BIVDA
British In Vitro Diagnostics Association

Summary of the MHRA response to the consultation on the future regulation of medical devices in the UK

MHRA published their response to the consultation on 26 June. BIVDA have reviewed this document and summarised the key messages below for members.

Please note we recommend you review the document in full to determine which aspects are applicable to your organisation, and this is not intended to replace your own due diligence.

Transition and routes to market

IVDs placed on the market in the EU under a valid **IVDR** certificate or declaration of conformity can continue to be placed on the market in Great Britain until the certificate expires, or for 5 years (2028). Importantly, the certification or declaration of conformity can be issued or drawn up **after** the new UKCA regulations take effect, but the 5 years will apply from the date of the regulation. This means a new IVDR certification can be issued in November 2023 (assuming this is after the date the regulations take full effect) and utilised to place on the Great Britain market until the 5-year transition period ends. The products do not need to have been registered with MHRA prior to when the regulation takes full effect.

IVDs placed on the market in the EU under a valid **IVDD** certificate or declaration of conformity can continue to be placed on the market in Great Britain until the certificate expires, or for 5 years (2028). The certification or declaration of conformity must have been issued or drawn up **before** the new UKCA regulations take effect. The products do not need to have been registered with MHRA prior to when the regulation takes full effect in order to continue to be placed on the Great Britain market. However, they must not have any significant changes and must comply with the full scope of post-market requirements.

IVDs placed on the market in Great Britain under a valid **UKCA** certificate or declaration of conformity can continue to be placed on the market in Great Britain until the certificate expires, or for 5 years (2028). The certification or declaration of conformity must have been issued or drawn up **before** the new UKCA regulations take effect. To utilise this, products must not have any significant changes and must comply with the full scope of post-market requirements.

MDSAP will continue to be utilised, and domestic assurance will remain as an alternative route to market allowing an abridged assessment. No further details have been provided on which geographic regions may be utilised.

Importantly, this does not provide a route for new products introduced to the market after 1 July 2023, unless those products utilise domestic assurance from other geographic areas.

There will be a path for innovation, but details of this have not been provided at this time while Government outlines the route. The response does say that this will be for specific circumstances and will have input from NICE and other key stakeholders.

No transition periods will be introduced for performance evaluation studies.

Definitions and scope

The definition of an IVD will be updated to be reflective of the definition of an IVD within the IVDR.

Despite the consultation receiving a high level of agreement to bringing diagnostic tests for health and wellbeing (eg. genomic testing for diet/nutrition optimisation) into the scope of regulation, they will not be implemented at this time. Instead, this will be kept under consideration.

The essential requirements will be updated to align with the GSPRs in the IVDR, with accommodations for technological advancements and specific UK interests.

Further clarity and definition on "kits" will be added to the regulations, hopefully including specifying which products may be included.

Classification

The IVD classification system will be amended to be rule based, allowing the classification system to align closer to the IMDRF system. This system is similar in concept to the IVDR classification structure which is also risk based, with some differences: risk classification will range from Class A to Class D.

The IMDRF classification rules for software as a medical device will also be used as a base for a UK classification structure, allowing software to be classified using a risk-based method.

Genetics tests will be classified in a risk-based manner rather than being classified within their own category. As well as this, there will be specific rules for companion diagnostics allowing a broader range of classification for both genetic tests and companion diagnostics. Therefore, these products will not all necessarily be categorised as Class C as is the case according to the existing IMDRF classification rules.

In-house tests

A definition will be included in the new regulations for "heath institution", using the IVDR as a base. In-house tests will need to meet the essential requirements (which will align broadly to the IVDR GSPRs) but will remain exempt from the full scope of the regulations. QMS

requirements, technical document retention requirements, registration of devices, registration of performance studies by a health institution, and provisions on adverse incident reporting will be implemented for these products.

This is increasing the requirements on in-house tests significantly in comparison to the requirements under the current UK MDR.

Economic operators

UK Responsible Persons will be required to have a physical address in the UK and will be legally liable for defective medical devices. They will also need to hold relevant information relating to non-implantable devices for 10 years.

Additional obligations will be introduced for distributors and importers including the need to report any issues they are made aware of on supply to MHRA. There has also been clarification that fulfilment centres will be considered importers or distributors (depending on which of these is appropriate) and so will need to meet these obligations. The regulations will provide insight into situations where economic operators will take on the obligations of a manufacturer.

Manufacturers and UKRPs must have a qualified person to support in regulatory compliance which appears to be similar to the role of Person Responsible for Regulatory Compliance required under the IVDR. They will need appropriate experience and be suitable for the level of responsibility.

Device labelling

The regulation will require UDI to be assigned to devices prior to being placed on the market and will include a definition of UDI and UDI-DI. These will need to be kept by economic operators, healthcare institutions and/or healthcare professionals to ensure traceability.

The use of e-labelling will be widened to include apps and software, and one of the new essential requirements will specify that products need to be designed and manufactured in a way that minimises risks posed to public health from debris or particles from the devices. There does not appear to be an intention to widen the scope of e-labelling further, and there is no reference to e-IFUs.

Approved bodies and conformity assessments

Approved bodies will have more stringent requirements but will be able to conduct remote or hybrid audits in specific circumstances. They will need to be a legal entity within the UK, and not just a branch in the UK. Approved bodies will also need to be UKAS accredited and make their fees available on request of the Secretary of State. This is different to what was initially proposed by the consultation, where fees would be available upon request of any

interested party. This may have an impact on how many Approved Bodies gain designation in the UK but does allow for non-UK Approved Bodies to become designated where they have or implement a legal entity in the UK.

Batch verification will remain for Class D IVDs, but the option of type examination will be removed as well as the option for production quality assurance. The structure of technical files will be defined in the regulations as well as the minimum content for certificates of conformity, making a more consistent approach to documentation.

Clinical evidence

Equivalence will continue to be considered an appropriate route to generate clinical evidence, but only where the device is entirely biologically, technically and clinically equivalent – this would make equivalence tighter than in the IVDR and likely require more organisations to need to conduct a performance study to generate clinical evidence. The requirements on performance studies will broadly align with requirements in the IVDR.

A full SSCP (summary of safety and clinical performance) will be required for high-risk products, which will be uploaded in full to the MHRA registration database and made publicly available.

Environment and sustainability

There are numerous pieces of existing legislation for environment and sustainability, and the response acknowledges the need to not duplicate this process. It therefore states that any new legislation for environment and sustainability will be put on hold under clarification can be sought cross-governmentally.

Although the use of e-labelling is being widened for apps and software, it is not expanding further to allow a sustainability or environmental benefit.

Summary

This is a hugely positive step for UK industry, and MHRA should be praised for generating such a detailed document. Although we do not yet have the formal Regulations, this gives clarity on how to begin with making sure products and organisations and compliant to the new Regulatory structure.

BIVDA will continue to support members on understanding the regulatory requirements applicable to them. For queries or further information, please contact Ashleigh Batchen.

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