Health Bill 2026 – Medical Device Licencing Regime

Lead department	Department for Health and Social Care
Summary of proposal	The proposal is to establish a medical device licensing regime, under which the Medicines and Healthcare products Regulatory Agency (MHRA) would be able to license medical devices directly. This would respond to structural weaknesses in the current regulatory model and is intended to support a sustainable domestic route to market for medical devices in Great Britain.
Submission type	Impact assessment
Legislation type	Primary legislation
Implementation date	TBD
RPC reference	RPC-DHSC-26162-IA(1)
Date of issue	27 July 2026

RPC opinion

Rating[1]	**RPC opinion**
Fit for purpose	The RPC considers the IA to be fit for purpose following resubmission. As originally submitted, the IA was not fit for purpose because it did not set out a sufficiently coherent rationale for intervention, did not provide a clear longlist and shortlist of options, and did not provide sufficient comparison of the shortlisted options to justify the preferred way forward. The Department has revised the IA to address these concerns, including by reframing the problem around the sustainability of the domestic route to market for medical devices, expanding the options analysis, providing a clearer qualitative comparison of shortlisted options, and adding indicative quantitative evidence on familiarisation costs and potential per-certificate cost savings.

[1] The RPC opinion rating is based only on the robustness of the rationale, options identification (including SaMBA) and justification for preferred way forward, as set out in the Better Regulation Framework guidance. RPC ratings are fit for purpose or not fit for purpose.

RPC summary

Category	Quality[2]	RPC comments
Rationale	**Green**	The IA now sets out a clearer and more coherent problem under consideration. It explains that the issue is not simply the withdrawal of UK Approved Bodies (UKABs), but the declining sustainability of the domestic route to market for medical devices in Great Britain. The IA explains the role of UKCA certification, the increasing reliance on CE marking and international reliance pathways, and the risks of GB becoming dependent on overseas regulatory decisions. The IA would be improved by providing further evidence on the scale and likelihood of the strategic risks identified, and the likely attractiveness of a a MHRA licensing regime compared to relying on CE marking, but the rationale is sufficient for this stage of policy development.
Identification of options (including SaMBA)	**Green**	The IA now includes a clearer longlist of nine options, assessed against critical success factors, and carries forward four shortlisted options: business-as-usual, the preferred medical device licensing power, legislative reform of the existing UKCA and UKAB model, and an expanded MHRA role for high-risk devices with a streamlined UKAB role for medium-risk devices. The IA also provides an improved SaMBA, including evidence that SMEs make up around 95 per cent of the UK medical technology sector and analysis of familiarisation costs and mitigations.
Justification for preferred way forward	**Green**	The IA provides an improved justification for the preferred option by comparing the shortlisted options against cost, benefit and risk categories. The IA does not provide a full NPSV estimate, reflecting that the proposal is for enabling powers and that the detailed regime will be developed through secondary legislation. However, it provides indicative estimates of familiarisation costs and potential per-certificate cost savings under a licensing regime, alongside a qualitative comparison of the preferred option and alternatives. This is sufficient and proportionate at this primary

[2] The RPC quality ratings are used to indicate the quality and robustness of the evidence used to support different analytical areas. The definitions of the RPC quality ratings can be accessed here.

		legislation stage, but the IA accompanying secondary legislation should include a full monetised assessment where possible.
Regulatory Scorecard	**Satisfactory**	The scorecard identifies the main impacts across total welfare, business, households and wider government priorities. It appropriately distinguishes between the direct effects of the enabling power and the indirect effects of the future licensing regime. However, it could be strengthened by more clearly reflecting remaining uncertainty around the detailed design of the regime, potential competition impacts between the MHRA and UKABs, and possible cost pass-through to the health system.
Monitoring and evaluation	**Satisfactory**	The IA now identifies relevant data sources, including MHRA administrative data, internal programme and delivery data, stakeholder feedback and external or secondary evidence. It also explains that a post-implementation review will be required within five years of implementation. The M&E section would be improved by setting out clearer success metrics against each objective and explaining how baseline data will be established before secondary legislation is implemented.

Response to initial review

As originally submitted, the IA was not fit for purpose for three reasons:

1. The rationale for intervention was not sufficiently coherent because the IA identified UKAB withdrawals as the central problem while also describing the preferred option as reducing reliance on UKABs.
2. The IA needed to provide a clear longlist and shortlist, expanding both to include further viable options for appraisal. The Department then needed to demonstrate how these longlist options had been narrowed down to the shortlist.
3. The justification for the preferred way forward needed to include a comparison of shortlist options and the IA needed to identify the full range of impacts across these options.

The Department has now:

1. Provided a sufficiently coherent rationale for intervention, which carries through to the options assessment.
2. Expanded the options analysis by setting out a longlist of nine options and applying critical success factors to explain how these were narrowed to the shortlist.
3. Compared the shortlisted options qualitatively across impacts on government, manufacturers, UKABs, patients, innovation and growth, strategic regulatory benefits and risks.
4. The Department has made further improvements to the SaMBA and monitoring and evaluation sections.

Summary of proposal

The Government proposes to introduce a new primary legislative power within the Health Bill 2026 to amend the Medicines and Medical Devices Act 2021. This would enable the Secretary of State for Health and Social Care to establish, through subsequent secondary legislation, a medical device licensing regime. The future regime would allow the MHRA to license medical devices directly, rather than relying solely on third-party conformity assessment by UKABs for medium- and high-risk devices.

The preferred option is to introduce enabling powers for a future medical device licensing regime. The details of the future regime would be developed through secondary legislation and would be subject to further policy development, consultation and a separate IA. The IA therefore focuses on the strategic impacts of creating the legislative framework necessary for a future licensing regime, rather than the detailed impacts of a specific licensing model.

The IA includes nine longlist options. It shortlists four options for further appraisal:

- 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 a streamlined UKAB role for medium-risk devices.

Option 2 is the Government's preferred option.

Rationale

Problem under consideration

The IA now provides a clearer explanation of the problem under consideration. It explains that the domestic UKCA route to market is becoming increasingly unstable and unsustainable because potential indefinite recognition of CE-marked devices and the introduction of international reliance pathways reduce incentives for manufacturers to seek UKCA certification. The IA explains that manufacturers have criticised the UKAB model as duplicative, costly, time-consuming and lacking in transparency, and that the UKCA route offers limited advantages where CE marking provides access to a larger market.

The IA also explains why this matters for the regulatory system. It states that, without intervention, the domestic route could become progressively less used, reducing the UK's ability to maintain independent regulatory expertise, respond flexibly to emerging technologies or public health needs, and maintain international influence. It also explains that international reliance is a one-way mechanism through which the UK recognises approvals granted by other regulators, rather than a reciprocal arrangement. As a result, without a sustainable domestic route to market, the UK would become increasingly dependent on external regulatory decisions. The IA provides some evidence to support the problem statement.

The rationale could be strengthened by providing further quantified evidence on the anticipated scale and likelihood of future UKAB withdrawals and the practical impact this would have on approval capacity, patient access and business certainty.

Argument for intervention

The IA sets out a sufficient argument for government intervention. It explains that the current framework does not provide the MHRA with powers to undertake device assessments and authorise devices directly. If UKAB capacity declined further, the MHRA could therefore be left without a mechanism to perform the assessments required under existing legislation, creating a regulatory capacity gap and threatening continuity of supply for medical devices. The Department explains the strategic risks of losing a GB domestic route to market.

The IA would be improved by giving clearer evidence on the expected relative speed and attractiveness of the future licensing regime compared with CE marking and international reliance routes. It includes qualitative reasoning on why the licensing regime could be more flexible, predictable and innovation-friendly, but the detailed regime has not yet been designed. The Department should therefore ensure that the

IA for secondary legislation provides stronger evidence on the expected route selection by manufacturers and on whether the final regime is likely to achieve sufficient uptake.

Objectives and theory of change

The IA has done well to set out specific objectives. These include maintaining a sustainable domestic route to market for medical devices in GB, supporting timely patient access to safe and effective innovative devices, strengthening the MHRA's ability to regulate emerging technologies, maintaining UK scientific and regulatory capability, supporting growth and investment, and preserving the MHRA's international regulatory influence.

The Department recognises that detailed success indicators will be developed as part of the future licensing regime and are expected to include measures relating to domestic route use, assessment timelines, stakeholder confidence, regulatory capability, patient access and the attractiveness of the GB market. The IA could be improved by mapping those anticipated indicators more directly to each SMART objective, but the current treatment is sufficient for an enabling power.

The IA also includes a theory of change which links the enabling powers and future secondary legislation to expected activities, outputs, outcomes and impacts. It explains that manufacturers would familiarise themselves with the framework, decide whether to use the licensing route or other routes, prepare and submit applications, and that expected outputs include more efficient and predictable assessment pathways and increased throughput of product assessments. Expected outcomes include improved certainty, earlier access for innovative and AI-enabled medical technologies, and improved supply resilience.

Identification of options (inc. SaMBA)

Identification of the 'longlist' of options

The IA now provides a clear longlist of options. The longlist considers options across three broad categories: maintaining or expanding reliance on overseas regulatory approvals, reforming the existing UKAB model, and increasing the role of the MHRA in medical device assessment. The nine options include business-as-usual, medical device licensing power, establishing the MHRA as a UKAB, expanding reliance and recognition, improving guidance and support within the existing UKAB model, legislative reform of the existing UKCA and UKAB model, targeted MHRA licensing for specific device categories, an expanded MHRA role for high-risk devices with a streamlined UKAB role for medium-risk devices, and medical device licensing as the sole route to market in GB.

Consideration of alternatives to regulation

The IA considers alternatives and lower-intervention options within the longlist, including maintaining business-as-usual, expanding reliance and recognition of overseas regulatory assessments, and improving guidance and support within the existing UKAB model. The IA explains that these options would not address the underlying causes of declining demand for the UKCA route or would increase long-term reliance on external regulatory decisions.

The IA could be improved by drawing out more explicitly why non-legislative options or operational improvements alone would be insufficient, particularly given that the proposal is for primary enabling powers. However, the longlist does include less interventionist options and the IA provides a reasonable explanation for not shortlisting them.

Justification for the shortlisted options

The IA uses critical success factors to explain how the longlist was narrowed to the shortlist. These factors include maintaining a sustainable domestic route to market, supporting timely patient access, enabling proportionate regulation of innovation, maintaining UK scientific and regulatory capability, supporting international credibility and influence, reducing unnecessary regulatory burden, and deliverability within a reasonable timeframe. The IA could be improved by adding some additional narrative to justify the ratings against each of the critical success factors.

The IA shortlists four options. Option 1, business-as-usual, is included as the counterfactual. Option 2, medical device licensing power, is the preferred option. Option 6, legislative reform of the existing UKCA and UKAB model, is included as the do-minimum option. Option 8, an expanded MHRA role for high-risk devices with a streamlined UKAB role for medium-risk devices, is included as an additional viable option.

The IA explains why Option 9, medical device licensing as the sole route to market in GB, was not shortlisted. It states that this would remove reliance and recognition routes and require the MHRA to assess all devices domestically. The IA states that, given the majority of medical devices currently rely on CE marking, this would create material risks to market stability, continuity of supply, patient safety and clinical outcomes.

SaMBA and medium-sized business (MSB) assessment

The Department states that around 95 per cent of the UK medical technology sector is made up of SMEs, meaning that the design of the future regulatory system is particularly important for smaller firms.

The IA identifies both potential benefits and potential burdens for smaller businesses. It explains that a more efficient, transparent and predictable regulatory system could particularly benefit smaller businesses, which may have less capacity to manage lengthy or opaque regulatory processes and may be more sensitive to delays in market access. It also recognises that short-term adjustment costs could fall disproportionately on SME manufacturers, including familiarisation costs estimated at approximately £550 to £2,000 per manufacturer.

The IA identifies mitigations for SMEs, including clear and timely guidance, appropriate transition periods, and access to regulatory advice and support. It also states that further mitigations will be considered in the design of secondary legislation, including possible fee waivers for MHRA scientific advice or reduced costs for registering a medical device with the MHRA, subject to further policy development.

The SaMBA is sufficient at this stage, although the IA accompanying secondary legislation should provide a fuller assessment of impacts on businesses of different sizes, including medium-sized businesses, once the detailed requirements and fee structures are known.

Justification for preferred way forward

Appraisal of the shortlisted options

The IA compares the shortlisted options across a range of impact areas. These include costs to government, manufacturers and UKABs; benefits to patients, manufacturers and UKABs; benefits to innovation and growth; strategic or regulatory benefits; and risks. This provides a clearer basis for comparing the preferred option against the do-nothing, do-minimum and additional viable option.

For Option 1, business-as-usual, the IA explains that current arrangements would continue but would not address risks to the commercial viability of UKAB operations or the possibility of losing a domestic GB route to market. For Option 6, legislative reform of the existing UKCA and UKAB model, the IA explains that reforms could reduce administrative burden and improve UKAB viability, but would not fully address the underlying structural decline in demand for UKCA certification. For Option 8, the IA explains that an expanded MHRA role for high-risk devices could strengthen oversight for high-risk products but would create complexity and retain dependence on the UKAB market for medium-risk devices.

For Option 2, the preferred option, the IA explains that a medical device licensing power would allow the MHRA to establish licensing capability, provide greater flexibility for innovation, reduce reliance on the commercial viability of UKABs, and support domestic regulatory resilience. The IA also explains that this option would involve implementation complexity and transition requirements, including the need for MHRA to establish capacity and systems.

The IA's appraisal is mostly qualitative but includes indicative familiarisation cost estimates and estimated per-certificate cost savings, which strengthens the appraisal. The IA explains that most costs and benefits cannot be quantified at this stage because practical changes will be delivered later through secondary legislation. The Department will produce an additional IA at secondary legislation stage.

The IA provides indicative familiarisation cost estimates for manufacturers. It estimates familiarisation costs of approximately £550 to £2,000 per manufacturer.

The estimate is based on one to two staff members spending 16 to 24 hours reviewing guidance.

The IA also provides indicative estimates of potential per-certificate cost savings under a future licensing regime compared with standalone UKCA conformity assessment. It estimates that the licensing regime could generate per-certificate savings of £2,214 to £7,381 for Class Is/Im/Ir devices, £4,724 to £16,238 for Class IIa devices, £10,333 to £32,476 for Class IIb devices and £29,524 to £88,571 for Class III devices. The IA explains that these estimates are presented on a per-certificate basis rather than as aggregate industry savings due to uncertainty about the total volume and risk classifications of future certificates.

The IA could have gone further in assessing whether the preferred option is likely to shift manufacturer behaviour in practice. While it compares potential costs under a future licensing regime with the current UKCA route, it does not fully consider whether manufacturers would choose the MHRA licensing route over continued reliance on CE marking, particularly given proposed indefinite CE recognition. This matters because the sustainability of the domestic route will depend on whether the new route is sufficiently cheaper, faster, more predictable or otherwise commercially attractive than the CE route.

Selection of the preferred option

The IA provides a sufficient justification for choosing Option 2. It explains that the preferred option addresses the structural problems identified more comprehensively than the alternatives, particularly declining demand for UKCA certification and risks to UKAB business viability. It also explains that a licensing regime would enable a more flexible regulatory system that can evolve in response to technological change, emerging evidence and international regulatory developments.

The preferred option is therefore justified on the basis that it offers the strongest long-term benefits for domestic regulatory capability, innovation support, strategic resilience and sustainability of the domestic route to market.

Regulatory Scorecard

Part A

Impacts on total welfare

The IA states that there is an uncertain impact on total welfare, as the design of the secondary legislation has not yet been finalised. Nonetheless, the IA sets out some of the expected impacts from the secondary legislation, explaining that the domestic licencing regime will generate net social benefits by ensuring the UK retains a functioning domestic approval route and resilience of supply. The IA could benefit from expanding on this impact, explaining the downstream public health and welfare benefits that may occur, with any quantitative value where possible.

Impact on business

The IA explains that businesses will experience no direct impacts from the primary legislation but indirectly, the power to create a licensing regime 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. The IA could benefit from providing some quantitative monetisation for these impacts to form an EANDCB estimate.

The IA accompanying secondary legislation should set out the operational impacts on the MHRA of establishing a medical device licensing regime. This should include any restructuring of MHRA functions, staffing, governance, systems, assessment processes, fee arrangements and use of external expertise, alongside the expected costs, delivery risks and transition arrangements.

Impacts on households, individuals or consumers

There are no direct impact on households from the legislation, although 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.

Distributional impacts

The IA identifies some distributional impacts, such as benefits for disabled individuals who may rely more heavily on medical devices. The Department also states that smaller UKABs may perceive uncertainty, but that their role is expected to continue under subcontracting arrangements. As the IA also references the MHRA relying on UKABs in the short-term and this uncertainty is mentioned throughout the IA, the scorecard could benefit from expanding on this risk and the range of long-term and short-term impacts on smaller UKABs.

Part B

The IA states that the proposal will support business environment, as a licencing regime will improve the regulatory landscape and support innovation. The Department could benefit from also considering the potential competition impacts from the proposal, particularly between the MHRA and UKABs. The IA could also summarise any impacts on barriers to entry for UKABs. The IA could also draw out potential competition and market access impacts. If the MHRA relies on a limited number of UKABs or external experts to support assessments, capacity constraints could create gatekeeper risks or advantages for manufacturers able to access assessment capacity earlier. The IA should also consider whether a less commercially attractive domestic route could lead some suppliers to reduce or exit GB market participation, with possible implications for NHS procurement, pricing, supply resilience and product availability.

The IA also indicates an uncertain impact on international considerations, stating that the enabling powers reduce reliance on external approvals and enhance the UK’s attractiveness as a location for developing and launching devices. The scorecard

could more clearly reflect the interaction between the proposed licensing regime and indefinite CE recognition. In particular, the IA should consider whether the future domestic route will be attractive enough, relative to the CE route, to maintain domestic regulatory capability and deliver the intended strategic benefits.

Monitoring and evaluation

The IA provides a satisfactory monitoring and evaluation section. It explains that monitoring is likely to take place in two phases, reflecting that primary legislation enables change while secondary legislation or non-legislative methods will deliver detailed framework changes.

For the primary legislation, the IA states that monitoring may include identifying changes that were previously not permitted but can now proceed, tracking expected timelines for planned improvements, counting the number of legislative reforms expected over time, obtaining feedback from MHRA, patients, industry and the NHS, and completing a formal PIR within five years of implementation.

The IA identifies data sources, including MHRA administrative data, internal programme and delivery data, internal data on costs and staff time, stakeholder feedback from industry, NHS bodies, UKABs and patient groups, and secondary evidence sources such as industry reporting and external benchmarking. It states that data will be collected and recorded through existing MHRA operational systems and programme monitoring frameworks, with regular internal reporting and additional data collection where appropriate.

The IA also explains that the secondary legislation will include a review clause to publish a PIR of the licensing framework after five years, and notes the existing duties in the Medicines and Medical Devices Act 2021 relating to consultation, review and parliamentary scrutiny of regulations made under the powers.

This section would be improved by specifying clearer indicators against each objective, including baseline measures for domestic route use, assessment timelines, stakeholder confidence, patient access, regulatory capability and attractiveness of the GB market. The Department should also explain how it will distinguish the effects of the licensing regime from other changes occurring at the same time, including CE recognition and international reliance pathways.