

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'

With the exception of the MDIS appraisal, 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.

The MDIS section goes further to estimate the costs use of the powers proposed here could generate as there is more clarity around the proposal and impacts are expected compared to both baselines. These are not included here as the impacts do not flow directly from this legislation and the assessment is provided for information purposes only.

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'

With the exception of the MDIS appraisal, 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.

The MDIS section goes further to estimate the benefits use of the powers proposed here could generate as there is more clarity around the proposal and impacts are expected compared to both baselines. These are not included here as the impacts do not flow directly from this legislation and the assessment is provided for information purposes only.

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%
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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 Years10	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. The MDIS section goes further to estimate the costs use of the powers proposed here could generate as there is more clarity around the proposal and impacts are expected compared to both baselines. These are not included here as the impacts do not flow directly from this legislation and the assessment is provided for information purposes only.

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.

The MDIS section goes further to estimate the benefits use of the powers proposed here could generate as there is more clarity around the proposal and impacts are expected compared to both baselines. These are not included here as the impacts do not flow directly from this legislation and the assessment is provided for information purposes only.

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%
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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 Directive¹ 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 monitoring 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 Directive² 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 transition 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 substances³. 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 monitoring.
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 alerts².
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 death³.
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 in 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 economy⁴ 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 studies³. In 2014/15⁵, 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 £700m⁶ in annual sales, while GVA of veterinary activities in the UK was £3.9bn⁷ 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 economy⁸, while the whole agri-food sector contributed £121.6bn of GVA in 2017⁹.
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

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

residues of veterinary medicines to protect human and animal health, and to facilitate 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 resistance.

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) EUWA¹⁰. 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

¹⁰ See annex A for further detail.

hospitals to manufacture and trial the most innovative new personalised and short life 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 changes¹¹ 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. 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. And additionally a relatively detailed appraisal of the proposal relating to Medical Devices Information and clinical registries system is provided in a separate 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 monitoring, 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 brought 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 in the Energy Related Products Regulations. The Post Implementation Review for this policy¹ described how some companies within this industry had subsequently become 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 monitoring 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 monitoring 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 implants² and occluder devices³.
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.

Medical devices information system

Introduction

124. At present, there is no national digital record of patients whose treatment included a medical device. This is of particular concern for implantable or high risk class III medical devices⁴. Instead, a piecemeal system of voluntary registries exists with coverage limited

⁴ <https://www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements#classification-devices>

to particular products or product groups. Examples of relatively well established and developed registries include the National Joint Registry (NJR) and Breast and Cosmetic Implant Registry (BCIR).

125. Critically, none of these registries can require the provision of information to them from all healthcare settings across the four nations so are unlikely to be complete.
126. This presents major challenges in situations where product recalls are necessary and precludes developing understanding of the impact different devices may have on groups sharing certain characteristics. In recognition of this, in November 2019 the Department of Health and Social Care (DHSC) directed NHS Digital (NHSD) to collect this data for England only.
127. It is further expected that the Cumberledge Review's recommendations will include establishing a UK wide registry for implanted medical devices.

Nature of the proposed amendment

128. This amendment seeks to provide a regulation making power for the creation of a UK-wide Medical Device Information System (MDIS), for the purpose of capturing data on the use of medical devices in the treatment of patients and linking information about any procedure undertaken (such as clinician details, location, device information) to individual patients. The intention is for MDIS to focus on implantable devices initially, following future consultation and secondary legislation. Information about the use of other devices may be captured elsewhere in the patient record but would not in the first instance be the subject of the MDIS regulations (albeit they could be amended at a later date to cover other types of devices as well).
129. Where directed to do so, NHSD is already able to require NHS providers in England to submit data using powers set out in the Health and Social Care Act 2012 (H&SC Act). The purpose of the power proposed here is to expand NHSD's current powers to allow for:
 - a) Mandating UK private providers to submit data relating to medical devices;
 - b) Mandating NHS providers in the devolved nations to submit data relating to medical devices; and
 - c) Dissemination of clinical and patient data to bodies with the legal basis to receive it even if that information is subject to a common law rule preventing disclosure.
130. It is planned to focus on implantable, high-risk medical devices only initially. Should the need arise in the future, this amendment also allows for the scope of the system to be broadened to include non-implanted devices.
131. The details regarding how this power may be used are not currently available and will be set out in future secondary legislation. That said, the data collected by NHSD from NHS providers in the devolved nations⁵ and UK private sector providers (i.e. those organisations

⁵ NHSD already has the power to require NHS providers in England to submit data. They will be required to provide the same information as listed for UK private providers and NHS providers in the devolved nations, but not as a result of future legislation enabled by this amendment.

NHSD do not currently have the power to direct) could include (but not be limited to and may be subject to change):

- Unique identifiers of individual devices used;
- The procedures undertaken in relation to the device (such as a method of implanting);
- The name and NHS number of the person the device was provided to or implanted into;
- Where the operation or procedure took place;
- The person responsible for carrying out the operation or procedure; and
- Potentially other patient information to ensure a holistic review including on the review of a device and patient experience once implanted.

132. The additional organisations NHS Digital may disseminate data to, how this could be accomplished and, similarly, who can access the information held would be set out in the subsequent secondary legislation. As could the categories of persons the regulations may make responsible for providing the data to NHSD.

Initial assessment of potential impacts

133. This initial assessment of potential impacts assumes that regulations will be made using the power provided here to establish a MDIS that will feed a consistent and proactive Medical Devices Registry system going forward. The intention is to provide an initial assessment of impacts the use of the power could have in the future given this assumption.

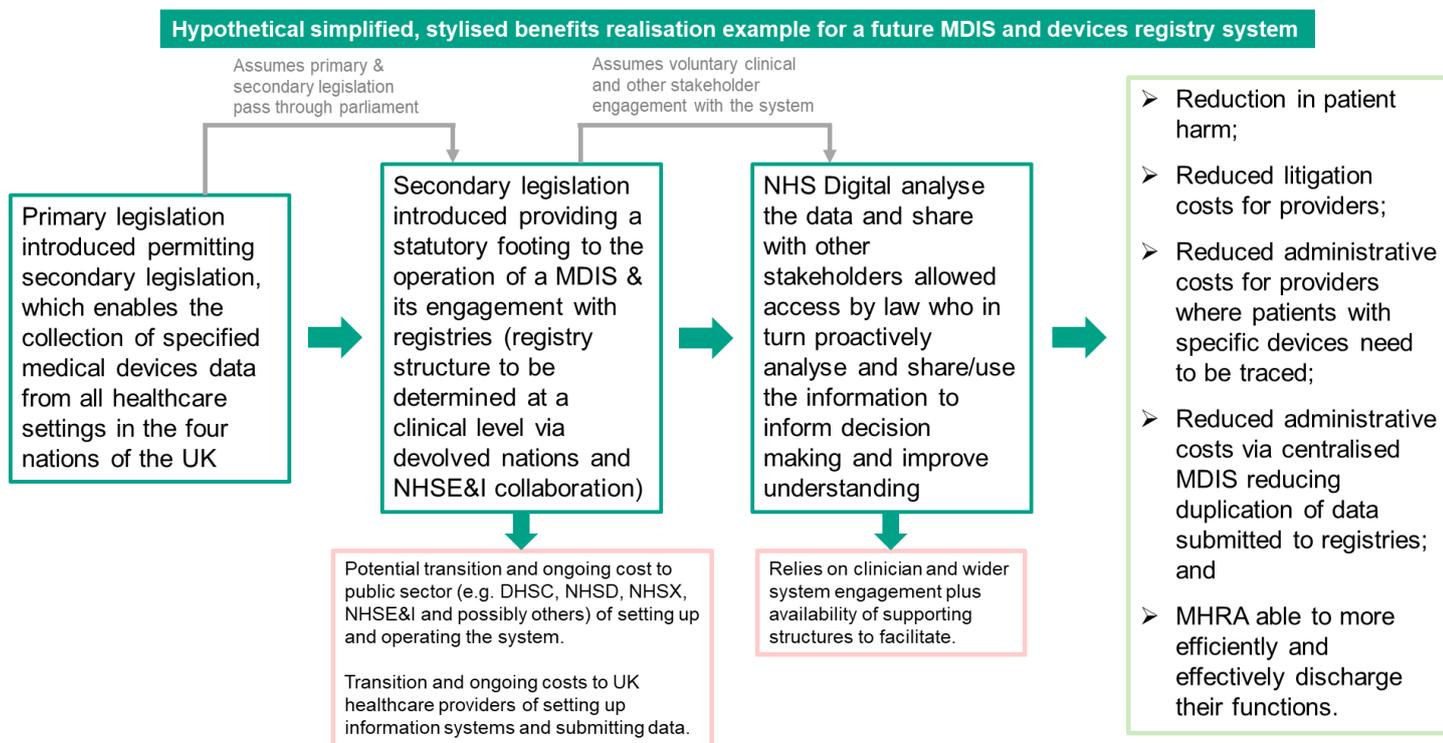
134. The discussion is necessarily high-level as the actual future impacts will depend on further policy development, responses to consultation and the content of future secondary legislation. That said, the appraisal provides a greater level of detail than that in subsequent illustrative example sections, given the more developed understanding of how the powers could be used compared to more hypothetical examples.

135. It is important to note that the indicative cost estimates have been compiled using the best available data currently identified relating to the cost of setting up and running existing registries. However, under the proposed new system data collection will be undertaken by the MDIS and individual registries will be established to draw data from this central repository.

136. As such, the cost estimates relating to existing registries are not a direct proxy for those that could be generated under a new system and are provided for illustrative purposes only. Initial analysis undertaken by NHS England & Improvement (NHSE&I) around the potential costs and benefits of a wider system of a MDIS, clinical registries and data capture are also considered. Please note these estimates have been developed from previously compiled business cases and the application of assumptions regarding optimisation and targeting of highest impact, clinical priorities initially. As such, they will be subject to change and refinement going forward and are referenced throughout as “initial NHSE&I analysis”.

137. Figure one below sets out a high-level summary benefits realisation process and notes where costs may be generated to stakeholders given the assumptions above. The potential costs and benefits are discussed in more detail in the following section along with, where possible, an indication of their potential scale.

Figure 1: Hypothetical simplified, stylised benefits realisation process for a future MDIS and devices registry system



138. The impact of the proposal is expected to be unchanged when compared to the static acquis versus do nothing baseline scenarios as the powers under ECA 2(2) would not have permitted us to create MDIS under secondary legislation. ECA 2(2) was principally used to amend UK law to give effect to EU law that had direct effect in the UK, and also to implement domestically EU law that had indirect effect.

139. This system operated on the basis that EU law was subject to prior scrutiny and made by the EU Commission, Parliament and Council (or some combination thereof, depending on the type of EU law) which included the UK's involvement as a member of the EU. This was then supported with the domestic regulations being the legislative mechanism to enable operation under UK law. In the particular case of MDIS, new primary legislation would have been required to create the framework to support any MDIS, even in a scenario where ECA 2(2) remained in place.

Costs

140. The policy around how the MDIS and eventual Registry system will be funded has not yet been developed and the costs of establishing and running the Registries will depend on their respective sizes and functions. This will be subject to further work plus ministerial clearance at a later date and options could include, for example:

- New public sector funding;

- Reallocation of funding from existing budgets; or
- A levy on trusts.

141. Funding and revenue will be actively considered by the Programme going forward, with a core design principle of self-funding as far as practicable. However, it is not anticipated that self-funding could be achieved initially and so the cost allocation across different groups could be subject to change over time.

Set-up costs

142. To give an indication of potential set-up and running costs we could consider those for the National Joint Registry. Following a comprehensive tendering process the contract awarded in 2002 provided just under £715,000 to develop the NJR and circa £1.6m per annum to operate the NJR in its first two years of existence⁶.

143. According to the Healthcare Quality Improvement Partnership (HQIP) which hosts the NJR's accounts, in 2018/19 the National Joint Registry (NJR) collected subscriptions totalling circa £3.4m. In addition, other income of around £0.7m included supplier contributions and income for a price bench marking service. These income figures could be taken as a proxy for the running costs of the NJR as its income is held in a separate bank account to be used solely to fund the work of the Registry by the HQIP⁷ (though there is no way to ascertain whether this would all be spent in one year).

144. If we take circa £4.1m as the latest annual running costs of the NJR and assume that the cost of establishing a Registry of this ilk would have increased by the same proportion as its running costs between 2002 and 2018/19 this suggests an initial set-up cost of £1.8m.

145. It is however important to note the cost of different registries will vary significantly according to their size. The NJR is a relatively large scale registry with, for example, just over 225,000 procedures reported to it in 2018⁸. In comparison, just under 15,600 operations were reported to the BCIR between July 2018 and June 2019⁹.

146. Estimates published by NHS Digital¹⁰ assessed the expected set-up costs of the BCIR collection to be £83,000. At the other end of the scale, estimated set-up costs for a US implant registry were around \$1.6m¹¹ based on an assumption that around 4 million records of new medical device implants would be gathered per year.

147. Whilst we anticipate that size will affect set-up costs, the scope and amount of activity undertaken by a future MDIS and medical device registries system is also expected to

⁶ <https://publications.parliament.uk/pa/cm200304/cmselect/cmpubacc/40/3112609.htm>

⁷ <https://www.hqip.org.uk/wp-content/uploads/2019/11/HQIP-Annual-Report-and-Accounts-2018-2019FINAL.pdf>

⁸ <https://reports.njrcentre.org.uk/>

⁹ https://files.digital.nhs.uk/62/8C3560/BCIR_Report_2019.pdf

¹⁰ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/584642/Breast_Implant_Registry_DPN_Private_providers_.pdf

¹¹ https://books.google.co.uk/books?id=Y4n5YTnNV6wC&pg=PA363&lpg=PA363&dq=cost+of+setting+up+a+medical+device+registry&source=bl&ots=2KPmwVqqia&sig=ACfU3U0-mDDYj6q-z9j_ra6TIqfx0U11YQ&hl=en&sa=X&ved=2ahUKewiCuK3J3_vpAhUCu3EKHYO_B2kQ6AEwCXoECAgQAQ#v=onepage&q=cost%20of%20setting%20up%20a%20medical%20device%20registry&f=false

have an impact. So, whilst the NJR only covers joint replacements its wide ranging activities and scope could be expected to exceed those of an initially established MDIS.

148. Therefore, whilst the potential set-up costs discussed above range from £83,000 (BCIR) to £1.8m (inflated NJR) it is expected that £1.8m could represent a reasonable high-end estimate for the set-up cost of a MDIS. This is not out of line with initial NHSE&I analysis which estimated a year 1 cost of £1.4m for a future MDIS system (comprised of Product Information Master, national perioperative data collection of procedure and device data plus patient follow-up data collection costs).
149. In addition, each individual registry will have its own associated establishment costs. The scale of these costs will in turn depend on each registry's activities for example the amount of linkage and analysis undertaken as well as the complexity of any track and trace monitoring systems.
150. For example, initial NHSE&I analysis estimates a potential cumulative cost of £75m over 5 years could be generated by moving from 1 to 10+ operational registries, rising from £3.5m in year one to £24.5m by year 5. Please note that these costs capture the set-up and ongoing costs, as opposed to just the set-up costs, of the registries and assume scaling of the NJR model (less data capture costs which would accrue to the MDIS).

Ongoing operating costs

151. Similarly, the potential ongoing costs of operating the system are expected to depend on the amount of information received and stored as well as how this is used. If we accept the NJR's reported income as a proxy for its running costs this indicates ongoing costs of £4.1m per annum compared with estimates for the BCIR of £183,000 analysis and publication costs per annum.
152. Applying the assumption that the NJR could represent a reasonable high cost estimate suggests the ongoing costs of a MDIS could fall in the region of £2.1m (mean average of BCIR and NJR) and £4.1m. It should however be noted that the time profile across which these costs could accrue will depend on the group(s) of implantable devices focussed on initially and the possible roll out of the system to cover non-implantable devices and the uncertainty associated with this estimate should be borne in mind.
153. For comparison, initial NHSE&I analysis suggests that the costs associated with a MDIS could rise from set-up costs of £1.4m in year one to £9.8m by year five with a cumulative total cost of £29.4m over the full five year forecast period, implying an average annual cost of circa £6m.
154. In addition to the uncertainty associated with these estimates, it is important to bear in mind that in order to get sufficient quality data into registries and for clinicians, regulators and industry to meaningfully use this data, a number of supporting processes, governance and organisations will be needed.
155. These range from electronic data capture (such as, for example, Scan4Safety) to inventory management at point of care to enhanced monitoring and others. Whilst we cannot

estimate the total potential costs at this time, NHSE&I initial estimates suggest that introducing Scan4Safety, limited to Electronic Point of Care Traceability, could generate cumulative costs of £120m over five years.

156. Having considered the available information regarding potential set-up and ongoing costs of the system itself, we now turn to considering the possible burden of reporting on providers. Note this high-level assessment considers the potential impact of a UK-wide MDIS and devices registry system. As such, the impact on all providers is considered, despite NHS providers in England already being obligated to submit data requested by NHSD under provisions of the H&SC Act.
157. There may be transition costs to providers that do not currently submit data to NHS Digital if new or upgraded IT systems are required to meet any future obligations. Ultimately the set-up costs for submitting providers will depend on individual organisation's IT systems.

Wider administrative costs

158. Ongoing administrative costs in terms of the time taken to submit the data required could also be generated with the scale dependent on what data is collected in the future, the persons able to submit data and whether individual organisations submit voluntarily to existing collections.
159. The lack of a digital record of medical devices used at present makes it difficult to assess how many times data could need to be reported and, therefore, the potential scale of this administrative cost.
160. To give an indication, data for the number of NHS procedures or finished consultant episodes in 2018/19 of the following types (those thought likely to involve an implanted medical device) was sourced for the four UK nations¹²:
- Prosthetic replacements (various);
 - Cardiac pacemaker systems; and
 - Balloon, shunt and stent procedures.
161. If we assume that each procedure or episode did involve the implanting of a medical device, this limited, broad brush approach suggested just under 350,000 data submissions, related to these types of NHS procedures only, could have been required had a MDIS existed in 2018/19.
162. In some cases, most notably for joint replacements, some organisations may already be submitting data to the National Joint Registry and so the additional burden could be offset by ceasing duplicative reporting. Annex C provides data tables detailing the procedures counted for each nation.
163. The Department is not aware of a dataset that estimates the total number of procedures carried out in the private sector and so cannot estimate the potential total burden on these

¹² Data for Scotland used a different classification system compared to Northern Ireland and Wales and the data differs in that it refers to procedures for Scotland, finished consultant episodes for Wales and finished episodes for Northern Ireland.

providers at this time. Data reported to the NJR and BCIR relating to activity by type of provider does indicate that the split of burden across the public and private sector will vary, potentially significantly, across different types of devices and procedures.

164. This is shown in tables 1 and 2 below where we can see for all procedures reported to the NJR 61% had NHS providers and 39% had private providers compared to 21% and 79% respectively for operations reported to the BCIR.

Table 1: NHS and private provider procedures reported to the NJR by type of procedure, 2018

NHS vs private provider split of procedures reported to the NJR by type of procedure - 2018					
	Number NHS	Number private sector*	Total number	% NHS	% private sector
Hip procedures reported to NJR	65,557	40,559	106,116	62%	38%
Knee procedures reported to NJR	65,256	44,284	109,540	60%	40%
Ankle procedures reported to NJR	821	183	1,004	82%	18%
Elbow procedures reported to NJR	846	53	899	94%	6%
Shoulder procedures reported to NJR	6,004	1,673	7,677	78%	22%
All procedure types reported to NJR	138,484	86,752	225,236	61%	39%

Source: <https://reports.njrcentre.org.uk/>

*Private sector defined as independent hospitals + independent sector treatment centres

Table 2: Number of operations reported to the BCIR by operation and provider type 2018

Number of operations reported to the BCIR by operation and provider organisation type July 2018 - June 2019					
	NHS	Independent	Total	% NHS	% independent
Primary cosmetic augmentation	210	9,755	9,965	2%	98%
Reconstruction	2,080	345	2,425	86%	14%
Replacement	745	2,015	2,760	27%	73%
Reposition	5	25	35	14%	71%
Explant	220	165	385	57%	43%
All categories of operation	3,260	12,305	15,570	21%	79%

Source: https://files.digital.nhs.uk/62/8C3560/BCIR_Report_2019.pdf

Please note totals may not sum due to rounding

165. In summation, the administrative cost to providers, and the split of this across NHS and private providers will depend on the frequency initially prioritised devices are used and how prevalent they are in the NHS versus private sectors.

166. Furthermore, administrative costs are expected to accrue to other public sector organisations such as NHSD, NHSX plus NHS England and NHS Improvement as a result of setting up, engaging with and collaborating on a future Registry system. For example, initial NHSE&I analysis suggests programme costs in the region of £2m per annum could accrue to NHSX as a result of clinical registries and traceability work.

167. Engagement from clinicians and wider stakeholders is also pivotal for a Registry system to work successfully which is not mandatory and deemed most likely to occur where links to patient benefits are identified.

168. Although entirely discretionary, a report of a HQIP thinktank exercise¹³ noted an “an overwhelming weight of enthusiasm for a national medical devices registry” with no dissention from attendees. Organisations represented at the event included the devolved nations, NHS England & Improvement, independent sector, professional organisations,

¹³ <https://www.hqip.org.uk/wp-content/uploads/2020/03/Final-HQIP-Proposal-for-a-medical-devices-registry-FULL-report.pdf>

patients and digital groups. As such, the findings could indicate broad support from across the system and therefore a good likelihood of engagement.

Benefits

169. The potential benefits of a successful Registry system being established using the data collected by the MDIS could include:

- **Reduction in patient harm** - capacity via a registry system to prevent future harm by earlier and more routine analysis of devices once implanted enabling rapid action to remove and prevent use in other patients where clinical concerns justify this. This would be independent of regulatory action to suspend from market sale and could include advice/limitations on use within NHS where novel use has taken place or is proposed.
 - For example, use of mesh may have been subject to 'high vigilance restriction' in use much earlier if the data had been in place and a proactive registry system capable of analysing the data had been developed. This may have prevented harm to hundreds of patients.
- **Reduced litigation costs for providers** - reducing scope of error or patient impacts through proactive system even if not all risk can be mitigated and on assumption registries operate consistently and proactively. This could reduce subsequent litigation costs against NHS and DHSC by preventing harm that results in such claims.
- Potential **reduction in administrative burden on providers** across the UK in the NHS and private sector via:
 - Reducing the administrative burden to trace patients in the case of product recall;
 - Avoiding duplication in information provided under a more piecemeal system; and
 - Minimising the burden of submitting data by use of one, standardised e-form submission system designed for swift and ease of use.
- **MHRA able to more efficiently and effectively discharge their functions** – capacity to understand scale of device use by category and brand even if not linked to patient data, enabling MHRA to operate more efficiently and prioritise its market monitoring and enforcement work, including in conjunction with registries when in place.

Overall value for money assessment

170. Analysis of patient safety incident reports has been undertaken to produce a general potential VfM assessment. This assessment is entirely indicative due to the lack of a digital record of patients whose treatment included a medical device and the outcomes of such treatment that this policy is designed to address. This assessment uses the best available data identified to give an indication of potential VfM and as such should be treated as illustrative and the caveats borne in mind. To supplement this, NHSE&I initial analysis

forecasting the potential costs and benefits of clinical registries and traceability work is also presented.

171. The National Reporting and Learning System run by NHS England and Improvement publishes datasets on the number of patient safety incident reports received in a given 6 month period. Patient safety incidents are any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare¹⁴.

172. These are further broken down by reporting organisation, degree of harm caused (all incidents only) and by incident category which, for acute specialist and non-specialist plus ambulance trusts, includes medical devices/equipment.

173. If we assume that the distribution of all incidents across degree of harm in each organisation type would be representative of that for medical devices/equipment category incidents only, this suggests the breakdown of incidents shown in table 3:

Table 3: Number of medical device/equipment patient safety reports assuming distribution of all incidents across degree of harm is representative for devices/equipment only, Apr-Sep19

Number of medical device/equipment patient safety reports assuming distribution of all incidents across degree of harm is representative Apr-Sep19					
	None	Low	Moderate	Severe	Death
Acute non-specialist	17,569	5,315	419	54	18
Acute specialist	1,208	274	20	1	1
Ambulance	642	158	16	8	3
Total	19,419	5,748	456	64	21

174. If we assume that a future MDIS and clinical registries system would cover the devices linked to these reports on the basis that the initial focus will be on the highest risk devices this illustrates the total number of incidents that could potentially be avoided. It is not possible to predict the proportion of such incidents that could have been avoided if a registry system were in place.

175. Illustrative scenarios are therefore presented below based on unevidenced assumptions regarding the proportion of incidents that may have been avoided had a MDIS and registry system existed. Please note that the patient safety incident data relates to April - September 2019 and has been uprated to produce a rough per annum equivalent.

Table 4: Scenarios for proportion of medical devices/equipment incidents that may be avoided due to a MDIS and registry system

Scenario assumptions for the % of reported patient incidents that could be avoided if a registry system were operating

Avoidance scenario 1	10%
Avoidance scenario 2	25%
Avoidance scenario 3	50%

Please note these scenarios are for illustrative purposes only.

¹⁴ <https://improvement.nhs.uk/resources/report-patient-safety-incident/>

Table 5: Potential devices/equipment incidents that could be avoided per annum, by degree of harm, in each "registry system avoidance" scenario

Potential devices/equipment incidents that could be avoided per annum*, by degree of harm, in each "registry system avoidance" scenario					
	None	Low	Moderate	Severe	Death
Avoidance rate scenario 1 (0.10)	3,880	1,150	90	10	0
Avoidance rate scenario 2 (0.25)	9,710	2,870	230	30	10
Avoidance rate scenario 3 (0.50)	19,420	5,750	460	60	20

Estimates rounded to the nearest 10 incidents

*April to September 2018/19 incidents data doubled to produce a rough per annum equivalent

176. Combining these estimates with the cost ranges and the best estimate £60,000 for the value society places on a Quality Adjusted Life Year set out in HM Treasury's Green Book¹⁵ suggests that:

- Between 68 and 98 QALYs could need to be generated to cover the cost of setting up and running the system in year one; and
- Between 38 and 68 QALYs worth of harm could need to be avoided per annum to cover the ongoing costs per annum thereafter.

177. Please note again that the set-up and ongoing costs are expected to accrue over time as opposed to immediately from year one in this simplified illustrative example. The time profile of cost and benefit generation will depend on the devices prioritised and the frequency of their use, plus the level of risk they represent.

178. On this basis, taking the high cost estimates for year one and the lowest scenario for the proportion of potential harm avoided as a result of the policy breakeven would be achieved if:

- Average QALY loss avoided per moderate incident = 0.6;
- Average QALY loss from a severe incident = 1.5; and
- Average QALY loss from death = 5.

179. Given the definitions applied to categorise incidents noted below¹⁶, and the prudent assumption that low harm incidents would have an average zero QALY loss, it appears likely the policy proposal represents VfM.

Low harm - any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons receiving NHS-funded care.

Moderate harm - any unexpected or unintended incident that resulted in a moderate increase in treatment, possible surgical intervention, cancelling of treatment, or transfer to

¹⁵https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/685903/The_Green_Book.pdf

¹⁶ https://improvement.nhs.uk/documents/1673/NRLS_Degree_of_harm_FAQs_-_final_v1.1.pdf

another area, and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.

Severe harm - any unexpected or unintended incident that appears to have resulted in permanent harm to one or more persons.

Death - any unexpected or unintended incident that directly resulted in the death of one or more persons.

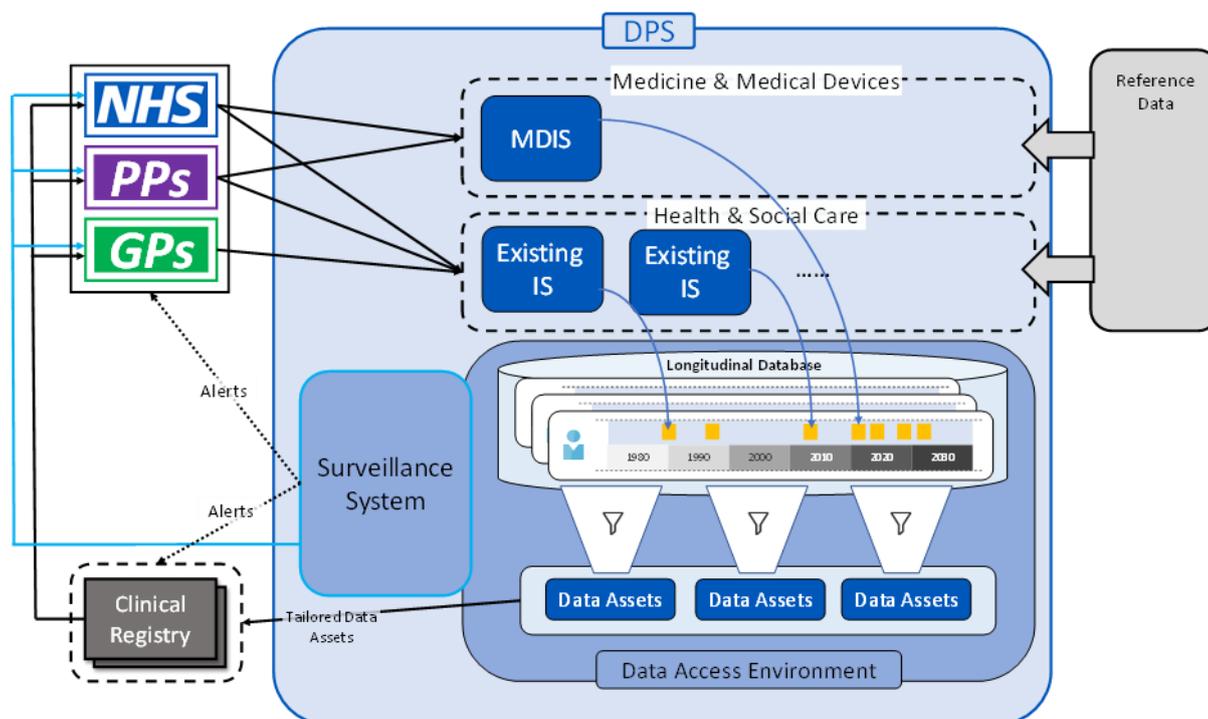
180. The findings of this limited assessment are also supported by initial analysis undertaken by NHSE&I covering a wider scope of costs and benefits. Although the figures will be subject to change and refinement, initial cost to value estimates for monitoring, assessment and traceability suggest a cumulative net benefit of around £36m could be realised over a five year period. This further supports the assessment that the proposal is likely to represent VfM.

181. Finally, please note that this initial high-level assessment does not consider the full details of a possible future system as these will be subject to further policy development, consultation and secondary legislation. That said, the extent of supporting systems that could be required to facilitate the realisation of benefits in this area should not be underestimated and could include but not be limited to, for example:

- Defining the registry and audit roadmap, data collection specification and follow-up protocols by product and procedure group;
- Collecting appropriate patient feedback on process, results and findings;
- Data analysis, cleansing, classification, augmentation and review (often several passes and validation on any given dataset as you get closer to published results);
- Statistical analysis and calculations taking into consideration clinical nuances in coding and practice and often using specialist academic resource;
- Exchanges with clinicians around surgical technique and context (this often takes the format of ad-hoc questionnaires about specific product behaviour);
- Exchanges with industry related to device PIM submission, registry results and comparative external evidence;
- Exchanges with providers, both public and private;
- Exchanges with the MHRA;
- Data report development (both surgeon, trust and national reporting);
- International registry data comparisons;
- Small volume and outlier investigations (often the early indicators of problems are found in complex low volume results that take a lot of work to identify and validate);
- AI/ML based data exploration and predictive analysis;
- Promotion / representation of registry across the NHS and Internationally; and
- Providing patient feedback and responding to patient requests for information.

Data storage, analysis, publication and dissemination

182. The NHS Digital infrastructure will be used to securely collect, store, analyse and link the data captured by the MDIS and related information systems (operated under the H&SC Act 2012) including the generation of longitudinal databases for the clinical registry system. All data will be securely stored, in separate registry specific databases, to allow targeted analysis.



183. Relevant anonymous aggregate statistical data derived from the MDIS may be published by NHS Digital. NHS Digital will also be authorised to disseminate relevant data from the MDIS to organisations who have a legal basis to receive the data for a specific legitimate purpose provided for in the regulations.

184. Alternatively, access to the relevant data could be made available through the NHS Digital Data Access Environment (DAE), which is a secure analytical environment available for use by approved individuals using Role Based Access Control (RBAC) to ensure only data that has been approved for use by this individual is accessible. The DAE may be particularly applicable for new clinical registries to avoid additional analytical costs and infrastructure that these organisations would otherwise incur and would ensure data and analysis is conducted to the same standard across the clinical registry system.

185. For example, de-identified data assets, for dissemination or access via DAE using RBAC, will be developed for use by the clinical registry system. The data assets will consist of the relevant longitudinal registry database (or sections thereof), to allow detailed analysis by clinicians and supporting analysts of patient journeys across the comparable longitudinal pathways.

186. This clinical analysis is expected to be conducted by clinicians and supporting analysts assigned to the clinical registry system, in conjunction with local clinical analysis of outcomes

by NHS and Private Provider organisations that have a duty of care to the patients treated by them, to support the identification of patients that require follow-up or additional clinical support where adverse outcomes or unexplained patient experiences are identified following treatment. Patients that require follow-up will be contacted using a monitoring system (processes and systems established by NHS Digital) including:

- Reidentification of patients for the cohort of patients identified as requiring follow-up;
- Collating analysis of responses from clinical registry system for issue to GPs and relevant Provider organisations in secondary care; and
- Coordinating appointment slots with relevant Provider organisations and issuing follow-up appointment letters to the identified patients.

187. It is essential that the clinical registry system have access to all relevant patient records so that the effectiveness of all medical devices, alternative procedures, and procedural combinations, are comprehensively understood and considered. In addition, exclusion of any patient records would mean that these patients are excluded from Patients will be offered the options to add more detailed outcome data using PROM and PREM surveys.

188. Deidentified extracts of relevant data will also be shared with the regulators, such as MHRA and CQC, who are responsible for monitoring and overseeing patient safety.

189. Relevant information held in the medical device information system will be shared with relevant organisations for specific and appropriate lawful purposes. The information will be shared safely and securely in an appropriate format and with appropriate safeguards. The relevant organisations will include registries, the clinical recipients of the information who will make clinical assessments on the safety and efficacy of medical devices.

190. The purposes for which data can be shared and the types of organisations that can receive this information will be specified in the regulations made under this amendment. The regulations will be subject to a public consultation and will be laid in Parliament as an affirmative statutory instrument to ensure full Parliamentary scrutiny. Regulations will determine the scope and limitations on data-sharing. All data sharing will need to comply with the data protection legislation.

Unique Device Identifiers (UDIs)

191. The application of a UDI to medical devices is an emerging safety measure that is being adopted across the international medical device regulatory community. The USA and the EU have both published regulations requiring this, with many more countries expected to follow. The system for the application of UDIs is predicated on the International Medical Device Regulators Forum publication “Unique Device Identification (UDI) of Medical

Devices 2013¹⁷”, which aims to incorporate the use of UDIs as one element of their global harmonisation of medical device regulation initiatives.

192. The EU Regulation on Medical Devices 2017/745 entered in to force on 25th May 2017 with an original implementation date for medical devices of 26th May 2020¹⁸. This contained, amongst other things, a requirement to assign medical devices a Unique Device Identifier (UDI) and record these on a central database.
193. On 23rd April 2020, the European Parliament and the Council of the EU adopted a proposal to extend the transitional period of the Medical Devices Regulation (MDR) by one year until 26 May 2021. The aim being to avoid shortages of medical devices during the ongoing COVID-19 pandemic due to the limited capacity of national competent authorities or notified bodies to implement the Regulation¹⁹.
194. This means that the full applicability of the MDR will fall outside of the transition period agreed with the EU. It is therefore considered that this requirement could be reimposed using powers in the MMD Bill.
195. If we assume that the UK scheme would be similar to the EU version, there would be three separate elements to the UDI displayed in an Automatic Identification and Data Capture (AIDC), i.e. machine readable, and human readable interpretation (HRI)²⁰:
- **Basic UDI-DI** that identifies a group of products in the same category of intended purpose, risk classification, essential design and manufacturing characteristics²¹;
 - **UDI-DI** the device identifier that is a static element of the UDI that identifies a specific device in a firm’s portfolio and remains unchanged for devices of the exact same product; and
 - **UDI-PI** the production identifier that is the dynamic part of the UDI that differs on every package and includes lot number, serial number, manufactured date and expiration date.
196. The Bill provides a power to introduce a functioning UDI system, 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.
197. Conversely, implementing option 1 is expected to generate impacts compared to the do nothing scenario. The UK would retain the ability to require, via subsequent secondary legislation, manufacturers of medical devices to place UDIs on the packaging of medical devices or on the device itself. This would enable the UK government to legislate to mitigate the risk of unidentifiable medical devices entering the UK supply chain and support the establishment of a Medical Devices Information System (MDIS).
198. It is not anticipated that imposing the UDI requirement for medical devices using the powers provided in the Bill will generate significant transaction or set-up costs to

¹⁷ <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf>

¹⁸ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/640404/MDR_IVDR_guidance_Print_13.pdf

¹⁹ <https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices>

²⁰ <https://easymedicaldevice.com/udi/>

²¹ This does not appear on individual devices packets but is for administrative purposes displayed on certificates (Notified Bodies), Declaration of Conformity, technical documentation and summary of safety and clinical performance.

manufacturers. Industry have been preparing for the implementation of the EU Regulations since 2017, for example most already have Basic UDI-DIs and UDI-DIs issued by the relevant bodies to make their devices compliant.

199. Proposals around the recording of UDIs are yet to be developed. That said, if a UK equivalent of EUDAMED is proposed there may be a one-off cost to the UK public sector of setting up a database on which UDIs could be stored. For context, EUDAMED is a new database required by EU Regulation 2017/745 on which companies and products will need to be registered once operational (expected in 2022). This requirement does not apply to products with a valid Medical Devices Directive certificate (which could be valid up to 25th May 2024 at the latest depending on date of issue)²².
200. There may be ongoing costs to manufacturers from the additional process required to add UDIs to newly produced individual product's packaging or, in the case of reusable devices, to the product itself. Additionally, if we assume that UDIs will also be recorded by manufacturers on a UK equivalent of EUDAMED, this too could generate additional ongoing administrative costs.
201. As noted previously we assume that manufacturers, in preparation for compliance with EU Regulation 2017/745, will already have understood and established the means for compliance with the EU UDI scheme. If we assume the UK scheme will mirror the EU's then there should be few if any additional costs relating to firms' current portfolios.
202. However, if a manufacturer were to include a new product in its portfolio or make one or more of the changes listed below to an existing product they manufacture, there would be additional costs of obtaining a new UDI-DI.
- Name or trade name;
 - Device version or model;
 - Labelled as single use;
 - Packaged sterile;
 - Need for sterilization before use;
 - The number of devices in a package;
 - Critical warning or contra-indication;
 - CMR / Endocrine disruptive;
 - Colour; or
 - Language.
203. The 'issuing entities' designated by the Commission under Article 27 of the MDR are understood to be independent bodies which already exist, are established in their functions and are not created by EU legislation or property of the EU. On this basis, there should be

²² <https://meso.vde.com/transition-period-medical-devices/>

no barrier to the UK designating one or more of these bodies as an issuing entity for the purposes of our regulations.

204. Therefore, no further transaction costs are anticipated as the UK could continue to utilise the existing system leaving only the additional administrative cost to manufacturers of applying for new UDI-DIs.
205. The benefits of a UDI system for medical devices could include those listed below²³ providing that the information is captured and used by healthcare providers further along the supply chain as discussed in the preceding MDIS section. Please note that the first two points are also covered in the assessment of establishing a Medical Devices Information and clinical registries system in the relevant preceding section. Having a UDI on devices that such a system could record is critical to realising the potential benefits of such a system, therefore the benefits are noted here also and should not be double counted.
- Improved patient safety - making it easier to trace devices and, where appropriate, record which patient they have been used on;
 - Better regulatory control - more accurate identification of devices if there is a product recall; and
 - More efficient business processes - improved monitoring of usage and costs for both industry and healthcare providers.

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

206. 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

²³ <https://www.abhi.org.uk/multimedia/docs/abhi-briefings/What%20is%20UDI%20paper.pdf>

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

207. 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.
208. 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 is accordance with a protocol approved by an NHS body or Ministers.
209. 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.
210. 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.
211. 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.
212. 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.
213. 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.

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

214. 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.
215. 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.
216. 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.
217. 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.
218. 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.
219. 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.
220. 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.
221. 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.

222. 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

223. In July 2015²⁴ 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

224. 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.

225. Conversely, option 1 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 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.

226. 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.

227. 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.

228. 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

²⁴<https://www.gov.uk/government/news/new-mandatory-logo-for-selling-medicines-online>

would have been incurred without the change. Human medicines regulations illustrative example iv - introducing a scheme to combat falsified medicine products

229. 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).
230. 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.
231. 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.
232. 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.
233. 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 iv - facilitate a distributed manufacturing model for products manufactured within or outside of clinical trials

234. 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.

235. 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).

236. 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.

237. 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.

238. 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).
239. 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.
240. 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.
241. 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.
242. 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.
243. 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.
244. 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.
245. 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.
246. 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.

247. 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.
248. 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.
249. 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 v – enabling hub and spoke arrangements across legal entities

250. 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.
251. 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.

252. 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.
253. 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).
254. 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.
255. 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.
256. 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.
257. 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.
258. 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.

Human medicines regulations illustrative example vi - importing, distribution and manufacture of active pharmaceutical substances

259. Active pharmaceutical substances are the raw ingredients used to make finished medicines and give medicine its therapeutic effect. The manufacture, importation and

distribution of active substances is regulated via the HMRs. The regulations underpin patient safety by ensuring that the active substances contained in final medicinal products are of appropriate quality to produce safe, effective medicines.

260. Manufacturers, importers and distributors of active substances must register with MHRA²⁵ who are required to enter the relevant details of successful application for registration into a publicly available database. MHRA must then be updated on any changes to the information initially submitted that could impact on quality or safety of the active substances that are manufactured, imported or distributed.
261. Once registered the MHRA may inspect businesses to ensure compliance with relevant good practice both before such businesses start trading and on an ongoing basis if non-compliance is suspected or based on risk-analysis.
262. The manufacture of active substances is subject to good manufacturing practice (GMP) regardless of whether those active substances are manufactured in the UK or imported. Where active substances are manufactured in third countries it must be ensured that the manufacturing meets the relevant standards of good manufacturing practice, to provide a level of protection of public health equivalent to that provided for by UK law.
263. Importers of an active substance from a third country must comply with the guidelines for good distribution practice (GDP) in relation to the active substance. Distributors of an active substance within the UK that has been sourced from a manufacturer or an importer within the UK will also have to comply with the guidelines for GDP for active substances and both activities will be the subject of a GDP certificate.
264. The ability to amend and update the regulations in relation to active substances is necessary to maintain supply of safe and effective medicines and thereby continue to assure patient safety. However, the power to amend the UK Regulations (section 2(2) of the ECA) will be removed by operation of the EUWA on exit day. Without equivalent delegated powers, the ability to make changes to these regulations without primary legislation would be lost.
265. The ability to amend regulations in relation to manufacture, importation and distribution of active substances is necessary to protect public health because the quality of the active substance is critical to assure the quality and safety of the finished medicinal product. Active substances that do not comply with applicable requirements relating to medicinal products for human use pose serious risks to public health.
266. It is not possible to predict the changes that may be required in the future in this area as they are expected to be driven by emerging developments in the market and public health issues in the future. Legislative changes could, for example, be required to assure the quality of medicines and active substance starting materials and supply chain visibility measures.

²⁵ Authorised manufacturers of medicinal products that also manufacture and/or import active substances, either for use in their own products or products manufactured by other companies are also required to register.

267. Please note the scale of the costs and benefits generated by future changes will depend on the policy detail to be developed and set-out in subsequent secondary legislation. This secondary legislation will be accompanied by its own, bespoke, economic appraisal.
268. The starting materials used in the manufacture of active substances need to ensure that active substances meet the requirements for quality and purity that they purport or are represented to possess. During synthesis residual materials can be carried over into successive batches of the starting material if there are not adequate control strategies in place. Such carry over would risk unacceptable quality of the active substance, impacting the efficacy and safety of the final product.
269. There is an on-going investigation relating to nitrosamine contamination of ‘Sartan’ medicines and ranitidine. Some ‘sartan’ medicines were manufactured using an active pharmaceutical substance that was found to contain impurities, leading to contamination in the finished medicinal product. This contamination has led to widespread product recalls from the UK market. This power would enable us to make legislative changes to the requirements for active substances to prevent similar incidents occurring in the future.
270. Considering the outcome of the investigation, it may be necessary to make legislative changes to react to public health risks. However, as this investigation is still ongoing and the MHRA is still working to establish supply routes, it is difficult at this time to outline specific legislative amendments that will be required.
271. There would be no impact of option 1 compared to the current legal mechanism. In this scenario, changes could continue to be made via secondary legislation using section 2(2) of the ECA or those proposed here in line with the focussed uses outlined in the Bill.
272. The impact of option 1 compared to the do nothing baseline will be dependent on the nature of future changes required. Please note any future changes would be implemented via secondary legislation and accompanied by bespoke appropriate economic appraisal at that time. Given that they are likely to relate to ensuring the quality of active substances, it is reasonable to expect that the impacts could be:
- Additional costs on UK manufacturers, importers and distributors of active substances, approximately 200 in total, and medicines and the MHRA in assuring quality;
 - Additional benefits on UK manufacturers, importers and distributors of active substances, approximately 200 in total, and medicines and the MHRA via avoidance of costly recall processes; and
 - Additional benefits to public health.

Human medicines regulations illustrative example vii – brokering of medicines

273. The scope of EU regulations at present cover brokers who are involved in the sale or purchase of medicinal products without selling or purchasing those products themselves, and without owning and physically handling the medicinal products. Regulation of brokering was deemed necessary following brokers being found to be a key feature of historical UK

and wider EU medicines counterfeiting cases before they were brought within the regulatory regime.

274. Under the current regulations, brokers are required to comply with a series of requirements including but not limited to²⁶:

- Registering with the MHRA;
- Implementing a quality system, including an emergency recall plan element, in line with Good Distribution Practice (GDP) guidelines;
- Training staff around falsified medicines and reporting any suspected falsified medicines to the MHRA; and
- Following the general provisions on documentation in EU Good Distribution Practice and establishing various procedural and documentation processes.

275. Brokers interact with wholesalers and play an active role in the supply chain for medicines. Therefore, the ability to make future changes to UK legislation regarding broker registrations and obligations after the UK leaves the EU will be necessary to secure the medicines supply chain and ensure the UK remains an attractive and less burdensome place to market medicines.

276. For example, should any new industry practices arise that risk supply chain infiltration with falsified medicines, it could be necessary to amend the definition of brokering to provide greater clarity in respect of the activities this captures.

277. It is not possible to set-out the potential impacts of future changes without knowing what will be required in the future to protect the supply chain from infiltration of falsified medicines.

278. We can however say that there will be no impact of option 1 compared to the current legal mechanism. In this scenario, changes could continue to be made via secondary legislation using section 2(2) of the ECA or those proposed here in line with the focussed uses outlined in the Bill.

279. Comparing option 1 to the do nothing baseline the impacts will be dependent on the nature of future changes required. Please note any future changes would be implemented via secondary legislation and accompanied by bespoke appropriate economic appraisal at that time. Given that they are likely to relate to introducing additional safeguards against falsified medicines entering the supply chain it may be reasonable to expect that the impacts could be:

- Additional costs may accrue to medicines brokers if requirements to safeguard against falsified medicines increase;
- Additional benefits may accrue across the supply chain via avoidance of costly recall processes; and

²⁶ See impact assessment detailing full list of requirements introduced in 2013 [here](#).

- Additional benefits to public health may be generated by reducing the risk that falsified medicines could enter the supply chain.

Human medicines regulations illustrative example viii – importing of medicines

280. Currently, a manufacturer's licence is required in order to import medicines into the UK from outside the EEA.

281. To enhance UK competitiveness, we may want to change the type of licence required for different types of import. For example, to allow importers to hold a wholesale dealer's licence, rather than a manufacturer's licence, when importing products from companies that are based outside the EEA where the medicines are already physically in the EEA. This would help reduce burdens on importers, as there are higher costs associated with holding and maintaining a manufacturer's licence compared to a wholesale dealer's licence.

282. There would be no impact of option 1 compared to the current legal mechanism. In this scenario, changes could continue to be made via secondary legislation using section 2(2) of the ECA or those proposed here in line with the focussed uses outlined in the Bill.

283. The impact of option 1 compared to the do nothing baseline will be dependent on the nature of future changes required. Please note any future changes would be implemented via secondary legislation and accompanied by bespoke appropriate economic appraisal at that time. At a high-level these are expected to include:

- Reduced costs in maintaining the required license for importing medicines (for imports from non-EEA based companies where the products are already in the EEA, the MHRA estimates there are possibly only around 10 companies engaged in this activity).

Human medicines regulations illustrative example ix – recording of additional information to pharmacy records

284. Regulation 253 of the HMR requires pharmacies to keep records in respect of the sale or supply of prescription only medicines (POMs). The records must include specific pieces of information including for example the date the POM was sold or supplied, the type of medicine supplied and the name and address of the person for whom the POM was prescribed.

285. Note that the current record keeping requirement set out in Regulation 253 only applies to a specific subset of prescriptions. It does not cover NHS prescriptions, oral contraceptives, supply by wholesale dealing and others²⁷. Requirements to make or keep records in these situations are set out elsewhere and may be amended through other powers or regulatory or contractual mechanisms.

²⁷ Also excluded are the supply of controlled drugs where a separate record is made in accordance with the Misuse of Drugs Regulations 2001 or the Misuse of Drugs Regulations (Northern Ireland) 2002 and in Scotland or Northern Ireland, supply to a doctor for immediate treatment or personal administration under the relevant General Medical Services regulations.

286. However, as part of the HMRs regulation 253 is made under section 2(2) of the ECA and we will lose the ability to amend it post exit. This would render the Government unable to amend the record keeping requirements for prescriptions subject to regulation 253 creating a risk of divergence in reporting requirements for different prescription types. Consequently, we would like the Bill to include the ability to amend this area of the HMRs going forward.
287. It is not possible to foresee all future uses of this power. Instead, the rest of this assessment focuses on the potential impact of a use of the power that is already being considered.
288. Under the current EU Falsified Medicines Directive scheme (FMD), all POMs must display a unique identifier which enables the medicine's authenticity to be verified as it passes through the supply chain. Medicines can be identified and verified down to pack level.
289. Before supply to the patient the medicine is decommissioned on the system, recording that it has been dispensed and location where it was dispensed, to ensure that the unique code cannot be used or successfully scanned again. This happens at the pharmacy, hospital or other healthcare institutions supplying medicines to patients (e.g. ambulance or mental health trusts).
290. Under the development of a UK national falsified medicines system, the policy proposal would enable the UK to add the unique identifier of the POM pack dispensed to the information already recorded by the pharmacy. This would enable dispensers to trace individual packs dispensed and identify the patients that received them.
291. There would be no impact of option 1 compared to the current legal mechanism. 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 as opposed to section 2(2) ECA.
292. Conversely option 1 is expected to generate impacts when compared to the do nothing scenario. The Department would envisage the unique identifier being recorded in the pharmacy's record automatically as part of the electronic scan of the product during decommissioning under the FMD scheme.
293. For example, if recording the medicine's unique identifier, software enables the information to be sent to the FMD central database to decommission the product could also record the medicine's unique identifier against the pharmacy's record.
294. The information would need to be recorded at the 'point of supply' to the patient – i.e. at the point when the supplier is able to confirm who will be receiving the medicine and we expect a level of transaction costs will be generated by enabling this functionality.
295. In terms of the expected benefits, these are expected to accrue to pharmacies by significantly reducing the cost of implementing product recalls. At present, the information pharmacies record depends on their system, but often they will only be able to identify the brand of product dispensed to patients.

296. In the event certain packs of a product need to be recalled, the pharmacy would need to contact all patients who received that medicine and arrange return of any remaining products.
297. Under the new proposals, dispensers will be able to easily identify the exact product packs dispensed to patients and therefore reduce the administrative and cost burden of implementing product recalls. There may also be public health benefits in reducing harm generated by products subject to recall via swifter completion of the process.
298. Additionally, further benefits are anticipated around improving the robustness of the system. The ability to potentially recover medicines where codes have been used twice on the system would support the investigation of falsified medicines.
299. For example, if a criminal replicates a barcode the system would only generate an alert when an attempt is made to scan or decommission the second pack. Being able to directly identify the patient who received the first pack means they could be contacted more quickly with more chance of recovering the product.
300. Correct identification of which product is falsified, and which is not, would also ensure that any UK falsified medicines system would be more robust, and more secure than that of the existing model – helping in tracking down criminal activity to deter attempts to infiltrate the legitimate supply chain.

Veterinary medicines regulations illustrative example i – online retailing

301. 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.
302. 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.
303. 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.
304. 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.
305. 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.
306. 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.
307. 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.

308. 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

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

310. 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.

311. The pharmaceutical industry has identified that compliance with labelling rules constitutes the largest part of their total administrative burden (34% of the total administrative burden⁴¹).

312. 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).

313. 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.

314. There would be no impact of option 1 compared to the current legal framework. 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..

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

⁴¹ 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

Veterinary medicines regulations illustrative example iii – data protection

316. The current VMRs, which will be carried over as retained EU law on exit day, include requirements for the periods of data protection for authorised veterinary medicines.
317. Data protection periods are used to encourage innovation by rewarding marketing authorisation holders with a period of exclusivity during which time a generic version of their product cannot be placed on the market. The data protection period starts from when a product first receives authorisation, and currently lasts for 10 years (13 years for fish and bees).
318. A marketing authorisation application for a generic version can be submitted 2 years before the end of the data protection period but the product, if authorised, cannot be placed on the market until after the data protection period ends.
319. Data protection periods can be extended by, for example, adding new species to an authorised product. Marketing authorisation holders would receive an extra year of data protection per new food-producing species added to an existing MA. This is provided additions are made within 5 years of the initial authorisation, and up to a total of 13 years. This encourages marketing authorisation holders to invest in further innovation.
320. The ability to make changes to the data protection periods in the VMR currently flows from ECA 2(2). An example of a change that we are considering is the increase in the data protection periods for medicines for certain species, for example bees. The current data protection for bees is 13 years, however we are considering extending this to 18 years.
321. The market for bee medicines is small and therefore many pharmaceutical companies do not develop medicines for this species. This policy option would make investing in new and novel products for bees more attractive, therefore increasing the availability of medicines for this important species.
322. Whilst extended periods of data protection benefit the innovator sector, the periods cannot be extended for too long as they disadvantage companies that market generic medicines. We must ensure a balance between these competing sectors, as a thriving generics market also increases availability and choice of medicines for animal owners.
323. There would be no impact of option 1 compared to the current legal mechanism. 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 as opposed to section 2(2) ECA.
324. Conversely, if option 1 were pursued in the do-nothing scenario we would retain the ability to introduce further changes to the data protection periods 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.

Impacts on small and micro businesses (SMB)

325. 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.

326. 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.

327. The ONS⁴² estimated the following distributions across business sizes for organisations within the Standard Industrial Classifications deemed relevant to this IA in 2019:

Table 6 - 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								
Standard industrial classification code and industry description	Employment Size Band							Total
	0-4	5-9	10-19	20-49	50-99	100-249	250+	
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

328. 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.

329. 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):

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

⁴² Source: <https://www.ons.gov.uk/releases/ukbusinessactivitysizeandlocation2019>

331. 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, 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 7 - 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 out 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.	

Annex C – activity data for procedures deemed likely to include the implanting of a medical device in the devolved nations, 2018/19

Broad list of procedures deemed likely to include a class III medical device - England 2018/19		Finished consultant episodes
Main procedures and interventions: 3 character code and description		
K60	Cardiac pacemaker system introduced through vein	42,136
K61	Other cardiac pacemaker system	2,338
K73	Other cardiac pacemaker system introduced through vein	2,686
K74	Cardiac pacemaker system	357
O06	Hybrid prosthetic replacement of shoulder joint using cemented humeral component	159
O07	Hybrid prosthetic replacement of shoulder joint using cemented glenoid component	833
O08	Hybrid prosthetic replacement of shoulder joint using cement	50
O18	Hybrid prosthetic replacement of knee joint using cement	178
O21	Total prosthetic replacement of elbow joint using cement	519
O22	Total prosthetic replacement of elbow joint not using cement	25
O23	Total prosthetic replacement of elbow joint	96
O24	Prosthetic replacement of head of radius using cement	63
O25	Prosthetic replacement of head of radius not using cement	396
O26	Other prosthetic replacement of head of radius	207
O32	Total prosthetic replacement of ankle joint	969
V36	Prosthetic replacement of intervertebral disc	233
W05	Prosthetic replacement of bone	763
W37	Total prosthetic replacement of hip joint using cement	33,008
W38	Total prosthetic replacement of hip joint not using cement	30,842
W39	Other total prosthetic replacement of hip joint	6,086
W40	Total prosthetic replacement of knee joint using cement	82,688
W41	Total prosthetic replacement of knee joint not using cement	2,455
W42	Other total prosthetic replacement of knee joint	2,176
W43	Total prosthetic replacement of other joint using cement	146
W44	Total prosthetic replacement of other joint not using cement	1,078
W45	Other total prosthetic replacement of other joint	737
W46	Prosthetic replacement of head of femur using cement	23,460
W47	Prosthetic replacement of head of femur not using cement	2,327
W48	Other prosthetic replacement of head of femur	716
W49	Prosthetic replacement of head of humerus using cement	488
W50	Prosthetic replacement of head of humerus not using cement	467
W51	Other prosthetic replacement of head of humerus	122
W52	Prosthetic replacement of articulation of other bone using cement	136
W53	Prosthetic replacement of articulation of other bone not using cement	177
W54	Other prosthetic replacement of articulation of other bone	346
W55	Prosthetic interposition reconstruction of joint	791
W72	Prosthetic replacement of ligament	179
W73	Prosthetic reinforcement of ligament	198
W93	Hybrid prosthetic replacement of hip joint using cemented acetabular component	2,800
W94	Hybrid prosthetic replacement of hip joint using cemented femoral component	22,198
W95	Hybrid prosthetic replacement of hip joint using cement	689
W96	Total prosthetic replacement of shoulder joint using cement	2,179
W97	Total prosthetic replacement of shoulder joint not using cement	3,520
W98	Total prosthetic replacement of shoulder joint	776
L27	Transluminal insertion of stent graft for aneurysmal segment of aorta	3,674
L57	Other replacement of aneurysmal femoral artery	297
O01	Transluminal coil embolisation of aneurysm of artery	1,723
O02	Transluminal balloon assisted coil embolisation of aneurysm of artery	583
O03	Transluminal stent assisted coil embolisation of aneurysm of artery	420
K59	Cardioverter defibrillator introduced through the vein	11,649
K65	Catheterisation of heart	2,888

Northern Ireland and Wales activity data for procedures deemed likely to include the implanting of a medical device 2018/19		
Principal Procedure	FCEs Wales	Finished episodes Northern Ireland
K43 - Prosthetic replacement of coronary artery	2	0
O18 - Hybrid prosthetic replacement knee joint using cement	106	32
O21 - Total prosthetic replacement elbow joint using cement	34	9
O23 - Total prosthetic replacement of elbow joint	4	5
O24 - Prosthetic replacement of head of radius using cement	1	<5
O25 - Prosthetic replacement head radius not using cement	11	<5
O26 - Other prosthetic replacement of head of radius	11	12
O32 - Total prosthetic replacement of ankle joint	16	18
V36 - Prosthetic replacement of intervertebral disc	2	0
W05 - Prosthetic replacement of bone	5	16
W37 - Total prosthetic replacement of hip joint using cement	1,306	457
W38 - Total prosthetic replacement of hip joint not using cem	2,005	651
W39 - Other total prosthetic replacement of hip joint	334	279
W40 - Total prosthetic replacement of knee joint using cement	4,054	443
W41 - Total prosthetic replacement of knee joint not using ce	237	976
W42 - Other total prosthetic replacement of knee joint	118	56
W43 - Total prosthetic replacement of other joint using cemen	12	<5
W44 - Total prosthetic replacement of other joint not using c	22	<5
W45 - Other total prosthetic replacement of other joint	47	5
W46 - Prosthetic replacement of head of femur using cement	1,318	769
W47 - Prosthetic replacement of head of femur not using cemen	197	7
W48 - Other prosthetic replacement of head of femur	59	96
W49 - Prosthetic replacement of head of humerus using cement	24	23
W50 - Prosthetic replacement of head of humerus not using cem	35	9
W51 - Other prosthetic replacement of head of humerus	4	23
W52 - Prosthetic replacement/articulation/other bone using ce	5	0
W53 - Prosthetic replacement/articulation/other bone not usin	4	<5
W54 - Other prosthetic replacement of articulation of other b	17	<5
W55 - Prosthetic interposition reconstruction of joint	61	19
W72 - Prosthetic replacement of ligament	6	5
W73 - Prosthetic reinforcement of ligament	8	0
W95 - Hybrid prosthetic replacement of hip joint using cement	61	26
W98 - Total prosthetic replacement of shoulder joint	45	14
K60 - Cardiac pacemaker system introduced through vein	2,079	1,066
K61 - Other cardiac pacemaker system	276	36
K73 - Other cardiac pacemaker system introduced through vein	115	124
K74 - Cardiac pacemaker system	8	21
L27 - Transl.insertion of stent graft for aneurysmal smt aort	117	94
M33 - Percutaneous ureteric stent procedures	83	23
O03 - Transluminal stent assisted coil embolisation of aneury	21	21
K49 - Transluminal balloon angioplasty of coronary artery	175	187
K75 - Percutaneous transluminal balloon angioplasty and inser	4,150	3,600
O02 - Transluminal balloon assisted coil embolisation of aneu	46	25

Scotland activity data for procedures deemed likely to include the implanting of a medical device 2018/19	
MAIN PROCEDURES BY CHAPTER	Number of procedures
Coronary angioplasty/stent	7,916
Angioplasty/stent of aorta	260
Arteriovenous shunt procedures	1,198
Primary total hip replacement	7,857
Other total hip replacement	1,180
Primary total knee replacement7	7,485
Other total knee replacement7	549
Other total joint replacement	632