Title: Medicines and Medical Devices Bill **IA No:** 9556 **RPC Reference No:** RPC-4422(1)-DHSC **Lead department or agency:** Department of Health and Social Care **Other departments or agencies:** Department for Environment, Food and Rural Affairs plus the Medicines and Healthcare Products Regulatory Agency	**Impact Assessment (IA)** **Date:** 10th February 2020 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Primary legislation **Contact for enquiries:**

Summary: Intervention and Options

RPC Opinion: Green

Cost of Preferred (or more likely) Option (in 2019 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status** Qualifying provision

What is the problem under consideration? Why is Government intervention necessary?

The regulation of medicines, medical devices, clinical trials and veterinary medicines has been a matter of EU competence since the UK joined the EU. The legislative frameworks are in the Human Medicines Regulations 2012 (HMRs), the Veterinary Medicines Regulations 2013 (VMR), the Medical Devices Regulations 2002 (MDRs) and the Medicines for Human Use (Clinical Trials) Regulations 2004 (CTRs). At the end of the transition period the EU (Withdrawal) Act 2018 (EUWA) will have preserved these frameworks as "retained EU Law" and supporting legislation will ensure they can operate effectively after the UK leaves the EU. But the EUWA will repeal the legislation allowing these frameworks to be amended. This Bill will replace these powers to ensure the UK can maintain an up to date, dynamic system for regulating these sectors as well as enacting changes to medical devices enforcement and information sharing powers.

What are the policy objectives and the intended effects?

The objective is to have a legal mechanism to amend the existing regulatory frameworks. The current power (section 2(2) of the European Communities Act (ECA)) will be removed at the end of the transition period. Without equivalent delegated powers, the UK Government and Northern Ireland would lose the ability to make changes to these regulations without primary legislation. This would prevent the maintenance of a dynamic, fit for the future regulatory system capable of adjusting for future innovation, with expected negative impacts on patient outcomes, population health and the UK's competitiveness in the food and life sciences sectors.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1 – Preferred option: This IA presents one option - delegate powers to allow, where necessary, changes and updates to be made to the HMRs, CTRs, MDR and VMR - and compares it to the dual baselines of the static acquis and do nothing (additional details regarding baselines are provided later). Option 1 meets the objectives of maximising patient safety and positive outcomes, ensuring availability of cutting edge treatments and medicines continues and enables the UK to continue to compete in the life sciences and food sectors. There will be no impact against the static acquis baseline as the ability to amend these regulations currently flowing from ECA 2(2) would be maintained. When compared to the do nothing baseline, new regulation-making powers would enable the UK Government to update medicines, medical devices, clinical trials and veterinary medicines regulation to keep up with developments and innovations. This would maintain the UK's ability to compete in the life sciences sectors and contribute to availability of innovative treatments and patient safety.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** Month/Year

Does implementation go beyond minimum EU requirements?		N/A		
Is this measure likely to impact on trade and investment?		N/A		
Are any of these organisations in scope?	**Micro** Yes/No	**Small** Yes/No	**Medium** Yes/No	**Large** Yes/No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:**	**Non-traded:**	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:  Date: 10/02/2020

Summary: Analysis & Evidence

Policy Option 1

Description: Introduce new primary legislation versus the static acquis baseline

FULL ECONOMIC ASSESSMENT

Price Base Year 2018	**PV Base Year** 2020	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate:**

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised costs by 'main affected groups'

There is no monetised impact of the proposed powers as the UK Government would continue to implement any desired changes via secondary legislation, with the only difference being the power used is in this Bill as opposed to Section 2(2) of the ECA.

Other key non-monetised costs by 'main affected groups'

There may be limited costs associated with the implementation of the Medical Devices proposals (Enforcement Powers and Information Sharing).

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	Unknown, likely small			

Description and scale of key monetised benefits by 'main affected groups'

There is no monetised impact of the proposed powers as the UK Government would continue to implement any desired changes via secondary legislation, with the only difference being the power used is in this Bill as opposed to section 2(2) of the ECA.

Other key non-monetised benefits by 'main affected groups'

There are unquantified benefits associated with the implementation of the Medical Devices proposals (Enforcement Powers and Information Sharing).

Key assumptions/sensitivities/risks	**Discount rate (%)**	3.5%

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			**Score for Business Impact Target (qualifying provisions only) £m:**
Costs:	**Benefits:**	**Net:**	

Summary: Analysis & Evidence

Policy Option 1

Description: Introduce new primary legislation versus the do nothing baseline

Price Base Year 2018	**PV Base Year** 2020	**Time Period Years**10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate:**

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised costs by 'main affected groups'

We have not identified any monetised costs of pursuing option 1 versus the do nothing baseline.

Other key non-monetised costs by 'main affected groups'

We have not identified any non-monetised costs of pursuing option 1 versus the do nothing baseline.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

The powers within the Bill ensure that the UK retains the ability to amend the HMRs, CTRs, MDRs and VMR as currently allowed for under section 2(2) of the ECA, which the EUWA will repeal. The benefits can be summarised at a high level as retaining the ability to make virtually any changes to the HMRs, CTRs, VMR and MDRs. It has not been possible to quantify the majority of the benefits at this stage given this is primarily enabling primary legislation, non-monetised benefits are noted below.

Other key non-monetised benefits by 'main affected groups'

Businesses, including medicines and medical devices manufacturers, the life sciences, food and academic and research sectors, would all benefit from operating within a dynamic, flexible, regulatory system with the ability to adjust for innovations or market developments. This could contribute to reduced costs of regulatory activity and facilitating business exploiting the new and innovative opportunities. Patients' access to innovative, cutting-edge treatments would not be impeded and the risk of unintended harm to consumers of animal-based food products could be mitigated, along with the resulting negative impacts on public health that could have transpired.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

Lack of certainty around future changes to domestic legislation that may be required in lieu of future development in the medicines, medical devices and clinical trials sectors, and therefore the extent and nature of future changes pursued. With the exception of specific medical devices proposals, changes enabled by the powers in this Bill will be made via secondary legislation at a later date, which will be accompanied by a full economic appraisal.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			**Score for Business Impact Target (qualifying provisions only) £m:**
Costs:	**Benefits:**	**Net:**	

Evidence Base (for summary sheets)

1. The Medicines and Medical Devices Bill will put in place the tools necessary for the UK to achieve the Government's vision for a world-leading, dynamic system of medicines regulation. This will allow the UK to continue benefitting from the opportunities brought by progress in the medicines sector and maintain competitiveness in this space.

2. This impact assessment (IA) covers the powers within the Medicines and Medical Devices Bill that will enable changes to be made to the Human Medicines Regulations 2012 (HMRs), the Veterinary Medicines Regulations 2013 (VMR), the Medicines for Human Use (Clinical Trials) Regulations 2004 (CTRs), and the Medical Devices Regulations 2002 at the end of the transition period.

Overview of current regulations

3. The Human Medicines Regulations 2012 (HMRs) set standards to protect public health and ensure that medicines are safe and effective. These regulations cover the licensing, manufacture, advertising, labelling, distribution, sale and supply of medicinal products in the UK. This includes pharmacovigilance to detect any safety issues with products. They also set rules governing which products can be prescribed, stored and administered by specified professionals in specified settings.

4. The HMRs convert the EU Medicines Directive[1] into UK law, as well as covering some additional areas of regulation. In an equivalent way, the EU Clinical Trials Directive, which regulates clinical trials involving human medicines, is transposed into UK law by the Medicines for Human Use (Clinical Trials) Regulations 2004 (the CTRs).

5. In the UK, all medical devices are currently subject to EU legislation as an area of joint competence with the UK. They are regulated under Directive 90/385/EEC on active implantable medical devices (AIMDD), Directive 93/42/EEC on medical devices (MDD) and Directive 98/79/EC on in vitro diagnostic medical devices (IVDD). These directives are transposed into UK law as the Medical Devices Regulations 2002 (MDR). The Medicines and Healthcare products Regulatory Agency (MHRA) is the national competent authority in the UK under a regulatory system that operates EU-wide.

6. Manufacturers of low risk devices (Class I medical devices and general IVDs) can self-declare conformity to the legislation before placing their product on the market. Higher-risk devices (such as Class IIa, IIb and III medical devices and in vitro diagnostic devices (IVDs) in List A and List B of Annex II of the IVDD) must be certified by an independent conformity assessment body, called a Notified Body (NB), before the product can be placed on the market. NBs are monitored by their national authority (the MHRA in the UK),

[1] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

following a process of designation which involves joint audits by two other national authorities and the European Commission.

7. The MDR apply in relation 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; exemptions. This often takes the form of direct reference to the Directives and their Annexes within the MDR.

8. It is necessary to maintain the ability to amend these regulatory frameworks once the UK has ceased to have recourse to use the section 2(2) power in the European Communities Act 1972 at the end of the transition period.

9. The Veterinary Medicines Regulations 2013 (VMR) set out the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration. This includes pharmacovigilance to detect any safety and efficacy issues with products. They also set rules governing which products can be prescribed, stored and administered by specified professionals in specified settings. The VMR convert the EU Medicines Directive[2] into UK law, as well as covering some additional areas of regulation.

10. The UK Government currently has powers to amend the HMRs, CTRs, MDRs and VMR through secondary legislation made under section 2(2) of the European Communities Act (ECA). By operation of the EU Withdrawal Act 2018 (EUWA), at the end of the tranition period the current power will be revoked. Section 2(2) ECA has been used for over 10 years to make changes to these regulatory frameworks, in order to give effect to changes to EU legislation and to keep up with changes in domestic practice, such as providing paramedics with prescribing rights. Please see the “previous use of equivalent powers” section for further detail and, where this was available, the outcome of appraisals undertaken.

11. Additionally, the “illustrative examples for how the powers might be used in the future” section describes changes that may be made going forward using the powers requested in this Bill to give an indication of the types of changes the powers may be used for. However, although we have sought to provide as much clarity as possible, policy development is at an early stage and so the descriptions remain indicative.

12. Any future changes implemented using the powers set out in this Bill would be implemented via secondary legislation and accompanied by a full economic appraisal. The exception is the medical devices proposals around Enforcement and Information Sharing powers, which are assessed in a stand-alone section “medicine devices appraisal”.

Scale and value of regulatory activity in the UK

13. The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK national regulator for human medicines, as well as medical devices, clinical trials and blood

[2] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.

products. During the transition period, the UK is treated as a member of the European Medicines Agency (EMA) and participates in the EU medicines regulatory network.

14. The primary role of the MHRA is to ensure that medicines supplied in the UK are safe and effective. The MHRA issued 1,900 licenses in 2017/18 including manufacturer and wholesale dealer licenses, and medicines licenses to manufacture, import and distribute active substances[3]. The licensing regime provides safeguards for patients ensuring that, once a licence is granted, the product meets appropriate standards of quality, safety and efficacy, that its use is clearly defined and that appropriate information is available for prescribers and patients. As part of the licensing process, the manufacturer or sponsor agrees to ongoing safety monitoring of product quality, manufacturing quality assurance and post-market surveillance.

15. The MHRA plays a key enforcement role, ensuring that the UK manufacture of medicinal products complies with approved quality standards, as well as ensuring the safety of the global supply chain. MHRA can suspend or revoke a licence to manufacture, import or wholesale distribute medicines if it identifies safety issues. MHRA carried out 1,700 inspections in 2017/18. It investigated 1,550 defective medicines reports and issued 15 drug alerts[2].

16. Securing global supply chains is another key area of MHRA business, with some estimated 70% - 80% of medicines used in the UK imported from other countries. Global strategic alliances have been agreed to harmonise standards, share information, co-ordinate inspection and enforcement, and inform the public on the dangers of falsified medicines and fake medical devices. In 2017/18, MHRA seized 9.5m falsified medical products with side effects including heart attacks, strokes and death[3].

17. The UK Life Sciences Sector also benefits from a sophisticated, proportionate and responsive medicines regulation system. The regulatory system ensures clinical trials and manufacturing of medicines and medical products meet quality and safety standards. It thereby safeguards the supply chain and provides manufacturers with a stable market to sell to. This is turn reduces business risks and costs. The Agency also provides expert scientific, technical and regulatory advice to support companies.

18. The UK Life Sciences Sector makes a significant contribution to the UK economy, as demonstrated below. The sector employs more than 40,000 people, and contributed £9.2 billion to the UK economy, representing 7.3% of UK manufacturing Gross Value Added (GVA) and 0.7% of GVA for the UK economy[4] in 2015. The UK has the second highest level of expenditure on health R&D behind the US.

19. The UK is also a key location for clinical trials, with a 3.1% share of patients recruited to global studies[3]. In 2014/15[5], clinical research activity supported by The National Institute of Health Research (NIHR) Clinical Research Network (CRN) generated £2.4bn GVA and 39.5k jobs. Furthermore, this activity generated savings of around £192m for NHS trusts

[3] Medicines and Healthcare products Regulatory Agency. Annual Report and Accounts 2017/18. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/728543/2018_Annual_Report.pdf.

[4] Office for Life Sciences. Life Science Competitiveness Indicators. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/706963/life-sciences-competitiveness-indicators-2018.pdf

[5] Currently the latest estimates available, an update is expected to be published in Autumn 2019.

(average revenue of £6.7k from sponsorship companies and pharmaceutical savings ~£5.2k per patient recruited to study).

20. The MHRA also promotes good practice in the safe use of medicines and medical devices and providing information to help inform treatment choices. It monitors adverse drug reactions through its Yellow Card scheme using reports from healthcare professionals and consumers.

21. The ability to update the HMRs, CTRs, MDRs and VMR will enable MHRA to continue its role as a forward-thinking regulator.

22. The Veterinary Medicines Directorate (VMD) is the UK national regulator for veterinary medicines. During the transition period, the UK is treated as a member of the European Medicines Agency (EMA) and participates in the EU medicines regulatory network. The VMD is also a leading regulator within the European system and undertakes a significant proportion of lead assessment work.

23. The primary role of the VMD is to promote animal health and welfare by assuring the safety, quality and efficacy of veterinary medicines, the market for which is worth an estimated £700m[6] in annual sales, while GVA of veterinary activities in the UK was £3.9bn[7] in 2018.

24. The VMD issued 223 marketing authorisations for new veterinary medicines in 2018/19. Marketing authorisations are issued to companies once they have demonstrated that their product is of the appropriate quality, can be used safely and will be effective when used in accordance with the label/leaflet instructions. This regime safeguards animal health and welfare, user safety, and consumer safety of those that eat the produce from animals; as well as playing a critical role in supporting the UK's agri-food industry. The meat and dairy manufacturing sectors contribute £6.3bn to the UK economy[8], while the whole agri-food sector contributed £121.6bn of GVA in 2017[9].

25. Following authorisation of products, the VMD monitors reports of suspected adverse events and reports of suspected lack of efficacy for veterinary medicines and examines the frequency of adverse events. The benefits of a product versus the risks are considered initially and then this analysis is re-examined at intervals to ensure it is appropriate for the product to remain available in its current form.

26. The VMD also ensures that the UK manufacture of veterinary medicines complies with approved quality standards, as well as ensuring the safety of the supply chain. The VMD can suspend or revoke a licence to manufacture, import, wholesale deal or retail in veterinary medicines if it identifies safety issues. The VMD carried out 1,424 inspections in 2018/19.

27. The VMD also has responsibility for the National Residues Control Plan. This plan demonstrates the UK has appropriate controls in place to safeguard consumers from residues of veterinary medicines to protect human and animal health, and to facilitate

[6] National Office of Animal Health (NOAH); https://www.noah.co.uk/about/industry-facts-and-figures/

[7] ONS low-level GVA estimates; https://www.ons.gov.uk/economy/grossdomesticproductgdp/datasets/ukgdpolowlevelaggregates

[8] Source: Defra Food Statistics Pocketbook, 2017; https://www.gov.uk/government/publications/food-statistics-pocketbook/food-statistics-in-your-pocket-food-chain

[9] Ibid

trade. This requires the UK to take over 30,000 samples per year from food producing animals to test for a wide range of active substances. Public confidence in the quality of animal products is a key factor in ensuring the commercial success of the UK farming industry in the face of intense competition from imported foods.

28. The ability to update the VMRs would enable the VMD to continue its role as a forward-thinking regulator. We will look to implement provisions that are in accordance with global standards, including reducing burden on industry and to tackle antimicrobial resistence.

Problem under consideration:

29. The EU Withdrawal Act 2018 (EUWA) has preserved the currently regulatory frameworks for human medicines, clinical trials, medical devices and veterinary medicines (the HMRs, CTRs, MDR and VMR) until the end of the transition period. Supporting legislation is also in place to ensure the UK legislation can operate effectively.

30. The current power to amend the UK Regulations (section 2(2) of the European Communities Act (ECA)) will be removed by operation of the EUWA at the end of the transition period. Without equivalent delegated powers, the UK would lose the ability to make changes to these regulations without primary legislation.

31. There are limited regulation-making powers available in the EUWA and the Medicines Acts 1968 and 1971. There are also some regulation-making powers in the amended HMRs, CTRs, MDRs and VMR which are contained in section 8(6)(a) EUWA[10]. For veterinary medicines, the only powers available are the limited regulation-making powers in the EUWA.

32. These powers are very piecemeal and by virtue of each being quite narrow they do not provide comprehensive powers by which all the necessary updates to human medicines legislation could be made. We do not consider that these powers taken cumulatively are sufficient to deliver our policy needs. Reliance on primary legislation as the vehicle for any change outside these limited powers would be highly likely to lead to an out-of-date and stagnating regulatory system for medicines, medical devices, clinical trials and veterinary medicines.

33. This Bill provides powers that can be used to ensure the UK remains at the forefront of the global life sciences industry. It allows our regulators, the Medicines and Healthcare products Regulatory Agency (MHRA) and Veterinary Medicines Directorate (VMD), to go even further in developing innovative regulation. This will cement our ability to enable early access to cutting edge technologies and break new ground in complex clinical trials.

34. Some of the major policies that would be enabled by powers in the Bill include:

- **Innovative regulation of novel therapies, precision medicines and complex medical devices.** The Bill confers powers that allow Government to make it simpler for NHS hospitals to manufacture and trial the most innovative new personalised and short life

[10] See annex A for further detail.

medicines, as their clinical uptake increases, and they require scaling out to clinic, hospital and theatre-based manufacturing facilities. This will place the NHS at the forefront of modern medicine – manufacturing specialist medicinal treatments at the patient's bedside, and delivering on the ambitions of the Life Sciences Industrial Strategy and commitments made in the Sector Deals;

- **Protecting public health.** We are committed to stopping medicines that are not authentic getting to patients, through a UK verification system if we do not remain part of the recently developed EU falsified medicines system. Similarly, we would wish to allow for a national registration scheme for online sellers if we are not part of the EU scheme. The Bill also enables provisions to be made to facilitate medicines and medical devices supply during events posing risk of serious harm to health. Future improvements to the pre and post-market assessment of medical devices to meet domestic safety priorities would also be possible;

- **A streamlined, internationally competitive approach to clinical trial regulation.** The Bill provides a mechanism for updating the existing framework, for example, to remove unnecessary and duplicative regulatory burdens for clinical trials, particularly the lowest-risk trials, and so make it easier for researchers and companies to rapidly trial new medicines while also ensuring we are consistent with global standards and best practice;

- **Supporting the availability of medicines.** We expect to continue to look at the range of professions able to prescribe and supply certain medicines to make the most effective use of the workforce and support patient access to medicines. We also want to enable all pharmacies to be able to utilise arrangements to support wider use of automation to bring increased efficiencies and improve accuracy, freeing up pharmacists' time for more clinical services; and

- **Developments in regulation of medical technologies.** This would allow the current regulatory framework to be improved in response to rapidly advancing innovations, including Artificial Intelligence. The MHRA and NHSX will develop proposals consistent with the ambition of the White Paper: Regulation for the Fourth Industrial Revolution

35. An inability to maintain a fit-for-the-future regulatory system would frustrate these objectives and potentially drive sub-optimal outcomes for industry, the public sector/NHS and patients. Furthermore, the Secretary of State for Health and Social Care has set out his vision for a world-leading and dynamic system of medicines regulation in the UK. The ability to make necessary changes to medicines regulation will be critical to achieving this.

Rationale for intervention:

36. New primary legislation is necessary to replace the broad regulation-making power currently available in section 2(2) ECA. This power will be repealed at the end of the transition period by the operation of the EUWA. In the absence of new powers, the majority of

changes[11] could only be implemented via new primary legislation which is highly likely to result in regulatory system stagnation.

37. The UK Government therefore proposes to create focussed delegated powers, that can be exercised to make changes to the current regulatory frameworks for medicines (human and veterinary), medical devices and clinical trials.

38. With the exception of the medical devices proposals assessed in more detail subsequently, any future changes implemented through secondary legislation allowed for by this Bill would have an accompanying, bespoke appraisal undertaken separately.

39. The need for new delegated powers in relation to human and veterinary medicines arises regardless of the outcome of the negotiation on the Future Relationship with the EU, as we will wish to amend and implement national policies that relate to medicines in order to respond to innovations and developments in this sector.

40. The vision for community pharmacy across the UK is one of expanding clinical services, especially in relation to medicines safety and optimisation, urgent care, and prevention, reducing pressures elsewhere in the health and care system.

41. To illustrate this for England, on the 22nd July 2019 the Department of Health and Social Care (DHSC) announced a new five-year deal for the Community Pharmacy Contractual Framework (CPCF). Together with NHS England and NHS Improvement, DHSC has worked with the Pharmaceutical Services Negotiating Committee (PSNC) to develop a programme to support transformation change within community pharmacy. This reflects the NHS Long Term Plan, which commits to making greater use of pharmacists' skills.[12] To this end, the NHS in England will continue to pay £2.592 billion per year for community pharmacy services for the next five years but will change the way funding is distributed across services, from dispensing to clinical services.[13]

42. Improving the efficiency of dispensing is central to this transformation. Regulatory changes permitting all pharmacies to utilise hub and spoke dispensing, if they wish, is part of the strategy to support the sector in this.

43. The following section describes previous uses of the powers exercised under the current legislation to give an indication of the type of measures implemented via this route in the past.

Previous use of equivalent powers

44. Between 2013 and the present, 10 amendments have been made to the HMRs. Of these, only 4 were deemed as having expected impacts significant enough to warrant a full IA being produced. The remaining 6 changes were determined to have no anticipated significant cost to business, the voluntary or the public sector and so no IA was produced.

[11] Excluding the small number of specifics allowed for by other legislation see annex A for more detail.

[12] NHS England, NHS Long Term Plan, January 2019. https://www.england.nhs.uk/long-term-plan/.

[13] https://www.gov.uk/government/news/negotiations-started-for-the-community-pharmacy-contractual-framework-2019-to-2020.

45. Of the 4 proposals that did have an associated IA, the aggregate NPVs over the 10 year policy lifetime ranged from -£9m to £82m. This range illustrates the possible scale of impacts based on previous changes made under equivalent powers. Annex B provides more detail on each of these measures.

46. Between 2013 and the present, two amendments have been made to the VMR. The first amendment brought in a number of minor changes to controls on veterinary medicines and improved the transparency and fairness of the fees system. The IA for this amendment showed that the expected impacts were very low, with an EANCB of -£0.077m, and a net present value of £0.085m. The other amendment was not deemed as having expected impacts on businesses, the voluntary or the public sector significant enough to warrant a full IA being produced. Annex B provides more detail on each of these measures.

Description of option considered:

47. This IA only presents one option – to propose delegate powers, to replace what will be removed at the end of the transition period via operation of the EUWA, to enable future changes to be made as required to the HMRs, CTRs, MDRs and VMR without requiring new primary legislation. **Throughout the IA, 'do nothing' is only considered as an illustrative baseline against which the impact of the preferred option is assessed.**

Option 1 – Preferred Option:

Human medicine regulations:

48. We are proposing to have a replacement focussed delegated power that would allow Ministers to use statutory instruments to bring forward necessary changes to the regulatory regime for medicines and clinical trials. Each future statutory instrument would be accompanied by its own bespoke economic appraisal.

49. This option best meets the policy objectives and largely replicates powers the UK currently has until the end of the transition period. With this option, the Government will be able to respond swiftly and effectively to emerging patient safety concerns, thereby maintaining a fit-for-purpose medicines regulation system.

50. It will also enable access to new and cutting-edge treatments for NHS patients to be maintained and so have positive health benefits. It will provide for the UK to maintain and increase its competitiveness by enabling us to keep up with international change.

51. Collectively, this mitigates the risk that UK businesses and NHS patients may be adversely affected by a disproportionate, static and out-of-date system for medicines regulation.

Medical devices regulations:

52. As with Human Medicine Regulations, this option best meets the policy objectives and largely replicates powers the UK currently has until the end of the transition period.

53. The UK is a world leader in the life sciences sector. In order to maintain this world leading status, the Government must be able to revise existing laws, and establish new ones, in order to adapt to regulate an evolving sector. The Government can envisage amending, or expanding, the laws and regulations in the three broad areas set out in the subsequent "Medical Devices appraisal" section.

54. In addition, more detailed discussion of the potential impacts of specific proposals related to Enforcement Powers and Information Sharing Powers is provided in the subsequent "Medical Devices appraisal" section.

Veterinary medicines regulations:

55. We are proposing to have a replacement focussed delegated power that would allow Ministers to use statutory instruments to bring forward necessary changes to the regulatory regime for veterinary medicines. Note that each future statutory instrument would be accompanied by its own bespoke economic appraisal.

56. This option best meets the policy objectives and largely replicates powers the UK currently has until the end of the transition period. With this option, the Government will be able to respond swiftly and effectively to emerging animal safety concerns and thereby maintain a robust and fit for purpose veterinary medicines regulation system.

57. This option will enable our regulatory framework to keep pace with developments in the field and provide clarity to industry, so that our approach is looked upon favourably in comparison with alternative systems and is acting simultaneously in the interests of animal welfare and pharmaceutical companies.

58. Collectively, this mitigates the risk that UK businesses and the animal industry may be adversely affected by a disproportionate, static and out-of-date system for medicines regulation.

Rationale and evidence that justify the level of analysis used in the IA

59. With the exception of proposals relating to Medical Devices, this is an impact assessment for primary legislation that introduces delegated powers to enable changes to be made to the existing regulatory framework after the end of the transition period. These are enabling powers and, while the primary legislation does not specify the precise detail of what future changes might be, the Bill does limit the situations in which the powers may be exercised as a safeguard to ensure that the powers are only used to update the current frameworks. Changes will be determined by future developments in the medicines sector as well as by continuing EU-UK talks outcomes.

60. For the Medical Devices Enforcement Framework and information sharing proposals only, this Bill will enact the proposals upon coming in to force and so there will not be opportunity for subsequent economic appraisal. As such, more detailed assessments of these measures are presented in separate sections throughout this IA.

61. Wherever feasible more detailed, quantified assessment compared to the static acquis baseline is presented, for example for the hub and spoke illustrative example. Impacts versus the do nothing baseline are described in as much detail as possible but not quantified in line with good practice for EU Exit IAs.

62. In addition, these delegated powers will be made available to the Devolved Administration of Northern Ireland allowing them to implement legislation for medicines regulation in areas of devolved competence.

63. Therefore, the aim of this legislation is to ensure the UK has all the necessary tools to enable continuing effective, proportionate and fit-for-purpose regulation of medicines in the future. This will avoid costs for patients and businesses, both in terms of real world impacts and a reduction in uncertainty as to whether the UK's medicine regulation can be updated in-line with developments in the sector.

64. In order to provide as full an appraisal as possible given the context set out above, the remainder of this IA is structured to first provide a high-level assessment of option 1 compared to both the static acquis and do nothing baselines. This is then followed by an assessment of the specific proposals related to hub and spoke dispensing and medical devices. Finally, we present a series of illustrative examples that more fully discuss ways in which the powers may be used in the future where the level of detail and knowledge currently available allows.

Impact of option 1 considered versus static acquis baseline

Clinical trials, human medicines, medical devices and veterinary medicine regulations - option 1

65. We have undertaken an initial assessment of the potential impact of option 1 compared to the static acquis and do nothing baselines. When compared to the static acquis baseline, the only impact of option 1 are costs and benefits due to the medical devices proposals that would be implemented via, as opposed to enabled by, this Bill. These are set-out in the following Medical Devices Enforcement Framework and information sharing appraisal section.

66. There would be no impact of any other aspect of option 1 in a static acquis scenario as we would continue to have the broad regulation making power found in section 2(2) of the ECA. Changes could continue to be made via secondary legislation using either section 2(2) of the ECA, or those proposed here in line with the focussed uses outlined in the Bill, with the only difference being the over-arching framework allowing us to implement secondary legislation.

Impact of option 1 considered versus the do nothing baseline

Human medicine regulations – option 1:

67. Under the "do nothing" baseline scenario the UK Government loses the ability to make further changes to the HMRs and CTRs at the end of the transition period. If option 1 were pursued in the do nothing baseline scenario it would give the UK Government the ability to make amendments (outside those limited changes allowed for by powers set out at annex A) to the HMRs and CTRs via secondary legislation.

68. This is considered critical if we are to avoid stagnation of the regulatory frameworks and would enable the Government to achieve the key purposes set out previously (enhancing patient safety and access to new and innovative treatments plus the competitiveness of UK-based companies in this field).

69. New and cutting-edge medicines could be introduced into the regulatory system in a timely manner to enable patient access and proportionality of regulation of currently regulated medicines could be maintained as new information becomes available.

70. To give a sense of the changes made to the HMRs in the past using section 2(2) ECA, a table setting out all these amendments is included at Annex B. Amendments have been made at an average rate of two per annum which is unlikely to be maintained if relying on primary legislation as the vehicle for change.

71. It is not possible to definitively list how the powers may be used in the future at this time. Instead, the following section sets out our assessment of the potential impacts of the proposals where there is relatively high surety around how the powers may be used going forward. Note that any changes made in the future via secondary legislation would be accompanied by the appropriate level of bespoke economic appraisal. Each proposal is separately compared to the dual baselines described previously and a summary of key groups likely to be affected is also noted.

Medical devices (high-level summary only, more detailed appraisal follows for the proposals that would be enacted via this Bill) – option 1:

72. When compared to the "do nothing" baseline, introducing this legislation (i.e. pursuing option 1) would:

- Maintain regulatory flexibility to introduce process changes to meet Government objectives, including those depending on the outcome of future negotiations both with the EU and elsewhere;
- Enable the Government to continue efficiently addressing issues where there is evidenced need for change within the healthcare system;
- Facilitate the UK maintaining its lead in innovation in technology and the life sciences;
- Allow MHRA to consolidate and expand its enforcement powers to drive compliance with medical devices regulation and enhance patient safety as a consequence; and

- Enable the MHRA to amend its information sharing capacity by deleting restrictions imposed in EU law after the end of the transition period, in the interests of medical devices vigilance and patient safety.

73. As previously described, the proposals relating to revising the existing framework of Enforcement and Information Sharing powers are being enacted as opposed to enabled by this Bill. As such these are assessed in more detail in the following Medical Devices Enforcement Framework and information sharing appraisal section.

74. Although the details of regulatory change that may be desired and or required in the future are not yet known, the broad costs and benefits are summarised below. In addition, there is a greater level of detail available around proposals for potential revisions to Enforcement and Information Sharing Powers. As such, the estimated costs and benefits of these 2 areas are explored more fully in the subsequent “Medical Devices appraisal” section of this IA.

Future Regulatory Change – Benefits

75. Allowing for future regulatory change to be made without the need for primary legislation enables any MHRA regulation of the sector to remain competitive in the future. This will enable the UK Regulations to adapt to innovations in the sector and let the sector innovate in the first instance.

76. Regulating the sector in the future can ensure the UK’s regulations accommodate world best practice and standards, ensuring we are competitive in our pursuit of free trade agreements. The benefit of enabling international trade agreements is that the UK industry could gain market share in other countries. Customers in the UK could also gain from greater price competition and choice.

77. Increased patient confidence and safety in the system, through greater post market surveillance, may reduce the cost of some administrative tasks by the regulator as consumers will have more confidence in their market transactions. Improved safety from any future change in regulations will have positive patient health impacts and potentially a learning benefit.

78. The ability for the MHRA to respond to developments in the MedTech sector will reduce the potential for any patient harm compared to a less well-regulated sector.

Future Regulatory Change – Costs

79. Any improvement in patient safety will be dependent on future compliance with such a system, and the associated cost of regulatory change for economic actors.

80. The MedTech sector will need to become compliant with any regulations in the future. The cost of this will be dependent on the nature of these regulations. As with all new regulations, the costs will require some transitional training and familiarisation and

investment in the necessary capital to gain compliance. The MHRA will have to take relevant action to ensure compliance with the new regulations.

Veterinary medicine regulations – option 1:

81. As with Human Medicines Regulations, pursuing option 1 in the do nothing baseline scenario would maintain the UK Government's ability to amend the VMR via secondary legislation. This would mitigate the risk of regulatory stagnation resulting from an inflexible regulatory system and allow Government to achieve the key purposes set out below in a timely and efficient manner:

    - Enhancing animal, consumer and environmental safety protections in connection with the effective regulation of veterinary medicines;
    - Availability of medicines, specifically to improve animal health and welfare; and
    - Innovation and improving the competitiveness of the regulatory environment for pharmaceutical companies and manufacturers.

82. This option mitigates the risk that the UK Government would not be able to maintain an effective, up-to-date system for medicines regulation. It would facilitate the introduction of innovative medicines into the regulatory system and the maintenance of proportional regulation for currently regulated medicines as new information becomes available.

83. It is not possible to definitively list how the powers may be used in the future at this time. Instead, the following section sets out our assessment of the potential impacts of the proposals where there is relatively high surety around how the powers may be used going forward. Note that any changes made in the future via secondary legislation would be accompanied by the appropriate level of bespoke economic appraisal. Each proposal is separately compared to the dual baselines described previously and a summary of key groups likely to be affected is also noted.

Overall assessment versus the do nothing baseline:

84. Overall, we have identified significant benefits of pursuing option 1 in the do nothing baseline scenario. These are primarily driven by enabling the UK Government to maintain an up to date and fit for the future system of regulation for medicines, medical devices and clinical trials. Implementing option 1 would also allow the UK Government to have a competitive regulatory regime that supports our negotiations on future trade relationships.

85. **On this basis option 1 is the preferred option in the do nothing baseline scenario.** The following section provides more detailed discussion around a series of illustrative examples for how the powers this Bill would provide for might be used in the future.

Medical devices appraisal

86. There are costs and benefits derived from the legislative provision on medical devices. The preferred option best meets the policy objectives. It largely replicates powers the UK currently has under section 2(2) of the European Communities Act; makes provisions to consolidate the existing framework of enforcement for medical devices; and revises current information powers to facilitate data sharing in relation to the safety of medical devices.

87. The UK is a world leader in the life sciences sector. In order to maintain this world leading status, the Government must be able to revise existing laws, and establish new ones, in order to adapt to regulate an evolving sector.

Revisions of the existing framework of Enforcement Powers

88. The Government is revising the existing framework of enforcement powers. Specifically, the Bill consolidates current enforcement powers and provides the Secretary of State with the ability to seek civil sanctions as an alternative to criminal prosecutions of offences. These revisions place the MHRA's enforcement powers on a more coherent and transparent footing and extend its range of enforcement options.

89. Firstly, consolidation of enforcement provisions supporting the regulation of medical devices. The Bill introduces an enhanced enforcement regime, which consolidates the existing powers to take enforcement action. The MHRA has various investigatory and enforcement powers to drive compliance, restrict market access or prosecute where required. This ensures the safety, quality and performance of medical devices. However, these powers are currently granted through several pieces of overlapping legislation, including the Medical Devices Regulations 2002 and the Consumer Protection Act 1987. Consolidation of these enforcement powers will provide greater transparency and certainty for industry with regards to their legal obligations and significantly improve the MHRA's ability to promote industry compliance and take swift and effective enforcement action when circumstances warrant it.

90. A handful of existing breaches of the regulations which are not criminal offences will now become criminal offences. The effect of the new criminal offence (regulation 60A of the Medical Devices Regulations 2002) inserted into the Medical Devices Regulations 2002 is that it will be an offence to contravene a prohibition or breach a requirement of a provision listed in a schedule to those Regulations. This preserves the status quo of offences, as failure to comply with such requirements is already an offence under section 12 of the Consumer Protection Act 1987 (offence against the safety regulations). However, the benefit of this new approach is that it provides greater clarity. Currently, a cross-checking exercise is required to determine whether a provision of the Medical Devices Regulations 2002 is "caught" by one of the parts of section 12. This change will set out clearly in the regulations which provisions result in the commission of an offence if breached.

91. All criminal offences will also have the option of enforcement through civil sanctions. The new civil sanction regime would enable the MHRA to impose a monetary penalty or accept an enforcement undertaking as an alternative to criminal prosecution in some

circumstances. An enforcement costs recovery notice can also be issued in order to recover the costs (including investigation, administration and costs of obtaining expert advice) incurred by the Secretary of State where a monetary penalty has been issued. Civil sanctions could be used for a breach of the medical devices regulations where it may not be considered appropriate to bring a full criminal prosecution. For example, where no harm has come to a member of the public but the breach could have been dangerous nonetheless. This will enhance the MHRA's ability to promote compliance with the devices regulations.

Appraisal of Costs and Benefits

92. Regarding medical devices, costs and benefits exist against the consolidation of existing powers and the introduction of civil sanctions.

93. DHSC/MHRA have not committed to publishing a full consultation on this Bill. This would prevent the ability of any consultation to ask stakeholders for input on specific parts of the policies because stakeholders would be less informed of how the policy will impact them compared to standard practice in consultations.

Revisions to the existing enforcement regime - Benefits

94. The consolidation of the enforcement powers in the Bill provides greater clarity for manufacturers and other actors in the supply chain. The purpose of this consolidation is that the medical device industry will be able to identify all their requirements more clearly, making it easier for all parties (MHRA, CPS and all stakeholders) to determine whether there has been a breach of the regulations. This clarification will also create greater transparency over which provisions of the regulations could result in the commission of an offence if breached and will enable the MHRA to secure compliance with the regulations more effectively. The benefit from this is threefold:

- Reduced public health risk – Manufacturers and other economic operators that have a better understanding of their responsibilities will have a reduced rate of non-compliance, potentially reducing any public health impacts.
- Compliance – There will be a greater rate of compliance within the industry as manufacturers and other economic operators will have a better understanding of their requirements.
- Prosecutions – There may be a reduced number of prosecutions against manufacturers and other economic operators because:
    - the consolidation of these regulations may act as a greater deterrent; and
    - increased transparency will enable manufacturers and other economic operators to more clearly understand their responsibilities

95. MHRA has sole responsibility for deciding what alternative enforcement measures to adopt in cases where MHRA decides not to prosecute. Therefore, the total number of prosecution cases bought should not be considered equivalent to the total level of non-compliance.

96. MHRA prosecutions for non-compliance are rare but do occur. Since 2008, the MHRA has brought 3 prosecutions, 2 of which ended in convictions, and one ended in acquittal. There was one prosecution brought by the Northern Ireland Department of Health and Social Services (NIDHSS) in Northern Ireland which was successful. The benefit from any reduced number of prosecutions is the additional capacity in the legal system, CPS and MHRA enforcement teams. Given that prosecutions are rare, and the cost of such cases are entirely dependent on their complexity and severity, data does not exist on the cost of such cases to the MHRA or the CPS.

97. Through greater compliance, there is the potential for improved public safety as the medical device supply chain will be more robust and secure. These safety impacts have not been quantified due to a lack of data and evidence on noncompliant devices that have caused patient harm.

98. The Bill also provides the MHRA with the ability to impose civil sanctions on manufacturers and other actors in the supply chain. The rationale for this new form of penalty is that it offers a clear alternative to resource intensive and costly criminal prosecutions. It is expected that the potential for civil sanctions will help achieve a high level of compliance. There is evidence from other regulators who have the option of civil sanctions that this is a more cost-effective and efficient route for tackling non-compliance.

99. There will be no change to the number of incidences/cases of non-compliance following this additional penalty. This is because these are new powers to enforce the existing requirements of those responsible in the supply chain. The Bill makes provision that the Secretary of State for Health and Social Care has discretion on the level of the fine associated with the sanctions, so there is the potential for the civil sanctions to act as a greater deterrent against breaches of the regulations than is the case with criminal prosecutions. When these monetary penalties are paid for by manufacturers, this will generate revenue for the Government and the taxpayer (an unmonetised benefit).

100. The number of civil sanctions expected to be imposed is not known, this is because reported incidences of non-compliance with the devices regulatory framework have not exhibited any set trend or pattern, making it difficult to project the incidences of non-compliance.

101. Notwithstanding the new method to ensure compliance, the MHRA will still ensure the a high standard of proof is met before taking any compliance action. This means that businesses will still be required to meet the same obligations before any action is taken by the MHRA - whether that be through a legal prosecution or a civil sanction. For instance, before issuing a monetary penalty, the Secretary of State must be satisfied that an offence has occurred beyond reasonable doubt, this is the same standard of proof that would be required in a criminal case. Therefore, we do not expect compliant businesses to incur any additional costs as a result of the introduction of civil sanctions.

102. The cost of implementing these civil sanctions will be lower than the current legal route as the MHRA will have the legal power to charge a fine without the need for extensive involvement by the courts. The involvement of the courts may only be required if an appeal is brought against the sanction, this is further explained in paragraph 117. This lower administration cost will be a benefit to the taxpayer. This is in line with other regulators.

103. Anecdotal evidence from other examples of civil sanctions being used in regulations have been positive, particularly those used as set out inthe Energy Related Products Regulations. The Post Implementation Review for this policy[1] described how some companies within this industry had subsequently became more aware of their obligations, as had others within the supply chain, with those companies subsequently achieving a high level of compliance. Other manufacturers explained that civil sanctions were easier to understand than other types of penalties.

Revisions to the existing enforcement regime – Costs

104. Transition costs for these policies are expected to be minimal, as most of the costs will relate to staffing costs for training and dissemination of information. There are no new administration tasks required.

105. It is possible that any transition costs can be outweighed by efficiency savings from the rationalisation of existing regulations (i.e. that there would be offsetting time savings for staff to check regulations on an ongoing basis). These benefits have not been quantified due to the nature of these benefits. For example, it is not known how frequently firms check regulations for the requirements and standards expected of them, furthermore this time is likely to vary significantly between firms of different sizes, considering the market for medical device manufacturers consists of firms of various sizes. These benefits are also likely to be experienced over a longer timeframe than the familiarisation costs – making any estimation of frequency difficult.

106. There may be some transitional costs for training the regulator's staff to fully understand the new civil sanction procedure. For example, the cost of lawyers drafting supplementary regulations; drafting guidance; and lawyers reviewing that guidance. These costs may be mitigated by time saved through dealings with the CPS.

107. Because the requirements and regulations for those involved in the medical device industry have not changed, there are minimal additional costs to the MHRA of ensuring compliance with the regulations as the manufacturers and other actors in the supply chain need to uphold the current standard.

108. Introducing the option of civil sanctions will make it simpler for the regulator to levy fines in the event of breaches, without needing to choose between taking no punitive action or a full criminal prosecution, which may not always be appropriate – particularly if the breach, however serious, did not actually result in harm to patients or the public. This should increase compliance with the regulations, while potentially reducing the number of criminal prosecutions and therefore the burden on the justice system.

109. In circumstances when a business has been non-compliant, they will need to face the cost of a civil sanction where one is imposed by the MHRA. Costs to non-compliant business are not considered societal costs as part of the appraisal but we include these for completeness. There are two tranches of costs in this circumstance:

1 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/498183/PIR_Ecodesign_for_Energy_Related_Products_Regulations_Accessible.pdf

- Preparatory work – this includes the costs to businesses of gathering and preparing data, documents and files to prove their compliance to the MHRA. Businesses will need to gather similar evidence for both a prosecution and a civil sanction, therefore these costs are not expected to change.

- Legal Costs – It is expected that legal costs (both the cost of using the legal system and legal fees) will be significantly lower as civil sanctions are imposed by the MHRA and will not involve a court process. The only circumstances in which we would expect there to be a cost to business for legal fees are if businesses choose to appeal the decision of the MHRA to lapply the civil sanction. If the business were to lose an appeal, the Secretary of State may choose to launch an enforcement costs recovery notice to recover the investigation, administration and legal advice costs of the case.

110. The number of civil enforcement actions is unlikely to grow in comparison to the number of criminal enforcement actions pursued. Approximately 2 cases per year receive serious consideration for referral to CPS for prosecution, but post assessment, alternative enforcement measures are decided upon by MHRA. Civil sanctions are more likely to result in a successful outcome versus the alternative enforcement actions currently available.

111. In the circumstance where a business was initially found to be noncompliant, but following an appeal was found to be compliant, the tribunal may have the power to make costs awards. This will be fully set out in supplementary regulations.

112. Industry will face costs to ensure compliance although this should be accounted for given there is no change to the original baseline, so this cannot be considered a direct cost of the policy.

Revisions to current Information Sharing Powers

113. The MHRA gains a significant amount of information from carrying out its regulatory and market surveillance functions. Within the NHS family, and the Government more broadly, there are organisations that will benefit from the greater availability of data which this provision in the Bill is intended to facilitate. Organisations that conduct research would also benefit from the availability of information on the operation of the market. The constraints on the ability of the MHRA to disseminate this information is due to commercial confidentiality currently provided for under EU legislation which will cease to apply at the end of the transition period. Legislative barriers to disclosure relating to confidentiality of information would continue as a matter of domestic law. This provision in the Bill is therefore intended, within certain limits relating to data protection and commercial confidentiality, to enable the regulator to share information it holds about medical devices with the wider NHS family, academia and, where warranted by safety concerns, the public; it will enable the MHRA to enhance market surveillance on devices, working with wider partners to protect patient safety.

Revisions to current Information Sharing Powers – Benefits

114. As these are permissive provisions, it is the MHRA's decision as to the how the information powers will be used (within the legal framework established by the Bill). The scale of the benefits of the information sharing powers will depend on how exactly they are utilised by the MHRA over time, the extent to which stakeholders engage with the information provided and how the provisions of the Act are used in the future.

115. The majority of the benefits under these provisions are non-monetary as the intention of the information-sharing powers is to improve patient safety outcomes.

116. Public and stakeholder engagement, including with patients and healthcare professionals, has indicated a strong desire for the MHRA to be more transparent regarding the data it holds on reported incidents with medical devices. Transparency schemes, aimed at improving devices safety data shared with stakeholders, are already operated by other international regulators. Existing exemplar schemes include the Australian Database of Adverse Event Notifications (DAEN) and the United States' Manufacturer and User Facility Device Experience (MAUDE). Data from these sources have been used to inform academia and policy decisions, for example reviews of these databases have been used in highly cited journal articles related to safety issues in breast implants[2] and occluder devices[3].

117. The sharing of information on devices with the NHS and, in some circumstances where necessary to warn of device safety risks, the public, will ensure that clinicians and the public are aware of urgent device safety risks and the corrective actions undertaken by manufacturers based on what has been reported to MHRA.

118. Academics may analyse the data and combine it with other data sources to identify other potential safety issues. We might expect that data could then be used to carry out further investigatory studies. These studies could be used by clinicians and regulators to inform their clinical practice and to make decisions about device safety.

119. At this stage, we cannot estimate how much demand there will be, from academics and the NHS, for the data provided by the MHRA. Use of the scheme will be kept under review and feedback obtained will inform future thinking in this area.

Revisions to current Information Sharing Powers – Costs

120. There will be no additional direct costs to business as the reports shared are already provided to the MHRA as part of its vigilance processes. There will be no additional cost to MHRA as the system will be provided for within existing resources.

121. Regulatory and clinical decisions about the availability and use of medical devices on patients will not result in any direct costs for patients. It is possible that over time patients will use the data to make decisions about whether to opt for certain devices or to inform a choice between one device and another. This is restricted to only providing safety information for the public where it is necessary to warn them. Information such as this will

[2] https://www.ingentaconnect.com/content/wk/prs/2017/00000139/00000005/art00001

[3] https://www.sciencedirect.com/science/article/pii/S0022522309003559

be captured over time as part of ongoing evaluation. The information and subsequent research on particular devices could lead to decreased demand indirectly for particular devices and therefore reduced profits for some businesses. However, these costs are likely to be outweighed by the public health benefit of ensuring devices are improved, and the potential consequential non-defined benefit to businesses of developing improved devices that meet higher safety thresholds that can then be marketed in the UK and elsewhere. As such, we are unable to monetise the costs to business of this policy.

Small and micro business assessment (SaMBA)

122. The number of small and medium businesses in the medical technology industry in the UK, according to the Office for Life Sciences, which will likely fall under the scope of parts of this legislation, is set out below. It would be disproportionate to outline how many small and micro businesses are affected by each individual proposal in the IA.

Med Tech Core	**SME**		**NON-SME**		**Total**	**Micro businesses: 1-9 employees**	
Number of businesses	2,264	87%	340	13%	2,604	1,422	55%
Turnover (£bn)	3.8	21%	14	79%	17.8	0.5	3%
Employment	31,153	32%	66,159	68%	97,312	4,899	5%
Med Tech Service & Supply Chain	**SME**		**NON-SME**		**Total**	**Micro businesses: 1-9 employees**	
Number of businesses	858	88%	121	12%	979	566	58%
Turnover (£bn)	1.3	29%	3.1	71%	4.4	0.2	4%
Employment	8,721	36%	15,829	64%	24,550	1,747	7%

Impact on Trade and Investment

123. The regulatory proposals in this IA could indirectly restrict products allowed on the market and therefore could impact trade. However, the severity of this impact is unknown and is likely to affect devices that do not meet the safety standards of the UK regulatory model. The impact is likely to be small and could be offset by investment in innovation due to improvements made to medical device technology as a result of this legislation.

Illustrative examples for how the powers may be used in the future

124. In this section we consider a series of illustrative examples for how these delegated powers may be used in future. For human medicines, these are:

- Dealing with public health emergencies
- Leafletting and labelling

- Introducing a registration scheme for online sellers of medicines
- Introducing a scheme to combat falsified medicine products
- Facilitate a distributed manufacturing model for products manufactured within or outside of clinical trials
- Hub and spoke

For veterinary medicines these are:

- Online retailing
- Pictograms

Human medicines regulations illustrative example i - dealing with public health emergencies

125. The current HMRs include provisions to remove certain regulatory requirements during a public health emergency (PHE). For the purposes of this document PHEs are defined as events that may cause serious harm to human health.

126. The ability to introduce further flexibilities during a PHE via secondary legislation is currently provided for under section 2(2) of the ECA. An example of a change we are already thinking about relates to Regulation 247 HMRs, which removes limits on circumstances in which prescription, pharmacy and over the counter drugs can be supplied where:

- There is a pandemic or risk of pandemic that poses a serious risk to human health; and
- The supply in accordance with a protocol approved by an NHS body or Ministers.

127. The dual criteria mean restrictions can only be loosened in the case of a pandemic, which is defined in the Standard Oxford English Dictionary as “(of a disease) prevalent throughout a country, a continent or the world”. In contrast “public health emergency” includes anything from a heatwave to environmental contamination to flooding to radiation incidents and many more.

128. Regulation 247 would not apply in a localised disease outbreak or any of these non-disease PHEs. We may therefore use the powers in this Bill to expand the criteria set out in Regulation 247 to ease the supply of prescription, pharmacy and over the counter drugs during non-pandemic PHEs. We anticipate the impact of any such expansion would be a reduction of business regulation and an improvement in health outcomes.

129. There would be no impact of option 1 compared to the static acquis baseline. The desired changes would continue to be made as required, with the only difference being the power to change the law would be provided for by this Bill.

130. When compared to the do nothing scenario, option 1 would maintain the UK Government’s ability to introduce further flexibilities during a PHE via secondary legislation. Because it is not possible to foresee all future PHEs, or to pre-empt how we might want to reduce

regulation to facilitate handling them, we cannot definitively set out the potential impacts of this.

131. Having the flexibility to introduce temporary relaxation of regulatory requirements during a PHE is expected to reduce the risk of harm to human and public health by delaying, or acting as a barrier to, access to medication. The aggregate scale of potential harm avoided will depend on the number and severity of future PHEs, which cannot be predicted.

132. We do anticipate that any use of the powers will have a deregulatory effect as they remove the requirement to comply with usual regulations in a PHE. However any changes would only apply temporarily in cases where they are required to prevent serious harm to human health or maintain, improve or protect public health.

Human Medicines Regulations illustrative example ii – leafletting and labelling

133. The current regulation around leafletting and labelling requires a hard-copy patient information leaflet to be included with every original box of relevant medicine supplied by manufacturers. Given the increasing appetite for digital information access, we could consider whether hard copy leaflets continue to be the most appropriate vehicle for delivering this information to patients.

134. An example of where we could legislate in this area is an information provision for “white-box” medicines. If a pharmacist is filling a prescription for 6 tablets, but the manufacturer sold the product in boxes of 10 tablets, the pharmacist will split the contents of the pack to dispense 6 of the 10 tablets in a plain white box. The original 10 tablet box is required under legislation to contain a patient information leaflet, but the repackaged 6 tablets dispensed to the patient is not. Therefore, patients receiving repackaged prescriptions will not receive a patient information leaflet under current regulations.

135. The Bill would allow us to propose a requirement for manufacturers to provide and maintain up-to-date statutory information about certain medicines on a variety of digital platforms and for all packs dispensed to signpost these resources. This might mean the regulations provide these changes in relation to a specific medicine only, a class of medicines or (at least theoretically) all medicines. This is necessary as we cannot foresee what medicines will be available in the future, nor whether information requirements might change for existing treatments if side-effects arise.

136. There is no impact of option 1 when compared to the static acquis baseline. The desired changes would continue to be made as required, with the only difference being the power to change the law would flow through the new delegated powers as opposed to section 2(2) ECA.

137. Conversely, option 1 would have an impact compared to the do nothing baseline. Implementing option 1 would maintain the ability to require, via secondary legislation, manufacturers to provide and maintain up-to-date statutory information about certain medicines on a variety of digital platforms and for all packs dispensed to signpost these resources.

138. The option of modernising processes by moving from hard-copy to digital provision of information would be kept open, as would the possibility of closing the information gap for "white box" medicines described in the illustrative example above. Furthermore, barriers to address any lag between pharmacies purchasing and dispensing boxes, with the associated risk that leaflets enclosed become out-of-date between the points of purchasing and dispensing, would not be increased.

139. Electronic delivery of the statutory information could ensure patient access to the latest safety information about their medicines. It could also empower patients with diverse abilities to access information about their medicines directly with the support of digital technology.

140. The impact on manufacturers (which would be assessed in full as part of the secondary legislation process) would comprise an upfront cost of establishing the digital platforms and familiarising staff with the new requirements plus the ongoing cost of staff time updating these. However, there may be ongoing benefits in potentially reducing production of hard-copy Patient Information Leaflets and replacing them with updates to the digital information provided. These could be of a similar scale to the costs described above, or even outweigh them over time depending on the amount of paper leaflets still produced. There will also be a new requirement for pharmacies to include a label sign-posting patients to digital resources where they split packs to fill prescriptions.

141. Ultimately, we anticipate patients will benefit from improved access to timely information about their medication and potentially avoiding adverse health outcomes if the current information gaps persisted. There may also be savings to manufacturers if there is a possibility of reducing the provision of hard-copy leaflets. These benefits will be balanced against the cost to manufacturers of providing the information digitally and to pharmacies of sign-posting these resources where they split packs.

Human medicines regulations illustrative example iii - introducing a registration scheme for online sellers of medicine

142. In July 2015[4] the EU introduced the introduction of an EU scheme for registration of online pharmacies requiring online sellers to register with the national authority, comply with certain standards and display a standard logo. However, this logo is copyrighted by the European Commission and participation in the scheme is dependent upon the outcome of the negotiations on the Future Relationship

143. This measure therefore provides a power to introduce a replacement national scheme, with flexibility to meet UK needs, There is therefore no impact of option 1 versus the static acquis baseline, where an assumption has been made that we would continue as a member of the EU scheme.

144. Conversely, option1 would have impacts compared to the do nothing baseline. The UK would maintain the ability to require through regulations for online sellers of medicine to register with the MHRA and display a common logo for authorised websites. This would

[4]https://www.gov.uk/government/news/new-mandatory-logo-for-selling-medicines-online

enable the UK Government to legislate to mitigate the risk of falsified medicines entering the UK supply chain and being dispensed to patients via unauthorised online sellers.

145. A further benefit of option 1 would be having the flexibility to design and implement a scheme tailored to the UK. There is a desire to be able to introduce additional safeguards or conditions as part of the scheme to prevent abuse of online sale and protect dispensers.

146. One such example might be to explicitly require additional steps alongside existing professional obligations to help protect the dispenser when deciding whether a medicine should be supplied to a patient, as they will have no face-to-face interaction with the patient.

147. This could act as an additional safeguard for the dispenser to ensure that the medicine they dispense reaches the intended recipient and would generate costs above those that would have been incurred without the change.

Human medicines regulations illustrative example iv - introducing a scheme to combat falsified medicine products

148. The EU Falsified Medicines Directive (2011/62/EU) (FMD) was adopted in 2011 and introduced new harmonised measures to ensure that medicines in the European Union (EU) are safe and that trade in medicines is properly controlled. The final part of the Directive, the 'safety features' Delegated Regulation (EU) 2016/161) came into force on 9th February 2019 and introduced a requirement for verification that medicinal products are not falsified throughout the supply chain. This included mandating:

- Packaging to include specific labelling including a unique 2D barcode for scanning;
- The set-up and ongoing management of the IT infrastructure and connections to that system (though with some flexibility over how it is implemented);
- Scanners to authenticate packs at all points in the supply chain; and
- Requirements on the supply chain to verify and decommission unique barcodes before the product is dispensed to the patient or if the product is no longer available for supply (e.g. recalls, or the product has been stolen so you want it blocked on the system to prevent unlawful supply).

149. The Safety Features Regulation came into force on 9th February 2019 taking direct effect in the UK. On the same day, the Human Medicines (Amendment) Regulations 2019 came into force amending the HMRs implementing the Delegated Regulation in the UK. The Regulations also introduce sanctions for breaches of the FMD requirements and implement flexibilities provided for in the Delegated Regulation to accommodate the characteristics of the UK supply chain.

150. This measure would provide the power for the Government to set-up a UK medicine verification system. As such, there would be no impact of option 1 versus the static acquis baseline.

151. When compared to the do nothing baseline, if option 1 were pursued, the UK would retain the ability to establish a requirement to verify that medicinal products are not falsified throughout the supply chain. This could reduce the prevalence of falsified medicines which present a risk to public health in the form of adverse reactions, dangerous ingredients, interaction with other medicine, no improvement in health condition, disincentive to take prescribed medicine and loss of faith in healthcare systems.

152. Businesses in the supply chain would remain assured that the products they are selling are genuine and the resource burden of recalling products would not increase as the system would continue to signal where stock is being held or if it is checked out and where.

Human medicines regulations illustrative example v - facilitate a distributed manufacturing model for products manufactured within or outside of clinical trials

153. Historically, medicines have been manufactured at a small number of facilities, released after testing and certification into the wholesale network and, due to a long shelf life, stored for extended periods in pharmacies and hospitals prior to use. Each manufacturer has a licence, a highly skilled “qualified person” (QP) to oversee activities, regulatory inspections etc. MHRA inspects and licenses these sites, which requires time, money and expertise. The inspection cycle is typically every 2-3 years but will vary according to the risk-profile of the site and products, and any issues identified.

154. Innovation in healthcare is moving to models such as:

- Personalised medicines manufactured close to the patient (in a clinic or hospital). Examples include cancer vaccines using the patient’s own tissue as a starting material, or 3D printed tablets with combinations of active ingredients unique to the patient’s needs.
- Medical gases, substances in a plasma state, cell-based and biological ‘advanced therapies’ with ultra-short shelf life (MHRA has knowledge of a product in development with a shelf life less than one minute. The product requires manufacture in an operating theatre and is administered immediately to the patient).

155. As clinical uptake increases, personalised/short life medicines require ‘scale out’ to many (potentially hundreds) of clinic/hospital/ theatre-based manufacturing facilities. With these products it would not be feasible to require a traditional manufacturing licence and inspections prior to the release of the product for each clinic/hospital/theatre.

156. As such, in order to maintain a regulatory system that is fit for purpose and in support of medical innovations it is proposed that this power is used to facilitate a distributed manufacturing model, initially for products manufactured for use in clinical trials. This will allow the holder of a manufacturing licence to use a centralised control centre to supervise each distributed manufacturing site’s quality system for specific products.

157. More specifically the regulations could be amended to:

- Define a central “control site” where a manufacturing authorisation would be required, with a QP;

- Exempt the distributed manufacturing sites from holding their own manufacturing authorisation and QP provided that they were named on the distributed manufacturers list, attached to the control centre manufacturing licence;
- Exempt products manufactured under agreed protocols at these distributed sites from the need for prospective QP certification;
- Extend existing powers to inspect and enforce to cover new requirements (with possible addition to inspection powers to address new needs);
- Define the process for a control centre to add new distributed manufacturing sites to their list to include defining agreed ‘comparability checks’, for instance manufacturing test products from known starting materials, to confirm that each site on the list is able to operate consistently; and
- Regard medicines which are manufactured at point of care to be, by virtue of their distributed manufacturing model, prepared industrially or manufactured by a method involving an industrial process (unless regarded to be exempt).

158. Sanctions in the event of a failure to follow good manufacturing practice or other regulatory requirements at either a remote or central facility would be aligned with provisions in the current legislation, with regulatory action and criminal offences available. Current legislative provisions for challenging regulatory decisions would apply to these sanctions.

159. There would be no impact of option 1 compared to the static acquis baseline. In this scenario the desired changes would continue to be made as required, with the only difference being the power to change the law would be via the new delegated powers available under the MMD Bill.

160. Conversely, when comparing to the do nothing baseline there would be significant impact if option 1 were pursued. The current regulatory framework is not suitable for the increasing flow of bespoke, innovative and short shelf treatments. The ability to apply updated practices to these new treatments would avoid a significant regulatory and cost burden, and potentially avoid limiting patient access to specialist therapies by travelling to a small number of authorised facilities.

161. For clinical trials, there is often continuous change in adding new trial sites and removing others as trial subject recruitment changes. This option could support avoiding the creation of an unnecessary time and cost burden to apply for manufacturing licence variations and inspections and thereby support the UK to maintain its competitiveness in the Clinical Trials sector.

162. For short shelf life products there may not be time for a qualified person to perform the regulatory checks before the product has expired. Alternative systems of ‘assurance’ are required to replace traditional end of process checks, perhaps with a single qualified person taking overall but indirect responsibility for the end process through approved quality management systems. Pursuing option 1 in the do nothing baseline scenario would allow the UK to make these changes and therefore support patient access to these treatments.

163. If option 1 were pursued compared to the do nothing baseline the MHRA could implement a revised approach to regulation of this ‘distributed manufacturing’ model to ensure regulatory oversight and quality assurance requirements that protect public health and avoid regulatory complexity that risk barriers to patient access and would be of particular benefit in clinical trials.

164. Currently this happens on an exemption basis and therefore the safety, quality and efficacy of the product is not evaluated. Proceeding under this exemption also imposes significant restrictions on their use, and advertising. There is also an issue of liability in the event of an adverse drug reaction.

165. The impact of this would be enabling UK patients to access new and innovative treatments and contributing to the competitiveness of the Clinical Trials and research environment within the Life Sciences sector by adopting a tailored and proportionate approach to regulations.

166. The impacts of this proposed use of the enabling powers provided for by the Bill would be deregulatory for medicine manufacturers and Clinical Trial sponsors as they would enable the introduction of a modernised regulatory approach tailored to this flow of new and innovative products. Patients would benefit from their ability to access the latest treatments.

167. Further consideration in relation to potential changes to clinical trials regulations would need as a matter of course to include the following stakeholders among others:

- The NHS (i.e. NHS England and Improvement);
- Relevant regulators (i.e. the Health Research Authority, Care Quality Commission, and the Human Tissue Authority);
- The Devolved Administrations;
- Manufacturers;
- The research and academic sector, including Research Councils, NIHR and research charities;
- Patient groups; and
- Established Government and industry partnership groups.

168. It would be expected that changes could be taken forward in respect of products whose technical attributes such as manufacturing method, shelf life and/or clinical use cannot be accommodated within the existing regulatory framework. This provides flexibility to accommodate future innovations while maintaining the established regulatory system for stable products that are suitable for manufacture and distribution on a large scale.

Human medicines regulations illustrative example vi – enabling hub and spoke arrangements across legal entities

169. The Government’s vision for community pharmacy is that it should provide expanded clinical services as part of the contractual arrangements with the NHS, helping to relieve

pressures on other parts of the system such as urgent care and meeting the manifesto commitment to help communities cope better with pressures on public services. To achieve this, dispensing needs to become more efficient to free up pharmacists' time for other activities. Permitting all pharmacies to access more efficient hub and spoke dispensing is part of the Government's strategy to support this transformation.

170. The term 'hub and spoke dispensing' refers to arrangements where a retail pharmacy, notionally at the end of a spoke, receives prescriptions, and sends them electronically to a remotely located hub, which in turn takes in prescriptions from multiple spokes. At the hub, medicines are selected, packaged and labelled and then transported back to the spoke to be checked by the pharmacist and collected by the patient.

171. The cost of setting up hub facilities requires a significant number of spokes before savings can be made. Several large UK retail pharmacy chains have set up centralised hubs providing automated prescription assembly services to their own pharmacies. Independent and small chain pharmacies lack the scale to do this within a single legal entity.

172. The law currently only allows hub and spoke arrangements within the same retail pharmacy business. The Government would like to remove this restriction to permit all pharmacies to develop or use external hub dispensing services. This would require an amendment to the Human Medicines Regulations 2012 (HMRs).

173. The costs and benefits remain uncertain, as do some details around the policy design, and the changes would be provided for by regulations made under the Bill. The proposed regulatory change is entirely permissive. No pharmacy business would be required to set up, use or offer hub dispensing services.

174. In practice therefore, costs and benefits will depend on pharmacy businesses' decisions and we would only expect to see take-up of hub and spoke arrangements where businesses deemed it would be beneficial for them to do so. The subsequent secondary legislation may also allow for different types of hub and spoke arrangements to be set-up:

- Large retail pharmacy chains with large, automated hubs could expand their capacity. We would expect to see these businesses offer chargeable prescription assembly services to independent and small multiple pharmacies;
- Independent and small multiple pharmacies could co-operate and centralise assembly of medicines in one of their pharmacies or through setting up off-site hub facilities; or
- New large-scale hub facilities could be developed by the NHS, wholesalers or new companies, although the hub would need to be a registered pharmacy.

175. The costs and benefits of these different hub and spoke arrangements may result in different costs and benefits falling on different affected parties. In principle, gains in dispensing efficiency and efficacy could be shared between hub operators, spoke operators, patients and the NHS.

176. At the highest level, it is anticipated that hub and spoke would involve set-up costs for those who chose to participate in terms of capital investment (hub) and changing business

processes, IT and logistics (spoke). The ongoing costs are expected to be comprised of employing pharmacy staff at hub facilities.

177. The benefits of hub and spoke are expected to include reduced staff time on dispensing at the spoke pharmacy (freeing up time to provide other services), potential for reduced rates of dispensing errors and potential for a calmer working environment at the spoke pharmacy.

Veterinary medicines regulations illustrative example i – online retailing

178. The Veterinary Medicines Directorate (VMD) 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 on in Schedule 3 of 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. There are currently 29 companies with 39 website registrations under AIRS.

179. The aim of the scheme is to provide assurance to the public and professional keepers of animals, that by purchasing their veterinary medicines from an accredited internet retailer they are:

- Buying the medicines from a reputable, UK-based retailer;
- At less risk of buying unauthorised, inappropriate or ineffective medicines for their animals; and
- Confident that the retailer meets the requirements of the Scheme and the law.

180. Retailers who meet the accreditation criteria display the special 'VMD Accredited Retailer' logo with their unique accreditation number. This logo includes a link to the list of accredited internet retailers so that customers can check the company is an accredited retailer.

181. AIRS was developed in response to the general public's concerns about buying veterinary medicines over the internet. We would like to make this accreditation scheme mandatory for all UK internet retailers through regulations made under powers in the Bill. This will provide further assurance for UK customers and prevent customers unwittingly buying illegal medicines from sites purporting to be UK based.

182. We plan to charge fees for this scheme on a cost-recovery basis. The scheme will have 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.

183. The implementation of this option would ring-fence legitimate businesses in the UK, as end users would be able to recognise legal internet retailers (those with a logo) from the rogue ones and so be able to make an informed choice when deciding to purchase veterinary medicines on the internet. This ensures that there is a level-playing field for internet retailers, which leads to benefits for consumers, as this gives them confidence in their purchases and reduces the uncertainty when purchasing products. This, in turn, leads to wider animal health, animal welfare and biosecurity benefits for UK society, as the unwitting consumption of unsafe or unauthorised veterinary medicines would likely be reduced. The UK would also be able to better enforce the legislation and identify and pursue illegal internet traders.

184. There would be no impact of option 1 compared to the static acquis baseline. In this scenario the desired changes would continue to be made as required, with the only difference being the power to change the law would be via the new delegated powers in the MMD Bill.

185. Conversely, if option 1 were pursued in the do-nothing scenario we would retain the ability to introduce further changes to the scheme under secondary legislation. Because it is not possible to pre-empt how we might want to change the scheme, we cannot definitively set-out the potential impacts of this.

Veterinary medicines regulations illustrative example ii – pictograms

186. The current VMRs include requirements for the labelling of authorised veterinary medicines.

187. The ability to make changes to the labelling requirements in the VMR currently is by using section 2(2) ECA. An example of a change that we are considering is the introduction of pictograms (standardised pictorial symbols for a word or phrase) to replace some of the written labelling requirements.

188. The pharmaceutical industry has identified that compliance with labelling rules constitutes the largest part of their total administrative burden (34% of the total administrative burden[18]).

189. This policy option would reduce the costs to the pharmaceutical industry of authorisation and production of veterinary medicines, as the costs of labelling are high. There would be no significant impact on animal or human health or safety to the environment in terms of information provided on the safe use of the product. Any risks associated with the reduction of information provided on the packaging and labelling would be counterbalanced by placing the information on the product leaflet and by making the information available through other sources (for example through electronic databases or barcodes).

190. The cost of packaging is a factor in preventing the marketing of medicines. In particular for minor species or conditions (for example: medicines for bees). If the costs of packaging are reduced, this may encourage companies to apply for authorisations for medicines for minor species or conditions, therefore increasing the availability of medicines.

191. There would be no impact of option 1 compared to the current legal fraework. In this scenario the desired changes would continue to be made as required, with the only difference being the power to change the law would be via the new delegated powers..

192. Conversely, if option 1 were pursued in the do-nothing scenario we would retain the ability to introduce further changes to the labelling requirements under secondary legislation. Because it is not possible to pre-empt all the ways in which we might want to change the

[18] Commission staff working document impact assessment on the revision of the framework on veterinary medicinal products https://ec.europa.eu/health/sites/health/files/files/veterinary/vet_2014-09/impact_assessment_en.pdf

labelling requirements in the future, we cannot definitively set-out the potential impacts of this.

Impacts on small and micro businesses (SMB)

193. Aside from the medical devices proposals, dealt with separately, the proposals set out within this Bill are not themselves intended or expected to bring about substantive changes to UK businesses in the medicines and life sciences sectors. Any changes will be implemented via secondary legislation which will be accompanied by its own bespoke economic appraisal.

194. However, if there are familiarisation costs these may affect smaller businesses more significantly and so we have considered the distribution of relevant businesses across employment size bands as an initial starting point.

195. The ONS[19] estimated the following distributions across business sizes for organisations within the Standard Industrial Classifications deemed relevant to this IA in 2019:

Table 1 - Number of VAT and/or PAYE based enterprises by Standard Industrial Classification (SIC) class by employment size bands

Count of businesses split by employment sizeband and standard industrial classification code/description, UK, 2019								
	Employment Size Band							
Standard industrial classification code and industry description	0-4	5-9	10-19	20-49	50-99	100-249	250+	Total
0128 : Growing of spices; aromatic; drug and pharmaceutical crops	15	0	0	0	0	0	0	15
2110 : Manufacture of basic pharmaceutical products	130	20	10	15	5	0	10	190
2120 : Manufacture of pharmaceutical preparations	280	45	25	25	20	30	30	455
4646 : Wholesale of pharmaceutical goods	1,580	370	310	240	110	65	50	2,725
4773 : Dispensing chemist in specialised stores	1,885	1,690	1,050	380	85	35	20	5,145
4774 : Retail sale of medical and orthopaedic goods in specialised stores	1,090	245	80	25	10	0	5	1,455
7500 : Veterinary activities	2,180	675	640	365	105	30	15	4,010
8621 : General medical practice activities	7,645	1,345	2,885	3,365	465	65	25	15,795

196. For hub and spoke in particular, there is an opportunity for smaller businesses to benefit from the proposals as, under current arrangements, they are less likely to be able to have the economies of scale required to benefit from automation. By removing the legal barriers to the use of hub and spoke dispensing across different legal entities, this would enable smaller pharmacies to begin to take advantage of these technologies.

197. Note that the proposals are entirely permissive and small businesses could choose whether to engage in hub and spoke dispensing or not. Therefore, we assess the proposal would be taken up only where it would generate net benefits and so is expected to have a net zero to net benefit impact on SMEs.

Post-implementation review (PIR):

198. The Government is committed to undertaking PIRs of any subsequent changes made using the powers in this Bill. We do not propose to undertake a PIR of the Bill itself

[19] Source: https://www.ons.gov.uk/releases/ukbusinessactivitysizeandlocation2019

because the majority of the powers in the Bill will simply enable us to make any necessary changes to domestic law.

199. For hub and spoke specifically, the Government intends to continue to work with the sector in order to explore and set out the framework for how hub and spoke could be operationalised in the NHS. Where this results in further changes to the NHS terms of service or future NHS regulations, a PIR would be conducted to cover these developments.

Annex A: Existing delegated powers in relation to human medicines split by allowing Act

Medicines Act 1968

- Section 15: power to revoke section 10 of the Medicines Act 1968 (exemptions for pharmacists) or provide for exception or modifications;
- Section 28: general power to suspend, revoke or vary product licences of right (a historical form of licence which is almost obsolete);
- Section 58(1): power to specify descriptions or classes of medicinal products as prescription only medicines;
- Section 58(4): power to create exemptions to or conditions attaching to reg 214 HMRs on the sale or supply of prescription only medicines;
- Section 58(4A): powers to impose conditions on appropriate practitioners for prescribing, administering or giving directions on administration of prescription only medicines;
- Section 58(4B): power to make exemptions to any conditions on appropriate practitioners for prescribing, administering or giving directions on administration of prescription only medicines;
- Section 62(1)(a): power to prohibit sale, supply or importation of any medicine, where necessary in the interests of safety;
- Section 62(2): power to make exceptions to the order created under section 62(1)(a);
- Section 72A: powers to specify conditions as to the registered premises of a responsible pharmacist and the records to be kept at the registered premises;
- Section 73: powers to add to, revoke or vary any conditions under sections 70 to 72;
- Section 74C: powers delegated to General Pharmaceutical Council to make rules in connection with applications for the registration of premises in Great Britain;
- Section 74D: powers delegated to registrar to impose such conditions as it considers necessary for securing the safe and effective practice of pharmacy at a registered premises;
- Section 74E: powers delegated to General Pharmaceutical Council to make rules in connection with applications for the conditions imposed to be varied or revoked in relation to the registration of premises in Great Britain;
- Section 74G: powers delegated to General Pharmaceutical Council to make rules in connection with applications for voluntary removal from the list of registered premises in Great Britain;

- Section 74H(8): powers delegated to registrar to impose conditions on restoration to registered premises list;
- Section 74I: powers delegated to General Pharmaceutical Council to make rules in connection with applications for restoration to the list of registered premises in Great Britain;
- Section 74J: powers to add premises to the list in emergencies related to loss of human life or human illness, including powers for the registrar to impose conditions for entry;
- Section 74K: powers to make temporary annotations in relation to emergency entry of premises;
- Section 79: powers to modify or extend restrictions on use of titles;
- Section 84A: powers delegated to General Pharmaceutical Council to make any rules it considers appropriate under Part 4 of the Act (on Pharmacies);
- Section 87: powers may make regulations related to sale or supply of medicines in containers;
- Section 88: powers to impose conditions related to colours, shapes and markings of medicines;
- Section 91: powers under section 87 can include powers to specify criminal offences for contravention;
- Section 104: powers to create exceptions or conditions on the application of the HMRs to certain medicines;
- Section 105: powers to make HMRs applicable to non-medicinal products;
- Section 108: power to give directions on enforcement in England and Wales;
- Section 109: power to give directions on enforcement in Scotland;
- Section 110: power to give directions on enforcement in Northern Ireland;
- Section 111: powers of entry;
- Section 112: powers to inspect, take samples and seize goods/documents
- Section 129: powers for Ministers to make regulations for any purpose permitted under the Act, except where powers are to be exercised by bodies other than Ministers, and powers to make regulations by way of statutory instruments in Northern Ireland
- Schedule 1: SoS may direct Advisory Body to appoint an Expert Advisory Group and Advisory Body may delegate functions to Expert Advisory Group
- Schedule 4: powers for Northern Ireland Minister for Health, Social Services and Public Safety to make orders applying exceptions or modifications to application of the Act to druggists

Medicines Act 1971

- section 1(1): powers to make regulations related to the payment of fees in connection with applications made under the Medicines Act 1968

Human Medicines Regulations 2012

- regulation B17(1) and (4): power to set out principles and guidelines of Good Manufacturing Practice (GMP) and amend existing provision on GMP.
- regulation 50(5A): power to amend Schedule 8 to further modify the reading of Annex I to the Medicines Directive [which sets out application requirements for marketing authorisations] in order to take account of scientific or technical progress.
- regulation 50G(5): power to amend Schedule 9 on orphan criteria etc
- regulation 59(3A) and 68(7A): power to specify the situations in which post-authorisation efficacy studies may be required
- regulation 65C(7): power to amend, revoke etc Schedule 10A which replicates the Variation Regulation [provisions governing the variation of the terms of a marketing authorisation],
- regulation 102(7): power to vary dilution requirement for homoeopathic medicinal products in light of new scientific evidence
- regulation 205A(2): power to amend to amend, revoke etc Schedule 12A which replicates the Pharmacovigilance Implementing Regulation [which sets out further obligations on a marketing authorisation holder and the licensing authority in respect of their performance of pharmacovigilance activities]
- regulation 257E: power to require certain forms of labelling in order to make it possible to ascertain specified things e.g. price and legal status
- regulation 344A: power to modify the application of specified Parts of the HMRs to deal with serious shortages of medicinal products arising from the UK withdrawal from the EU. This power is sun-setted 2 years from the end of the transition period.

Medicines for Human Use (Clinical Trials) Regulation 2004

- regulation 57(1)(a): power to amend conditions and principles of Good Clinical Practice
- regulation 57(1)(b): power to specify requirements for document making up the trial master file on archiving
- regulation 57(1)(c): power to amend or revoke requirements of trial master file regulation 31A

- regulation 57(1)(d): power to require that regulation 58 guidance is taken into account

EU Withdrawal Act 2018 (relevant powers only)

- section 8: power to amend deficiencies arising from EU Exit. This power is sun-setted 2 years after the end of the transition period.
- Schedule 4, Part 1: power to provide for fees and charges in connection with new functions introduced by regulations made under sections 8 or 9 of the Act.
- Schedule 4, Part 2: power to modify or remove pre-exit fees and charges made under section 2(2)(b) and /or section 56 of the Finance Act 1973.

Annex B: Previous use of powers flowing from ECA 2(2)

Table 2 - Previous amendments made to the HMRs

Table of amendments made to the HMRs using section 2(2)(b) ECA.			
Year	**Nature of amend**	**Description of amend**	**IA?**
SI 2013/1855	Public health: changes to restrictions on the supply of medicines (national policy (NP))	Enabling physios and podiatrist independent prescribers to supply certain prescription medicines	Yes
	Implementing EU changes	New EU provision on active substances, brokering and online sales of medicines	
SI 2013/2593	Implementing EU changes	New EU provision on pharmacovigilance	No
	Public health: changes to restrictions on the supply of medicines (NP)	Enabling over the counter medicines to be sold on planes and trains	
SI 2014/490	Implementing EU changes	EU provisions on cross-border/mutual recognition of prescriptions	No
SI 2014/1878	Public health: changes to restrictions on the supply of medicines [national policy]	Enables salbutamol (asthma inhaler) to be supplied by schools in emergency situations	No
	De-regulatory (NP operating within discretion of EU law)	Relaxes some of the mandatory requirements for medicines adverts intended for health professionals so that web links can be used and existing information re-used	
	Implementing EU changes (follow up to Pv Directive)		
	Provides for application process for parallel import licences (NP)	This filled in some gaps in the existing processes to ensure the MHRA authorised applications and hence had proper oversight	
SI 2015/323	Public health: changes to restrictions on the supply of medicines [national policy]	Enables contractors carrying our search and resource operations for Maritime Coastguard Agency to supply prescription medicines under direction of a doctor	No
	Public health/deregulatory: changes to restrictions on the supply of medicines (NP)	Enable PHE to supply prescription medicines under direction of a doctor	
SI 2015/903	Corrects errors		No
SI 2015/1503	Public health changes to restrictions on the supply of medicines (NP)	Enables a heroin substitute to be supplied by Drug Treatment Services in an emergency	Yes
	Public health: changes to restrictions on the supply of medicines (NP)	Enables PHE to enter into arrangements with retail pharmacies to supply prescription medicines	
SI 2016/186	Public health: changes to restrictions on the supply of medicines (NP)	Enables midwives to supply certain prescription medicines (including morphine, diamorphine and pethidine)	Yes
	Public health - changes to restrictions on the supply of medicines (NP)	Enables therapeutic radiographers to prescribe certain prescription medicines	

	Public health: changes to restrictions on the supply of medicines (NP)	Enables orthoptists to supply certain prescription medicines	
	Public health - changes to restrictions on the supply of medicines (NP)	Gives dietitians limited prescribing rights	
SI 2017/715	Public health/deregulatory: changes to restrictions on the supply of medicines (NP)	Enables schools to hold and administer epi-pens in emergencies	No
SI 2018/199	Public health/deregulatory - changes to restrictions on the supply of medicines (NP)	Enables paramedics to prescribe certain prescription medicines	Yes
	Public health/deregulatory: changes to restrictions on the supply of medicines (NP)	Enables medicines containing Potassium Iodide/Iodate to be supplied in the event of a nuclear emergency	
SI 2019/62	Implementing EU changes (Falsified Medicines Directive 2011/62/EU)	Requires safety features and unique identifiers	Yes
	Public health/deregulatory - changes to restrictions on the supply of medicines (NP)	Implements Serious Shortage Protocol allowing pharmacists to dispense medicines of s different strength, quantity or pharmaceutical form to that ordered by the prescriber	
	Public health/deregulatory - changes to restrictions on the supply of medicines (NP)	Amends the exemption for drug treatment services to supply Naloxone Hydrochloride for administration in emergencies involving a heroin overdose so that this is no longer limited to Naloxone Hydrochloride products that are for injection.	