify the kind of certificate to be provided if those devices meet those requirements;

c) set the criteria which these bodies have to meet such as:

i. the number of qualified staff, the nature of those qualifications and ongoing training requirements;

ii. where the body's staff may be based;

iii. any limitations on the body's corporate structure;

iv. how such bodies ensure independence from the industry;

v. how such bodies ensure confidentiality;

vi. how such bodies should deal with risk and liability;

vii. the financial requirements for such a body;

viii. documentation such bodies may be required to keep.

d) impose obligations on those bodies to ensure they cooperate with the Secretary of State for example where the Secretary of State wants to carry out an audit to ensure that a body is meeting its obligations

e) impose any additional obligations on such bodies related to whether such a body can carry out assessments under the legislation of another state under the terms of an international agreement.

(1)(d) treating confirmation that relevant requirements are met by one or more persons who are not appointed under provision made in reliance on paragraph (c) in the same way as confirmation given by a person who so is appointed

166. This power could be used to recognise the validity for the UK market of conformity assessments carried out by bodies based outside the UK so as to ensure that relevant requirements have been met in relation to medical devices.

167. This could be required to support new international trading relationships after the end of the Transition Period.

168. The power is unlikely however be used to set out detailed practices or procedures for these bodies (such as those set out for UK appointed bodies above). Such practices and procedures as a basis for enabling the UK to recognise the conformity assessment of the device carried out by such a body are likely to be set out in any international agreement and would apply as a matter of international law.

(1)(e) the making of declarations confirming that device requirements are met

169. This power relates to the making of a declaration of conformity by a manufacturer to the effect that their device meets relevant standards or requirements. This power may be used in relation to all classes of device or only in relation to those devices where the manufacturer is not required to seek certification by a conformity assessment body.

170. The power could therefore be used to impose a requirement to draw up such a declaration and to specify the content of such a declaration. This requirement currently exists as a matter of EU law so a power to amend and update this requirement and the contents of the declaration will be important to ensure both rigour in the conformity assessment process and to give effect to any future conformity assessment improvements required by the Government.

(1)(f) requirements that medical devices carry evidence that relevant requirements are met, including evidence that confirmation has been given as mentioned in paragraph (c) or (d)

171. This power is most likely to be used to specify the mark to be placed on the device and possibly an identifying number of a conformity assessment body that has assessed that device. Currently medical devices which meet the requirements of the current Directives are “CE” marked and, where appropriate, contain a notified body number.

(1)(g) the packaging of medical devices, and information, labelling or instructions to be supplied on, with or in relation to them

172. This power would allow the Secretary of State to specify requirements for labelling and instructions for use for devices prior to placement on the UK market, including where devices are produced against agreed standards outside of the UK.

173. For example, the power may be used to:

a) specify the medium, format, content, legibility and location of a label or of the instructions for use;

b) specify specific markers or numbers which must appear on the label such as the serial number, lot number of the device, the unique device identifier or expiry date;

c) specify the details which must be present on a label e.g. the name and trade name of the device, the name and registered trade name or mark of the manufacturer.

d) specify where a label should be placed when it is not possible to place it on the device itself;

e) specify which labelling requirements co-packaged (devices packaged with medicines) should meet;

f) specify the language requirements for labels and instructions for use;

g) specify labelling requirements for devices which require sterile packaging.

(1)(h) one or more registers of medical devices, their manufacturers or their suppliers, including provision -

i. Conferring functions relating to establishing and maintaining a register,

ii. requiring information of a sort specified in the regulations in relation to a medical device ("relevant information") to be entered in a register,

iii. permitting or requiring some or all relevant information entered into a register to be made publicly available

174. This would allow the Secretary of State to make provision relating to the registration of medical devices, those who manufacture them and other actors in the supply chain.

175. This limb of the power could be used to make provision creating such registration systems, including in relation to devices themselves specifying:

a) what must be provided in terms of information about the device. This could include some of the information discussed above relating to labelling, namely matters such as the UDI and serial numbers;

b) the device model, catalogue number, nomenclature code;

c) information about certificates issued by conformity assessment bodies;

d) the class of the device;

e) whether the device is a reprocessed single use device.

176. In relation to registering manufacturers, their representatives or other economic operators the power could be used to specify the name and address details which need to be provided.

177. The power also allows for the Secretary of State to make provision that information included on a register be made available to the public.

178. It should be noted that the exercise of this power to establish a UK register(s) of devices will be contextualised by the nature of the UK's trading relationship with the EU and associated data access.

(1)(i) investigations into or evaluations of the safety, performance or clinical effectiveness of medical devices,

179. This limb of the power would allow the Secretary of State to make provision regarding the investigation and/or evaluation of the safety or performance of medical devices.

180. Currently, medical devices are required to undergo a clinical evaluation to confirm that essential requirements relating to safety and performance are met, in line with the Annexes to the Directives (in particular Annex X to Directive 93/42/EEC). A clinical evaluation must be based on clinical data, following either a clinical investigation into the specific device, or a review of clinical data in relation to a device that has been demonstrated to be of adequate equivalence. The new EU Regulations 2017/745 and 2017/746 include more stringent requirements relating to clinical evaluations and investigations.

181. Accordingly, this power could be used to do the following:

a) introduce bespoke requirements for clinical evaluations/investigations into emerging types of device that may not neatly fit within the current framework, for instance, devices that incorporate some level of artificial intelligence. This would both support the UK life sciences sector, and enable the public to access innovative medical devices;

b) respond to new information relating to high risk medical devices which may be done by implementing more stringent/bespoke clinical evaluations/investigations;

c) make provision relating to the recognition of clinical evaluation/investigations carried out internationally, where required as part of international trading arrangements with third country partners and/or as part of any negotiated future relationship with the European Union.

(1)(j) surveillance of the market in medical devices

182. This limb of the power would allow the Secretary of State to make provision regarding the surveillance of medical devices in order to ensure patient safety.

183. This power could be used to specify action the Secretary of State could take for the purposes of conducting market surveillance such as:

a) imposing post-market surveillance obligations on manufactures such as providing specific post-market surveillance plans and reports to the Secretary of State and taking relevant action to correct problems detected by those reports.

b) conducting assessments into trends and taking action or requiring action to be taken as a result of that assessment;

c) taking action in response to field safety corrective actions taken by the manufacturer;

d) carrying out inspections, drawing up reports for economic operators and carrying out periodic reviews of the system and publishing those reviews.

Clause 14 – Fees, information, offences

(1)(a) about the charging of fees in connection with the exercise of a function conferred by a relevant provision, including the charging of fees by a person appointed under provision made in reliance on clause 13(1)(c)

184. This power enables the Secretary of State to make changes to current charging regimes for medical devices. Currently statutory fees are charged for:

a) registration of certain categories of device,

b) for assessing clinical investigation notices and

c) for auditing notified bodies.

185. The Government requires this power in order to revise and extend these fees to ensure the effective operation of the MHRA and its capacity to recover costs in delivering a critical public service for medical devices.

186. Additionally, we could use this power to introduce new fees, following appropriate public consultation, to support that system as it expands or otherwise changes to increase its response to protecting patient safety.

(1)(b) about the recording of information regarding the safety and efficacy of medical devices, including the extent to which relevant requirements that apply in relation to the devices are met

187. This power will enable the Secretary of State to make provision relating to the recording and keeping of specified information by economic operators about the safety and effectiveness of medical devices, as well as whether or not they meet relevant requirements. This information would be required to be kept by the manufacturer (or other economic operator) and be available to the Secretary of State for a specified period of time (10-15 years) after the device has been placed on the UK market and might include documents such as the declaration of conformity, technical documentation about the device and examination certificates.

188. The ability to make provision of this kind is essential in order to support the Secretary of State's role in regulating medical devices, particularly in carrying out market surveillance and enforcement.

(1)(c) permitting or requiring such information to be disclosed to the Secretary of State or to a person appointed under provision made in reliance on clause 13(1)(c)

189. This power will for example enable the Secretary of State to require manufacturers to disclose information about devices to persons appointed to carry out conformity assessment procedures.

190. This power is necessary to ensure that, where bodies have been appointed to carry out conformity assessments, they have the requisite power to obtain information in order to carry out that function. Where the Secretary of State performs that function it would be equally important that this information can be freely disclosed to the Secretary of State.

(1)(d) amending the Schedule to the Medical Devices Regulations 2002 (list of regulations the breach of which is an offence under Regulation 60A) (as inserted by Schedule 2 to the Bill)

191. This power will enable the Secretary of State to make amendments to the last Schedule to the Medical Devices Regulations 2002, thereby ensuring that future regulations made under clause 12(1) do not fall outside of the criminal offence framework. This Schedule is being inserted by Schedule 2 to this Bill and will list which provisions of the regulations the breach of which is a criminal offence under Regulation 60A of the Medical Devices Regulations 2002 (also inserted by Schedule 2 to this Bill).

192. By contrast, clause 14(1)(d) will enable the Secretary of State to maintain a transparent framework for criminal offences, where provisions to which criminal sanctions attach are clearly set out in legislation. This will ensure greater legal certainty for both industry and the Secretary of State.

Clause 15 – Emergencies

(1) Regulations made under clause 12(1) may provide for the disapplication of a medical devices provision in circumstances which give rise to a need to protect the public from a risk of serious harm to health

(2) Regulations made in reliance on clause 15(1) may provide for the disapplication to be subject to –

(a) conditions set out in the regulations

(b) conditions set out in a protocol published by the Secretary of State.

(3) where regulations made in reliance on subsection (1) provide that the Secretary of State may publish a protocol setting out conditions, the regulations must provide –

(a) that the Secretary of State may withdraw or amend the protocol and

(b) that the protocol is to have effect only for a period of time specified in the protocol

193. This power allows the Secretary of State to respond to public health emergencies (such as, for instance, a pandemic flu outbreak) by relaxing requirements that must be met by medical devices before they can be supplied. In some circumstances the Secretary of State may issue a temporary supply protocol that must be met in order for devices that do not conform the relevant requirements to be supplied.

194. The power could be used pre-emptively or reactively. Pre-emptively would mean making provision in anticipation of a future crisis and these provisions would become active when specified conditions are met; reactively would mean making provision to deal with an unfolding situation with the provision to take immediate (albeit temporary) effect.

195. The MDRs already contain provisions that allow the Secretary of State to respond to ease device requirements in the interests of the protection of health. Regulation 12(5) of the MDRs in particular provides that the Secretary of State can, following a duly justified request and in the interests of the protection of public health, authorise the placing on the market of a medical device notwithstanding that certain requirements relating to compliance with essential requirements and CE marking have not been met. However, we still require this new power in order to make further amendments to this provision if needed.

196. We could use this power to respond to the following situations:

a) A shortage of medical devices resulting from stocks being damaged by an emergency; and

b) The outbreak of a pandemic resulting in an urgent need for greater numbers of medical devices. Some medical devices, for instance protective medical clothing and gloves and syringes, would be key in prevention of transmission, treatment and the administration of vaccinations.

PARAGRAPH 9 (1) OF SCHEDULE 1

9 (1) The Secretary of State may by regulations ("supplementary regulations")—

(a) make provision as specified in paragraphs 10 to 12 supplementing that made by this Schedule;

(b) make provision that is consequential on or incidental to that made by this Schedule.

(b) make transitional, transitory or saving provision (in respect of supplementary regulations that have already been made).

197. This power allows the Secretary of State to make regulations that supplement the new civil sanction regime for medical devices introduced by this Bill. As explained above, under the new civil sanctions regime, the Secretary of State will be able to:

a) impose a monetary penalty on a person where he is satisfied beyond reasonable doubt that the person has committed an offence,

b) accept an enforcement undertaking offered by a person who he reasonably suspects has committed an offence; and

c) where a person has been served with a monetary penalty, serve an enforcement costs recovery notice on that person.

198. This regulation making power is confined to provisions relating to the following aspects, which limits how it can be used by the Secretary of State. We have set out these provisions below in paragraphs 10 to 12.

Paragraph 10 – monetary penalties and costs

199. This paragraph sets out the matters in relation to the Secretary of State's power to impose a monetary penalty under paragraph 1 or costs under paragraph 6 in respect of which supplementary regulations under paragraph 9(1) can make provision. Such matters include:

a) Early payment discounts

i. This power could be used to specify that a discount on the amount of monetary penalty will be available where an early payment is made. This power is subject to the restriction at paragraph 10(2), which provides that such provision cannot provide for interest or other penalties for late payment which would exceed the amount of the penalty or costs.

b) Payment of interest, or other financial penalties for late payment

ii. This power could be used to set out what interest rates are applicable, or what other penalties attach, to late payment.

c) Enforcement

iii. This power could set out how payment of a monetary penalty or costs will be enforced and, as set out at paragraph 10(3), may include provision that penalty or costs be recoverable as a civil debt.

Paragraph 11 - Enforcement undertakings

200. This provision sets out the matters in respect of which supplementary regulations may make provision in respect of enforcement undertakings, in particular provision:

a) for the procedure for entering into an undertaking;

b) as to the terms of an undertaking

c) publication

d) variation

e) circumstances denoting compliance;

f) monitoring of compliance;

g) certification that an undertaking has been complied with ;

h) relating to appeals against refusal to give such certification;

i) regarding inaccurate or misleading information in relation to an undertaking; and

j) regarding part-compliance.

Paragraph 12 – Appeals

201. This paragraph provides that supplementary regulations can make provision in respect of an appeal against the imposition of a requirement or the service of a notice (so, for instance, the imposition of a monetary penalty or an enforcement costs recovery notice), in particular:

a) Provisions suspending any requirement or notice pending the outcome of the appeal,

b) Provision as to the powers of the tribunal to which the appeal is made. This could include, but is not limited to, giving the tribunal a power to withdraw or confirm the requirement or notice, take steps that could be taken by the Secretary of State in relation to the act or omission that led to the requirement or notice being imposed / issued, and to remit the decision as respects the requirement or notice to the Secretary of State.

PARAGRAPH 13 OF SCHEDULE 1

13(1) The Secretary of State must prepare and publish guidance as to:

(a) the sanctions that may be imposed on a person who commits an offence under section 23 or regulation 60A of the Medical Devices Regulations 2002;

(b) the action that the Secretary of State may take in relation to such a person;

(c) the circumstances in which the Secretary of State is likely to take any action.

202. This creates a duty on the Secretary of State to publish guidance setting out in greater detail how the civil sanctions regime will operate. Sub-paragraphs (2) to (4) set out more specifically the matters that must be covered in such guidance.

203. The guidance may, for instance, state that the Secretary of State is unlikely to impose a monetary penalty when alternative enforcement measures are deemed more appropriate. Or, for example, if the subject is a first time offender and can evidence that remedial measures have been put in place to bring their organisation into compliance with the regulations.

Paragraph 13 (2) – Monetary penalties

204. This paragraph requires the Secretary of State to include in guidance information about how the Secretary of State will use the power to impose a monetary penalty, including information about circumstances in which a penalty may not be imposed, how a penalty will be calculated, how liability for a penalty may be discharged and rights of representations, objections and appeal.

205. For example, the guidance may specify the following matters when setting out how monetary penalty amounts are to be determined:

- aggravating and mitigating factors;
- seriousness of the breach leading to the imposition of the monetary penalty, including resultant risks to safety;
- size of the organisation (which may be measured by turnover);
- financial loss associated with a related product recall;
- any relevant recent convictions and / or a history of non-compliance;
- economic benefit derived from the offending; and
- public interest factors, including the need for the penalty to have real economic impact versus the organisation's ability to pay.

206. In terms of rights of representation, objections and appeals, the guidance may for instance provide that the Secretary of State will:

- notify the person of its intention to serve the notice;
- provide an opportunity to make representations in writing;
- give the person a specified timeframe within which to make representations;
- consider the representations received before making a final decision on whether to serve the penalty
- notify the person of the final decision
- give concise reasons for doing so

207. The guidance will also set out the appeals procedure (that will be established by supplementary regulations pursuant to paragraph 9 of Schedule 1 to this Bill (and as detailed in paragraph 12)).

Paragraph 13 (3) – Enforcement costs recovery notices

208. This paragraph requires the Secretary of State to include in guidance information about how the Secretary of State will use the power to serve an enforcement costs recovery notice (such a notice can only be served where a monetary penalty has already been issued). This will include information about the circumstances in which such a notice may not be served, the amount a person will be required to pay and how that amount is determined, how liability can be discharged and rights of representations, objections and appeal.

209. For example, the guidance may state that in calculating enforcement cost recovery notices, the Secretary of State will conduct a costing exercise which details the number of personnel, their pay rates, number of hours worked on a given case. Investigation, administration and legal/expert advice costs will be included in the calculation.

210. In terms of rights of representation, objections and appeals, the guidance may for instance provide that the Secretary of State will:

- notify the person of its intention to serve the notice
- provide an opportunity to make representations in writing;
- give the person a specified timeframe within which to make representations;
- consider the representations received before making a final decision on;
- whether to serve the recovery notice;
- notify the person of the final decision; and
- give concise reasons for doing so.

211. The guidance will also set out the appeals procedure (that will be established by supplementary regulations pursuant to paragraph 9 of Schedule 1 to this Bill (and as detailed in paragraph 12)).

Paragraph 13 (4) – Enforcement undertakings

212. This paragraph requires the Secretary of State to include in guidance information about how the power to accept an enforcement undertaking will be used. For example, the guidance may state that in deciding whether to accept an enforcement undertaking offer, the Secretary of State will likely take into consideration the following:

- whether the offer is forthcoming early and proactively;
- whether the Secretary of State is confident the terms of the enforcement undertaking will be complied with;
- The Secretary of State considers the enforcement undertaking to be the correct regulatory outcome taking into account:
    - the nature of the offence and its impact
    - other forms of enforcement available
- the offer is above what the company would normally need to do to comply;
- the offer is given in good faith; and
- the offeror makes a positive commitment, at the right company level to stop the offending conduct or alleged breach and to maintain compliance.

213. In contrast, the guidance may state, for instance, that circumstances where the Secretary of State is unlikely to accept an offer of an enforcement undertaking include:

- where the Secretary of State has already started legal proceedings;
- where the offence was intentional or of the most severe safety impact;
- where the Secretary of State has already decided that a prosecution is appropriate in the public interest;
- the offer contains a clause denying liability; and
- any clause that sets up defences for possible breach of an enforcement undertaking.