BIVDA UKCA Sub-group position paper: Domestic Assurance

British In Vitro Diagnostics Association
BIVDA

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1. Introduction

BIVDA is the national trade association representing approximately 250 organisations within the in vitro diagnostic (IVD) medical device sector in the UK, ranging from start-ups to large manufacturers.

This paper establishes the position of BIVDA members in relation to domestic assurance and the preferred routes to place IVD products on the UK market. This comes at a crucial time when the UK Government is developing a new regulatory framework for medical devices. The authors and contributors to this paper request that the content be taken into consideration by the UK Government during the ongoing development of the future legislation.

2. Background

On 26 June 2022, the Medicines and Healthcare products Regulatory Agency (MHRA) published the results and conclusions from the consultation process regarding the new Medical Device Regulations (UK MDR) for the UK. One of the critical aspects considered in this consultation was the requirements for accessing the British market, covered in Chapter 14 of the consultation.

Within this response, MHRA proposed the acceptance of medical devices from other international markets through abridged assessments. At this time, MHRA has not publicised which markets they are considering for an international recognition route; MHRA needs to consider which regional regulatory regimes will be accepted and the appropriate level of assessment necessary to allow devices onto the British market.

On 1 August 2023, the Department of Business and Trade (DBT) announced that they intend to continue recognition of the CE mark indefinitely for most products entering the British market. MHRA have confirmed that this indefinite recognition does not include medical devices. The announcement by DBT indicates that products on the EU market already meet equivalent requirements to UK legislation, and therefore do not require further certification. Although medical devices have been treated differently by the UK government due to their unique nature, continued UK recognition of CE marked medical devices would be hugely beneficial for the sector.

Throughout this paper, the authors and contributors have assumed that international recognition would be unilateral. However, mutual agreements with major markets accepting UKCA conformity (conformity to British regulations) would provide a substantial boost to UK companies, UK patients and the UK economy.

Equivalent Acceptance

It is essential to have equivalent acceptance requirements between medical devices that have undergone a standard UKCA route and those that are placed on the British market through international recognition. This would ensure equality between UK manufacturers and manufacturers from overseas. More importantly, it would protect patients since all products, independent of the compliance route, meet the same level of safety and performance.

To simplify this process, gap analyses would determine the bridging requirements needed to enter the British market. This would provide transparency and consistency for the requirements of manufacturers and any required assessments by UK Approved Bodies. By demonstrating that their products meet bridging requirements, manufacturers would have a clear route to achieve UK regulatory compliance.

The international recognition route must be agile and responsive to changes in overseas regulatory pathways. By publishing bridging requirements in guidance rather than regulations, MHRA will be able to react quickly to changes in overseas legislation without UK statutory changes. Like guidance issued for compliance with the IVDR, it is recommended that MHRA produce guidance for the documentation expected to comply with these bridging requirements. It is important that this guidance is released alongside legislative amendments, to simplify the process for manufacturers and UK Approved Bodies.

Involvement of the UK Approved Bodies

MHRA's consultation response discusses the involvement of UK Approved Bodies in conducting abridged assessments, but does not define their role in the international recognition process. UK Approved Bodies are designated by MHRA to assess if manufacturers and their medical devices meet the UK MDR (as amended). They are responsible for the certifications that they provide to medical device manufacturers and manage that responsibility through an extensive conformity process.

The intended benefit of accepting products from other geographic regions is to fast-track availability of products that have already met regulatory standards elsewhere, allowing the British population access to state-of-the-art medical technology. In this fast-track, abridged process, UK Approved Bodies can only be responsible for assessing the devices against the bridging requirements identified by MHRA through gap analyses. As such, MHRA must be confident in the foreign regulatory process. For example, the US Food and Drug Administration (FDA) rigorously assesses the clinical performance and safety of a device through Pre-Market Approval (PMA) and De-Novo processes. MHRA may be justified in accepting these assessments, and therefore require UK Approved Bodies to only assess against the bridging requirements to meet British requirements. By comparison, FDA 510k clearance relies on comparison to a predicate device, a process that appears to not be planned for the UKCA regulatory regime. Therefore, MHRA may not accept this process as suitable for placing on the British market unless full PMA / De Novo documentation on the predicate device can also be supplied.

Table 1 compares different regulatory routes globally and indicates the estimated similarity to future British requirements, based on information currently available in guidance.

Routes highlighted in green are seen to have a very similar regulatory structure, those in yellow are seen to have a similar regulatory structure, and those in red are seen to have a different regulatory structure. These colours can therefore be used to demonstrate the level of additional evidence that would likely be needed to comply with British requirements.

Country	Regulatory route	Similarity to proposed UK MDR
Australia	Therapeutic Goods Administration (TGA) Approval	High similarity; development of bridging requirements likely to be straightforward.
Canada	Health Canada Medical Device License	High similarity; development of bridging requirements likely to be straightforward.
EU	CE Conformity	High similarity; development of bridging requirements likely to be straightforward.
Japan	Pre-market notification (Todokede) (Class I)	No technical assessment; suitable for self-declared devices (as defined by UK MDR).
	Pre-market certification (Ninsho) (Class II)	Differences in classification and definitions of IVDs likely to require careful consideration for bridging requirements - likely only appropriate for lower risk devices (as defined by UK MDR).
	Pre-market approval (Shonin) (Class III, IV)	Stringent requirements; differences in classification and definitions of IVDs likely to require careful consideration of bridging requirements.
Singapore	MEDICS Approval	High similarity; development of bridging requirements likely to be straightforward.
Switzerland	CE certification	High similarity; development of bridging requirements likely to be straightforward
USA	PMA	Stringent requirements; substantially different regulatory structure likely to require complex bridging requirements.
	De Novo	Stringent requirements; substantially different regulatory structure likely to require complex bridging requirements - likely only appropriate for lower risk devices (as defined by UK MDR).
	510k	No similar process; unclear how bridging requirements would be developed.

Table 1: Comparison of different geographic regulatory routes and their similarity to the proposed British requirements (green = very similar structure; yellow = similar structure; red = different structure).

Although there is significant focus on an international recognition route from the US, the table suggests that more straightforward processes could be developed with Australia, Canada, the EU, and Switzerland. These geographies are also aligned to the Medical Device Single Audit

Program (MDSAP) and International Medical Device Regulator Forum (IMDRF) principles, further reinforcing similarity with the future British regime. The Therapeutic Goods Administration (TGA) in Australia has published an international benchmarking document that compares global regulatory regimes and provides guidance on utilising these regions for the Australian market. This document may be reviewed for a more detailed comparison.

Organisations that are designated both as a UK Approved Body and an EU Notified Body already offer combined assessments for CE and UKCA certification. MHRA have indicated that amendments to the UK MDR will increase harmonisation between British Regulations and the EU In Vitro Diagnostic Regulations (EU IVDR), increasing the overlap between the conformity assessment and the benefit of a combined assessment. However, a very small number of organisations are designated for both purposes, giving few options for manufacturers. By publishing bridging requirements, MHRA will allow companies to work with any EU Notified Body and UK Approved Body.

BIVDA recommends that MHRA produce bridging requirements in guidance for international recognition for each individual overseas regime. These guidance documents will then be used by UK Approved Bodies for assessments. Different overseas processes vary significantly, in some cases varying within the same country (i.e., FDA PMA and De Novo routes), requiring multiple sets of bridging requirements per geography. Furthermore, device classification needs to be strongly considered.

Although the overall burden on UK Approved Bodies will be reduced compared to a full conformity assessment to British requirements, burden will still exist. An international recognition route will still require significant preparation and resources for UK Approved Bodies. MHRA should address the readiness of UK Approved Bodies to participate in any international recognition process well in advance of roll out of the process to ensure that a new bottleneck is not created.

To navigate through uncertainties, resource allocation, compliance consistency, collaboration with foreign regulatory authorities, and clear guidance and transparency will be needed for successful implementation of any routes.

Impact on commercial strategies to market access and support for innovation

A manufacturer's approach towards a domestic assurance route depends on their product, the development stage, and their target markets. A significant number of manufacturers have indicated would prefer international recognition rather than the domestic UKCA conformity route as they believe it to be quicker and more cost-effective.

The domestic UKCA route offers limited benefits and added value for the industry; it is seen as unnecessarily costly and burdensome for such a small market. If this continues to be the perception, most manufacturers are likely to utilize the international recognition route. It is important to recognise that the domestic UKCA route does provide an option for manufacturers looking to supply into Great Britain only. Economically, this preference for an international route could push Great Britain into becoming a secondary market, with British patients accessing medical technology after overseas markets.

A fully supported route to market for innovative products, building on the MHRA's Innovative Devices Access Pathway (IDAP), is needed. BIVDA recommends increasing the scope and benefits of such programmes to attract all innovative technology driving early access to devices for UK patients. With direct support from MHRA for regulatory compliance, appropriate funding from horizontal bodies, and a clear route to market, companies with innovative technology could be attracted to Great Britain to develop and market their products.

This innovative product route should be designed to support the full IVD industry, not only innovative UK startups and SMEs. Although the British market is globally small, companies could be incentivised to enter this market first prior to accessing the larger USA and EU markets. Such incentives must be balanced with patient safety, and they should provide support through a coordinated UK innovation and regulatory ecosystem.

The programme should cover the development pathway including regulatory support; development funding; access to clinical data and clinical samples; support for clinical trials and performance evaluations; and support for market access through NHS procurement.

3. Recommendations

Based on the above discussion, BIVDA proposes the following recommendations:

- The international recognition route should prioritize devices in "green" geographies (highlighted in the above table), where there are already strong similarities in requirements: Australia, Canada, the EU, Singapore and Switzerland.
- Second priority should be given to the remaining geographies, with emphasis on the US where the level of complexity would likely result in difficulty identifying an appropriate abridged process, but where many companies would likely benefit from recognition.
- The UK Government should strive for acceptance of UKCA conformity in other geographies.
- Devices should be required to meet the same safety and performance requirements whether accepted through international recognition or UKCA conformity assessment.
- MHRA should publish timely guidance developed through gap analyses, providing bridging requirements between each recognised foreign regulatory route and British requirements, including expected documentation to meet these requirements.
- A comprehensive and fully supportive innovative product route to market must be established to attract innovative technologies to the UK.

4. Summary

This paper presents the perspective of the IVD industry regarding domestic assurance routes, outlining considerations and the preference for introducing IVD products into the British market.

BIVDA acknowledges the existing ambiguity around pathways for entering the British market as well as the scope and implications of the UKCA marking (BIVDA's position on labelling can be found in our published labelling position paper). The need for collaboration is emphasized

among industry, UK Approved Bodies, and other relevant stakeholders to design well-structured routes to the British market.

The paper also highlights the importance of recognizing international markets within domestic assurance. Such recognition holds particular importance alongside an innovative route and would expand the availability of medical devices on the British market.

Although BIVDA favours international recognition, both the UKCA domestic and international recognition routes must be balanced in time and cost, to prevent manufacturers from rejecting the Great Britain market entirely. By striking a balance between regulatory requirements and market access, while prioritizing patient safety and encouraging innovation, Great Britain can establish a thriving market for medical devices. This approach would positively impact patient care through improved access to medical devices.

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