Health Bill: MHRA reforms - impact assessments

This document contains the following impact assessments:

1. Title: MHRA information sharing reforms - IA number: DHSCIA9722
2. Title: Streamlining MHRA processes for regulatory change - IA number: DHSCIA9723

Final stage impact assessment

Title: MHRA information sharing reforms

Type of measure: Primary legislation

Stage: Final

Source of intervention: Domestic

Department or agency: Department of Health and Social Care (DHSC)

Other departments or agencies: Medicines and Healthcare products Regulatory Agency (MHRA)

IA number: DHSCIA9722

RPC reference number: N/A

Contact for enquiries: healthlegislation@dhsc.gov.uk

Date: 28/08/2026

Summary: Intervention and Options

Cost of preferred (or more likely) option

Total net present social value (in £m): N/A (not quantifiable but expected low positive)

Business net present value (in £m): N/A (not quantifiable but expected low positive)

Net cost to business per year (in £m): N/A (expected negligible)

What is the problem under consideration? Why is government action or intervention necessary?

Effective data sharing across the UK health system is essential for the Medicines and Healthcare products Regulatory Agency (MHRA) to regulate medicines and medical devices, protect patients, and support access to new products. Current legislation restricts the MHRA's ability to share information with UK and international partners, creating delays and inefficiencies. The MHRA often relies on resource-intensive Memoranda of Understanding or Information Sharing Agreements with individual organisations, reducing the speed and quality of collaboration needed to respond to emerging safety issues and improve regulation. Government intervention is required to reform the restrictions and deliver improvements.

What are the policy objectives of the action or intervention and the intended effects?

- Provide clear primary powers that set out the MHRA's ability to share information with appropriate UK and international bodies and health system organisations.
- Deliver simpler, more effective and more efficient knowledge sharing and management.
- Facilitate faster market access for new medical products by enhancing information sharing and alignment with health system partners, by minimising administrative delays.
- Support health surveillance to enable publication of timely guidance that keeps pace with innovation, followed by safe and efficient patient access to medical products.

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

Option 1 (business as usual): Retain existing legislation in relation to MHRA information sharing.

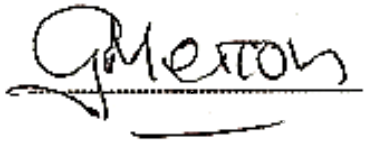
Option 2 (preferred option): Amend legislation to remove current restrictions where appropriate and simplify the legislative framework for the sharing of information by the MHRA. The sharing of personal data is not within scope of these changes.

Other options considered but rejected during earlier analysis include removing or reducing the need for information to be supplied to regulators (counter-productive, would increase risks to patients), and encouraging business to supply information to multiple regulators or organisations, avoiding the need for the MHRA to share more widely (complicated, expensive for businesses, and likely to leave gaps in information and delays in securing it).

Will the policy be reviewed? It will be reviewed. If applicable, set review date: TBC				
Is this measure likely to impact on international trade and investment?		No		
Are any of these organisations in scope?	Micro Yes (indirect)	Small Yes (indirect)	Medium Yes (indirect)	Large Yes (indirect)

What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)	Traded: N/A	Non-traded: N/A

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

Signed by the responsible Minister:  Date: 8-9-26

Summary: Analysis & Evidence

Policy Option 1

Description: Amend legislation to remove current restrictions where appropriate and simplify the legislative framework for the sharing of information by the MHRA

Full economic assessment

Price Base Year N/A	**PV Base Year** N/A	**Time Period Years** N/A	**Net Benefit (Present Value (PV)) (£m)** Positive but not quantified		
			Low: N/A	**High:** N/A	**Best Estimate:** N/A

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

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

Due to policy uncertainty around estimating the timing and content of the future pipeline of medical product launches, most costs are unquantified.
One-off familiarisation costs to understand the legislative changes and new processes include £20,000 for the MHRA to develop training and guidance, with that training then provided free to businesses and other stakeholders (with only a small, time opportunity cost to them).

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

The main costs considered for these changes (all relatively low) are:

- One-off legal costs (primarily to the MHRA) associated with preparing new guidance.
- Operational costs of sharing information or IT systems (unlikely to be materially different from the status quo, as there is no change to the information being requested).
- Compliance and monitoring costs (likely low).

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

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

Uncertainty over future product launches means that benefits cannot be robustly quantified. The exception is expected administrative cost savings by reducing the need for bespoke information sharing agreements. This is estimated to save around 40% of the current costs (£50k out of £113k per year) for the MHRA and £10 to £20k for counterparties, on an annual recurring basis.

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

Other benefits considered qualitatively in this impact assessment are:

- Improved clarity of regulation.
- Enabling faster patient access to new medicines and medical devices.
- Improved consistency across businesses.
- More efficient research and development.
- Future consequential benefits, such as health gains from faster access to medicines, improvements in NHS implementation planning and patient safety (both from improved information flows).

Distributional impacts

It is possible that enabling patients to access medicines more quickly, or addressing safety concerns more effectively, may have a distributional effect, but that is not known at this time.

Key assumptions/sensitivities/risks	Discount rate	N/A

The key policy risks are:

- Those relating to all information sharing related policies, such as inappropriate sharing of confidential information and information security breaches. These are mitigated by existing appropriate security and business continuity measures to protect information that the MHRA already holds, routinely receives and shares externally.
- The low risk of businesses changing their willingness to share information with the MHRA following these legislative changes. This is expected to be mitigated by ongoing engagement with stakeholders by MHRA, and the setting of clear expectations for no onward sharing of information within legislation and handling instructions.

There is also an analytical risk related to uncertainty around the future volume of applications the MHRA will receive. This means that costs and benefits may be higher or lower than expected.

Business assessment (Option 2)

Direct impact on business (Equivalent Annual) £m: N/A (but likely to be negligible)		
Costs: N/A	Benefits: N/A	Net: N/A

Evidence Base

Problem under consideration and rationale for intervention

Problem under consideration

An ability to share information across the UK health system is essential for the MHRA to perform its regulatory functions, protecting patient safety and facilitating access to medical products.[1] However, current legislation constrains the MHRA's ability to share information about medicines and medical devices with other relevant UK and international bodies and health system organisations. In addition, information sharing powers differ for medicines and medical devices for historical reasons, which causes additional inefficiency.

As a result, the current information environment is not optimal and presents an obstacle to effective collaboration, quality and speed of information sharing. To ensure that necessary information can be shared to enable access to new medicines and medical devices and to protect patient safety, time consuming and inefficient Memoranda of Understanding (MOUs) or Information Sharing Agreements must be agreed with each organisation. This significantly impedes more responsive information sharing between health partners to address emerging issues or needs.

The MHRA regulates medicines, medical devices and blood components used in transfusion for the whole of the UK. The Department of Health and Social Care (DHSC) is responsible for regulations regarding the safe supply, prescribing and administration of medicines. As the UK regulator, any arrangements made by the MHRA to enable information sharing must consider health system partners from all devolved governments.[2]

Under existing legislation, the MHRA faces significant barriers to sharing information which it holds in relation to medicines and medical devices with other organisations that are responsible for patient protection and access to safe, clinically effective, and cost-effective medicines and medical devices. This includes devolved governments, DHSC, UK health system organisations, and relevant international bodies.

For medicines, the current legislation inhibits information sharing nationally, and also internationally without the presence of an agreement. In contrast, for medical devices, the current legislation provides for more areas of lawful information sharing, but these are also constrained in many aspects including with respect the statutory conditions that must be met in s39(7). For example, disclosures of information must fall within prescribed purposes and satisfy specified legal thresholds, which can restrict the extent to which information can be shared with other regulators, approved bodies, healthcare bodies, and international partners. This makes it significantly more challenging and time-consuming to ensure that the necessary information is shared to drive regulatory improvement, ensure patient safety and facilitate access to newly authorised medical products.

The problem is due to the following issues:

- The MHRA is part of the same legal entity as DHSC, and yet the process for sharing information with the devolved governments, DHSC and its Arm's Length Bodies (ALBs),

[1]This refers explicitly to the MHRA sharing data it holds with others. Processes whereby others share information with the MHRA are out of scope and will not change with these proposals.

[2] For Scotland and Wales, the regulation of medicines and medical devices is reserved. For Northern Ireland, human medicines are transferred matters under the Northern Ireland Act 1998, meaning that any changes would require consent from the Northern Ireland Assembly. For medical devices, under the terms of the Windsor Framework, each of the EU medical devices regulations, the EU Medical Devices Regulation (EU MDR 2017/745) and the EU *In vitro* Diagnostic Medical Devices Regulation (EU IVDR 2017/746) apply in Northern Ireland.

such as the UK Health Security Agency (UKHSA), lacks clarity and carries the risk of legal challenge.

- The current legal basis for sharing audit and safety information with relevant bodies outside the UK is unclear and too narrow. It also does not reflect the creation of a new International Reliance system, as set out under the International Recognition Procedure on GOV.UK, whereby approvals by foreign jurisdictions will be accepted as evidence that a product is suitable for use in the UK. To deliver this system effectively, the MHRA requires clear legal powers to share relevant information (not covered by the current permitted categories) it holds with foreign jurisdictions, such as audit information.

- To overcome these legislative barriers, information sharing agreements have historically been used by the MHRA to mitigate risk of confidentiality breaches and provide a framework under which information about medicines and medical devices can be shared. This process requires individual set-up for each organisation with specific remits. This is time consuming and inefficient, slowing down (and in some cases preventing) the sharing of information in a timely manner. It also limits the information which can be shared between organisations to that specified in the original agreement, which can cause issues where other relevant information is available but cannot be shared due to agreement restrictions.

- Failure to address the current restrictions will hamper initiatives which rely on information sharing to enable wider progress. This includes the Government's Growth Agenda, the 10 Year Health Plan for England and the Life Sciences Sector Plan. Improved information flow would directly support these wider strategic plans to drive growth in life sciences, reduce regulatory burdens, enhance patient access and choice.

For reference, the existing provisions and constraints relating to information sharing for medicines and medical devices are:

- Section 8 of the Medicines and Medical Devices Act (MMDA) 2021 enables the 'relevant authority', which could be the MHRA, to disclose information about **medicines** to bodies outside of the UK, when giving effect to an international agreement. However, there are no provisions about sharing information about medicines domestically, or without the presence of an international agreement.

- Regulation 332 of the Human Medicines Regulations (HMRs) places limits on the sharing of information obtained under the regulations. While the MHRA may disclose information when carrying out its regulatory responsibilities, the legislation does not always provide clear boundaries on what falls within those responsibilities. This can make it difficult to determine when information sharing is permitted, potentially limiting effective collaboration with other organisations and regulators.

- Section 39(3) of the MMDA 2021 provides for the Secretary of State of Health and Social Care, and therefore, in practice the MHRA on its behalf, the ability to disclose information held about **medical devices** with other organisations who provide services or exercises functions in relation to medical devices. It also supports information sharing to bodies outside of the UK where international agreements exist (s39(5)). Section 39 therefore provides for broader powers for medical devices, with no equivalent provision for medicines.

As a response to these problems, the MHRA has launched a non-statutory, voluntary information sharing service with cross-UK health system organisations in relation to the timeline and progress of Marketing Authorisation (MA) Applications under the Operational Information

Sharing programme[3]. Currently, MA Applicants can consent to operational information about individual applications being shared as part of the online MA application process on MHRA's Human Medicines Portal. The proposed reforms seek to streamline this process, reducing administrative burden that may cause delays to patient access.

Operational evidence from MHRA and their customers

Informal engagement, as well as feedback submitted to formal consultations as part of the statutory review of the MMDA[4] and the Post Implementation Review of the HMRs, indicates that there is a mutual interest between businesses and regulators in ensuring that regulatory processes across the health system are completed as quickly and efficiently as possible. More specifically, potential delays in patient access to new medicines and medical devices may have a direct impact on marketing timelines and profitability for businesses.

The MHRA records the consent rate by Marketing Authorisation Applicants (MAAs) in response to information sharing requests under the Operational Information Sharing Programme, and this shows an 87% consent rate across nearly 200 requests made between Jan 2024 and April 2025. This indicates that businesses accept the need to share information in most cases with health system partners to improve patient access to innovative medicines. Only in a minority (13%) of cases, did companies object to (some) sharing of information for specific individual products. The proposed policy will cater for this concern (see Risk section covering risks and mitigations).

There has also been implicit support from industry trade association representatives for other information sharing initiatives, such as the current consent-based Operational and Pilot Technical Information Sharing Programmes, which were introduced to help share information with health system partners including the National Institute for Health and Care Excellence (NICE) as part of no-deal EU Exit planning. Whilst these are consent based sharing initiatives, they imply an underlying support for increased information sharing. Industry trade associations have engaged constructively in the current programmes.

Technical evidence – examples arising from current information sharing

The following recent, real-world examples illustrate the types of problems that can arise from delays or restrictions in sharing information:

- NHS England, the Scottish Medicines Consortium and NICE requested information from the MHRA to help the health system prepare for the adoption of new dementia drugs. An information sharing agreement, alongside consent from the Marketing Authorisation Applicant, enabled the Summary of Product Characteristics (SmPC) to be shared with the requestors. However, the information shared was limited to that defined in the information sharing agreement, presenting limitations to the information which could be shared.

- NICE often requests pre-market information about new products from the MHRA. For example, safety signals and potential Field Safety Notices were required for digital mental health technologies (DMHT) so that NICE could agree timelines for publishing associated guidance. Such information is outside the current remit of the Operational and Pilot Technical Information Sharing programme and could not be shared promptly, delaying the required guidance.

[3]The MHRA has set up a consent process on an application-by-application basis where Marketing Authorisation Applicants submitting a medical product are asked for consent to share specific and limited operational timeline information with health system partners. This enables the most efficient patient access and applies to Marketing Authorisation Applications for innovative medicines submitted via the Human Medicines Portal. There are a few exceptions where data for certain types of application are not shared, but these are a very small proportion.

[4] DHSC (2026), Medicines and Medical Devices Act 2021: 5 year report - GOV.UK (accessed April 2026).

- The UKHSA is a major partner working with the MHRA on multiple joint work programmes including pandemic preparedness. However, such work is hampered because the sharing of medicines' clinical trial data relating to the product, information and physical materials is not straightforward. This is due to data sharing agreements having to be developed for every new piece of information needing to be shared. The impact of this cannot be quantified but adds risk, cost and delay.

While not precisely quantifiable, the effect of these and similar examples adds significant risk to the timeliness and quality of MHRA work, and it helps demonstrate the nature of the problem this reform is trying to resolve.

Rationale for Government intervention

This bill proposes to address existing obstacles to information sharing between health partners. The aims of the 10 Year Health Plan will be supported by improved information sharing between organisations in the health system.

Barriers to information sharing have existed for a long time and are overdue for reform. Further delay would miss the opportunity to address these issues and risk entrenching existing limitations. Reforming the regulations now aims to deliver the following benefits:

- the most efficient access to innovative medicines and medical products (minimising delays in patient access to all newly authorised medicines and devices) and removing barriers to streamlined information sharing;
- improvements in patient safety;
- enhanced health protection;
- enhanced alignment between MHRA and key health systems partners;
- enhanced public confidence; and
- improved information and intelligence sharing by the MHRA to other relevant cross-Government health system partners, reducing administrative burdens, duplication and supporting collaboration.

MHRA will engage with health system partners nationally, in particular with the devolved governments. Additionally, international partnerships, especially through the International Reliance routes, are also pivotal to enhancing the route to market for innovative products.

The Industrial Strategy, various Sector Plans and the 10 Year Health Plan all called for increased collaboration between different health system partners, in which information sharing underpins greater collaborative efforts to create 'the world's most collaborative public healthcare provider'.

There are specific commitments in the 10 Year Health Plan for the MHRA and NICE to increase alignment through information sharing. This includes the launch of an integrated scientific joint advice service. Therefore, these bill proposals will help health system partners to deliver this, as well as broader commitments outlined in the 10 Year Health Plan, such as the expansion of NICE assessments to include MedTech, use of genomics and access to novel medicines to tackle obesity.

These proposals would also support the Government's Regulatory Action Plan, which aims to reduce the burden of regulation by 25%, and would provide a small benefit in this regard by reducing the need for bespoke information sharing approvals to be agreed.

Description of options considered

Main options considered in this assessment

Option 1 (business as usual): This option retains existing legislation in relation to MHRA information sharing.

Option 2 (preferred option): This reform will amend the MMDA 2021 to remove current restrictions and simplify the legislative framework for the sharing of information by the MHRA as follows:

- enable the MHRA to share information about **medicines** with appropriate UK health system organisations and relevant international bodies, which brings the power to share information about medicines in line with that for medical devices
- enable the MHRA to share information about **medical devices** with the devolved governments, appropriate UK health system organisations, and public research bodies in a broader range of circumstances, including registration information inspections, audit reports and safety reporting information
- enable the MHRA to share audit, compliance and safety information related to **medicines and medical devices** with relevant public authorities outside the UK where the UK may not necessarily have an international agreement or arrangement in place.

These changes will ensure health system organisations have information about medicines and medical devices to protect patients and the public, facilitate more efficient access to these, and improve collaboration between organisations.

These changes will enable the MHRA to share information and intelligence it holds about medicines and medical devices with other parts of the UK and international health system and regulators without the need for individual information sharing agreements with such bodies, except in exceptional cases outside the statutory information gateway. These organisations would include other government departments, other health regulators and the devolved governments, and other relevant bodies or organisations, for the purposes of improving or protecting patients and public health.

Wider options considered

In principle, the main options addressing the current issues with information sharing are:

- Remove or reduce the need for information to be supplied to regulators and other health system partners. This is considered not viable and would be counter-productive, increasing risks to patient safety as regulatory decisions would not be informed by sufficient evidence.

- Encourage businesses to supply information to multiple regulators or organisations, avoiding the need for the MHRA to share more widely. This is possible but could be complicated if the required list of recipients is situation-dependent. It is also unlikely to result in full information sharing if done on a voluntary basis, meaning that there are likely to be considerable gaps in information and delays in securing it. It would also add costs to business, particularly if mandated. It would perpetuate many of the issues that the current arrangements of voluntary information sharing agreements already present, in terms of limitations and undue burden, and would not provide for greater efficiency or more responsive information sharing.

- Grant the MHRA explicit legislative powers to share information where necessary and appropriate to do so **(the preferred option)**. This option would reduce the risk of delays

in patient access while reducing costs to both regulators and business. It also provides clarity, consistency and a robust framework (including safeguards) for sharing information.

The preferred option recognises that the MHRA sharing information across the health system is essential to protect patients, improve public safety and to build a world-class system of surveillance. All of these require a much richer information environment than in the past. The preferred option:

- Allows the MHRA to share more information with health system organisations, such as NICE, the devolved governments or international bodies, to ensure the whole system can work together effectively.

- Reduces administrative burdens on other health system organisations including businesses, albeit modestly, by removing the need to deal with bespoke information sharing agreements.

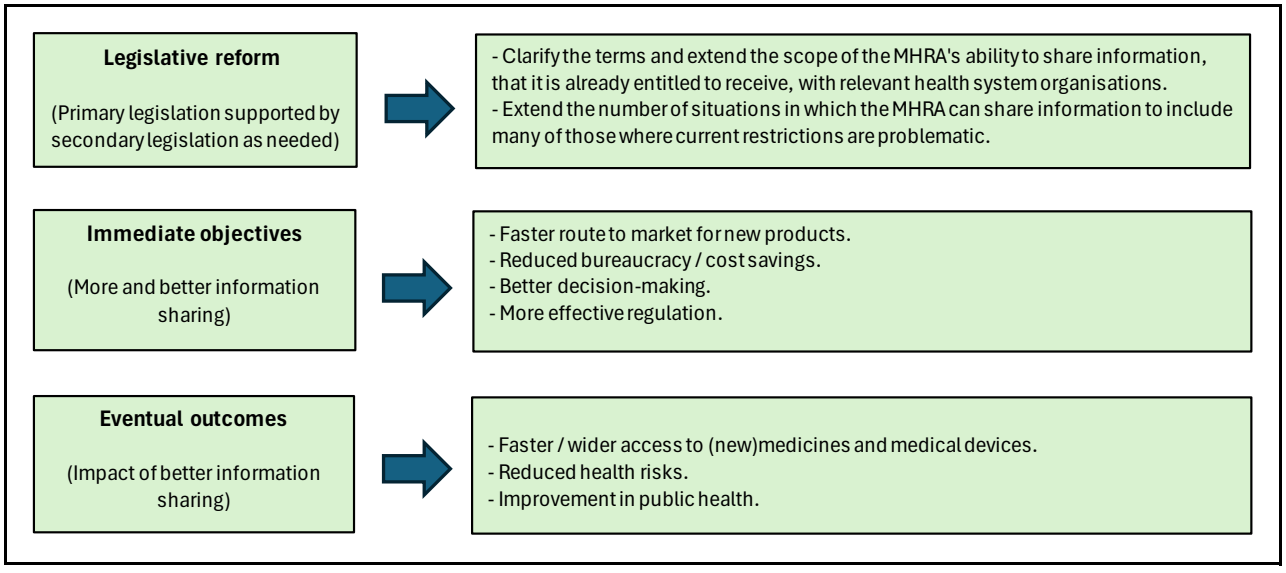
- Includes appropriate safeguards. The MHRA will, for example, develop comprehensive information sharing guidance, setting out the information sharing process and purpose. This guidance will be adapted to support different scenarios. In addition, it will specify that there should always be a clear purpose for sharing the information, and limitations for onward sharing, as set out in the legislation.

Policy objective

Overview

Objectives for these information sharing proposals can be considered on 3 levels, as shown in Figure 1.

Figure 1: Theory of change for information sharing proposals



The legislation aims to define and enhance the broad powers authorising the MHRA to share information. It will provide clarity on, and extend, the specific circumstances in which information can be shared. It will include safeguards, controls and other provisions to ensure information is handled appropriately (see Risk section).

The immediate effects of this will be (1) a reduction in the time and administrative cost associated with seeking consent to share information, and (2) an increase in information sharing itself. This will benefit the MHRA, health system organisations and patients or the public. Reductions in administrative burdens will largely be experienced by the MHRA as they will be the organisation handling and sharing the information. Other health system organisations are likely to benefit by receiving information through a more streamlined process without the need to agree and manage information sharing agreements with the MHRA. Specific metrics can be defined for these improvements.

Procedural improvements are useful in themselves, but the expectation is that public health improvements would arise in time as shown in the above diagram. It is not possible to quantify these improvements at this stage or to set targets.

Objectives

One of the key purposes of the proposed changes is to enable effective sharing of information from the MHRA to other bodies and organisations. This then aims to improve patient access to medicines and medical devices, support patient safety and improve collaboration between health system organisations.

The first objective of the proposed primary powers is to enable the most efficient access to newly authorised medicines and medical devices for patients, by **minimising delay.** This will be achieved by:

- enhancing information management arrangements to allow formal sharing of pre-market information about medicines and medical devices
- ensuring legal input and safeguards are sufficient to cover any risks of sharing, such as information leakage, and associated mitigations
- as a result of the above, ensuring that the MHRA has the ability to share licensing and relevant pre-market information in a timely manner with Health Technology Assessment (HTA) and NHS bodies to support their associated processes.

Information sharing will facilitate and inform the planning, scheduling, evaluation, commissioning, and patient pathway decisions of health technology evaluation by HTA bodies across the United Kingdom to support the **publication of timely guidance**. It will also enable NHS services across the 4 UK nations to schedule any preparatory activities necessary to proactively manage access arrangements related to the commissioning of new medicines and services for patients. This sharing will also inform the HTA bodies' evaluation process, support HTA recommendations and allow for proactive infrastructure in the NHS to enable implementation of new medicines and medical devices.

A further objective is to **increase patient safety**. This can be increased by a combination of improvements to criminal investigation, audit and inspection reporting, and sharing and collaboration with other agencies. Collectively, this will increase (through information sharing by the MHRA) the evidence base to identify potential safety issues and help ensure that NHS and other health system organisations are alerted early to any potential safety issues or potential disruptions in the supply of medicines and/or medical devices. This in turn supports decision-making on the best action to take to protect patients.

Another aim is to further **improve the response to emerging public health risks** by using better information sharing to support collaborative projects with relevant UK and international bodies and organisations, such as UKHSA, DHSC, other UK regulators, law enforcement agencies and others.

Specific metrics

Table 1 sets out the detailed objectives and metrics will be used to monitor the overall effect of the reform.

Table 1: Overview of SMART objectives to monitor the overall effect of this policy proposal

SMART component	Actions
Specific objective(s)	• achieve simultaneous, or as close to this as possible, approval of new medicines and publication of HTA guidance • reduce the time it takes for new products to be made available to patients through NHS services (when appropriate as per HTA guidance) • enable NHS services to prepare for any additional arrangements with better advance notice before the MA being granted • closer alignment between MHRA and other health system organisations supporting collaborative projects and ensuring patient safety
Measurement	To adopt a suite of measures to monitor progress, such as: • monitor the average delay between the approval of new products and publication of HTA guidance • monitor the time taken for new products to be made available to patients • monitor and/or seek feedback on whether NHS services are receiving better advance warning and/or are better prepared following these changes • feedback from industry or the NHS on regulatory timescales being applied • feedback and case studies from key health system partners on alignment
Achievable	• the proposals are achievable within existing resources • actual improvements may be very case-dependent: the expected indicative improvement is around 3 to 6 months in bringing new products to market, including having full guidance available
Relevance	• the objectives are fully aligned with broader health strategy, the 10 Year Health Plan and wider government ambitions to improve innovation and efficiency
Timing	• the MHRA expect to be able to implement changes relatively quickly, once the required legislation is in place, although precise timing is uncertain • benefits will arise gradually as different products are considered within the new information sharing rules

Summary and preferred option with description of implementation plan

To ensure that safety investigations, preparation of guidance and preparatory activities by HTA bodies and NHS services can be conducted efficiently to avoid delays to patient access, it is critical that the required information is made available, promptly, to the organisations involved.

The information generally originates from medicine and medical device manufacturers or related businesses. However, it may also come from other sources, such as safety signals received by the MHRA, or generated by the MHRA itself. Businesses provide product information to regulators to support approvals, authorisations, guidance and other practical aspects necessary before a product can be used in the UK health system.

In many cases, information is provided by businesses to the MHRA but not to other agencies and health system organisations. This requires the MHRA to then seek permission to share the information in some instances. In others, the MHRA is unable to share information with relevant organisations. While in most cases consent by the companies is given (through the Operational and Pilot Technical Information Sharing Programme), the need to seek their permission and develop an information sharing agreement with health system partners for every instance of information sharing causes delays. If consent is not given, this risks causing delays in patient access to new medicines, as alignment across the health system relies on health system partners having greater access to information to ensure a streamlined process.

Table 2 is not exhaustive, but it illustrates the types of information sharing envisaged as part of the reform.

Table 2: Potential information sharing made possible as part of these proposals

<table>
<tr><th></th><th>Proposal</th><th>How it supports SMART objectives</th></tr>
<tr><td>1</td><td>Amend the MMDA 2021 to enable information sharing related to medicines and medical devices</td><td>General enabler, removing existing restrictions and facilitating information sharing</td></tr>
<tr><td>2</td><td rowspan="2">Facilitate sharing with the following organisations, subject to meeting the statutory criteria:

• DHSC and its Arm’s Length Bodies (ALBs)
• Department for Science, Innovation and Technology and its ALBs
• the devolved governments
• UK Health Technology Appraisal Bodies, like NICE, Scottish Medicines Consortium (SMC), All Wales Therapeutics and Toxicology Centre (AWTTC)
• Care Quality Commission (CQC)
• Healthcare Improvement Scotland (HIS)
• Heath Inspectorate Wales (HIW)</td><td>Addresses delays or barriers with individual organisations, contributing collectively to the overarching objective.

(continued from left)</td></tr>
<tr><td></td><td>• Other UK regulators interacting with medicines or medical devices regulation, like Advertising Standards Authority (ASA), Office for Communication (Ofcom)
• Law enforcement
• Crown Prosecution Service (CPS)
• National Crime Agency (NCA)
• HM Revenue & Customs (HMRC)
• Local authority trading standards
• Office for Product Safety and Standards (OPSS)
• Food Standards Agency (FSA)</td></tr>
</table>

	• The Regulation and Quality Improvement Authority (RQIA) • General Medical Council (GMC) • General Pharmaceutical Council (GPhC) • General Dental Council (GDC) • British Dental Association (BDA) • NHS Service Bodies • Health Research Authority (HRA) This list is not exhaustive. It should be noted that the disparity between the legislation for medical devices and medicines means it is harder to share information with some of these organisations for certain purposes in relation to medicines than for medical devices.	• Home Office, Ministry of Justice • Foreign Office • Department for Work & Pensions • National Cyber Security Centre • EU Competent Authorities • EU Notified Bodies • EU Commission • Public research bodies • International Regulators and National Regulatory Authorities in other countries
3	Allow safety information (such as known or suspected adverse side-effects, drug-exposure information, measures that need to be taken by companies, healthcare professionals or patients to minimise risk) to be shared with health system organisations such as the UKHSA, NHS Service Bodies, NICE, public health and HTA bodies in the devolved governments	Increases the evidence-base that health system partners use to identify potential safety issues, such as during HTA evaluation, strengthening safety and access for UK patients. This is particularly important for Software as a Medical Device (SaMD) and Digital Mental Health Technologies, which can be incorrectly classified. Thus, self-certification of these products, which is different from the assessment of medicinal products, may mean that the MHRA would not be able to flag a safety signal earlier in the process Enables collaborative working with UKHSA to help inform responses to emerging public health risks or to respond to new clinical trials Enables the NHS to have access to Controlled Access Pathway information for medicines and medical products where such access is currently restricted owing to a lack of legislative provision
4	Enable information sharing related to company compliance with medicines regulatory requirements	This reform will allow the MHRA to share information and intelligence with other UK health system

	The MHRA carries out inspections, including of manufacturing sites, distribution sites or safety monitoring (pharmacovigilance activities), to ensure companies are complying with the regulatory requirements. The HMRs (regulations 325 to 329) set out the requirements for inspections	organisations or agencies (like CQC, other agencies or regulators who inspect the same clinical research activity facilities, UK professional regulators, the HRA, cross-UK NHS bodies, and DHSC) and international Mutual Recognition (MRA) partners where this information might be important, whilst keeping suitable restrictions in place to protect information shared (for example through a statutory onward disclosure prohibition). This aims to enhance collaboration, minimising delays in patient access
5	Enable information sharing related to medical device audits and compliance The ability to share information related to the inspection of medical devices is spread across different regulations. These include MMDA 2021, UK Medical Device Regulations (MDR) 2002 and Consumer Protection Act 1987 and the Regulation on Accreditation and Market Surveillance (RAMS) 765/2008 (RAMS) Medical device compliance and audit activity has been based on provisions within the UK MDR 2002, which are underpinned by MMDA 2021.	Removes the need to rely on provisions, such as Regulation on Accreditation and Market Surveillance (RAMS) No 765/2008, for audit of the manufacturer rather than the proposed more explicit provisions within MMDA 2021. This also addresses restrictions arising from Section 39 (10)(c) of MMDA 2021 on the extent to which the MHRA can disclose information following an audit with European counterparts where the MHRA has identified concerns relating to a CE-marked product.
6	Enable information sharing related to advertising	The MHRA would be able to share information about concerns of potentially illegal advertising of medicinal products to the public on social media platforms. This could include details of the advertisement of concern, details of the advertiser, current and past case history, and paraphrased informal legal advice on the concern and proposed actions. Improved information and intelligence sharing between the MHRA and other relevant cross-Government bodies is imperative. It would also support improved cooperation on public health concerns created from the advertisement of prescription medicines and unlicensed medicines to the public.

7	The MHRA would be able to share devices registration information that is not currently publicly available, inspections of manufacturers of medical devices and audits of Approved Bodies or Conformity Assessment Bodies (designated by the MHRA to conduct conformity assessments) without having individual information sharing agreements for each organisation on a case-by-case basis. The sharing of medical devices information is supported by Section 39 of the MMDA 2021, which provides powers for the sharing of this information with health system organisations, provided it supports the partners' and the MHRA's duties and functions related to medical devices. At present there are several individual information sharing agreements with various health system partners, but no overarching consistent system.	This information will be shared: • to protect public health and maintain public confidence • to inform procurement decisions in the event of supply disruption • to prevent disruptions in supply • to identify counterfeit products • for compliance purposes • for safety or incident reporting Reform would include safeguards to ensure that the information is not shared on further by health system partners.

Proportionality

The MHRA recognises that some information that is legitimately required to be shared may be commercially sensitive[5]. This creates a need for due care, consistency of treatment and fairness. Proportionate regulation ensures that information is shared appropriately by the MHRA in line with the interests of patient and public safety. The proposed reform is designed to provide the legislative safeguards to achieve this.

The scope of the reform is limited in 3 ways. Firstly, it extends only to the sharing of information that the MHRA already has access to. It does not create any new obligations for any person or organisation in the UK or overseas to provide information to the MHRA. Secondly, it focuses specifically on the MHRA's ability to share information with other regulators and health system organisations. It does not extend to these organisations sharing further with third parties. Any current, statutory restrictions on onward transmission are maintained.

Thirdly, these new powers are not intended to compromise the current confidentiality of commercially sensitive information the MHRA holds under the product approval processes.

[5] Examples of commercially sensitive, technical or anonymised clinical trial information that might be covered include: indications, dosage information, contraindications, warnings and precautions, interactions with other medicinal products, use in specific populations (like pregnant women, elderly), and information on side effects. Confidential patient data remains protected under the UK General Data Protection Act (UK GDPR).

Monetised and non-monetised costs and benefits of each option (including administrative burden)

This IA provides a proportionate assessment of costs and benefits based on the best available evidence and in line with HMT Green Book guidance. However, these proposals depend on future policy decisions regarding the application of the powers and therefore, as those policy decisions have not yet been made, it is not possible to fully quantify costs and benefits at this stage.

The costs and benefits of the preferred option are set out as a comparison to the business-as-usual option (which often involves bespoke and time-consuming information sharing agreements between the MHRA and other health organisations).

It is not possible to provide a comprehensive net present value for this proposal, given the difficulty of estimating health impacts, especially in the longer term. The future pipeline of product launches is uncertain, and while the reforms will add value, the exact timing and size of those impacts are not known.

Costs

The costs associated with improved information sharing are expected to be minimal, given there is no change being made to the information currently supplied to the MHRA. The new process will incur a transition cost to the MHRA to set-up but is expected to be cheaper than the status quo. The change is in what the MHRA is then allowed to do in regards of sharing information that they already hold with health system organisations, and in the processes followed to authorise and manage that sharing.

Overall, there is a one-off training, familiarisation and guidance development cost. This will largely fall on the MHRA and is expected to be low (less than £0.1million). There may also be a requirement for the MHRA to make minor system changes to amend the current consent-related questions businesses are asked to respond to, specifically under the Operational Information Sharing programme. It is less certain whether any costs will arise from exceptions, where information might need bespoke handling arrangements.

The reforms are not expected to introduce any ongoing costs. Benefits in terms of reductions in spend and time are expected primarily for the MHRA, but also other health partners and businesses. The following section sets out the expected costs in more detail.

Familiarisation with the new rules

Familiarisation costs will largely be incurred by MHRA (who will be sharing information) and other health system organisations (who will be receiving information).

Training (for both internal and external stakeholders) is expected to be delivered through guidance and an initial series of training events produced and run by the MHRA National Partnerships Team. The estimated cost to the MHRA is around £20,000 to develop and implement the training and guidance. This cost to the MHRA is one-off (as the guidance will then be subsumed within general training and engagement sessions in future years). The training will also come at an opportunity cost to MHRA staff who have to undertake training instead of performing other duties. The number of MHRA staff affected is uncertain at this stage. One-off legal costs are also likely to be incurred in reviewing the guidance and any accompanying statements.

The MHRA expects to use existing engagement channels to communicate the new rules to stakeholders. Also, businesses (who may want to be aware of how some of their information is

being used) would have to familiarise themselves with these new legislative proposals, which is expected to incur minimal cost.

Changes to information supplied by businesses

Businesses may decide that the enhanced sharing means the information they currently supply need to be reviewed or changed. This impact is not expected to be significant because the information concerned is already required by the MHRA to fulfil their regulatory duties, and this will not change.

Exceptions to sharing

Some information may not be suitable for sharing, and appropriate exceptions or constraints might need to be agreed to address any concerns via the publication of guidance. This would incur an ongoing opportunity cost to agree exceptions when required, however it is expected to be minimal. Agreeing not to share information in particular cases would differ from the current approach, whereby businesses currently need to decide whether to consent or not across the board. The costs are not expected to change significantly, although this is uncertain and would depend on the number and complexity of permitted exceptions.

Operational costs of sharing information

Regulators and health partners, including some international agencies, may incur operational costs for sharing information. The process by which the MHRA shares information under information sharing agreements will be case-specific. Where there is a change in timing or content of sharing, or with whom material is shared, there may a time cost requirement to review and agree the new arrangements.

Development and enhancement of information sharing IT systems

This cost would primarily affect regulators and health partners sharing information but could also affect businesses. It is expected to be minimal as the information is already collected by MHRA and necessary systems are in place. The MHRA already uses secure file transfer platforms to transfer information securely to multiple external organisations. This has worked well for transferring sensitive information to health system organisations. These systems provide all appropriate protection, safeguards and security to enable the sharing envisaged.

Compliance & monitoring

Future monitoring and compliance systems are expected to be proportionate to the frequency of information sharing and associated risk level. Regulators and businesses will both need to follow any protocols set out for sharing information. Costs are unlikely to change significantly compared to the business-as-usual option, as effective systems are already in operation.

Benefits

The benefits associated with improved information sharing are split between immediate benefits, mainly related to introducing greater regulatory efficiency, and longer-term consequential benefits, relating to increased patient safety and faster patient access to new medicines and medical devices.

These benefits are expected to occur relatively frequently. For example, with the benefit of the new sharing powers it would be expected that the MHRA, through its Operational Information Sharing programmes, would share information weekly as it completes different regulatory activities and updates partners on the predicted MHRA decision date for products in the pipeline. Greater collaboration with health system organisations during the pre-market stage also enables more efficient patient access to new medicines and offers the MHRA the ability to continuously improve the programme, ensuring that it is consistently fit for purpose.

Overall, the reforms should lead to cost savings, primarily for the MHRA but also for counterparties in any information sharing and related work. These savings are worthwhile but modest, at around £1million in total per year. The benefits are set out in more detail below:

Administrative cost savings associated with setting up information sharing agreements

The MHRA and health system organisations receiving information would face ongoing cost savings from these legislative changes reducing the need for bespoke information sharing agreements.

The MHRA estimates that around 6 to 8 new agreements are currently agreed per year, with a further 3 to 5 revisions to established agreements. These numbers are indicative, and do not include any agreements being held in abeyance or otherwise looked at without a final decision being taken.

The current cost to the MHRA is around £113k per year or around £10k per agreement (total administrative cost divided by the approximate volume) to facilitate the Operational Information Sharing Programme. Current time spent by the counterparty (the organisation that the MHRA is sharing with) is expected to be less, at around £1k to 2k per agreement. For businesses that already supply information, savings would be minimal but related to not having to review consent guidance and provide consent for information sharing during every Marketing Authorisation Application.

The MHRA expects the proposals to save around 40% of current costs: £50k for the MHRA and £10k to £20k for counterparties, all per year and recurring.

Improved clarity of regulation

This bill proposal may lead to a reduction in errors and queries, although, due to uncertainty around this, this benefit cannot be quantified. There could also be savings in legal costs resulting from not needing the Government Legal Department to interpret legislation or review agreements. The MHRA currently spends £250k per year on legal advice, although only a fraction of this will be on information sharing.

Faster patient access to new medicines and medical devices

These information sharing changes are expected to lead to faster access to medical products for patients by reducing the bureaucracy of the current approvals process through MHRA. However, this benefit cannot be robustly quantified because the circumstances are unique to each individual case, so are uncertain.

The NHS may also be able to better prepare for adoption of medicines and medical devices faster, benefiting patients, manufacturers and suppliers.

Improved consistency for businesses

By minimising the delays that affect some businesses or regulators more than others, this should ensure equitable information access across the health system for businesses and other organisations that require the information to fulfil their activities in a timely manner.

Businesses may have small administrative cost savings on consenting to share information for individual applications under the Operational Information Sharing Programme. Subsequently, costs will also be saved on engagement with individual organisations by improving collaboration across the health system.

More efficient research & development

As a result of faster decisions from MHRA due to more efficient information sharing, businesses developing new products would benefit from more efficient research and development processes.

Future potential benefits

There are 3 main consequential benefits expected as a result of this policy proposal (which are not quantifiable):

- Health gains resulting from faster and better access to medical products by patients
- Improvements in efficiency and planning for the NHS, by having more information available to decision-makers
- Improved patient safety (fewer incidents) results from better information flows and awareness

Direct costs and benefits to business calculations and impact on small and micro businesses

Overview

The proposals will affect several types of business that interact with the MHRA and health system organisations. The total number of businesses affected is not known exactly because future volumes of new products emerging from those businesses are uncertain, but the types of business affected are:

- developers of medicines or medical devices
- marketing authorisation applicants (MAAs) for medicines or medical devices
- researchers involved with product development and assessment
- indirectly, other businesses involved in the supply chain for medicines and medical devices

The reforms do not impose any new obligations on business. Nor should developers of medicines or medical devices be required to significantly change any processes on how they share information with the MHRA, as in many instances it is information they already share. In practice, the main effects on businesses are likely to include the following, with an overall mildly positive impact.

Benefits

The benefits to businesses are expected to be:

- small saving in administrative costs associated with reviewing and agreeing bespoke consent agreements
- improved clarity of regulation
- reduced delays in delivering patient access to medical products
- improved consistency of official guidance issued by minimising delays that affect some businesses or regulators more than others
- more efficient research & development, resulting from faster market access (less wastage of time and resources)

Costs

The costs to businesses are expected to be:

- familiarisation with and acceptance of the new rules
- agreeing to exceptional arrangements where information is restricted
- compliance costs (low)

Small and micro-sized business impacts (SAMBA)

The rules relating to safety and approval of medicines and medical devices are focused on the product itself rather than the product manufacturer or developer. This is considered correct and reasonable. It would not be appropriate, for example, to allow different safety standards to apply to different manufacturers of the same type of product, just because one firm was larger than the other.

As such, the proposed changes will affect all businesses in proportion to the number of products they bring to market and their resultant degree of interaction with official agencies. The impacts on small and micro enterprises (SMEs) are expected to mirror those on larger firms, with similar effects per interaction. The impacts are not expected to be disproportionately positive or negative for SMEs, and thus the proposals do not seek to mitigate the impact on smaller firms.

Wider impacts on the market

The overall effect of information sharing speeding up route to market will be case-dependent as stated. Although unlikely to materialise in every case, potential wider effects may include:

- competition: bringing new products to market more quickly could increase levels of competition and improve the market environment

- innovation and market entry: the reforms should reduce delays and costs for bringing novel, innovative products to market

- profitability: in principle, faster decisions and lower regulatory burdens may enhance profitability (albeit by a modest amount) through faster delivery of products to the market

- consumer choice: as with increasing competition, the reform would improve consumer choice, and also inform consumers about safety and effectiveness issues, allowing them to make more informed choices

- supply and demand: the market is expected to adjust as new products are approved and come to market, as a new product would likely capture some market share from established treatments, or, if the product is completely innovative, from other spending.

Risks and assumptions

Policy risks

Policy risk refers to the chance that the proposed policy fails to deliver the intended outcomes, delivers unintended consequences, carries higher costs or lower benefits than expected, proceeds more slowly than expected, or otherwise does not meet expectations.
In the case of this reform, the policy risk is judged to be low. The main risks and proposed mitigations are set out below.

Risk of inappropriate sharing of confidential information.

There is a low risk of these changes leading to inappropriate sharing of confidential information. However, this will be mitigated by guidance and training for MHRA staff setting out when and how information may be shared. Information can only be shared for the purpose(s) set out in the legislation. When appropriate, information sharing requests will have a multi-level method of clearance (such as initial clearance from individual team managers then second-level through a centralised team). Standard operating procedures will continue to be robust (like stating the use of security markings, encryption and password protected files). Legal clearance of information sharing arrangements will ensure that they stay within the confines of the power.

Risk of information security breach

These proposals carry a low risk of information security breaches. As mitigations, appropriate security and business continuity measures are already in place to protect information that the MHRA already holds, routinely receives and shares externally (where permitted under current arrangements). As the proposals do not require the MHRA to request any further information beyond what it already collects, and as there will be no changes to existing information security infrastructure, no material change in risk is expected.

Recipients of shared information will be vetted health system organisations. The MHRA will not share personal data (which is separately covered by data protection legislation).

Risk of information sharing not delivering the intended benefits

Reduced delays in information sharing or improvements in safety are very case-dependent and may be uncertain. They could be lower than expected but, at worst, would match the business-as-usual situation. Additionally, longer-term benefits to health cannot be quantified precisely. They do logically follow from faster access to medicines and medical devices but would remain very variable.

The risk of not delivering intended benefits aims to be mitigated by training provided in MHRA to cover reliability and resultant handling.

Risk of businesses changing their willingness to share information

Consent-based sharing of pre-market information by the MHRA with other health partners is broadly supported by businesses under the Operational and Pilot Technical Information Sharing Programmes, with consent being given over 80% of the time. However, there is a low risk that the proposals on information sharing may impact on the information businesses choose to share with MHRA. It should be noted that much of the information in scope is already required to be provided by businesses to meet their existing regulatory obligations, meaning the

proposals would primarily affect how information is shared between relevant public bodies rather than creating new reporting requirements for industry

To further mitigate this risk the MHRA and the legislation itself will set clear expectations for no onward sharing of information within legislation and handling instructions. The minority of cases where a business might have concerns will be addressed by stakeholder engagement to explain what type of information the MHRA aim to share, with whom and for which purposes, establishing clear boundaries. These limits will not significantly differ from the business-as-usual option.

These new powers are not intended to compromise the current confidentiality of commercially sensitive information MHRA holds under the product approval processes.

Risk of costs being higher than expected

There is a low risk that training and familiarisation costs are higher than estimated in this assessment. The system changes to the Human Medicines Portal, and time spent sharing information could take longer than expected, but costs are still likely to be low given most of the information sharing structures and processes are already in place.

Analytical Risks

The cost benefit analysis in this IA is limited but proportionate to the amounts of money involved. The extent of cost and benefit that will materialise from the reforms will vary on a case-by-case basis and therefore cannot be quantified at this stage. Savings, while worthwhile, are relatively small in the context of wider health reform. Evidence of the cost-benefit to organisations outside the MHRA, and to business, is very limited. Improvements are expected to be achieved, but their size and frequency are uncertain.

The greater benefit for society and business lies in faster access to medicines and medical devices, together with the timely resolution of safety concerns. Ongoing monitoring work will clarify which products have been impacted and thus enable case-by-case evaluation to be done where appropriate.

Monitoring and Evaluation

The HMR 2012 and The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 were last reviewed in 2025. The MMDA 2021 was last reviewed in 2026 and is due for review again in 2031, with the latter providing a statutory opportunity to review the effects of any changes. Non-statutory monitoring may also take place.

Any post-implementation review would look to address the following types of questions:

- Is the policy working as intended?
- Is this still the most appropriate approach?
- Have there been any unintended consequences?
- What refinements could be made to improve the policy?
- Are additional safeguards required?

Metrics will be considered in line with the SMART objectives and may include:

- has the MAA application rate risen or fallen?
- feedback from industry (using existing engagement channels)
- feedback from health system partners (using existing engagement channels)
- evidence of earlier adoption of medicines and medical devices into NHS services (if this is possible to measure)

- evidence that manufacturers of medicines and medical devices are choosing not to register their products in the UK, leading to supply issues for medicines and medical devices

In summary, the review would be expected to focus on the efficiency and speed of the regulatory processes followed, and the number of products affected by the reforms. The longer-term benefits to health are unlikely to be quantifiable, but a qualitative assessment, based on faster delivery of new products and estimates of the patient numbers involved, may be possible in the longer term.

Final stage impact assessment

Title: Streamlining MHRA processes for regulatory change

Type of measure: Primary legislation

Stage: Final

Source of intervention: Domestic

Department or agency: Department of Health and Social Care (DHSC)

Other departments or agencies: Medicines and Healthcare products Regulatory Agency (MHRA)

IA number: DHSCIA9723

RPC reference number: N/A

Contact for enquiries: healthlegislation@dhsc.gov.uk

Date: 28/08/2026

Summary: Intervention and Options

Cost of preferred (or more likely) option (base year = 2026)

Total net present social value (in £m): N/A

Business net present value (in £m): N/A

Net cost to business per year (in £m): N/A

What is the problem under consideration? Why is government action or intervention necessary?

The current regulatory framework for medicines and medical devices continues to safeguard public health effectively. However, it is overly complex and detailed, making it difficult for stakeholders to operate within it efficiently, and difficult to update, even when changes are minor or technical. Amending regulations is often slow, costly and bureaucratic, with scrutiny requirements that are not always proportionate. This creates unnecessary burdens for industry and also makes the framework harder to keep aligned with innovation, international standards and changing clinical practice. Regulatory improvements can be delayed, slowing access to innovative treatments and reducing system efficiency. There is also a specific issue with the system slowing the Medicines and Healthcare products Regulatory Agency (MHRA)'s ability to adjust its fees to recover its costs, in line with the statutory requirements of HM Treasury's Managing Public Money guidance. Government intervention is required to enable future improvements in these areas.

What are the policy objectives of the action or intervention and the intended effects?

- Support faster access to safe, effective innovations for patients.
- Enable more efficient and proportionate updating of medicines and medical devices legislation.
- Ensure that regulations can keep pace with innovation, clinical practice and international standards.
- Simplify procedures by allowing targeted rather than automatic full public consultation in appropriate cases, and by enabling greater use of the Parliamentary negative procedure for minor or technical changes.
- Enable more timely and agile updating of select MHRA's fees to reduce the risk of delays and income loss.
- Reduce unnecessary burdens on industry and government.

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

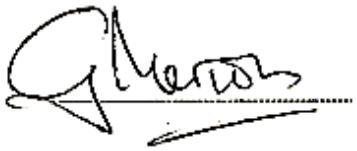
Option 1: business as usual, retaining the current legislative framework and existing consultation, parliamentary scrutiny and fee-setting arrangements. This doesn't require any action but fails to address the problems identified.

Option 2 (preferred): introduce targeted primary and secondary legislation via this bill to streamline the process for updating medicines and medical devices regulations. For primary legislation, this would allow greater use of ambulatory references to specified external documents, introduce more proportionate consultation requirements, and expand the use of the negative parliamentary procedure for minor or technical regulatory changes. It would also simplify the process for updating select MHRA fees.

For secondary legislation, this would enable an existing list of recognised countries for medical devices, which is currently set out in legislation, to be maintained through an external document that can be updated more efficiently as evidence and international regulatory frameworks evolve.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: TBC				
Is this measure likely to impact on international trade and investment?		No		
Are any of these organisations in scope?	Micro Yes (indirect)	Small Yes (indirect)	Medium Yes (indirect)	Large Yes (indirect)
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		Traded: N/A	Non-traded: N/A	

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

Signed by the responsible Minister:  Date: 8/9/2026

Summary: Analysis & Evidence

Policy Option 2

Description: Streamlining MHRA processes for regulatory change

Full economic assessment

Price Base Year N/A	**PV Base Year** N/A	**Time Period Years** N/A	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**Best Estimate:** N/A

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

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

The proposed legislation is an enabler (it facilitates the introduction of later reforms but does not introduce them itself). As such, no significant monetised costs are expected from the primary legislation. The main direct cost is limited to normal policy development activity, including officials' and parliamentary time, neither of which is particularly exceptional.

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

Although not incurred under the primary legislation, future reform may involve stakeholder time for familiarisation or adapting to revised processes. These are expected to be limited and largely one-off. Such impacts would be assessed once specific reforms were identified.

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

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

No direct monetised benefits are quantified for the primary legislation and the secondary legislation change, as they are enabling measures. In due course, enabled reforms are expected to reduce the cost and resource of maintaining regulations, and support more timely updating of MHRA fees, helping avoid income loss where periodic fees are not uprated on time.

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

Key non-monetised benefits from enabled secondary legislation will include a more agile and proportionate regulatory system, reduced burdens on industry and government, better alignment with innovation and clinical practice, and faster access for patients to safe and effective medicines and medical devices.

Distributional impacts

There is no particular expectation that distributional impacts would be significant. They are unquantified at this time as they would be assessed as enabled reforms are identified and considered under secondary legislation.

Key assumptions/sensitivities/risks	Discount rate	N/A

This assessment is based on the enabling legislative changes proposed as part of this bill only. For the primary legislative changes, most impacts will largely depend on the subsequent secondary legislation that is taken forward. Later reforms may be delayed or deprioritised, and impacts may be better or worse than envisaged. Some improvements (such as updating ambulatory guidance) may require publicity. These risks will be mitigated through the narrow scope of the powers, continued ministerial and parliamentary accountability, proportionate consultation and analysis, and effective stakeholder communication by DHSC and the MHRA.

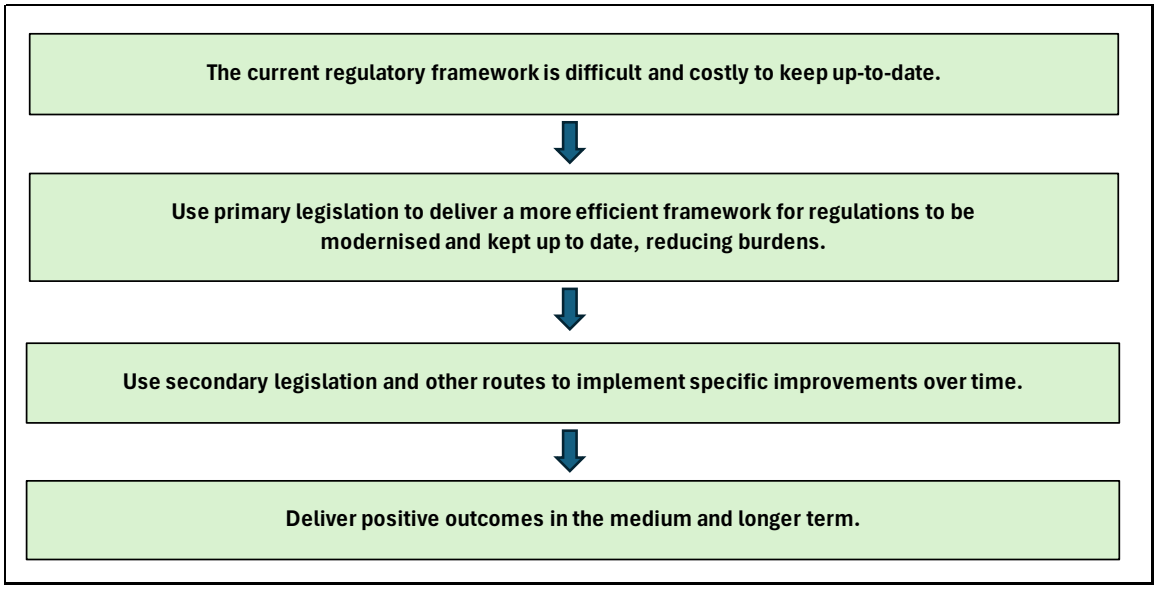
Business assessment (Option 1)

Direct impact on business (Equivalent Annual) £m:		
Costs: N/A	Benefits: N/A	Net: N/A

Evidence Base

Problem under consideration and rationale for intervention

Key points at a glance



Regulations for medicines and medical devices need to be regularly updated and maintained to keep pace with wider change and innovation.

However, within the current legislative framework, making such changes can be disproportionately costly, time-consuming and bureaucratic, leading to delay and inefficiency. This creates burdens for industry and slows access to innovative therapies and treatments for patients.

Change is required to reform the current powers in primary legislation, to enable more streamlined processes for amending secondary legislation, so that regulations can be maintained and updated more efficiently, while still allowing for a proportionate level of scrutiny.

Subsequent changes to secondary legislation, made under the revised powers contained in this bill, will be used to make the specific improvements required. There is one change proposed to secondary legislation as part of this bill, to enable an existing list of countries, which is currently in the regulations, to be referred to in an external document that can be updated more efficiently.

This impact assessment (IA) covers the impact of the legislative changes proposed as part of this bill only, which are enabling and largely do not have any significant costs or benefits of its own. The changes it enables will come about through later secondary legislation, which will be assessed separately at that stage.

This IA indicates the broad types of reform that would be enabled by this bill but does not amount to a commitment from the government to introduce any measure.

Overview of the challenges

The current regulatory framework for medicines and medical devices continues to safeguard public health effectively. However, there are several cross-cutting issues being caused by the structure of the framework, and the processes required to update it. For example, feedback from stakeholders, including part of a recent statutory review of the Medicines and Medical Devices Act 2021 (MMDA), found that the regulatory framework is:

- **complex and difficult to navigate for stakeholders**: this adds cost for industry through creation of extra burdens, and acts as a barrier to market entry, particularly for smaller businesses
- **overly-detailed**: this can contribute to the regulations quickly becoming out of date, given current limited powers to incorporate international agreements and standards into regulations in relation to medical devices on a dynamic (or ambulatory) basis, and no such power in relation to medicines
- **disproportionately burdensome to change**: the requirements of the process to amend the regulations, using powers under the MMDA, are often not proportionate to the changes being proposed, such as the requirement for public consultation and debates in Parliament and the Northern Ireland Assembly, regardless of the substance and significance of the regulatory change
- **slow to respond to innovations and change:** burdensome process requirements mean that regulations are slow to update in response to innovations or changes in clinical practice, for example changes to prescribing regulations to reflect latest clinical practice have been put on hold, thus limiting the current flexibilities of frontline healthcare workers

As a result of these issues, the current regulatory framework is not as optimal as it could be. Consequently, this may present a barrier to growth and innovation and hinders the MHRA strategic aims of protecting public health and of enabling the most efficient patient access to medicines and medical devices.

Legislative Context

Medicines, clinical trials and medical devices regulations were originally made using powers under section 2(2) of the European Communities Act 1972, transposing EU law into domestic legislation. The MMDA was taken forward following EU withdrawal to ensure the UK had powers to amend the regulatory regime for medicines and devices.

The MMDA provides delegated powers which enable the regulatory regime for medicines and medical devices to be updated. The Act provides powers to amend the following regulations:

- Human Medicines Regulations 2012 (HMRs): which set out the regime for the manufacture, authorisation, supply, and pharmacovigilance of medicines
- Medical Devices Regulations 2002 (MDRs): which provide the regulatory framework for medical devices, including requirements for safety, performance, and conformity assessment, including the associated fees payable to the MHRA in relation to regulatory services for medical devices
- The Medicines for Human Use (Clinical Trials) Regulations 2004: which provides the regulatory framework and governs the conduct of clinical trials of medicinal products
- The Medicines (Products for Human Use) (Fees) Regulations 2016: which outlines the fees payable to the MHRA in relation to regulatory services for medicines.

In addition, while the setting of the MHRA's fee regime relies on powers within the MMDA, it also relies on powers in the European Union (Withdrawal) Act 2018 (EUWA) to update fees provisions in the Medical Devices (Northen Ireland Protocol) Regulations 2021 (which outline the fees payable to the MHRA in relation to regulatory services for medical devices) and the

Blood Safety and Quality Regulations 2005 (which outline the fees payable to the MHRA in relation to regulatory services for blood products for transfusion).

Problem under consideration

The MMDA provides the power to amend or supplement existing regulations. However, the MMDA also places several stipulations on how the power should be applied, which causes these problems:

- the MMDA requires public consultation when the power is used, regardless of the size or importance of the change[1]
- the MMDA requires the use of the draft affirmative[2] procedure in Parliament to make most amendments (as does EUWA, for at least some updates to the fees regulations made under its powers), which takes considerably longer than the negative procedure and is arguably disproportionate for minor or technical changes
- the regulations need to be consistent with certain types of external documents which are updated frequently, such as lists of countries meeting required product standards. Except for a limited power to refer to international agreements and standards in relation to medical devices regulation, the MMDA does not enable the government to refer to these documents in legislation on an ambulatory basis. This means that whenever these documents are updated, the legislation needs to be amended, rather than allowing updates to be adopted automatically. Given the lengthy process for updating the legislation (including for the reasons set out in the 2 bullets above), in practice this often leads to divergence between the regulations and external documents, creating undue burdens and uncertainty for industry.

In addition, the 2 pieces of legislation referenced above that the MHRA uses as part of the fee uplift process (MMDA and EUWA) have different procedural requirements, that are not in alignment. There is therefore a case for aligning requirements between the 2 pieces of legislation to streamline the process and reduce the risk of delays and financial loss.

The regulations require regular updates to reflect public health threats, new products, technical advances, changes in costs, international agreements, and other innovation in the health sector. However, the points set out above mean it is relatively more time consuming and costly to update the regulations, resulting in a backlog of necessary legislative changes. This in turn may cause delays in patient access to new medicines and medical devices and otherwise delivering a good level of regulatory support to business, wider health partners, the NHS, and the public.

The relative complexity of the UK regulatory framework impedes growth and innovation and is likely to influence businesses' decisions as to whether to market and develop new products in the UK or in other markets. Addressing this complexity could therefore support growth in research and development in life sciences.

Evidence to support the problem statement

A recent internal MHRA exercise revealed a significant pipeline of potentially desirable legislative reforms in medicines, and a similar number for medical devices, that would require secondary legislation. All would deliver benefits of varying degree and complexity, with some being very minor or technical in nature. However, without simplifying the legal framework for amending regulations, there will always be a backlog of necessary updates, as the changes

[1] For example, there is no requirement to consult placed on the MHRA when they use the EUWA 1972 to update their medical devices fees (in the Medical Devices (Northern Ireland Protocol) Regulations 2021) and their blood components for transfusion fees (in the Blood Safety and Quality Regulations 2005).

[2] Draft affirmative is a type of parliamentary scrutiny which means a statutory instrument (SI) is laid in draft but cannot be made into law (signed by the minister) unless the draft is approved by both Houses following a debate (or the Commons alone for financial SIs). It differs from the negative procedure which requires debate only if an objection is raised.

cannot all realistically be implemented. Additional changes will continue to be added to the backlog as new developments or public health challenges occur.

In September 2025, an MHRA survey of businesses, health professionals and individuals[3] reported that the legislative frameworks continue to safeguard public health effectively. However, while the system was functioning, respondents reported some dissatisfaction with the current Medicines and Medical Devices Act 2021 regulations. Specifically:

- 62% said they had encountered issues, blockers or ambiguities in the regulations
- 53% felt some regulations impose unnecessary or excessive regulatory burdens
- 43% felt some regulations were duplicative, overlapping, outdated
- only 20% felt the regulations provide the appropriate balance of flexibility to respond to new technologies or emerging public health issues, and robust regulatory oversight
- only 19% agreed the balance between regulation and guidance was appropriate

A major challenge with the current framework is that the procedural requirements placed on the MHRA and DHSC to change secondary legislation are not always proportionate to the significance of the changes proposed. As most amendments are automatically subject to both a public consultation and the affirmative parliamentary procedure, whether proportionate and appropriate or not, any legislative change requires significant time and resources.

For patients, the current difficulty in updating the legislation generates barriers in accessing new treatments, products, and pathways.

Consulting those impacted by a regulatory change is important to ensure effective policy development and mitigate unintended consequences. While a full public consultation will continue to be appropriate in many cases, it is not proportionate for minor or narrowly scoped changes. In such cases, tailored consultation with relevant experts and stakeholders can be more effective and less burdensome for participants. For example, in a recent DHSC consultation regarding changes to prescribing regulations for certain professional groups, 99% of respondents were healthcare workers or students within the relevant professions. A more tailored approach to consultation requirements would help ensure that minor improvements to the regulatory regime are not delayed by lengthy and resource-intensive processes, while enabling government, Parliament and stakeholders to focus their attention on significant policy reforms where broader consultation is most valuable.

The view that the default draft affirmative parliamentary procedure is often disproportionate is supported by the fact that the debates surrounding some changes have been extremely short, and with low attendance. There is potential to better focus parliamentary scrutiny on more significant or controversial changes, with the negative procedure preserving a right for Parliament to object on less controversial matters, should it wish to.

On the specific issue of fees, the MHRA sets and reviews its statutory fees in line with HM Treasury Managing Public Money guidance, aiming for ongoing full cost recovery. This means the income from fees continues to cover the total cost of delivering services, so that fees neither generate a profit nor make a loss and are applied in a fair and transparent way.

There are cases where a full public consultation and the parliamentary debates of the draft affirmative procedure are appropriate, but there are also cases where it is disproportionate, such as moderately increasing existing fees only to ensure ongoing cost recovery.

[3] DHSC (2026), Medicines and Medical Devices Act 2021 5-year Report, (viewed July 2026)

The risk of financial loss mainly arises from the MHRA's periodic fees. These are annual charges for holders of certain types of licences or registrations to cover ongoing regulatory costs. These fees become due on the first of April every year. If they are not updated before then, the MHRA must charge the previous lower fee for that financial year, and this causes a loss of income in the region of £4 million to £4.5 million (in 2026 to 2027 prices). In addition, if changes to the MHRA's wider non-annual fees do not come into force on time, the MHRA must charge the previous lower fees in the meantime. This will cause a loss of income depending on how long the delay is.

The need for legislative change

The backlog of necessary secondary legislative changes for medicines and medical devices is a direct consequence of the disproportionate procedural requirements and complexity, and will be improved through the proposed reforms, enabling many of these changes to be taken forward.

Without these reforms, the backlog of necessary updates will increase as additional changes are required to account for rapid scientific progress, new health evidence, evolution in clinical practice, and public health needs. There is also a considerable opportunity cost. The resource required within the DHSC and MHRA to take forward changes to regulations means that that resource is diverted from other priorities within the MHRA and DHSC, which would have greater impact in supporting strategic objectives for the health system. The detailed proposals are dependent on future policy decisions, so will be set out at the secondary legislation stage.

For the secondary legislation change, the current requirement to specify the list of countries in legislation means that any update must be made through a legislative process, which can be lengthy and resource intensive. The proposed reform would allow the list to be maintained in an external document, enabling updates to be reflected more quickly in the regulatory framework. Without this change, updates to the list may be delayed, reducing the ability to maintain alignment with international partners and emerging best practice.

Requirement for government action or intervention now

This regulatory complexity is a long-term issue which is expected to worsen without reform, as set out above. Until legislation is simplified to allow more efficient and proportionate updating, it is likely that patients will face unnecessary barriers to accessing new treatments, products, and pathways. It is also likely that it will impede growth in the life sciences sector, by imposing unnecessary costs and regulatory complexity on businesses. The benefits of reform are likely to be highest if secured now. Any delay to reform would defer and exacerbate the problem rather than address it.

Possible gaps or harms if government doesn't intervene

Failure to intervene would mean that the UK retains an overly complex and rigid legislative framework which creates barriers for reform and prevents government from responding swiftly to innovation, public health needs, or operational challenges. Gaps in the legislation may also render the MHRA and DHSC unable to respond quickly to emerging health concerns or technological advances. Without modernised powers, there are risks of failing patients, slowing industry growth and undermining the UK's reputation as a place for innovation. The impact of this on different stakeholders and issues would include:

- **Patients and Public Health**: Measures needed to protect and improve public health would be delayed or not implemented at all. Access to innovative new treatments and products would take longer, with patients waiting while legislative bottlenecks are resolved. Changes to prescribing regulations that boost the efficiency of NHS care would be delayed.

- **Industry**: Companies facing higher costs and longer timelines to bring products to market, reducing the UK's attractiveness as a location for research, development, and launch. As a result, businesses may increasingly look to other markets where regulatory systems are more flexible and adaptive.
- **Regulatory System**: The challenge of keeping the regulatory system up-to-date and responsive to innovation would become progressively more difficult to meet under the current rules. This would slow down progress and stretch resources without delivering real benefit.
- **10 Year Health Plan for England (10 Year Health Plan)**: The system's current rigidity could inhibit the ambitions set out in the 10 Year Health Plan, by limiting timely access to innovative therapies and creating blockers to the 3 key shifts: hospital to community, analogue to digital, and from treatment to prevention. For example, swift updates to prescribing regulations are key to enabling progress across the 3 shifts.
- **Admin burden reduction**: The reforms provide an opportunity to simplify and reduce the burden of regulation on business, contributing to the government's target reduction of a 25% admin burden reduction during this Parliament. Under the status quo, this opportunity would be more difficult to achieve and more likely to be delayed.

Post-implementation review of existing regulation

The outcome of a statutory review of the Medicines & Medical Devices Act 2021 (MMDA) was published in February 2026. The purpose of this review was to evaluate whether the legislation is operating as intended, in terms of whether it continues to effectively protect public health and avoids imposing unnecessary or excessive regulatory burdens. The review also looked at the structure of the legislation and whether restructure or consolidation would make the regulations clearer or easier to implement. It drew on internal DHSC subject matter expertise and evidence gathered through external stakeholder engagement: namely, a joint MHRA and DHSC survey and 3 targeted workshops.

The review found that "stakeholders report growing challenges in navigating the legislation due to cumulative amendments, increasing regulatory complexity, and reliance on guidance to support interpretation". Specifically, it concluded that procedural rigidity under Part 5 of the MMDA, particularly mandatory consultations and extensive use of the draft affirmative procedure, delays amendments to the legislation and may not be proportionate to the amendments. It recommended that the government "consider a more proportionate approach to consultation and parliamentary scrutiny of changes to regulations, to enhance regulatory agility without compromising oversight or safety".

The MHRA also published a second statutory post implementation review (PIR) of the Human Medicines Regulations 2012 (HMRs) in March 2026, exploring the effectiveness of the HMRs from 2017 to 2026. This PIR covers specific provisions of the HMRs (outlined in Regulation 346 HMRs) and evaluates the objectives of those provisions, the extent to which they are achieved and whether they remain appropriate or could be achieved with a system that imposes less regulation. The PIR sought qualitative evidence through a questionnaire to stakeholder organisations affected by the HMRs, and discussions with subject matter experts within the MHRA and DHSC, to determine whether the HMRs had met their objectives and whether the way they had been implemented could be improved.

The PIR found that there have been additional burdens on businesses, particularly pharmacists, from several factors which ultimately point back to outdated and overly complex regulations that require updating. For example, the PIR found that a perceived lack of a streamlined verification process made it challenging to verify cross-border prescriptions. Respondents also noted additional administrative burden and regulatory cost involved with the requirement for a wholesale dealers licence.

This evidence supports this bill's proposals for primary legislative reform.

Description of options considered

There are only 2 options considered in this assessment: Introduce primary legislative reforms to streamline the regulatory process and a secondary legislation reform to allow a specific list in regulations to sit in guidance; or leave the regime as it is. The MHRA and DHSC have drawn on legal advice confirming that legislative reform is required to introduce the changes described above. No other viable options have been identified.

Option 1 (business as usual): The current MHRA regulatory framework and approach to fees is maintained. The costs or benefits haven't been quantified in absolute terms as this section focusses on the differences between the business-as-usual option and the preferred option.

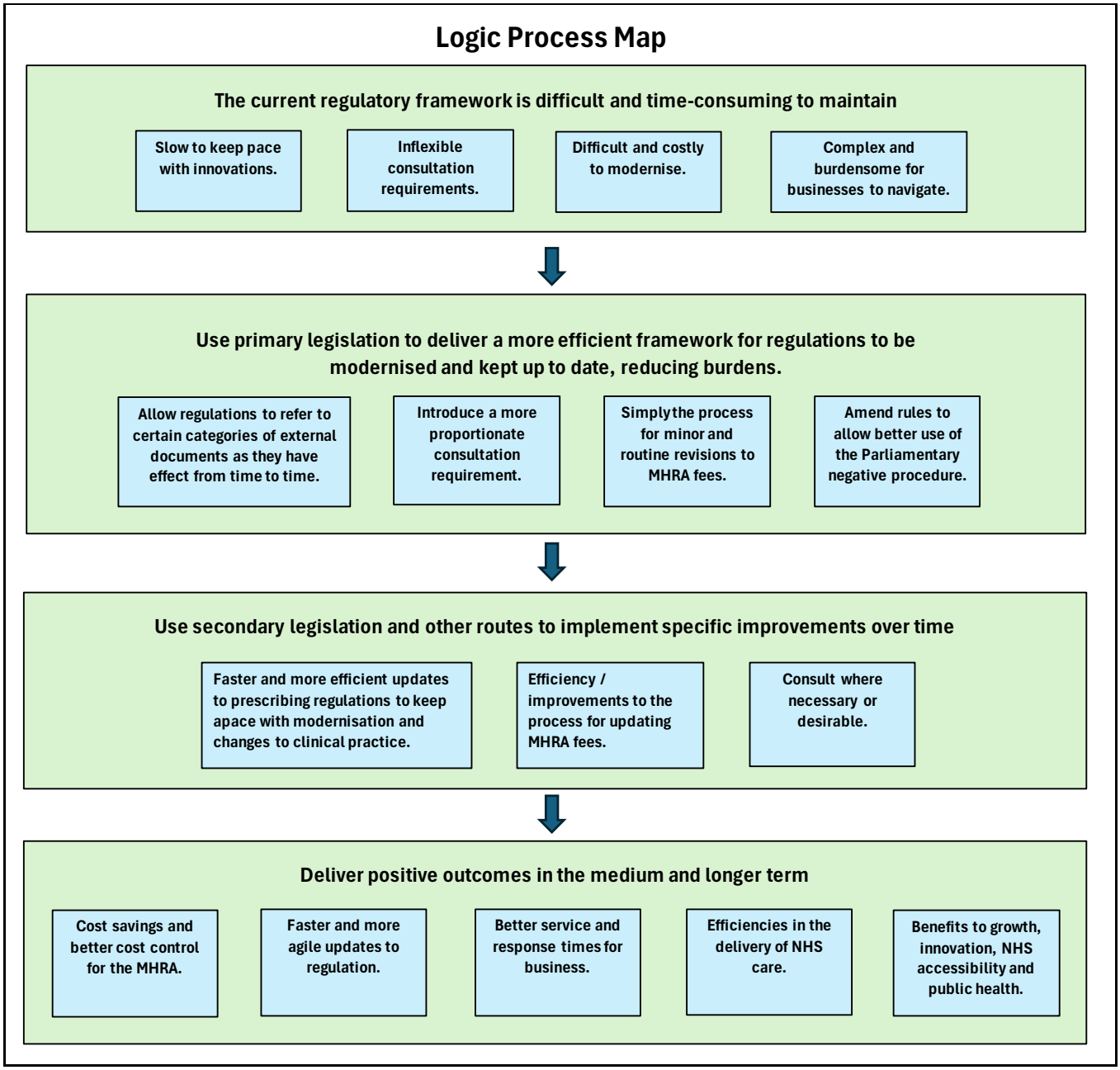
Option 2 (preferred option): This option seeks to make 3 legislative changes to the regulatory framework for medicines and medical devices. These are to:

- introduce a power, and expand a current power, to incorporate by reference certain categories of external documents as they have effect from time to time
- amend consultation requirements where they are disproportionate
- allow selective use of the parliamentary negative procedure

Policy objective

The proposals in this bill will enable more streamlined processes for amending secondary legislation, so that regulations can be maintained and updated more efficiently, while still allowing for a proportionate level of scrutiny. This is designed to enable later improvements which can be delivered through secondary legislation or non-legislative mechanisms over time. These subsequent changes will deliver the MHRA's strategic aims of protecting public health, and of enabling the most efficient patient access to medicines and medical devices. This is set out in Figure 1 below.

Figure 1: Theory of change for MHRA regulatory framework proposals



This impact assessment focuses on the primary legislative changes rather than any subsequent amendments to regulations using the new powers, which will be subject to future policy decisions. Table 1 below sets out the objectives for these proposals.

Table 1: SMART objectives for MHRA regulatory framework proposals

Element of SMART objective	**Details**
Specific objective(s)	Removing barriers which slow down or limit the MHRA and DHSC's ability to keep regulations up-to-date, specifically by ensuring that regulations can refer to certain categories of externally maintained documents as they have effect from time to time. Ensuring that consultation and parliamentary scrutiny processes are proportionate.

Measurement	Measurement of success is likely to involve a combination of process monitoring (to see if change processes are more efficient) and outcome monitoring (to see if enabled changes have actually led to improvement). The former applies to the primary enabling legislation, and the latter to subsequent secondary or non-legislative changes. Further detail is provided in the Monitoring and Evaluation section.
Achievable	The MHRA and DHSC have assessed the proposals as being fully achievable within existing resources (and indeed are designed to save regulatory operating costs).
Relevance	The objectives are fully aligned with, and will support delivery of, the broader health strategy as outlined in the 10 Year Health Plan, as well as cross-government priorities on promoting productivity and growth,
Timing	Future implementation dates for any secondary legislation proposals are uncertain as they are dependent on Parliamentary timetables and future policy decisions. The monitoring and evaluation plan will consider the most appropriate timescales to evaluate when policy detail is known.

The longer-term aim is to use a more flexible regulatory framework to deliver a series of specific improvements that will have tangible impacts on the NHS, businesses and patients, as well as driving growth in the life sciences sector. This is a longer-term initiative embracing a range of potential reforms (discussed in detail below).

Summary and preferred option with description of implementation plan

The MHRA has considered, with legal advice, options for broader powers to allow (1) regulations to be repealed and replaced, and (2) a broadening of topics for which regulations can be made. These would allow for more significant reform of the secondary legislative framework. Having considered the balance of risk and the scope of this bill, narrower powers have instead been developed, which are tightly defined to address the issues identified, while maintaining safeguards to ensure proportionate consultation and scrutiny of subsequent secondary legislative changes.

Legislative changes

Therefore, there are 3 main categories of legislative changes proposed as part of this bill. They are separate but synergise to enable changes to be made to modernise and simplify the legislative framework.

(A) Introduce a power, and expand a current power (through a change to secondary legislation), to incorporate by reference certain categories of external documents as they have effect from time to time

The MMDA provides only limited powers to incorporate external documents as they have effect from time to time. This makes it difficult to achieve the correct balance between detail in the regulations themselves and information that sits elsewhere. The proposal is to allow, specifically:

For **medicines**, to be able to make reference in regulations to international agreements or standards as they have effect from time to time. This means that domestic legislation would automatically update when the underlying document is updated. For example, it could be helpful to refer to quality guidelines by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH Q12) in regulations, by way of an ambulatory reference, as this provides a framework for managing post-approval changes to products.

For **medical devices**, the above power to make ambulatory references to international agreement or standards already exists. However, the proposal is to expand this existing power to reflect the different policy aims in this area. Therefore, the proposal is to allow references in regulations to certain domestic lists and to certain British technical standards. For example, to refer to a list published by the Secretary of State for Health and Social Care (Secretary of State) of countries subject to mutual recognition agreements, or to a list of devices or categories of device that are eligible for an international reliance pathway. The list of international jurisdictions eligible to be recognised in this way must be approved in a regulation passed by Parliament.

Through a secondary legislative change, the proposal will enable an existing list of countries, which is currently in the regulations, to be referred to in an external document that can be updated more efficiently.

(B) Amend consultation requirements where they are disproportionate

The MMDA requires a public consultation exercise to be carried out before regulations can be made under Part 2 (Human Medicines) or Part 4 (Medical Devices). For minor changes this can be disproportionate, slowing down progress and generating limited engagement and response. The unintended consequence is that necessary reforms can be held back and consulted on in batches, rather than being considered at the most opportune time and made in a timelier fashion.

The proposals are to:

- Amend the requirement to publicly consult in all cases when amending regulations, to provide a more flexible approach that allows the Secretary of State to consult such persons as he considers appropriate. This would allow full public consultation to continue where proportionate and appropriate but allow more targeted discussion where suitable. Decisions on whether and who to consult would continue to reflect all relevant factors including the breadth and technical nature of the amendment, the people likely to be affected, accessing relevant expertise and experience, and to ensure diverse representation of respondents to support analysis of Public Sector Equalities Duty (PSED) impacts.

(C) Allow targeted and appropriate use of the parliamentary negative procedure

Section 47 of the MMDA requires that a provision made under Part 2 (Medicines) or Part 4 (Medical Devices) is primarily subject to the draft affirmative parliamentary procedure. This is a

more involved and lengthy scrutiny process, regardless of the nature or content of the change being made to regulation.

This is considered restrictive, as very minor amendments still require debate in both Houses of Parliament and the NI Assembly. This lengthens the process of updating and improving the regulations and is arguably an inefficient use of parliamentary time.

The proposal is to enable greater use of the parliamentary negative procedure (which requires debate only if objections are raised) for legislation which makes minor or technical changes. Regulations which make more impactful or complex change would remain subject to the draft affirmative procedure, as is appropriate.

The list of situations where the negative procedure would be permitted would be specified in detail in the primary legislation, but in summary include:

- Independent Prescribing: Amendments to who counts as an “appropriate practitioner” and the specific medicines certain professionals can prescribe
- Patient Group Directions (PGDs) and Vaccine Group Directions (VGDs): Changes to the list of professions allowed to administer medicines via PGDs and VGDs
- Exemptions (Schedule 17): Updates to which professions can supply, sell, or administer medicines under specific exemptions, including the medicines that can be supplied, sold or administered, and the conditions under which this can be done
- Emergency Administration (Schedule 19): Adjustments to the list of medicines that can be administered in emergencies
- Technical Details of Sale or Supply: Amendments to technical requirements, such as pack sizes, wholesale dealing, and emergency supply provisions
- Fee changes: the MMDA already allows the use of the negative procedure for updating fees in relation to medicines and medical devices, but the EUWA (which is needed to update regulations relating to other fees set by MHRA, including in relation to blood safety and quality) generally requires the draft affirmative procedure, which is inconsistent. The changes to EUWA would allow the use of the negative procedure in 3 instances, which are:
    - Altering the amount of a fee or charge to reflect changes in the value of money. This is already possible under EUWA and does not represent a change from the current law.
    - Altering the amount of a fee or charge to be charged in connection with a function that is currently in the Medical Devices (Northen Ireland Protocol) Regulations 2021, which relates to the EU medical devices regulations.
    - Altering the amount of a fee or charge to be charged under the Blood Safety and Quality Regulations 2005.

In all these cases, the change would allow a faster and more agile response to evolving clinical practice, new medicines or stakeholder feedback, and is considered a proportionate and appropriate use of the negative procedure.

Implementation of the preferred option

The preferred option has a tightly defined focus set out above. This focus provides improvements in flexibility and efficiency by allowing regulations to refer to appropriate, externally maintained, documents, ensuring that consultation activity is proportionate and that, through the use of the negative procedure, parliamentary time for scrutiny is also proportionate. This aims to create a tangible improvement and addresses the core issues identified, while ensuring that any new powers are balanced and proportionate.

Once these amendments to primary powers are in place, the subsequent reforms made via secondary legislation would be designed to deliver changes to modernise and update the regulations. These will contribute to the UK's ability to address new and emerging public health needs, thereby providing more certainty and reduced complexity for industry which, in turn reduces the costs of regulatory compliance. They may also allow swifter updates to prescribing regulations and enable prompt responses to innovations in clinical practice, in order to deliver more efficient NHS care. The secondary legislative change happening as part of this bill will be implemented as soon as it comes into effect.

This will enable MHRA's strategic aims of protecting and promoting public health and enabling the most efficient patient access to medicines and medical devices and to better support the delivery of government commitments on economic growth, such as reducing the burden of regulation, and/or encouraging health technology companies to stay and launch innovative products in the UK. Supporting rapid access to innovative technologies will also be critical in supporting delivery of the 10 Year Health Plan, the Life Sciences Sector Plan and Life Sciences Healthcare Goals.

Under the proposed new powers, proportionate safeguards remain to ensure that secondary legislation that DHSC or MHRA takes forward will still be subject to due consultation and scrutiny, in line with existing secondary legislation processes.

Following the implementation of these legislative proposals (subject to the will of Parliament), planned improvements will start be developed via secondary legislation. Benefits are expected to be ongoing as it will create enabling powers for MHRA to more effectively and efficiently maintain the regulatory framework on an ongoing basis.

Monetised and non-monetised costs and benefits of each option (including administrative burden)

General approach

This IA provides a proportionate assessment of costs and benefits based on the best available evidence and in line with HMT Green Book guidance. The costs and benefits of the proposed reforms cannot be quantified, because the primary legislative proposals covered by this IA is to introduce enabling powers, rather than practical and substantive changes. Practical change will be delivered later through secondary legislation and/or non-legislative changes that are enabled by the new powers. These subsequent changes would be subject to due scrutiny and consultation to inform decision making, including analyses of costs and benefits, which may involve separate impact assessments where required in line with normal processes.

As such, this IA focuses on the opportunities and risks that would be enabled by these new powers. The assessment is that the proposed reforms are likely to deliver a worthwhile net benefit. Given that specific, practical changes are not being proposed at this stage, the nature of costs and benefits is identified, with an indication of scale, but without detailed quantification.

Costs

The costs of laying primary legislation are limited to officials' and parliamentary time, which by convention is classed as part of normal policy development activity, and not itemised separately.
The costs of subsequent change, enabled by the primary and secondary legislations, are expected to be minimal and will include:

- one-off secondary legislation development: officials' and parliamentary time (again classed as part of normal policy development) plus any associated consultation time (where used).
- one-off familiarisation costs for all stakeholders (mainly the MHRA's customer base and NHS healthcare professionals) to understand any new regulations as and when they take effect
- ongoing operating costs for all stakeholders (such as following new processes) are likely to be lower post reform and are classed as a benefit

Benefits

The legislative changes are enabling with benefits depending on the degree to which the new powers are used. They provide the opportunity for the following benefits to be realised through subsequent changes to secondary legislation:

- for patients, a streamlined regulatory landscape is expected to remove a barrier to their accessing of new treatments, products, and pathways, and to enable better use of the community sector to drive a shift in care from hospital to community
- reduction in the costs of maintaining and updating regulations (by being able to refer to wider guidance material, by limiting disproportionate consultation and by reducing Parliamentary requirements)
- more timely and less bureaucratic setting of MHRA fees, providing stronger financial control for the MHRA
- better maintenance of up-to-date regulation, keeping pace with updates and developments, and reducing divergence with technical guidance.
- For businesses, a more responsive regulatory regime, that is quicker to update on the back of scientific developments and easier to navigate and operate.

Direct costs and benefits to business calculations and impact on small and micro businesses

Business impacts

There are no direct business impacts resulting from this primary legislative change. Any future secondary legislative changes that impact on businesses would be considered in more detail at that time once future policy decisions have been made.

For context, the types of business that either interact directly with the MHRA, or might be indirectly affected by these future reforms, include:

- developers of medicines and/or medical devices
- businesses involved in the supply chain of such products
- front-line businesses providing such products to patients, such as pharmacies, private healthcare providers
- businesses providing third-party support, such as training, product assessment, safety checks and similar services

The types of impact on businesses resulting from future secondary legislative changes, could include:

- upfront, one-off familiarisation and training costs associated with any change that the business will need to comply with
- reduction in ongoing regulatory operating costs: a general reduction in complexity, coupled with improved guidance, is expected
- any indirect benefits arising from rules being updated more quickly, reduced complexity and ambiguity, and from improved regulatory support from the MHRA

The reforms to primary legislation will not directly lead to any significant change in economic growth in themselves, but they will enable subsequent changes to regulations which are likely to support economic growth through reduced regulatory burdens. The extent of this growth will depend on the specific changes that are pursued at a secondary legislation level.

Small and Micro Business Assessment (SAMBA)

In general, regulation of medicines and medical devices follows the same standards for all businesses, regardless of size (which is deemed appropriate given that patient safety is paramount). As such, it is unlikely that smaller businesses will be impacted differently. All businesses are likely to be affected in proportion to their level of involvement with these markets and their regulators. If they are involved, smaller firms may experience proportionately greater costs and benefits, simply because the impacts may be spread over a smaller organisation. All proposals at secondary legislation stage will be cognisant of this and consider any possible mitigation.

Risks and assumptions

Policy risks

Policy risk refers to the chance that the proposed policy fails to deliver the intended outcomes, delivers unintended consequences, carries higher costs or lower benefits than expected, proceeds more slowly than expected, or otherwise does not match up to expectations.

In the case of this reform, the policy risk is judged to be low following the mitigations set out below. The main risks and proposed mitigations are set out below.

Legislation fails to deliver the flexibility required

There is a low risk the legislative changes happening as part of this bill do not deliver the flexibility required. This is mitigated by the narrowing and refinement of these legislative changes.

Subsequent reforms do not proceed

There is a medium risk of subsequent reforms (like secondary legislation) not proceeding, for example because of resource constraints. Adequate resourcing, for example within the MHRA to deliver legislative reforms, alongside triaging of proposals, aims to identify synergies and inform decisions on which to proceed with to greatest impact, if prioritisation is required.

Costs are higher than expected

There is a low risk of costs for training and familiarisation costs, as well as system changes, taking longer than expected or costing more than anticipated. These will be kept under review as future policy decisions on approach and secondary legislation are made.

Inappropriate use of new powers

There is a medium risk of the powers introduced as part of these proposals being used inappropriately. The power to take some decisions without public consultation, or with the negative procedure, comes with responsibility. This risk has already been addressed significantly by narrowing the scope of the proposals that might have been considered. It is also mitigated by wider responsibilities and duties that apply to the Secretary of State, who will also remain accountable to Parliament.

Lack of compliance

There is a low risk of a lack of compliance with the new legislative changes. Changes to regulation may be less obvious to the public and businesses if only external documents are updated. This risk would be mitigated by effective communication and stakeholder engagement by MHRA to ensure awareness.

Analytical Risks

The evidence base supporting the need for specific reforms will need to be presented at the secondary legislation stage, as proposals for subsequent secondary legislative change progress to implementation. That would include analysis such as proportionate cost-benefit analysis, additional qualitative evidence, sensitivity analysis, stakeholder engagement and baseline monitoring.

Based on the potential benefits of reform, the expected minimal costs, the risk analysis, the mitigation available for those risks and the fact that further analysis and/or consultation will be possible, it is reasonable to take the view that the initial primary legislation enabler is likely to be beneficial and worthwhile.

Monitoring and Evaluation

Monitoring for this reform is likely to take place in 2 phases. The primary legislation is designed to enable change, while subsequent secondary legislation, or non-legislative methods, will be used to deliver actual improvements to the regulations.

This IA focuses on the primary legislation and one secondary legislation change and as such, monitoring may include:

- identifying changes that were previously not permitted but which can now proceed
- tracking the expected timeline of planned improvements, and comparing with the status quo, with the expectation of faster delivery
- counting the number of legislative (statutory instrument) reforms expected over time
- obtaining feedback from the MHRA, patients, industry, and the NHS system on the gap between identified need for reform or change (via regulation or non-regulatory routes) and it being in place
- a formal post-implementation review is required to be delivered within 5 years of implementation

The initial primary legislation can only really be judged in terms of how well it enables subsequent change, so the timeframe for assessment is likely to be similar for both primary and secondary changes, which is to say within 3 to 5 years.

Feedback from businesses, NHS stakeholders and regulator staff will provide early warning of any concerns.

Subsequent delivery of individual improvements to regulations will require separate bespoke analysis and monitoring (and is somewhat beyond the scope of this initial IA). Monitoring may include, in due course:

- full pre-implementation appraisal (because detailed cost-benefit analysis has not yet been conducted)
- tracking any improvement in efficiency, such as MHRA spending on and delivery of updated regulation, timelines to deliver certain procedures, and/or business feedback
- identification and review of wider impacts, such as on business confidence or innovation timelines as new products are brought to market

The secondary legislation change will be effective immediately and will be monitored in line with usual procedure, which may include those set out in the bullets above.

The MHRA and DHSC are expected to lead all monitoring efforts in line with their individual responsibilities.