# Final stage impact assessment

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| Title: | Health Bill: Medical Device Licensing Regime |
| Type of measure: | Primary legislation |
| Department or agency: | Department of Health and Social Care (DHSC) |
| IA number: | DHSCIA9724 |
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# 1. Summary of the proposal

### Summary of issues and powers being introduced

The Health Bill 2026 proposes the introduction of new primary legislative powers to confer powers in the Medicines and Medical Devices Act 2021 for the Secretary of State for Health and Social Care to establish, through subsequent secondary legislation, a medical device licensing regime.

This proposal is intended to ensure that Great Britain (GB) continues to have a safe, effective and sustainable system for allowing medical devices onto the market, while also introducing a new regulatory model that better supports innovation and growth, in line with Government priorities. Medical devices in GB are currently regulated through a combination of domestic assessment and European Union (EU) assessment:

1. **Domestic UKCA route** – under which manufacturers obtain a UK Conformity Assessment (UKCA) marking. For manufacturers of medium and high-risk medical devices, this requires a conformity assessment by a UK Approved Body.
2. **EU CE marking** – with current time-limited recognition of Conformité Européene (CE) marked devices, the EU's conformity marking, until 2030 for most device types. The Medicines and Healthcare products Regulatory Agency (MHRA) has recently consulted on indefinite recognition of CE-marked medical devices[1], with a Government response expected in autumn 2026.

In addition, the MHRA has outlined its intention to introduce international reliance[2] pathways for medical devices with approval from Australia, Canada and the US.

These arrangements support patient access, but the introduction of international reliance and recognition pathways risk further reducing demand for domestic approvals and raising questions around the long-term sustainability of the model. This raises concern for the current domestic model, which relies on third-party UK Approved Bodies (UKABs)[3] to carry out conformity assessment of all but the lowest-risk medical devices. (UKABs) rely on sufficient market demand to remain commercially viable. This leads to a decision point for Government – to either change the domestic route to market to improve its attractiveness, or to accept the

[1] MHRA (2026), Medical devices regulations: targeted consultation on the indefinite recognition of CE marked devices - GOV.UK (viewed April 2026)
[2] MHRA (2025), Response to international reliance, UKCA marking and in vitro diagnostic devices consultation proposal - GOV.UK (viewed April 2026)
[3] A UK Approved Body (UKAB) is an organisation that has been designated by the MHRA to assess whether manufacturers and their medical devices meet the requirements set out in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (MDR 2002). Approved bodies for medical devices - GOV.UK

risk that it diminishes and access to the GB market is solely through international reliance or recognition.

Without intervention, there is a risk that the domestic route becomes progressively less used, reducing the UK's ability to maintain independent regulatory expertise, respond flexibly to new technologies or public health needs, and maintain international influence. The loss of a UK domestic route would also see the loss of MHRA's ability to develop and implement regulatory levers to drive rapid and safe uptake of innovation. Maintaining an active domestic regulatory function enables the UK to respond effectively to emerging technologies and public health needs.

International reliance is a one-way mechanism that enables the UK to recognise approvals granted by other regulators, rather than reciprocal arrangements. Without a sustainable domestic route to market, the UK would become solely dependent on external regulatory decisions, limiting the MHRA's ability to shape international regulatory approaches, maintain scientific and technical expertise, encourage UK research and development, and overall support UK Medical Technology innovation and growth in the sector.

The MHRA does not currently have powers to undertake device assessments and authorise devices directly. The proposal is therefore to grant the Secretary of State with new licensing powers for medical devices, which would be delivered through the MHRA as the medical device regulator and future licensing authority.

As this proposal relates to an enabling power rather than the implementation of a detailed licensing regime, the analysis is based on the Government's current policy intent. A further Impact Assessment (IA) will be produced alongside any future secondary legislation establishing the detailed licensing framework.

**Policy aims**

This policy aims to:

- strengthen resilience, maintain and grow a sustainable domestic route to market for medical devices in Great Britain;
- preserve and strengthen UK regulatory capability and resilience;
- support innovation and growth in the UK medical technology sector;
- provide greater regulatory flexibility to respond to emerging technologies and public health needs;
- maintain high standards of patient safety while supporting timely access to innovative medical devices; and
- support the UK's international regulatory influence and long-term trade objectives.

**Territorial extent**

References in this IA distinguish between the role of the MHRA as the UK-wide regulator and the territorial application of medical device legislation. The MHRA exercises regulatory functions for medical devices across the UK. However, under the terms of the Windsor Framework, medical devices placed on the Northern Ireland market comply with relevant EU medical device legislation. The Medical Devices Regulations 2002 and any future medical device licensing regime enabled by these powers would therefore apply to the Great Britain market (England, Scotland and Wales) rather than the whole UK market.

References to the “Great Britain market” relate to market access arrangements and regulatory requirements that apply in Great Britain. References to the “UK” are used where discussing the MHRA's institutional role, UK-wide regulatory capability, international influence, trade and innovation objectives, or the wider UK medical technology sector.

# 2. Strategic case for intervention

### Current model

Before medical devices can be supplied in GB, manufacturers must demonstrate how they meet certain regulatory requirements to ensure product safety, quality and performance. For low-risk devices, the manufacturer can self-declare conformity with the regulatory requirements. For medium and high-risk devices, a conformity assessment body must independently assess that a medical device meets the requirements as set by the MHRA. UK Approved Bodies (UKABs) are MHRA-designated conformity assessment bodies. They are third-party organisations that assess whether medical devices meet regulatory requirements and issue UKCA certificates for conforming devices. They are private, commercial organisations. The UKAB must also monitor post-market surveillance of the products and manufacturer premises whilst the devices are supplied on the GB market.

Under the current UKCA model, UKABs operate on a fully commercial basis. They fund their activities through fees charged to medical device manufacturers for conformity assessments and ongoing certificate management, which are set independently by each UKAB and designed to recover their operating and accreditation costs. UKABs also pay statutory designation and audit fees to the MHRA. No government funding is provided to support UKAB operations.

UKCA marked medical devices currently account for approximately 7% of the GB market, with the remaining 93% coming from the recognition of CE-marked devices. Since becoming a valid route to market in 2021, in each calendar year from 2021 to 2025, there have been 61,000-100,000 UKCA device registrations. Approximately 450,000 medical devices on the GB market are UKCA-marked, with medical devices falling into 3 broad categories:

- General Medical Devices: Medical products used to diagnose, prevent, monitor, treat or alleviate disease or injury. This includes software, bandages, thermometers, and surgical instruments.

- Active Implantable Medical Devices: Devices that are intended to be totally or partially introduced into the human body and which rely on a source of energy other than that generated by the human body or gravity to function, such as pacemakers.

- In Vitro Diagnostic Devices (IVDs): Tests and related equipment intended for use to examine specimens derived from the human body (such as blood or tissue) to provide information concerning physiological or pathological states, congenital abnormalities, compatibility with potential recipients, or to monitor therapeutic measures.

Alongside the domestic UKCA model, there are also existing or upcoming international reliance or recognition routes to the GB market:

- Consultation response to international reliance[2]: The MHRA identified 4 comparable regulatory countries whose regulatory approvals it will recognise or rely upon when assessing conformity with GB regulations, namely Australia, Canada, the EU and the USA. The MHRA is proposing to rely on the approvals or certificates issued by the regulatory authorities in 3 of these comparable regulator countries (Australia, Canada, and the USA), subject to certain conditions and requirements. The MHRA is consulting on indefinite recognition of CE-marked devices from the EU.

- Consultation on indefinite recognition of CE-marking[1]: CE-marked medical devices can be placed on the GB market under the UK's transitional arrangements, up to 2028 or 2030 depending on the specific EU rules followed. The MHRA launched a consultation (from February to April 2026) on proposals to indefinitely recognise CE-marked devices beyond these transitional deadlines, with a Government response expected in autumn 2026.

## Issues with the current model

### Declining demand for domestic approvals

The domestic UKCA route to market is becoming increasingly unstable and unsustainable. The potential indefinite recognition of CE marked medical devices and the introduction of international reliance pathways have driven down demand for the UKCA marking. While these policies support access to medical devices, they also reduce incentives for manufacturers to seek UKCA certification. As a result, demand for domestic approvals has fallen significantly below original expectations when the UKCA system was established.

Manufacturers have consistently criticised the UKAB model as being duplicative, costly, time-consuming and lacking in transparency. With the recognition of CE marked medical devices, the current UKCA model offers no advantages to manufacturers over the EU CE marking. It is essentially a mirror image of the EU system that provides access to a much smaller market. This is particularly challenging for small and medium-sized enterprises, who may lack the capacity to manage multiple regulatory pathways efficiently, leading to deprioritisation of the GB market or delayed product launches. This is evidenced by the low use of the UKCA mark by manufacturers with only 7% of devices registered with the MHRA utilising this route. To grow the use of the GB domestic route to market and ensure that GB patients can quickly and safely access the devices they need, the current system

must be fundamentally reformed to differentiate it from the EU model and provide incentives for manufacturers to use it.

### Manufacturer costs

Cost estimates for obtaining CE marking from a manufacturer perspective are drawn from an April 2026 MedDeviceGuide article.[4] The below estimates are provided on a per-certificate basis rather than a per-device basis, where a single certificate can cover many devices if they fall within the same scope[5]:

**Table 1: Cost estimates for obtaining CE-mark certificate in 2026**

| Classification | Self-Declaration? | Typical Total Cost (£)[6] | | Typical Timeline |
|---|---|---|---|---|
| | | Low | High | |
| **Class I (non-sterile, non-measuring)** | Yes | 6,926 | 22,511 | 3 to 6 months |
| **Class Is / Im / Ir** | No | 12,987 | 43,290 | 6 to 12 months |
| **Class IIa** | No | 27,706 | 95,238 | 9 to 18 months |
| **Class IIb** | No | 60,606 | 190,476 | 12 to 24 months |
| **Class III** | No | 173,160 | 519,481 | 24 to 60 months |

The MHRA Approved Bodies team have determined the costs and timelines for obtaining the UKCA marking as a standalone marking would be similar to the above table for CE-marking.

It is worth noting that most products holding a UKCA marking hold both a CE and UKCA certification, where they have undergone an abridged route to UKCA. This is where the product already has a CE certification and provides evidence from their CE assessment as evidence towards UKCA certification. Additional cost is limited in this instance and would not involve paying the full cost for CE certification and then the full cost for UKCA certification again.

### Financial sustainability of Approved Bodies

[4] MedDeviceGuide (2026), How Much Does CE Marking Cost for Medical Devices? Complete 2026 Budget Breakdown | MedDeviceGuide (viewed April 2026)

[5] The device is the product being sold whereas the certificate is the approval showing compliance.

[6] Converted from EUR (in the MedDeviceGuide article) to GBP at rate of 1.1550:1 from HMRC June Monthly Exchange rates: June 2026 HMRC currency exchange monthly rates - GOV.UK

Following the decision to introduce international reliance pathways and likely plans to extend the period for the recognition of CE marking (both discussed on page 6), there has been minimal interest in UKCA marking from device manufacturers. As a result, UKABs have reported concerns with commercial viability of the current model.[7] Since 2025, 2 UKABs have decided to withdraw their designation and cease operations, leaving 9 UKABs in the market currently, with a material risk of further UKAB withdrawals in the next 3 to 5 years. Manufacturers also consistently report high fees and uncertain assessment timelines from UKABs as barriers to use of the UKCA marking, reducing its attractiveness as a route to market.[8]

If indefinite recognition of CE marked medical devices is introduced following consultation earlier this year (with a government response expected in autumn 2026), it is highly likely that demand for UKCA certification will fall, and more UKABs will leave the market in the next 3 to 5 years, raising concerns about the long-term sustainability and capacity of the UKAB ecosystem.

UKABs have indicated that limited UKCA turnover, when set against the relatively high costs of maintaining UKAB designation, makes continued market participation commercially unattractive. If further UKABs exit the market, GB could see a return of the capacity pressures highlighted in the 2022 study on medical device regulatory reform[9], which identified a shortage of UKABs as a core systemic risk. That study linked low UKAB capacity to slower approvals, regulatory bottlenecks and knock on risks to patient safety and access to medical technologies. Therefore, the current challenges not only threaten UKAB commercial viability but also risk the same capacity related vulnerabilities previously identified.

Under the existing framework, UKABs are required to maintain organisational capability, specialist expertise and a physical UK office, in order to meet their designation and monitoring requirements. Many of these rules and associated costs for UKABs derive from retained EU law (Regulation 920/2013) and were designed for a regulatory environment where the policy intention was that all devices on the GB market would be UKCA-marked, and there were no plans for international reliance or recognition. As a result, UKABs must continue to maintain technical capability and therefore fixed costs in order to retain their designation, regardless of the volume of assessment work they undertake. These rules have become disproportionately costly now that MHRA is the sole designating authority and new market routes like international reliance and continued CE marking recognition are emerging. While the MHRA is seeking to update these requirements in a way that

[7] UK Association for Medical Device Approved Bodies (Team-AB) produced a paper for the MHRA on 10th November 2025 highlighting these issues.
[8] Reported through discussions with Trade Associations representing medical device manufacturers in the UK, and through Association of British HealthTech Industries report: UK HealthTech Regulatory Survey Flashes Warning Light on Growth Opportunity
[9] Ji Eun Diana Han, MSc and otherscir (2022), Opportunities and Risks of UK Medical Device Reform | Therapeutic Innovation & Regulatory Science | Springer Nature Link (viewed April 2026)

creates a more cost-proportionate model, this alone will not address the structural deficiencies of the model itself.

However, further government intervention outside of the UKAB model must be taken to account for the risk of UKABs dropping out of the market despite this streamlining and to ensure that the GB's domestic route to market is best-placed to support innovation and drive growth.

**Lack of flexibility to support innovation**

The UKAB-based model lacks the flexibility to apply the regulations in a way to support innovation. The Medical Devices Regulations 2002 are necessarily highly prescriptive in order to provide a comprehensive and consistent basis for third party conformity assessment by UKABs. However, this can limit the ability to apply requirements proportionately where technologies are novel, iterative, or do not fit neatly within existing regulatory categories. UKABs have expressed concerns about liability exposure, which constrains their willingness and ability to engage flexibly with novel or early-stage technologies, where innovative products may not have the full clinical or technical data to support a full conformity assessment. UKAB liability concerns restricts the flexible application of the current model.

Taking the decision to authorise a product in-house will allow the MHRA to take on the liability for the decision, allowing more flexible application of the regulations to support innovation in areas of unmet clinical need or where identified as priorities for the healthcare system.

**Rationale for intervention**

Government intervention is required to establish a sustainable and credible domestic route to market for medical devices in GB, as the current UKCA model is failing.

1. **The current regulatory model is not functioning effectively for UKABs, industry, or the regulator**

Under the existing UKCA framework, UKABs face operating costs that significantly exceed their revenue from conformity-assessment work. Reliance and recognition also impact the sustainability of UKABs. Manufacturers do not view UKCA as an attractive route to market due to a perception of high cost, duplication and long lead times for assessments[10], and UKAB liability concerns limit the flexible application of the regulations to support early-stage innovation. The decline in demand has contributed to instability in the UKAB market and increased concerns with the long-

[10] Reported through discussions with Trade Associations representing medical device manufacturers in the UK, and through Association of British HealthTech Industries report: UK HealthTech Regulatory Survey Flashes Warning Light on Growth Opportunity

term sustainability of domestic regulatory capacity. In combination, these pressures indicate that the present system is unsustainable for all parties.

2. **Without intervention, the GB risks a gradual loss of UKAB capacity and the domestic route to market**

Given the financial pressures and anticipated decline in demand for UKCA certification, there is a material risk of further withdrawals of UKABs from the system. If additional UKABs exit, the MHRA could be left without any mechanism to perform the assessments required under existing legislation. This would create a regulatory capacity gap and threaten continuity of supply for medical devices, as the MHRA currently lacks the power to approve devices domestically under its own rules.

Government intervention is also required because the current framework does not provide sufficient flexibility to regulate innovative technologies proportionately. The Medical Devices Regulations 2002 are necessarily highly prescriptive in order to provide a comprehensive basis for third party conformity assessment by UKABs. However, this can make it more difficult to accommodate novel technologies that do not align neatly with existing regulatory requirements.

Intervention is therefore required to preserve the MHRA's ability to operate an effective domestic regulatory system, maintain scientific and technical capability within the UK, drive growth in the UK medical technology sector, support international influence and trade objectives, and ensure the regulatory framework can respond proportionately and flexibly to future technological innovation.

3. **Losing a GB route to market would reduce UK influence and leave the system dependent on external regulatory decisions**

While the introduction of international reliance and extended recognition of CE marked medical devices support patient access and supply continuity, they do not maintain long-term domestic regulatory capability. Reliance and recognition routes depend on decisions taken by external regulators and do not provide the UK with equivalent standing in international negotiations or regulatory cooperation agreements.

If the domestic assessment route collapses, GB would become a reliance-only market, dependent on devices approved through external systems. Sole dependence on overseas assessments carries strategic risks. For example, over-reliance on CE marked medical devices would expose GB to EU regulatory bottlenecks, shifts in requirements, and fluctuations in notified-body capacity, while removing domestic control over safety regulations. It would also reduce the MHRA's ability to influence international regulatory fora and weaken efforts to drive global harmonisation that supports UK trade and innovation.

Without intervention, there is a significant risk that the GB domestic route to market could substantially diminish over time, leaving GB solely dependent on decisions made by overseas regulators. This will reduce the MHRA's credibility, influence, and ability to respond flexibly to emerging technologies and GB-specific public health needs. It will also weaken the MHRA's position on potential mutual recognition discussions, which would otherwise support GB manufacturers and drive growth.

**Proposed intervention**

The proposed intervention is to introduce an enabling power allowing the creation of a licensing regime through secondary legislation.

Under a future licensing regime, the MHRA would be the licensing authority, responsible for decisions and able to license devices directly based on its own inhouse assessments. The regime would also provide flexibility for the MHRA to draw on external technical or scientific expertise where appropriate, through subcontracted assessment activity or specialist advisory support to bolster capacity and capability. This could include expertise currently held with UKABs, but the future regime would not be structurally dependent on the continued operation of the current UKAB market. Instead, it is intended to provide the MHRA with greater control and resilience in how domestic regulatory capability is maintained over time.

The regime would also allow for flexible approaches such as conditional licensing, meaning time-limited or evidence-generating licences for devices that show early promise but do not yet have a full evidence base. This would support earlier patient access to innovation and support developers, by giving them a controlled route to market while further data is collected, maintaining strong regulatory oversight and patient safety.

This creates an opportunity to deliver a more innovation-supportive and growth-oriented regulatory approach. It is intended to modernise the framework governing market access for medical devices in GB, while ensuring that patients continue to benefit from timely access to safe, effective, and innovative technologies. The regime is designed to create a clearer and more proportionate route to market for manufacturers, while strengthening safeguards relating to patient safety, product quality, and post-market oversight.

In the short-medium term, the intention is for the current UKCA system to continue while MHRA develop the new regime, so that it can become the sole *domestic* route to market in future.

It would operate in parallel to the indefinite recognition of CE marking (pending consultation outcome)[1] in autumn 2026, and the international reliance pathways to be introduced in 2027 (subject to parliamentary process). The proposed primary legislation does not in itself set out detailed regulatory requirements for the licensing

of medical devices. Instead, it provides enabling powers that are essential to the development of a domestic route to market in which the MHRA authorises products. These enabling powers will allow the MHRA, through secondary legislation, to create and operate a licensing regime through which it can directly assess and license medical devices. This future regime is intended to remove reliance on UKABs, mitigate risks from over-dependence on international regulatory systems and create a more robust, efficient and innovation friendly domestic framework.

The secondary legislation will set out the operational detail of the future licensing regime, including the MHRA's assessment processes, the scope of devices eligible for licensing, terms and conditions attached to licences and any transitional arrangements. The primary legislation proposed in this bill confers the necessary powers to establish a licensing regime through secondary legislation at a later stage, including powers to impose terms and conditions, expansion of enforcement powers to sufficiently cover the licensing regime (for example facilitating the MHRA to conduct pre-market inspections before making a decision on a licence application), and the power to make exemptions from the requirements where there is a public health need (for example a pandemic). The future secondary legislation establishing the detailed regime will be subject to public consultation and parliamentary process.

The proposed licensing regime would also bring the regulation of medical devices in GB into closer alignment with the approach already used by the MHRA for medicines, where the MHRA is responsible for making authorisation decisions directly. A number of international regulators also operate licensing or authorisation-based models for medical devices, including the United States Food and Drug Administration (FDA), who undertake regulatory review and approval activities directly rather than relying primarily on third-party conformity assessment bodies. While the detailed design of regulatory systems will likely differ between jurisdictions (subject to future policy design and secondary legislation), a licensing regime would provide the MHRA with greater flexibility, accountability and oversight of regulatory decision-making, while supporting closer alignment with international regulatory practice and facilitating engagement with global regulatory partners.

The MHRA has engaged with key stakeholders from medical technology trade associations (Association of British HealthTech Industries, British Healthcare Trades Association, British Dental Industry Association) and the UKABs (through Team-AB, the association of UKABs) to workshop and test the proposed policy intervention, which has been met broadly favourably. The MHRA will continue stakeholder engagement ahead of potential introduction to fully explore the impacts and risks in the design of the policy, should it be implemented subject to the will of Parliament.

# 3. SMART objectives for intervention

The overall objective of the intervention is to ensure that GB maintains a sustainable, effective and innovation-supportive domestic route to market for medical devices, while continuing to protect patient safety and support timely access to medical devices.

The proposed enabling powers are intended to provide the legislative foundation for a future medical device licensing regime through secondary legislation. The detailed design of that regime will be subject to further policy development, consultation and a separate IA. However, the Government's current policy intent is that a future licensing regime would contribute to the following objectives:

- Maintain a sustainable domestic route to market for medical devices in GB that is not dependent on the continued commercial viability of UKABs.
- Support timely patient access to safe, effective and innovative medical devices by enabling more flexible and proportionate regulatory approaches, including imposing terms and conditions where there is a patient safety need.
- Strengthen the MHRA's ability to regulate emerging technologies, including software and AI medical devices, through more adaptable assessment and licensing mechanisms.
- Maintain and develop UK scientific, technical and regulatory capability in medical devices.
- Support GB growth, innovation and investment by creating a more attractive and predictable regulatory environment for medical technology developers.
- Preserve the MHRA’s international regulatory influence and ability to engage effectively with global regulatory partners.

These objectives align with wider Government priorities set out in the Life Sciences Sector Plan and 10 Year Health Plan for England, to drive economic growth, support innovation, strengthen the life sciences sector, and improve patient access to innovative healthcare technologies.

Success of the intervention will be assessed through indicators developed as part of the future licensing regime, which are expected to include measures relating to domestic route use, assessment timelines, stakeholder confidence, regulatory capability, patient access to innovation and the attractiveness of the GB market for medical device developers.

# 4. Description of proposed intervention and explanation of the logical change process whereby this achieves SMART objectives

**Future model**

The Government proposes the introduction of a new primary power in the bill that amends the Medicines and Medical Devices Act 2021 to allow the Secretary of State for Health and Social Care to establish, through subsequent secondary legislation, a medical device licensing regime. This will replace the current model transposed from EU law where all but the lowest risk devices must be conformity assessed by UKABs. In this future model, licences would be required for all risk classifications of products, but the level of scrutiny would vary depending on risk classification.

The objective of the primary legislation is to confer enabling powers to make the subsequent secondary legislation. The objective of the secondary legislation is to establish the medical device licensing regime, for which a Regulatory IA will be conducted and submitted to the Regulatory Policy Committee for scrutiny. This IA relates to the primary legislation that proposes to confer the enabling powers, with the specific details of the licensing regime to be decided following introduction of these powers.

**Theory of Change**

**Input**

- Introduction of **new enabling powers** through primary legislation, allowing the Government to establish a **domestic medical device licensing regime** through secondary legislation. This itself has no direct impact or cost on business, however it allows for secondary legislation to be passed thereafter.

- Secondary legislation setting out the **requirements, processes and standards** for the new licensing route, designed to be more agile and innovation-focused than the current UKAB model.

**Activities**

- Medical device manufacturers using the domestic route to market will:

    - **Familiarise themselves** with the new domestic licensing framework, guidance, and assessment processes.

    - **Decide whether to pursue licensing or other route to market through reliance or recognition**.

- **Prepare applications** under the new regime, which will involve updating internal processes or documentation to align with the new assessment process.

- **Submit applications** under the new licensing regime, reducing exposure to delays or capacity issues within the current UKAB system.

**Outputs**

- **More efficient and predictable assessment pathways**, with shorter assessment timelines relative to the current UKCA or UKAB process.

- **Increased throughput** of product assessments through targeted deployment of MHRA capacity and sub-contracting of third-party expertise

- A **greater number of devices obtaining domestic approval** through licensing where this pathway is chosen.

**Outcomes**

- **Streamlined and more reliable route to the GB market**, reducing uncertainty associated with assessment delays or potential market exit in the do-nothing scenario.

- **Reduced business risk and improved financial planning**, as manufacturers gain greater clarity regarding assessment timelines, regulatory expectations, and likely time-to-market.

- **Earlier access to the GB market** for innovative and AI-enabled medical technologies due to more flexible and responsive licensing criteria.

- **Increased competitiveness**, as domestic firms can innovate at pace and respond more rapidly to clinical need and market opportunities.

- **Improved supply resilience**, as manufacturers have a dependable domestic regulatory route even if international marking regimes fluctuate. While ongoing work to streamline the existing UKAB framework will make existing processes more efficient, it cannot address the structural risk that UKAB capacity may continue to decline due to commercial pressures. The licensing power therefore provides a long-term and sustainable domestic route, through inhouse licensing.

**Impacts**

- A **more resilient and diversified regulatory ecosystem**, reducing sole reliance on UKABs and mitigating risks associated with their potential withdrawal from the GB market.
- A **stronger, innovation-friendly domestic environment**, supporting investment, R&D activity, and the growth of GB-based med-tech firms.
- **Earlier patient access to innovations**, through the adaptability of the licensing regime for novel technologies that would not be well suited traditional assessments, and through conditional licensing where safety has been sufficiently demonstrated.
- **Greater attractiveness of the GB market** as a destination for developing, validating and launching new technologies, including AI-enabled and software-based devices.
- **Enhanced international influence**, as the MHRA contributes actively to global regulatory forums and promotes internationally recognised standards through a credible domestic regime.
- **Improved long-term supply of safe and effective medical devices**, benefitting patients and the wider healthcare system, while strengthening GB's health-tech sector and supporting economic growth.

# 5. Summary of longlist and alternatives

In line with HM Treasury Green Book guidance, a longlist of potential options was developed to explore different approaches to addressing the identified problem: the declining sustainability of the GB domestic route to market for medical devices and the associated risks to domestic regulatory capability, patient access to innovation, GB medical technology sector support, and international influence.

The longlist considered options across 3 categories:

- Maintaining or expanding reliance on overseas regulatory approvals.
- Reforming the existing UKAB model.
- Increasing the role of the MHRA in medical device assessment.

The longlist was developed and assessed against a set of critical success factors derived from the policy objectives. These were:

- Maintaining a sustainable domestic route to market.

- Supporting timely patient access to safe and effective medical devices.
- Enabling proportionate regulation of innovative medical devices.
- Maintaining UK scientific and regulatory capability.
- Supporting international credibility and influence.
- Reducing unnecessary regulatory burden.
- Deliverability within a reasonable implementation timeframe.

**Longlist options**

A summary of the assessment of each option against the critical success factors is in Table 2 on page 23.

**Option 1: business-as-usual**

Retain the existing UKCA regulatory framework without further reform to the model in which it operates, while continuing progressing recognition of CE marked devices and introduction of international reliance pathways.

This option would not address the declining sustainability of the domestic route to market, continued reduction in demand for UKCA certification, or risks to domestic capability.

**Option 2: Medical device licensing power**

Introduce a licensing regime giving the MHRA licensing authority, and therefore greater oversight and control of the domestic approval process. The licensing regime would exist alongside recognition and reliance routes to market.

This option is intended to support a sustainable domestic route to market, maintain UK regulatory capability, improve flexibility for innovation, support timely patient access to safe medical devices, and reduce structural weaknesses associated with the current model.

**Option 3: Establish the MHRA as a UKAB**

Establish the MHRA as a UKAB alongside existing UKABs.

This option would maintain the current UKAB model and framework but would introduce resilience should UKABs all exit the market. It would not address limitations with flexibility in the current system, or the decline of UKCA certification demand. Becoming a UKAB would require the MHRA to meet all the designation requirements that apply to private UKABs. These requirements are costly and the

potential revenue available from UKCA-based conformity assessment is already known to be limited. Establishing the MHRA as a UKAB would therefore replicate the same structural weaknesses that currently challenge the private UKAB model and risks creating a publicly funded UKAB that would operate at a financial loss.

**Option 4: Expand reliance and recognition of overseas regulatory assessments to more jurisdictions**

Continue and expand the jurisdictions included in the international reliance framework (in addition to Australia, Canada and the US), alongside indefinite recognition of CE marked devices as the primary route to market in GB. No domestic route to market for Great Britain.

This option could reduce costs and duplication for manufacturers. However, it would further reduce use of the domestic approval route and increase long-term reliance on external regulatory decisions. It would not maintain a sustainable domestic regulatory capability or strengthen the MHRA's international regulatory position.

**Option 5: Improved guidance and support for the existing UKAB model**

Retain the current UKCA framework and seek to improve its operation through the provision of additional guidance, clarification of regulatory requirements, increased stakeholder engagement, and enhanced support for manufacturers and UKABs.

This option could improve understanding of regulatory requirements, reduce uncertainty for manufacturers, and promote greater consistency in the application of the existing framework and reduce costs to UKABs. It would be relatively straightforward and low-cost to implement compared with wider structural reforms. However, this option would not address the underlying causes of declining demand for the UKCA route. It would also not address concerns regarding assessment capacity, commercial viability of UKABs, or limitations in the flexibility of the current conformity assessment framework. As a result, while guidance may improve user experience, it would be unlikely to materially improve the long-term sustainability of the domestic route to market.

**Option 6: Legislative reform of the existing UKCA and UKAB model**

Retain the current UKCA and UKAB framework while introducing legislative changes to reduce regulatory burden and improve efficiency. This could include reforms to UKAB designation and monitoring requirements, amendments to the conformity assessment processes, greater flexibility in the application of regulatory requirements, and measures to reduce administrative costs and timelines for manufacturers and UKABs.

This option could enhance the attractiveness of the UKCA route and increase the financial sustainability of UKABs. These reforms could help sustain the current

model for longer and improve manufacturer experience when seeking access to the GB market through the domestic route. Such changes could help reduce delays and increase predictability of assessment activities. However, stakeholders have indicated that many underlying challenges are structural, including reduced market demand resulting from international reliance and CE recognition. This option would therefore be unlikely to fully address concerns regarding long-term sustainability of the domestic route to market or flexibility for innovative technologies, leading to reliance on international pathways. This would reduce MHRA's ability to differentiate the GB domestic route to market from the EU, and therefore the option to offer an attractive alternative for manufacturers over seeking a CE marking.

**Option 7: Targeted MHRA licensing for specific device categories**

Introduce a targeted licensing model, limited to certain categories of devices (such as novel devices, devices addressing an unmet clinical need), while retaining the existing UKAB framework for other device categories.

This option could improve flexibility for innovative technologies and preserve elements of domestic capability. However, operating parallel systems could increase complexity for manufacturers and may not fully address sustainability concerns with the domestic framework. This risks establishing a two-tier system where certain manufacturers benefit from more rapid and cost-effective assessments from the MHRA, while others must seek third-party UKAB assessment. This would not address the challenges that could otherwise delay patient access to vital medical devices, that may not be classified as novel.

**Option 8: Expanded MHRA role for high-risk devices with streamlined UKAB role for medium-risk devices**

Introduce direct MHRA licensing for high-risk devices while retaining a modified UKAB route for medium-risk devices.

This option could strengthen domestic capability and allow more direct regulatory oversight for high-risk devices. However, it could increase confusion or complexity for manufacturers, may not fully address sustainability concerns with the current domestic framework, and could create boundary and classification challenges between the MHRA and UKABs. While classification rules are set out in legislation, there are recognised borderline cases where classification is not always straightforward. Splitting oversight based on risk class could therefore introduce additional complexity, uncertainty for manufacturers, and potential inconsistency in regulatory pathways.

**Option 9: Medical device licensing as the sole route to market in GB**

Introduce a medical device licensing regime under which MHRA licensing becomes the sole domestic route to market for medical devices in GB, replacing the existing

UKCA conformity assessment route and removing all plans for recognition and reliance on overseas regulatory assessments.

This option would maximise the benefits associated with a licensing-based system by creating a single, streamlined domestic approval route and embedding MHRA oversight of all medical devices. It could provide the greatest degree of regulatory consistency, flexibility and domestic capability. However, it would also require the most significant operational transformation and remove reliance on international approvals (including CE marking), meaning access to the GB market would depend solely on the MHRA licensing route. This would risk reducing device availability if manufacturers choose not to engage with a GB-specific pathway, particularly where this introduces additional cost or complexity compared to other markets. Reduced availability of devices would in turn have negative impacts on patient safety and clinical outcomes, particularly where alternative products are limited or unavailable. It would also place the greatest resource requirement on the MHRA. This would also be perceived by the MedTech sector as increasing regulatory barriers and administrative burden, which would undermine the Government ambitions set out in the Regulatory Action Plan[11].

**Initial conclusion**

Options 4 and 5 were not shortlisted because they would not maintain a sustainable domestic capability and would result in sole reliance on international regulatory assessments over time. Option 4 would significantly expand reliance on international regulatory assessments, resulting in no domestic function. Option 5 would not address the structural issues relating to the declining demand for UKCA certification and would therefore be insufficient to sustain the existing UKAB model.

Options 3 and 7 were not shortlisted because, while they could improve operational performance and resilience of the current system, they would not sufficiently address the structural decline in demand for UKCA certification or wider sustainability concerns with UKAB model. Option 3 would also introduce governance and structural limitations associated with MHRA taking on the role of a UKAB and risk establishing a publicly funded loss making body, while option 7 would risk increased system complexity without resolving the UKAB viability concerns.

Option 9 was not shortlisted because it would significantly risk essential supply of medical devices in the health system, given over 90% of medical devices currently on the UK market have a CE marking.

Options 1, 2, 6 and 8 were shortlisted for further appraisal because they each maintain a meaningful domestic regulatory function while offering differing degrees of

[11]HMT and DBT (2025), A new approach to ensure regulators and regulation support growth - GOV.UK (viewed April 2026)

MHRA involvement and flexibility. These options provide a spectrum, ranging from no intervention through to an MHRA licensing regime being the only route to market, allowing assessment of incremental, hybrid and transformative approaches against the success criteria.

A ‘do maximum’ option has not been shortlisted as part of the final appraisal, and as such there are only 4 options shortlisted. Option 9, where medical device licensing would be the sole route to market in GB, would be the do maximum option. It would be a fully transformative approach that removes international reliance and recognition and entirely relies on the MHRA for assessment. This has not been taken forward because it is not considered proportionate or viable. Given the current market structure, in which the majority of devices rely on CE marking, moving to a sole domestic licensing model would introduce material risks to market stability and continuity of supply. This would introduce subsequent risks to patient safety and outcomes.

**Table 2 key:**

| | |
|---|---|
| ✓ | Substantially meets the critical success factor |
| ~ | Partially meets the critical success factor |
| ✕ | Does not meet the critical success factor |

| Table 2: Longlist options assessment<br><br>Option | Sustainable domestic route | Timely patient access | Proportionate regulation of innovation | UK scientific and regulatory capability | International credibility and influence | Reduced regulatory burden | Deliverable within reasonable timeframe | Shortlisted? |
|---|---|---|---|---|---|---|---|---|
| **1 – Business-as-usual** | ✗ | ~ | ✗ | ~ | ✗ | ✗ | ✓ | ✓ |
| **2 – Medical device licensing power** | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ~ | ✓ |
| **3 – MHRA as a UKAB** | ~ | ~ | ✗ | ~ | ~ | ✗ | ✓ | ✗ |
| **4 – Expand international reliance and recognition** | ✗ | ✓ | ~ | ✗ | ✗ | ✓ | ✓ | ✗ |
| **5 – Guidance and support within existing UKAB model** | ✗ | ~ | ✗ | ✗ | ✗ | ~ | ✓ | ✗ |
| **6 – Legislative reform of existing UKAB model** | ~ | ✓ | ✓ | ~ | ~ | ✓ | ~ | ✓ |
| **7 – Targeted MHRA licensing for specific device categories** | ~ | ~ | ~ | ~ | ~ | ✗ | ~ | ✗ |
| **8 – Expand MHRA role for high-risk devices with streamlined UKAB role for medium-risk** | ~ | ~ | ~ | ✓ | ✓ | ~ | ~ | ✓ |
| **9 – MHRA licensing as the sole route to market in GB** | ✗ | ✗ | ✓ | ✓ | ✓ | ✗ | ✗ | ✗ |

# 6. Description of shortlisted policy options carried forward

### Table 3: Costs and benefits of shortlisted options

| Impact area or Option | Option 1 – business-as-usual | Option 2 – medical device licensing power | Option 6 – legislative reform of the existing UKCA and UKAB model | Option 8 – expanded MHRA role for high-risk devices with streamlined UKAB role for medium-risk devices |
|---|---|---|---|---|
| **Cost to government** | The current administrative costs to MHRA for overseeing UKABs, setting regulations and guidance would continue. | The MHRA would need to establish licensing capability including recruiting and training staff, developing processes and systems. This would lead to one-off implementation and familiarisation costs. These costs would be met through time-limited, non-baseline government funding to support initial implementation, as agreed through the Spending Review process. Although these costs would not fall on businesses, they would represent an opportunity cost to government in terms of displacing funding from other areas.<br><br>There would also be an ongoing operational cost to enable MHRA to run the licensing scheme. The MHRA would recuperate this cost from manufacturers once the scheme is established, charging at cost-recovery under HMT Managing Public Money principles. | Making legislative and operational reforms within the existing framework would incur potential costs for new systems but are uncertain as they would be subject to detailed policy design. | MHRA would require capability for high-risk assessments while maintaining UKAB oversight arrangements. The MHRA would need to establish licensing capability including recruiting and training staff, developing processes and systems. This would lead to one-off implementation and familiarisation costs, although these are expected to be lower than for option 2, given the narrower MHRA remit and changes for manufacturers for status quo. These costs would be met through time-limited, non-baseline government funding to support initial implementation, as agreed through the Spending Review process. Although these costs would not fall on businesses, they would represent an opportunity cost to government in terms of displacing funding from other areas.<br><br>There would also be an ongoing operational cost to enable MHRA to run the licensing scheme. The MHRA would recuperate this cost from manufacturers once the scheme is established, charging at cost- |

| | | | | |
|---|---|---|---|---|
| | | | | recovery under HMT Managing Public Money principles. |
| **Cost to manufacturers** | Manufacturers would continue to face existing compliance costs for the UKCA route. There would be risks of increased costs to manufacturers if there are further UKAB withdrawals due to reduced competition in the UKAB market. | Manufacturers would face transition and familiarisation costs to understand the new licensing regime. Manufacturers would also face ongoing costs to pay for assessments. This is assumed to replace existing costs paid by manufacturers to UKABs for UKCA assessment. The ongoing costs for assessments are expected to be competitive compared to UKAB fees that manufacturers currently pay. | There may be marginal transition and familiarisation costs in learning the new model, however these would be expected to be minor as the option involves reform of the current model rather than substantive change. | This option creates potential additional complexity from operating different routes for different device classes, which could impose additional familiarisation costs on manufacturers.<br><br>Reduced business for UKABs, due to MHRA assessments for high-risk devices, may increase UKAB fees for manufacturers seeking medium-risk device assessment or risk withdrawal of ABs from the UK, decreasing competition and increasing costs.<br><br>Manufacturers would also face one-off or ongoing costs of paying MHRA to review high-risk devices. |
| **Cost to UKABs** | UKABs would continue to operate under the current regulatory approach, with the same ongoing operational costs. | As MHRA would take on the licensing process, Potential a reduction in business for UKABs would be expected. It should be noted these organisations do not exist solely as UKABs; they act as UKABs only for specific regulatory scopes while most of their revenue typically comes from broader commercial testing and certification work.<br><br>With the MHRA issuing licences, the costs of designation or auditing associated with UKABs becoming and maintaining status would be eliminated. Although the MHRA may continue to subcontract work to these organisations for opinions. | This option largely continues the existing UKAB model and operational costs. There may be marginal transition and familiarisation costs in learning the new model, however these would be expected to be minor as the option involves reform of the current model rather than substantive change. | UKABs would face existing operating costs for parts of their existing role. However, for high-risk devices, this would reduce their business and, subsequently, revenue streams. This could reduce business viability further for UKABs. |

| | | | | |
|---|---|---|---|---|
| **Benefit to patients** | Patients would continue to access to devices through CE recognition and international reliance routes. There would be risk to access to of UKCA devices, with further UKAB withdrawals and capacity reductions expected. | The proposed approach of MHRA to operate a licensing scheme would increase the flexibility of the application of the regulations. This would allow an innovation-focused regulatory landscape which may improve patient access. This benefit is highly uncertain as it is dependent on the detailed policy design. | This option would create limited benefit to patients compared to the business-as-usual option. However, reduced administrative burden may improve the attractiveness of the GB market for manufacturers, thereby improving patient access. | This option maintains and strengthens capability in higher-risk areas but retains dependence on UKAB market, ensuring patients continue to access devices, but with less risk to access than maintaining status quo. |
| **Benefit to manufacturers** | There would be no benefit or cost-saving to manufacturers under this option. | There is cost-saving expected for manufacturers certifying devices through the licensing regime rather than UKCA pathway. As the MHRA will charge at cost-recovery, whereas UKABs charge at profit-margin, prices charged to manufacturers should be lower. Monetised estimates are produced below in Table 5. | This option has potential incremental cost-saving for manufacturers undergoing UKCA assessment, as reduced UKAB costs may lead to reduced prices charged by UKABs. | This option has potential cost-saving for high-risk devices as the MHRA charges at cost-recovery whereas UKABs charge at profit-margin. However, no cost-savings are anticipated for medium-risk devices. |
| **Benefits to UKABs** | There would be no anticipated benefits to UKABs under this option. | The anticipated benefits to UKABs under this option would depend on the detailed policy design. Should the MHRA subcontract UKABs for their opinion for assessments, there could be new benefits to UKABs, where they take on a new role that does not require high costs of designation and auditing in the current format, but retains or even increases their business. | This option may improve UKAB viability through process improvements and cost reduction for their associated designation and auditing. | There would be no anticipated benefits to UKABs under this option. |
| **Benefits to government: innovation and growth** | There are no expected benefits to innovation and growth under this option. | This option has the strongest potential to support innovative technologies through flexible licensing approaches and conditional approvals. This has the potential to produce significant benefits for both medium and high-risk devices. | Some incremental improvements to innovation and growth could be possible under this option, but these would be constrained by the existing conformity assessment model. | Greater flexibility for high-risk innovative products with MHRA conducting the assessment, but less comprehensive than full licensing model. Therefore, benefits could only be produced for higher-risk devices, with no benefits for medium-risk devices. |
| **Benefits to government: strategic or** | There would be risk of gradual decline of domestic capability and increased dependence on | This option has the strongest potential for maintaining domestic capability, expertise and regulatory resilience. This has knock- | This option maintains current capability in the short-term but remains exposed to long-term | This option provides greater flexibility for high-risk innovative products with MHRA conducting the assessment, |

| | | | | |
|---|---|---|---|---|
| **regulatory benefit** | overseas decisions. This would result in risk to international influence and leadership, and a loss of levers to support innovation. | on impacts for the MHRA's international reputation. | decline in UKABs due to declining UKCA demand. This in turn risks the MHRA's international footing. | but is less comprehensive than full licensing model as there would be no innovation and growth benefits for medium-risk devices. |
| **Risks** | Under the current model, there is continued risk to the commercial viability of UKAB operations. As UKABs operate as a single service within organisations that provide broader testing and commercial certification work, they are likely to cease their operations under the current model. Without UKABs operating, there would be no domestic GB route to market. | There is risk that the licensing scheme costs more to manufacturers than the existing UKCA system. This is not the intention of the option and will be mitigated be detailed design of the secondary legislation. | There is risk that this option does not reduce UKAB costs enough to prevent their market exit, leading to their withdrawal and leaving no domestic GB route to market. | There is a risk that this option reduces UKAB revenue by limiting their assessment to medium-risk devices only, driving their withdrawal faster than the business-as-usual scenario and leaving no domestic GB route to market. |

## Options preference

### Option 2 (preferred option): Medical Device Licensing Power

The Government has assessed the shortlisted options against the policy objectives and considers the medical device licensing regime (Option 2) to be the preferred approach.

This option is preferred because it addresses the underlying structural issues identified more comprehensively than the alternative options, particularly the declining demand for UKCA certification and therefore the risk to UKAB business viability, while also providing a more coherent long-term basis for domestic medical device regulation. In particular, it moves beyond incremental reform of the existing UKCA conformity assessment model and instead enables the development of a more flexible and resilient regulatory system.

The licensing regime also provides greater long-term adaptability and flexibility. It enables the MHRA to develop and refine assessment approaches through secondary legislation and guidance, allowing the regulatory system to evolve in response to technological change, emerging evidence and international developments. This is particularly important given the increasing prevalence of novel technologies such as software and AI medical devices, which may not align well with traditional conformity assessments.

The option also strengthens strategic resilience by reducing reliance on the business viability of UKABs. While the MHRA would need to ensure it develops sufficient internal capacity and capability to deliver a licensing model, this approach provides a more stable foundation for maintaining capability without being exposed to capacity constraints in the UKAB market.

Compared with the remaining shortlisted options, the licensing regime offers the most comprehensive balance of regulatory flexibility, sustainability and strategic capability. As set out in Table 3, the preferred option performs more strongly across the assessed impact areas than the other shortlisted options, including benefits to innovation and growth, strategic and regulatory resilience, and long-term sustainability of the domestic route to market. While other options may deliver more incremental improvements or lower short-term implementation requirements, they do not sufficiently address the structural challenges identified, particularly the long-term decline in UKCA demand and associated risks to UKAB viability and domestic regulatory capability.

The Government recognises the preferred option would involve greater implementation complexity and transition requirements than more incremental reforms. Table 3 identifies that alternative options would either retain significant dependence on the current UKAB market, provide only partial flexibility for innovative

technologies, or increase long-term dependence on overseas regulatory decisions. On balance, the Government considers that the benefits delivered by these alternative approaches would not be sufficient to meet the policy objectives in a sustainable way.

Overall, based on the qualitative assessment of costs and benefits in Table 3, the Government considers that the licensing regime provides the most coherent, future-proofed and robust option. It establishes a clearer and more flexible framework capable of supporting both patient safety and innovation objectives while addressing the structural limitations of the current system. The Government considers that the alternative options would not deliver sufficient benefits to justify pursuing them over the preferred licensing regime, particularly in relation to long-term sustainability, regulatory resilience, innovation support and maintenance of domestic capability.

**Option 6 (do minimum option): Legislative reform of the existing UKCA and UKAB model**

The main alternative considered was option 6, legislative reform of the existing UKCA and UKAB model. This option would retain the current UKCA conformity assessment framework while improving its operation.

As a do minimum option, it could deliver incremental improvements for manufacturers and UKABs. Potential measures could include legislative changes to streamline conformity assessment requirements, reform UKAB designation and monitoring arrangements, reduce unnecessary administrative obligations, introduce greater flexibility in the application of regulatory requirements, and simplify regulatory processes where these no longer reflect the current market environment. As identified in Table 3, this option could reduce administrative burden, improve predictability of assessment activities, and support more timely patient access to devices, while also potentially improving UKAB viability through reduced operational and designation costs. The option would also be less disruptive and faster to implement than a licensing regime, as it would build on existing regulatory structures and processes rather than introducing a new framework.

However, while this may improve the efficiency of the existing system, Table 3 highlights that the benefits of this option would remain incremental and constrained by the underlying structure of the current conformity assessment model. It would not address the underlying structural challenges affecting the domestic route to market. It would remain dependent on a UKAB market whose long-term viability is increasingly uncertain as demand for UKCA certification declines.

It would not provide the same degree of flexibility to develop alternative assessment approaches or respond to novel technologies that may not align well with traditional conformity assessment processes. As reflected in Table 3, the option would therefore provide weaker strategic and regulatory benefits, offering only limited

improvements to domestic resilience, innovation support and long-term sustainability when compared with the preferred licensing model.

The Government therefore considers that, although this option would represent a lower-risk and less resource-intensive intervention in the short term, the balance of qualitative costs and benefits indicates that it would not deliver sufficient long-term benefits to address the wider structural risks associated with the current regulatory framework.

# 7. Costs and benefits of preferred option

## General approach

This IA provides a proportionate qualitative 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 all shortlisted options have been assessed in Table 3 on pages 23-26. As a result of this assessment, a more detailed assessment of option 2 (medical device licensing power) is set out below. The assessment has been conducted against:

- Costs to government
- Costs to manufacturers
- Costs to UKABs
- Benefits to patients
- Benefits to manufacturers
- Benefits to UKABs
- Benefits to innovation and growth
- Strategic or regulatory benefits

## General approach for preferred option cost benefit analysis

Most of the costs and benefits of the proposed licensing regime cannot be quantified at this time because the primary legislative changes covered by this IA is to introduce enabling powers, rather than practical and substantive changes. Practical change will be delivered later through secondary legislation enabled by the new powers. These subsequent changes would be subject to due scrutiny and a statutory consultation to inform decision making, including full monetised analyses of costs and benefits with full Net Present Social Value (NPSV) calculation for shortlisted options, as the policy specifics of the licensing regime are agreed.

This IA provides indicative high-level estimates of familiarisation costs to manufacturers and estimated cost saving for UKCA vs licensing regime per certificate. This IA will therefore not produce a NPSV estimate, however where costs and benefits are not quantified, they will be described qualitatively in as much detail as possible.

The proposed reforms are assessed as being 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 line-by-line quantification.

The timeframe is, indicatively, that an initial package of changes would be implemented over the next 3 to 5 years.

## Costs

*Administrative costs*

The primary legislation aspect of this new policy will not introduce additional administrative costs as it is concerned with obtaining enabling powers and does not include any regulatory provision.

The secondary legislation aspect would involve administrative costs of establishing the medical device licensing regime. This would include costs establishing internal systems around the new licensing regime. Given the MHRA will carry out licensing activity inhouse, there would be costs around hiring and training the relevant staff. These would be upfront costs.

These costs would be met through time-limited, non-baseline government funding to support initial implementation, as agreed through the Spending Review process. Although these costs would not fall on businesses, they would represent an opportunity cost to government in terms of displacing funding from other areas.

*Familiarisation costs*

The primary legislation aspect of this new policy will involve no familiarisation costs, as it is concerned with obtaining enabling powers and does not include any regulatory provision.

The secondary legislation aspect would involve familiarisation costs as medical device manufacturers familiarise themselves with the new licensing requirements, where they obtain licensing from the MHRA rather than conformity assessment certificates through UKABs.

Around 4,000 manufacturers with UKCA-marked medical devices would be affected by this change, most of which are small and medium-sized enterprises.

These costs are anticipated to be low, as the new licensing regime is intended to be simpler and more cost-effective than the current model and the MHRA will work closely with manufacturers and trade associations to ready them for the changes.

Familiarisation costs are expected to be around £550 to £2,000 per manufacturer. This large range reflects the large ranges in the assumptions on staff requirements,

time requirements and corporate overhead allocation, which are set out in Table 4. The secondary legislation aspect would also involve familiarisation costs for any expert bodies who are subcontracted to support assessments, as they familiarise themselves with the new licensing regime and their potential role within it.

**Table 4: Familiarisation cost for manufacturers estimate**

| Assumption per manufacturer | Low | High | Justification |
|---|---|---|---|
| **Number of staff required** | 1 | 2 | SMEs constitute the majority of the market and typically have small regulatory teams, often with 1-2 staff covering regulatory and quality assurance functions. |
| **Hours required** | 16 | 24 | The licensing regime will align with existing UKCA framework and is intended to be simpler and more efficient. The process is intended to be incremental learning as opposed to full retraining on an entirely new pathway. The guidance review is a non-trivial but bounded task. It is assumed the review will take 2-3 working days (16-24 hours) per manufacturer. |
| **UK Quality Assurance and Regulatory Professionals Median Pay** | 26.89 | 26.89 | UK 2026 Pay data: Quality assurance and regulatory professionals Pay UK 2026 — Annual & Hourly Pay Data \| Wage Wizard |
| **Loaded cost uplift** | 1.25 | 1.5 | Uk 2026 Benchmark: https://grove.financial/blog/fully-loaded-employee-cost<br><br>This is the cost of labour in addition to salary, covering corporate overhead. |
| Familiarisation Cost per manufacturer (£) | **538** | **1936** | |

There are currently 9 UKABs designated by the MHRA to assess medical devices. Only approximately 7% of the medical devices on the UK market have a UKCA marking, with even fewer requiring UKAB assessment (as manufacturers of low-risk medical devices can self-declare conformity with the regulations and affix a UKCA marking). These organisations do not exist solely as UKABs; they act as UKABs only for specific regulatory scopes while most of their revenue typically comes from broader commercial testing and certification work.

## Benefits

*Non-monetised benefits*

The primary legislation aspect of this new policy has no direct benefit on society, as it is solely concerned with obtaining enabling powers.

However, it generates indirect benefits by allowing the MHRA to introduce a medical device licensing regime through secondary legislation. The specific details of the licensing regime are to be decided after the enabling powers have been obtained.

The intention of this licensing regime is to improve MHRA's control and oversight of medical devices on the GB market, more closely align with other mature international regulators' systems, and support a more flexible, domestic regulatory framework. It will also create the ability to introduce conditional licensing, allowing licensing of devices earlier using initial evidence with conditions requiring further data to ensure safety and performance. This could support earlier access to safe, innovative technologies while full evidence is gathered, allow the MHRA to be responsive to public health needs, and provide an innovation-friendly route that UKABs are currently unwilling to offer due to liability constraints. The intention is to help position the UK as a leading place to undertake research, and to develop, test and launch innovative medical devices and health AI. By creating a more supportive home-grown licensing regime, this is intended to attract investment, boost R&D and contribute to the government's goal of growing the economy.

The new licensing regime could also ensure that the UK maintains its influence in international regulatory fora, in doing so supporting international harmonisation and UK trade and export.

From a manufacturer point of view, the policy would also benefit manufacturers by providing a faster, more predictable and more reliable domestic route to market, reducing their exposure to delays within the current UKAB system. It would give businesses greater certainty over assessment timelines and regulatory expectations, helping them plan production, investment and cashflow with more confidence. It would enable earlier access for innovative and AI-enabled technologies through a more flexible assessment model, supporting quicker access to market.

*Monetised benefits*

Use of the full UKCA conformity assessment route is limited, not only because the majority of medical devices on the market bear a CE marking. The majority of UKCA marked medical devices achieve their marking and conformity assessment through an abridged assessment process, where the manufacturer leverages existing conformity assessment from a CE marking. This is instead of undergoing a full standalone UKCA conformity assessment.

The Government considers that the current abridged UKCA assessment data should not be relied upon as the primary comparator in assessing costs with the proposed licensing regime. This is because this pathway only exists due to current manufacturer uncertainty around the future GB recognition of CE marked medical devices, with manufacturers using it as precautionary route in case full UKCA compliance were to become mandatory without any recognition of the CE marking. If CE recognition is made indefinite, this is expected to change and the abridged UKCA assessment will likely cease.

Therefore the abridged UKCA assessment is not considered to be an appropriate basis for long-term cost comparison. Instead, the Government considers the relevant comparison to be between full UKCA assessment with the potential licensing regime.

The policy intent is to support and strengthen the domestic route to market over time, which could be achieved through the introduction of a licensing regime (option 2) or reforms to improve the attractiveness and operation of the UKCA and UKAB system (option 6). In parallel, the Government is conducting wider work to increase the attractiveness of the GB domestic route to market through international engagement and partnerships. The ambition is for other regulators to rely on or recognise the GB regulatory assessment (either UKCA marking, or a future MHRA licence) and collaboration to support this is already underway, for example with the US FDA. If successful, GB medical device regulatory assessment will also support access to other international markets, which in turn could drive greater uptake of the domestic regulatory route.

The cost comparison has therefore been conducted between the existing standalone UKCA assessment and the proposed licensing regime. The key cost saving through introduction of a licensing regime is that the MHRA would charge manufacturers at cost-recovery (in line with HMT Managing Public Money principles), rather than charging a margin to make profits, as private UKABs do currently. Using Testing Inspection and Certification firms as a proxy for UKABs[12], a 17.05% operating margin for UKABs[13] has been estimated. Therefore, if the MHRA issued licenses in place of UKCA markings, these would be costed at 17.05% cheaper than equivalent UKCA certificates, as the profit element is removed from the pricing. The below table details for each risk classification[14], the estimated cost saving per certificate under the licensing regime:

**Table 5: Estimated Cost of UKCA vs licensing regime per certificate**

[12] As financials for UKABs as most UKABs are divisions within larger firms and do not publish segment-level financials.

[13] SGS 16.00% operating margin 2025, Intertek 18.10% operating margin 2025 2025 Full Year Results Record Financial Performance | SGS Intertek 2025 Full Year Results Announcement

[14] Excluding low-risk Class I which carry out Declaration of Conformity without UKAB assessment.

| Risk Classification (lowest to highest) | Estimated cost per UKCA certificate (£)[15] | | Estimated cost per certificate under licensing regime (£) | | Estimated cost saving per certificate UKCA vs licensing regime (£) | |
|---|---|---|---|---|---|---|
| | Lower | Upper | Lower | Upper | Lower | Upper |
| **Class Is / Im / Ir** | 12,987 | 43,290 | 10,773 | 35,909 | 2,214 | 7,381 |
| **Class IIa** | 27,706 | 95,238 | 22,982 | 79,000 | 4,724 | 16,238 |
| **Class IIb** | 60,606 | 190,476 | 50,273 | 158,000 | 10,333 | 32,476 |
| **Class III** | 173,160 | 519,481 | 143,636 | 430,909 | 29,524 | 88,571 |

The analysis indicates that moving from a UKCA framework to a new licensing regime could generate per-certificate cost savings ranging from approximately £2,000 to £7,000 for lower-risk devices to £30,000 to £90,000 for high-risk devices. These savings increase with device risk classification, reflecting higher baseline costs for complex conformity assessment. Given that most UK medical device manufacturers are SMEs, these reductions in upfront regulatory costs are likely to be proportionately more significant for smaller firms, improving cash flow, lowering barriers to entry, and supporting innovation.

These estimates are presented on a per-certificate basis, rather than as aggregate industry cost savings, due to uncertainty regarding the total volume and risk classifications of certificates that will be issued under the licensing regime upon implementation (expected in 2029).

[15] Standalone UKCA certificate costs taken from Table 1, as the MHRA Approved Bodies team have asserted standalone UKCA costs are similar to standalone CE-mark costs.

## Small and Micro Business Assessment (SAMBA)

The primary legislation aspect of this new policy has no direct impact on SMEs, as it is solely concerned with obtaining enabling powers.

The vast majority of the UK medical technology sector is made up of SMEs (around 95%)[16]. This means that the design of the regulatory system is particularly important for smaller firms.

Regulatory requirements for medical devices are the same for all businesses, regardless of size (which is appropriate given that patient safety is paramount). While the requirements themselves are not differentiated, the changes are intended to deliver a more efficient, transparent and predictable regulatory system. This is likely to be particularly beneficial for smaller businesses, which typically have less capacity to manage lengthy or opaque regulatory processes and are more sensitive to delays in market access, due to the impact on cash flow, fundraising, and the ability to reach revenue-generating stages.

Evidence from across the sector indicates that SMEs are more likely to rely on external regulatory expertise[17] and are more exposed to uncertainty and delays in approvals. As a result, improvements in regulatory clarity and timelines are likely to have disproportionate benefits for these firms.

Overall impacts are therefore expected to be proportionate to a business's level of engagement with the regulatory system and relevant markets, rather than its size alone.

While the reforms are expected to reduce administrative burden over time, there may be short-term adjustment costs which could fall disproportionately on SME manufacturers. These familiarisation costs of approximately £550 to £2,000 per manufacturer are set out in Annex A.

Mitigations to address disproportionate impacts on SME manufacturers include providing clear and timely guidance, allowing appropriate transition periods for implementation, and maintaining access to regulatory advice and support for smaller firms. Further mitigations will also be considered in the design of the secondary legislation that will set out the licensing regime and its associated IA, such as fee

[16] Calculated from Table 24: Number of life sciences companies by size and subsector, UK, 2023/24 [note 3] Office of Life Sciences dataset: https://assets.publishing.service.gov.uk/media/68dabab9dadf7616351e4bc7/BaHTSS_accompanying_data_tables_2023-24.ods (viewed April 2026)

[17] CPI (2024), New £5m Accelerator Programme to Support UK MedTech Innovation | CPI (viewed April 2026)

waivers for MHRA scientific advice or reduced costs for registering a medical device with the MHRA. This is subject to further policy development.

As discussed below in section 6, there is a risk that smaller UKABs prematurely exit the market as they may perceive the MHRA obtaining enabling powers as a signal their role as UKABs is being replaced, although the risk of their exit is arguably greater in option 1 where the status quo is maintained, where the cost of the business outweighs the revenue generated. This risk may be particularly relevant for smaller UKABs operating at smaller scale. This will be mitigated by clear communication from the MHRA about the UKAB's continued role within the future licensing model.

# 8. Risks and assumptions

### Premature exit of UKABs

UKABs that intend to remain in the market may interpret the MHRA obtaining enabling powers as a signal that they will be replaced by a new licensing regime. UKABs may not realise that there will be a role for them in delivery of the new regime, through sub-contracting of certain aspects of the assessment process. This misperception could prompt some UKABs to withdraw from the market prematurely or accelerate plans of exit, even though they would otherwise have continued operations within the licensing regime. This risk is more significant for smaller UKABs.

This risk will be mitigated by clear communication about the UKABs' future role within the new licensing model. The MHRA will communicate that the future approach moves away from the current, costly designation framework and towards the licensing-based model, which will reduce their costs and liability, as MHRA will take liability for licensing decisions. In the short term, the MHRA will continue to rely on UKABs and the UKCA route while the new licensing regime is being developed. In addition to this, the current UKAB operational rules for UKCA certification, inherited from retained EU law and now disproportionately costly, will be streamlined through updated regulation to create a more cost-proportionate and efficient regulatory model. Furthermore, work is ongoing to reduce or stratify MHRA fees charged to UKABs for designation and ongoing surveillance will help ensure the costs of participation remain proportionate, while MHRA develop and implement the future model.

### Increased risk to patients from conditional licensing

Conditional licensing would allow the MHRA to grant a licence subject to specified conditions, restrictions, or ongoing obligations that must be met by the manufacturer after the licence is granted. This could be used in a range of circumstances. For example, it could support earlier access to promising technologies where additional evidence is still being generated, permit market access subject to enhanced post-market surveillance requirements, restrict use of a device to particular patient groups or clinical settings, or require manufacturers to provide additional data on safety, performance or long-term outcomes. It could also be used for well-understood technologies where the MHRA considers that additional controls or monitoring are necessary to manage specific risks or uncertainties. The precise circumstances in which conditional licensing may be used would be determined through future design of the regime through secondary legislation.

If conditional licensing is introduced, this could increase risks to patients if devices are permitted onto the market subject to conditions, restrictions, or ongoing evidence-generation requirements that would not apply under a standard license.

Depending on how the regime is designed, this could create uncertainty about the availability of evidence at the point of the licence being granted, compliance with licence conditions, real-world effectiveness, rare adverse events, and long-term outcomes.

These risks will be mitigated through clearly defined and tightly governed control measures designed to protect patient safety. Conditional licences would be restricted to devices that meet stringent eligibility criteria, where there is a compelling public health or patient safety rationale. Conditional approval will be time-limited, with clearly and transparently communicated requirements and robust surveillance and real-world data collection. Active safety monitoring, including enhanced vigilance and routine review of emerging real-world data, would be embedded from the point of approval, supported by defined formal governance oversight, escalation routes and rapid regulatory intervention where new risks or uncertainties emerge. Through transparent communication and strong MHRA oversight, a clear pathway can enable the MHRA to support earlier access to innovation while maintaining high levels of patient safety.

The MHRA also already has experience at assessing the risk and benefit in relation to medical devices where evidence may not be fulsome, through its existing exceptional use authorisations[18]. An exceptional use authorisation (EUA) allows non-UKCA or CE certified medical devices to be placed on the UK market when doing so in the interest of the protection of public health. EUAs are granted by the MHRA for a specified period and exempt manufacturers from certain regulatory requirements. The MHRA reviews each EUA application individually. EUAs are subject to specific conditions and require that the manufacturer demonstrate ongoing progress towards full conformity with the applicable regulations.

**Risk of inadequate enabling powers for the licencing regime**

Primary legislation may fail to deliver the flexibility needed to deliver the licensing regime through secondary legislation.

This has been mitigated by working closely with policy and legal representatives to ensure the scope of the primary legislation is broad enough to allow for future policy to be enacted, while still providing sufficient parliamentary safeguards. The exact extent of the secondary legislation is still to be determined, but the primary powers will be broad enough to cover this.

**Uncertainty around MHRA's active role in the new licensing regime**

As operational details of the new licensing model are still being developed, there remains uncertainty for market participants regarding the extent of the MHRA's

[18] MHRA (2025), Exceptional Use Authorisation - GOV.UK (viewed April 2026)

active involvement in licensing decisions. Stakeholders may interpret the introduction of the new regime as signalling a potential shift towards intensive regulatory oversight by the MHRA. This uncertainty may affect the confidence of current and prospective market participants, potentially delaying investment, deterring entry, or prompting firms to reconsider their long-term participation if they fear an unpredictable or burdensome regulatory role for the MHRA.

This risk will be mitigated by clear communication on the MHRA's expected role within the licensing model as policy design progresses, and engagement with trusted stakeholders to support policy development. As operational details are clarified, the MHRA will provide timely guidance explaining how the licensing regime will interact with existing UKCA processes (including potential grandfathering of existing certificates) and what level of regulatory involvement businesses should expect. Engagement with industry will help identify areas where uncertainty may be discouraging participation and allow MHRA to refine the model accordingly. Regular updates will help ensure stakeholders have visibility of how responsibilities, processes, and timelines will evolve, enabling firms to plan with confidence while the regime is developed and implemented

**Analytical risk**

The IA's analysis assumes the current costs from UKABs to manufacturers remain stable, yet there is a risk that UKABs in fact increase their fees to manufacturers, which would change the IA.

The evidence base supporting the need for specific reforms will need to be presented at the secondary legislation stage, as particular ideas progress to implementation. That will include 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 the risks that have been identified and subject to further analysis and/or consultation, it is reasonable to take the view that the initial primary legislation enabler is likely to be beneficial and worthwhile.

**Inadequate market surveillance and enforcement powers risk**

The current GB legislation does not provide the MHRA with sufficiently strong market surveillance and enforcement powers to cover a future licensing regime, as the powers do not extend to pre-market inspections, which could result in poor-quality devices being supplied to the GB market. With the introduction of the new licensing regime, enforcement powers will need to be extended to cover devices approved through the licensing route, including pre-market inspection powers. Without these strengthened powers, gaps in oversight could make it harder to act against non-

compliant manufacturers and could undermine the safety and trustworthiness of the GB medical device market.

This risk will be mitigated in 3 ways:

- By ensuring the same investigatory and enforcement powers currently at the disposal of the MHRA will be applicable and available to the MHRA for the purposes of regulating the new licensing route. In addition, ensuring any market intervention powers (currently the sole preserve of UKABs) are available to MHRA in the event UKABs exit the market.

- By commencing Schedule 3 of the Medicines and Medical Devices Act 2021, which creates a new criminal offence for breaching certain provisions in the Medical Devices Regulations 2002, giving the MHRA stronger legal tools to act against non-compliant manufacturers. Schedule 3 also sets out the associated penalties and prosecution time limits, strengthening the UK's overall enforcement framework for medical devices.

- By commencing Schedule 2 of the Medicines and Medical Devices Act 2021, which creates a civil sanctions regime. Civil sanctions act as a flexible, proportionate enforcement mechanism to encourage compliance across a wide range of stakeholders. Civil sanctions are being introduced alongside sanctions for breaches of the Medical Devices Regulations 2002. Civil sanctions provide an additional deterrence to manufacturers from wrongdoing and equip the MHRA with an additional tool to take action to protect the public, where criminal prosecution may not be possible or appropriate.

**Divergence in patient access to medical devices between Great Britain and Northern Ireland**

Under the terms of the Windsor Framework, Northern Ireland continues to follow EU medical device legislation, while any future licensing regime enabled by these powers would currently apply to the GB market only. This creates a risk that certain medical devices may become available in GB through the domestic licensing route before equivalent access is available in Northern Ireland. This risk already exists, given medical devices approved under the UKCA route cannot be placed on the Northern Ireland market, unless they also have a CE marking through the EU regulations.

However, this risk could be increased where the MHRA adopts more flexible or innovative regulatory approaches, such as conditional licensing or accelerated assessment pathways. In these circumstances, patients and healthcare providers in GB could gain earlier access to some technologies than those in Northern Ireland, creating differences in the timing of market access across the UK.

The scale of this risk will depend on the detailed design of the future licensing regime and the extent to which it diverges from EU regulatory requirements, which will be developed through detailed policy development and consideration of divergence.

The MHRA will continue to engage with relevant Government departments, including the Windsor Framework Taskforce, Northern Ireland Office and Northern Ireland Executive, during this policy development. The impact of any divergence, including implications for patient access, healthcare delivery and the medical technology sector, will be considered further as part of the development of secondary legislation and the accompanying IA.

This can also be mitigated by existing powers within the EU legislation, where Government has powers to exceptionally authorise medical devices for the Northern Ireland market in the interest of public health or patient safety or health.

**Potential for increased costs to manufacturers and downstream pass-through to the health system**

While the licensing regime is not intended to increase manufacturer costs and is intended to improve efficiency and provide a more proportionate and flexible regulatory approach over time, there is a risk that it could result in higher regulatory costs for manufacturers compared to the current UKCA conformity assessment model.

Should this happen and increased costs arise, there is a risk that these may be passed through the supply chain and ultimately reflected in higher costs for the NHS and wider health system, and potentially patients, depending on procurement arrangements and market dynamics.

This risk will be mitigated through the detailed design of the secondary legislation, including consideration of proportionate fee structures, avoidance of unnecessary duplication with existing international evidence, and the use of efficiency measures such as reliance on subcontracted expertise and streamlined assessment pathways. A full assessment of cost impacts, including distributional effects across different types of manufacturers and devices, will be undertaken in the IA accompanying the secondary legislation.

# 9. Regulatory scorecard for preferred option

## Part A: Overall and stakeholder impacts

| (1) Overall impacts on total welfare | | Directional rating |
|---|---|---|
| **Description of overall expected impact** | The primary legislation is enabling only and does not introduce direct regulatory requirements. Its welfare impact arises indirectly through the future ability to establish a domestic licensing regime. In principle, this is expected to generate net social benefits by ensuring the UK retains a functioning domestic approval route, supporting innovation, improving resilience of supply, and reducing long-term risks associated with declining UKAB capacity. However, because the design of the secondary legislation has not yet been finalised, there remains uncertainty over the scale and timing of these benefits and any associated costs. | **Uncertain** |
| **Monetised impacts** | Limited monetised impacts can be presented at this stage. These are estimates of cost-saving comparing UKCA to the licensing regime (on a per certificate basis) and familiarisation costs for manufacturers. The primary legislation does not introduce operational changes; therefore, no quantifiable business or societal costs or benefits occur directly. Any future monetised impacts will arise from secondary legislation and will be subject to detailed appraisal later. | **Neutral** |
| **Non-monetised impacts** | Potential non-monetised benefits include: improved regulatory resilience; maintenance of a domestic route to market; earlier patient access to innovative technologies; and improved UK influence in international regulatory fora. Potential non-monetised costs include transitional uncertainty for some UKABs. | **Positive** |
| **Any significant or adverse distributional impacts?** | No significant distributional impacts are expected at the primary-legislation stage. Future secondary measures will apply to all manufacturers and economic operators consistently. Some smaller UKABs may perceive higher risk due to uncertainty, but this will be mitigated through clear communication and the future regime should support their business viability due to faster approvals. | **Neutral** |

| (2) Expected impacts on businesses | | |
|---|---|---|
| **Description of overall** | Businesses will experience no direct impacts from the primary legislation. Indirectly, the power to create a licensing regime | **Positive** |

| | | |
|---|---|---|
| **business impact** | would give manufacturers access to a more predictable and flexible domestic route to market, reducing exposure to UKAB delays and improving certainty over regulatory timelines. UKABs may incur low familiarisation costs under the future regime, but these are expected to be more proportionate than current costs. The proposal may also reduce long-term commercial risk for manufacturers by stabilising the regulatory environment. | |
| **Monetised impacts** | No monetised business impacts arise at this stage. Familiarisation and process-change costs will occur only when secondary legislation is introduced. Indicative estimates have been provided in this impact assessment and will be followed up in more detail with the secondary legislation. | **Neutral** |
| **Non-monetised impacts** | Benefits include: improved regulatory certainty; reduced dependency on UKAB capacity; potential faster access to the GB market; stronger incentives for innovation; improved ability to plan investment and cashflow. Potential risks include transitional uncertainty for some smaller UKABs; however, these risks are subject to mitigation through communication and streamlined UKAB requirements. | **Positive** |
| **Any significant or adverse distributional impacts?** | No significant distributional effects are expected during the primary-legislation phase. Smaller UKABs may perceive increased uncertainty, but their role is expected to continue under subcontracting arrangements. The regime applies proportionately across business types, with no differential cost burdens identified at this stage. | **Neutral** |

| **(3) Expected impacts on households** | | |
|---|---|---|
| **Description of overall household impact** | No direct monetary impacts on households arise from the primary legislation. Indirectly, the future regime is expected to improve public health outcomes by supporting earlier access to safe and innovative medical technologies and ensuring continuity of supply. These improvements represent potential benefits for patients, carers, and NHS users. | **Positive** |
| **Monetised impacts** | No quantifiable household impacts are available at this stage. | **Neutral** |
| **Non-monetised impacts** | Non-monetised benefits include: improved patient access to effective technologies; reduced risk of device shortages if UKAB capacity declines; and greater assurance that the UK | **Positive** |

| | | |
|---|---|---|
| | maintains robust pathways for market entry. No adverse household impacts have been identified. | |
| **Any significant or adverse distributional impacts?** | No significant negative distributional impacts anticipated. Disabled individuals, who may rely more heavily on medical devices, may benefit from improved availability and earlier access to innovative products. | **Neutral** |

## Part B: Impacts on wider government priorities

| Category | Description of impact | Directional rating |
|---|---|---|
| **Business environment:**<br>**Does the measure impact on the ease of doing business in the UK?** | The primary legislation does not immediately affect the business environment. Indirectly, a licensing regime could improve the regulatory landscape by providing clearer, more predictable routes to market, supporting innovation, and strengthening GB as an attractive market for commercialisation. Some uncertainty may persist until secondary legislation is finalised, but overall the long-term effect is likely positive. | **Supports** |
| **International Considerations:**<br>**Does the measure support international trade and investment?** | The enabling powers support continued UK participation in international regulatory dialogue, maintaining competitiveness and reducing reliance on external approvals. A domestic licensing regime could enhance the UK's attractiveness as a location for developing and launching devices. However, impacts remain uncertain until details of the regime are set out. | **Uncertain** |
| **Natural capital and Decarbonisation:**<br>**Does the measure support commitments to improve the environment and decarbonise?** | No significant environmental or decarbonisation impacts are expected. Regulation of medical devices is not anticipated to materially alter environmental outcomes. | **Neutral** |

# 10. 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 framework change.

This IA focuses on the primary legislation 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, the NHS on the gap between identified need for reform or change (via regulation or non-regulatory routes) and it being in place; and
- a formal post-implementation review is required to be delivered within 5 years of implementation.

Monitoring will draw on a combination of administrative data, stakeholder feedback, and internally generated management information. Key datasets are expected to include:

- MHRA administrative data, including internal data on regulatory processes, timelines for implementing changes, and records of approvals and regulatory updates;
- Internal programme and delivery data, including tracking of planned versus delivered regulatory reforms and associated timelines;
- Internal data on costs and staff time to operate the licensing regime;
- Stakeholder feedback, gathered through engagement with industry, NHS bodies, UK Approved Bodies, and patient groups, including consultations and targeted surveys where appropriate; and
- Secondary evidence sources, where relevant, including industry reporting and external benchmarking of regulatory performance.

Data will be collected and recorded through existing MHRA operational systems and programme monitoring frameworks, with regular internal reporting processes used to track progress over time. Where appropriate, additional data collection (for example targeted surveys or stakeholder engagement exercises) may be undertaken to support evaluation.

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

The secondary legislation will include a review clause to formally publish a post implementation review (under the Better Regulations Framework) of the impact of the licensing framework after 5 years – as is currently in the MDRs (reg 67). This bespoke review duty will sit alongside the existing duties in the Medicines and Medical Devices Act 2021. Under section 46, the Secretary of State must report on how any regulations made under the MMDA powers during the reporting period (which is 24 months) are operating, consult the relevant authorities and people affected and consider any issues or suggestions they raise. Any regulations made under this new power would be subject to this review requirement at the relevant time. Section 45 requires there to be a public consultation before making the regulations. Section 47 also sets out how Parliament will scrutinise any future secondary legislation, including through the draft and made affirmative procedures.