ABHI
REGULATORY

UKCA MARK HANDBOOK: UK REGULATION OF HEALTH TECHNOLOGIES BEYOND 1st JANUARY 2021

December 2020

CONTENTS

BACKGROUND & INTRODUCTION

Four and a half years after the UK-Brexit referendum of June 2016, the UK and Europe will come to the end of the EU Exit Transition Period, on 1st January 2021. The relationship between the UK and the EU will evolve over the months and years ahead, but what is clear is that there is a legal requirement for sovereign regulation from the 1st January 2021.

When considering sovereignty and how this will shape future regulation, it is important to understand the distinction between Harmonisation of Technical Standards (HoTS) and Mutual Recognition (MR).

HoTS demands that countries align their technical regulatory requirements exactly to facilitate trade across borders, in the knowledge that if a product is manufactured in one, then it matches the requirements in another. MR however, being essentially based on trust and regulatory understanding, allows for one country to assess, or carry out compliance processes against a partner country's regulation, in order to facilitate trade.

HoTS implies a surrender of sovereignty, as the regulations are not developed with one country in mind, but are the will of a collective. The legal requirement for sovereign regulation in the UK, therefore, means that application of European regulation is not an option, implying that GB, distinct from Northern Ireland at least, will not be adopting either the new Medical Device Regulation (MDR) or the In-Vitro Diagnostic Medical Device Regulation (IVDR).

The Medicines and Healthcare products Regulatory Agency (MHRA)'s Regulating medical devices from 1st January 2021 guidance, published by the UK Government on 1st September 2020, provided a top-line vision for a future sovereign regulation of medical technologies in the UK, starting from 1st January 2021. However, economic operators should be aware that it is probable that the regulations which apply from January 2021 (and which follow the Medical Device Directive [MDD], In Vitro Diagnostic Medical Devices Directive [IVDD] and Active Implantable Medical Devices Directive [AIMDD]), are likely to be amended and strengthened using powers afforded by the Medicines and Medical Device Act.

With the political background firmly in mind, consideration in this handbook is given to the implications of the guidance released on 1st September 2020. It is not to be considered the final word or a checklist to UK Conformity Assessed (UKCA) marking, as many of the technical requirements are currently under development. It does, however, outline the principles of future regulation, and through Frequently Asked Questions, provides top-line strategic thinking on the emerging UK regulatory process.

Importantly, these Frequently Asked Questions will be continuously updated and validated against MHRA guidance and input, thereby providing a real-time, yet authoritative view, of the requirements for UKCA marking. The current Frequently Asked Questions have been validated by consultation with the MHRA, a process that will continue. If you have any further questions, or comments, please let us know as part of our editing responsibility.

OVERVIEW

The MHRA guidance issued on 1st September 2020 detailed the principles related to the use of a UKCA mark as a route to the GB market from the 1st January 2021. Whilst this document specifically relates to medical devices, it is important to note that a UKCA mark will also be required for other manufactured goods that are currently covered by the allied European Union New Approach Directives.

These other allied directives include Restriction of Hazardous Substances (RoHS), Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Waste Electrical and Electronic Equipment (WEEE) which are environmental, and chemical based, whilst others, such as machinery, low voltage and electromagnetic compatibility directives cover finished goods and or functions of those goods.

This report does not cover these allied directives, but note should be made of their respective transition periods, as they may not directly mirror those defined for medical technologies with which they potentially overlap.

The guidance describes the principles of the UKCA mark from 1st January 2021. Whilst no technical details are provided, it can be assumed that requirements to achieving compliance can be found within the amended 2002 Statutory Instrument for Medical Devices, which is the UK's transposition of the MDD. Therefore, the technical requirements of the UKCA mark are seen as equivalent to those of the current EU CE mark.

This Statutory Instrument has been amended over 150 times since 2002, to ensure that it maintains parity with the European Regulations. Importantly, legislation for medical devices and IVDs will be introduced via secondary legislation, established through the Medicines and Medical Devices Act.

Any manufacturer wishing to place product onto the UK market from 1st January 2021, should therefore be aware of the following fundamental requirements:

- The UK Competent Authority (the MHRA), will unilaterally recognise the affixing of the European CE mark on medical technology products, as a route to placing on the GB market, until 30th June 2023.
- The UKCA mark can be affixed to product being placed on the UK market from 1st January 2021 and must be affixed from 1st July 2023. (There is however, no mutual recognition of the UKCA mark in Europe, CEE countries or Northern Ireland, where the EU CE mark is the legal route to product compliance).
- For higher risk devices the UK CA mark must be supported by certification issued by UK-based Conformity Assessment Bodies (CABs). These UK CABs will be designated by the MHRA from 1st January 2021. (At present, there will be no mutual recognition of certification issued by UK CABs as a basis of compliance to the European CE Mark process).
- If the manufacturer of the medical technology is based outside of the UK, they must identify and contract a UK Responsible Person (RP), to act on their behalf.
- Likewise, if the manufacturer is GB or Northern Ireland based, and they intend to market in Europe, they must identify and contract a European based Authorised Representative (AR).
- The new UKCA mark must be affixed to product placed on the UK market from the 1st July 2023, implying medium-term labelling changes.
- The MHRA will be increasing the scope of its current registration scheme, to ensure that all products placed on the UK market and any respective RPs, are registered during 2021.
- This registration process will be staggered according to product risk, demanding that Class III, Class IIb implantable medical devices and List A IVDs are captured by May 2021, other Class IIb and Class IIa medical devices and List B and self-test IVDs by September 2021 and all other devices by January 2022.
- Timescales for the registration of the RP will also be dictated by the risk of products they cover.
- There will be specific requirements in Northern Ireland, as the European Union CE mark will still be mandated as the applicable regulation.

TIMINGS

The UKCA mark deadlines are represented in **figure 1**.

From 1st January 2021, up until 30th June 2023, the European Union CE mark can be used by manufacturers as a route to placing medical devices and IVDs on the UK market. This is irrespective as to whether the manufacturer is following the AIMD/MDD/IVDD or MDR/IVDR; as long as the product is affixed with a CE mark, it can be placed on the UK (GB and Northern Ireland) market. Furthermore, although still to be resolved, it is hoped that if the product is within the UK supply chain on 30th June 2023, it can be placed in the UK up until 30th June 2024.

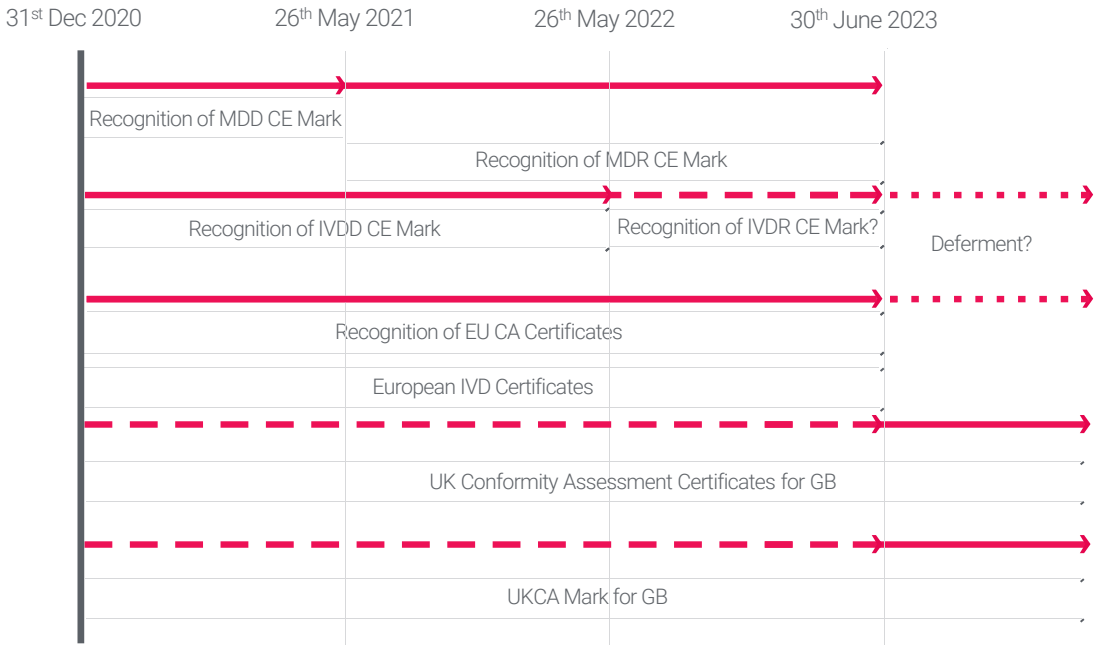
The UKCA mark can be affixed to medical devices from 1st January 2021. Importantly however, it should be noted that whilst the mark can be applied, it has to be in compliance with the requisite requirements, which would imply certification by a UK-based CAB, which are not to be designated until after 1st January 2021.

With this in mind, it is clear that the early adopters of the UKCA mark are likely to be the low-risk Class I medical device products, and low-risk, self-declared IVDs designated through the current IVDD. As the UK CABs become designated by the MHRA, the process of affixing the UKCA mark will become clearer and more widespread.

Importantly, this process will continue in the UK beyond the end of the European Union transition periods of 26th May 2021 for MDR, and 26th May 2022 for IVDR, with the UK demonstrating no desire for transposing either.

Whilst affixing of the UKCA mark is voluntary up until the 30th June 2023, it is mandated from 1st July 2023. If a manufacturer therefore wishes to place product on the GB market (England, Scotland and Wales) after this date, it **must** have a UKCA mark.

Figure 1: UKCA Mark Timings and Deadlines



NORTHERN IRELAND

The requirements for regulatory control in Northern Ireland are subject to intense political debate. As such, the comments detailed in this handbook are potentially subject to change as a result of the ongoing trade negotiations.

As it currently stands, from 1st January 2021, Northern Ireland, although part of the United Kingdom, will be a de facto Member State of the European Union, as a result of the need to ensure border security and movement of goods to and from the Republic of Ireland.

The special political status of Northern Ireland adds complications to the UKCA mark timeframes, as well as those for registration of products and the status of the UK RP. Importantly, the UKCA mark **will not** be recognised as a route to the Northern Ireland market, even beyond 30th June 2023. Here, continued recognition of the European CE mark will occur up to and beyond the transition periods for MDR and IVDR. Indeed, Northern Ireland will be duty bound to honour the transition times for the regulations and will apply, both to the MDR and IVDR.

Alternatively, if a product is intended **only** for the Northern Ireland market, a manufacturer may affix a UK(NI) mark. Importantly however, this separate mark is not recognised in GB or in the European Union. The UK(NI) mark can be supported by certificates issued by UK-based CABs, but not by certificates issued by European Union Notified Bodies.

Whilst the value of the UK(NI) mark has yet to be determined, its availability clearly demonstrates the special significance of the Northern Ireland market and the difficulties expected in regulatory control.

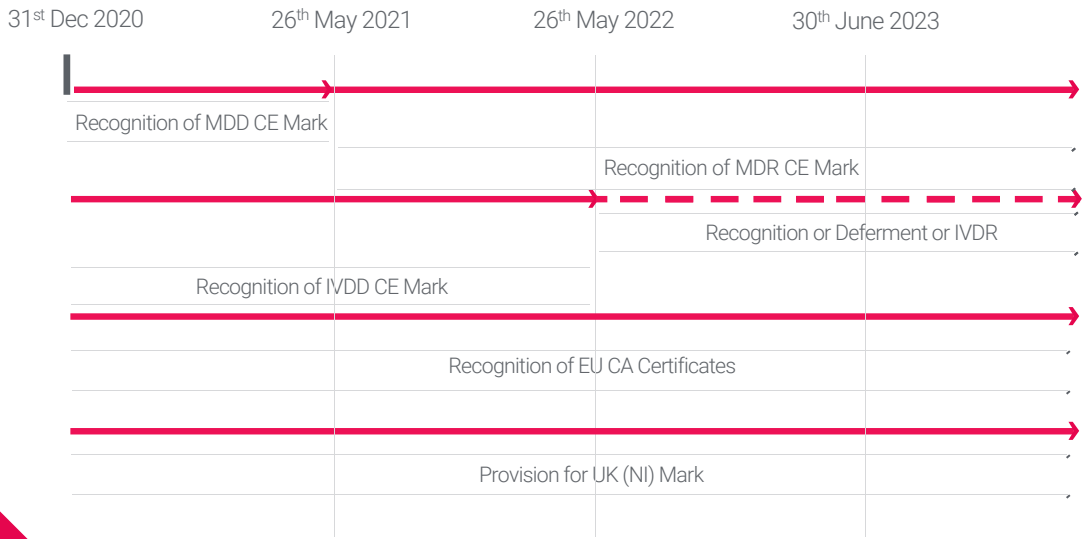
The current discussions on the NI Protocols, also allow for unfettered access of product manufactured (and potentially distributed) by Northern Ireland companies. This will allow for Northern Ireland CE marked product, to be distributed throughout the rest of GB, even after 30th June 2023 date.

Furthermore, it is equally important to note that the provisions will demand that the UK RP, if situated in Northern Ireland, will have to be registered from 1st January 2021, as none of the grace periods described for registration in GB will apply.

The timings for Northern Ireland are therefore separate from those of the UKCA mark and are detailed in **Figure 2**.

2All arrangements in Northern Ireland are subject to the Northern Ireland Protocol and its continued ratification, or otherwise, by the people of the Province.

Figure 2: Northern Ireland Protocols



GENERAL FAQS

Q1: Can we have confirmation that the Guidance only comes into play if no agreement is reached? Should an agreement be reached then UKCA mark could be off the table from 1st January 2021 at least?

A1: *The guidance reflects the Government's position on the arrangements that will be in place from 1st January 2021. The Government is legislating to create powers for a UKCA route to market. UKCA route to market will apply in any scenario as it would not be incompatible with a mutual recognition of the results of conformity assessment (as set out in the Government's approach to the negotiations).*

The 'standstill period' in the guidance allows for the recognition of a European CE mark until the 30th June 2023, after which any 'new' product being placed on the UK market must include a UKCA mark. Note however, that special provisions in Northern Ireland will mean that products being placed on the Northern Ireland market specifically, must include the EU CE mark or the CE UK(NI) mark.

Q2: Why can we not simply unilaterally recognise regulatory approvals from third countries to facilitate market access in the longer term, rather than just the short term?

A2: *The UK Government will be exploring all options in developing a robust, world-leading regulatory regime for medical devices that prioritises patient safety. The Government will take into consideration international standards and global harmonisation in the development of the UK's future system.*

The Government will engage with stakeholders within the life sciences and healthcare sectors on this proposed regime this autumn and winter. As part of these discussions, the UK will identify and prioritise elements of international practice that promote public health and patient safety. This will be followed by a formal public consultation with the aim of delivering an attractive world-class regulatory system.

Q3: Am I correct in thinking that regardless of the EU-UK negotiations, the UK will not align with the EU regulations for medical devices based upon the latest government guidance? Or if negotiations go well, this guidance will be removed we continue to follow MDD and MDR?

A3: *The MDR and IVDR will fully apply in EU Member States from 26th May 2021 and 26th May 2022 respectively. As these regulations will not take effect until after the Transition Period with the EU has ended, they will not be EU law automatically retained by the EU Withdrawal Agreement Act and will therefore not automatically apply in GB although they will apply in Northern Ireland.*

The MDR and IVDR were based heavily on international standards and global harmonisation, which will be key considerations for us in the development of the UK's future system.

As part of the UK Government's approach, the MHRA will carefully consider international standards and other international regulatory regimes to identify where the UK's domestic regulatory framework should be made stronger. The aim is to better protect patients, adopting best international practice to meet the needs of the UK's unique domestic healthcare system.

RESPONSIBLE PERSON

The UK RP, according to the MHRA's guidance, is analogous to the European Union AR and is identified by a manufacturer who is situated outside of the UK to act on their behalf in working with the MHRA.

In the same way that the AR operates, the Roles and Responsibilities identified between manufacturer and RP, should be documented in a contract, which will ultimately be auditable by the CAB.

The guidance identifies the following as primary roles for the UK RP:

- Ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer.
- Keep available a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements for inspection by the MHRA.
- In response to a request from the MHRA, provide the MHRA with all the information and documentation necessary to demonstrate the conformity of a device.
- Provide samples of a device to the MHRA or allow the MHRA access to the device where the UK RP has samples or access or, where they do not have access or samples, forward to the manufacturer any request for samples or access.
- Cooperate with the MHRA on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices.
- Immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated.
- Terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the MHRA and, if applicable, the relevant Notified Body of that termination.

Whilst there is a requirement within the MDR in Europe for the AR to have a Person Responsible for Regulatory Compliance (PRRC), there is no such stipulation in the UK. The PRRC at present, does not form part of the UKCA mark compliance process. The UK RP is not analogous to the EU PRRC.

RESPONSIBLE PERSON FAQS

Q1: With the UK RP being analogous to the EU AR, will the UK system allow for the AR being the same as the Importer (as in the EU)?

A1: *The role of the UK RP is set out in the guidance document and regulation 7A of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (in the form in which they exist on 1st January 2021). The role is very similar to that of the EU AR. It will be possible for an importer or distributor to act as a UK RP.*

Q2: Details of the role and responsibilities for the UK RP have not yet been finalised. Do we know when these will be released?

A2: *The role of the UK RP is set out in the guidance document and regulation 7A of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (in the form in which they exist on 1st January 2021).*

Furthermore, the UK RP will be required to identify importers of the device to the MHRA and importers will need to inform the UKRP of intention to import a device. Further guidance on this will be issued in due course.

As with compliance to MDR/IVDR/MDD/IVDD, it would be highly recommended to ensure that any contract that the manufacturer outside of the UK has with their UK RP, reflects the Roles and Responsibilities, as this is likely to be auditable.

Q3: For class III products (and implantable IIb products) there is potentially a lot of work to do to appoint a UK RP ready for the registration deadline of April 2021.

A3: *For the purposes of GB the MHRA strongly recommends that you have in place your UK RP by 1st January 2021. In Northern Ireland it will be mandatory to have the UK RP place by 1st January 2021 in line with the EU's requirement for the AR. These requirements, or similar requirements to have a UK AR, apply across all New Approach goods. The legal framework implementing these changes (the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019) has been in place since 2019 in preparation for leaving the EU.*

Q4: Is it the expectation that non-UK manufacturers would be seeking a third-party UK RP or would this be anticipated to be part of the role of the Importer/ Distributor?

A4: *A UK RP must be appointed for manufacturers based outside of the UK. It will be possible for an importer or distributor to act as a UK RP.*

ECONOMIC OPERATORS

The MDR and IVDR detail in greater depth, the Roles and Responsibilities for several stakeholders than in earlier directives. These include the Importer, Distributor, AR as well as the increased roles for the manufacturer. These Roles and Responsibilities are currently undefined in the 2002 Statutory Instrument, as this reflects the directives, rather than the newer regulations.

Also, of significance, is the lack of future UK requirements for the PRRC, which is defined in the new European regulations.

To distinguish between the European Union AR, the UK equivalent is titled the Responsible Person (RP), whose role is broadly similar.

In any event, as per good quality principles, it is incumbent on the manufacturer to clearly identify the roles and identity of the individuals, ideally formalised into an auditable contract.

ECONOMIC OPERATORS FAQS

Q1: Will the concept of Economic Operators be part of the UKCA mark, as they are for the EU CE mark?

A1: *In January 2021, the obligations on distributors and importers will remain the same as those set out in the EU MDD, EU IVDD and EU AIMDD, as transposed by the UK MDR 2002 (in the form in which they exist on 1st January 2021). The MHRA will not define Importer and Distributor roles within the MDR 2002, however where a medical device is imported into GB by a person other than a manufacturer or UK RP, that person has an obligation to inform the manufacturer or UK RP responsible for that device. The MHRA will provide further information on this in due course.*

Q2: Will there be defined Importer and Distributor roles and requirements in GB?

A2: *See question 1.*

Q3: Will the GB Importer details need to accompany imported products, in product literature for example?

A3: *Importers will not be required to be named on the device labelling. The UK Government will consult with industry ahead of introducing any such requirements.*

Q4: Can the GB Importer, Distributer and UK RP all be the same legal entity?

A4: *As long as their Roles and Responsibilities are compatible, defined and documented, yes.*

Q5: Who places the product on the market in GB – the Importer, Distributor or UK RP?

A5: *The placing on the market responsibility falls to the manufacturer. If the manufacturer is not based in the UK, they must designate a UK RP who is responsible for the placing on the market of the device. If any other economic operator is placing the device on the market and is not the UK RP, they must notify the UK RP before they place the device on the market. The MHRA will issue further guidance on this in line with the legislative changes in due course.*

REGISTRATION OF PRODUCT

The registration of **all** medical devices placed on the market will be required in GB from 1st January 2021. In Northern Ireland not all devices will need to be registered with MHRA (i.e. Class I, custom-made and general IVDs, that are registered in the EU).

Whilst in the European Union, the UK MHRA (and Department of Health and Social Care) has been able to ascertain those products which are on sale in the UK, by interrogation of European databases via the European Communities Act. With the UK out of this mechanism from 1st January 2021, this will no longer be possible, with the requirement however, no less critical.

At present, the MHRA's database only includes a requirement to register self-assessment Class I, Custom-made, Procedure Packs and Clinical Trial materials, i.e. those that do not require a Notified Body intervention. This database is to be extended to include **all** devices, in order that the MHRA and Department of Health and Social Care have visibility of what products are available on the UK market and being used on patients.

It is recognised however, that if manufacturers attempt to register all of the thousands of devices which will need registration on 1st January 2021 and all IVDs (including IVDs for performance evaluation), the system will soon become overwhelmed. A staggered system of registration, therefore, based on product risk has been proposed, with Class IIIs, implantable IIb's and List A IVDs requiring registration by 1st May 2021, remaining Class IIb's, Class IIa's List B and self-test IVDs by 1st September 2021 and remaining products by 1st January 2022.

The MHRA are preparing guidance as to how the system will work (particularly as it relates to the grouping of products per submission) along with the fees applicable for each submission, which will be made available prior to 1st January 2021.

Registration in GB will be combined with the likewise registration of the UK RP, which can also be staggered according to the product risk deadlines mentioned above. In Northern Ireland the UK RP appointment will not be linked to grace periods and should be completed as soon as possible to the 1st January 2021 date. Also, importantly, it should be noted that if the manufacturer is in the UK, then it is they that should conduct the registration. Submissions to be made for other manufacturers, however, should be made by the UK RP.

REGISTRATION OF PRODUCT FAQS

Q1: Can we register all classes of medical devices straight away? This could reduce cost and could be more efficient.

A1: *Manufacturers/UK RPs must register products within the grace period applicable to the class of device. It will be possible to register devices of different classes, that are subject to different grace periods, at the same time as long as they register within the grace period for the highest class of device in their application.*

Q2: Will registrations be by Global Medical Devices Nomenclature (GMDN) and the same as the current class I registrations system? E.g. once you have registered a GMDN against a Legal Manufacturer you can sell any product with the same GMDN in GB and Northern Ireland?

A2: *To register any class of device with MHRA, you will need to use GMDN to describe your device. You do not need to be a member of the GMDN Agency to find and select the appropriate GMDN terms within the MHRA's online registration system.*

Initially, the MHRA will require all devices to be registered at the level of GMDN code. If you do not know which GMDN code applies to your device, you will need to select the relevant description term from the system.

Q3: Can we have a list of fields required by the registrations database to prepare?

A3: *Not at present, as this is under development. However, as soon as this is available along with the planned guidance document on registration, they will be shared with industry.*

Q4: If devices are going to change from MDD to MDR just outside the mandatory registration timelines, will manufacturers/RP have to re-register the devices under the MDR after the initial MDD registration? If so, will there be additional costs? Can the registration be delayed until products are MDR compliant?

A4: *Yes, products that change compliance from MDD to MDR (or IVD to IVDR), will need to be re-registered, which will incur the additional £100 registration fee.*

Registration has to start by 1st January 2021 according to the timescales in the guidance, i.e. Class III's, Implantable IIb's, and List A IVDs by 1st May 2021, remaining Class IIb's, Class IIa's, List B and Self-test IVDs by 1st September 2021 and all other products by 1st January 2022. If therefore, the transition to MDR/IVDR can be made before these deadline dates, indeed, one submission will be needed.

Q5: Will there be a new IT Portal for uploading the required data within the 4. 8 and 12 month periods? Is there guidance on the process?

A5: *Further information on registrations can be found in the MHRA's registrations guidance. This page will be updated with further detailed guidance in due course.*

Q6: Will more detailed guidance on device registration be issued for those having to register for the first time with MHRA?

A6: *See question 5.*

LABELLING

The guidance indicates that the European Union CE mark will be unilaterally recognised in GB until 30th June 2023, which would imply any requirements for labelling will be aligned with Europe until this date. With the European transition to the MDR expected by 27th May 2021 and IVDR by 27th May 2022, and with continued recognition of the European Union CE mark, it is expected that labelling in the UK will be applied equally to compliance with AIMD/MDD/IVDD and MDR/IVDR.

LABELLING FAQS

Q1: Can you have a CE mark and a UKCA mark on the same label?

- **Will the EU allow it?**
- **Could you have MDR complaint labelling with both a CE mark and UKCA mark as GBs labelling requirements will not be as stringent as the EU's?**

A1: *When placed on the market in GB, devices can have both marks present on the labelling prior to 1st July 2023, and will continue to be accepted on the GB market after 1st July 2023, so long as both are clear and visible. The MHRA is not aware of any guidance published by the EU on this.*

Q2: Does the Importer, Distributer and UK RP have to be included on the label?

A2: *There is currently no requirement for the Importer, Distributor or UK RP to be named on CE marked devices. The UK Government will provide guidance to industry on any future changes to this. However, where a UK RP is required for the purposes of the UKCA mark, the UK RP must appear on the label, or the outer packaging, or instructions for use.*

Q4: As Northern Ireland is effectively a quasi-EU country from 1st Jan 2021, what will happen if the product labelling has not been updated to have an EEA based Notified Body and/or European AR? Can it be still be placed on the market in Northern Ireland after Jan 2020 in the following two scenarios:

- **Product is already in a GB warehouse before 1st January 2021, but not in Northern Ireland.**
- **Product is placed on the market directly into Northern Ireland from outside GB?**

A4: *To place a device on the Northern Ireland market from 1st January 2021, it must have a valid CE certificate issued by an EU Notified Body. Alternatively, a manufacturer can undergo a conformity assessment with a UK Approved Body and affix the CE UK(NI) mark.*

If a product is in a GB warehouse and has not been placed on the Northern Ireland market before 1st January 2021, it can only be placed on the Northern Ireland market if it has a valid CE mark or CE UK(NI) mark. Any GB-based manufacturers will be required to have a Northern Ireland based or EU-based AR before they can place the device on the market.

Q5: Will the name of the UK RP (Legal Entity) and address need to be on the product labelling?

A5: *See question 2.*

CONFORMITY ASSESSMENT BODIES

For higher risk devices the UK CA mark must be supported by UK-based Approved Bodies (UK-CABs).

Whilst it is unsure at present as to the designation requirements for UK-CABs, it is expected that the MHRA will have started the process of designation by the 1st January 2021. This process will no doubt take time, but it is understood that a certain degree of grandfathering will be applied to those European Union Notified Bodies who also have existing operations in the UK. This would suggest that BSI, SGS and UL will have priority in this process.

Importantly, the certificates issued by UK-CABs will not be recognised in support of European Union CE marking activity. This adds additional complications to the strategic decision making process for manufacturers in Northern Ireland, where the CE mark is a pre-requisite of placing on the market.

CONFORMITY ASSESSMENT BODIES FAQS

Q1: How will the MHRA ensure capacity within Approved Bodies to issue UKCA certificates for all the products placed on the UK market in 2.5 years?

A1: *The Government recognises the importance of having competent Notified Bodies in place to ensure continuity of supply of products to the UK market. Therefore, the MHRA has been engaging with Notified Bodies on an ongoing basis to ensure that they are prepared for January 2021 and beyond. Discussions are being undertaken with potential new applicants for the UK. In addition, a clear drive for any designation roll over or application will be a need to demonstrate capacity for the UK market specifically.*

Q2: If all product to be placed on the UK market needs the UKCA mark at that point, how will this be catered for?

A2: *See Question 1.*

Q3: Will there be target turnaround times for reviews? Thinking being that given a common lead time for a CE mark Technical File review by various Notified Bodies is around 6 months, if the UK could do better, this could be a great advantage.

A3: *This requires further discussion and consideration in conjunction with the UK Approved Bodies. Review periods are capacity driven as well as commercial incentives offered. This will fall into MHRA's assessment of capacity and whether the Approved Body can complete assessments in a given timeframe. MHRA's focus will be on the quality of the assessment rather than speed.*

Q4: Also, to go into the planning stage for providing adequate CAB resource with set review periods (think FDA 60 day 510(k) reviews for example. To have more certainty/confidence when planning review activities would be quite attractive.

A4: *See Question 1 and 3.*

Q5: With the introduction of the UKCA mark I would expect comes additional certification cost and the need for further Notified Body resource. Has this been evaluated and do we know yet how the Notified Bodies are going to respond?

A5: *See Question 1. Certification costs are a matter for the UK Approved Bodies. MHRA do not comment on commercial aspect such as fees charged. However as defined in Question 1 the MHRA's focus will be to ensure any existing or applicant approved body have sufficient capacity for the UK Market.*

Q6: The increase in audit costs to accommodate the MDR were significant and it is a concern that similar increases could be seen for this.

A6: *Certification costs are a matter for the UK Approved Bodies. MHRA consider these will be similar to existing Directives costs (this matter should be raised directly with Approved Bodies).*

Q7: Are we to expect an additional audit to assess UKCA or is it anticipated that while the UK regulations are the same as EU MDR that the Notified Body could audit a technical file and then issue two certificates?

A7: *Manufacturers will be required to undergo a conformity assessment process for the purposes of the UK mark. Whilst the systems are aligned it is unlikely that an additional audit would be required, but the scope of the audit extended to include UKCA processes.*

Q8: Between now and the end of the 2020, MHRA will come up with a conformity assessment process for the UKCA mark. Does this mean we will need an EU based Notified Body (to sell into EU/Northern Ireland) and a UK based one to sell into GB/Northern Ireland?

A8: *The conformity assessment process for the UK mark will mirror the process under the current Directives which have been transposed to UK law through the UK Medical Devices Regulations 2002. The assessment time will vary depending on the devices under assessment and the resources of the Approved Body performing the assessment. However, the MHRA expect this will reflect the time it takes for devices under the EU Directives.*

Q9: When are we going to find out about the new conformity assessment requirements i.e. when is the UK MDR going through parliament? Is it likely that the UK will adopt an MRA approach i.e. CE marking or 510(K) will be accepted?

A9: *The powers to amend the UK's legislation at the end of the Transition Period are currently being created by the Medicines and Medical Devices Bill. MHRA will consult with industry before making any changes to the regulations.*

Q10: The current Notified Bodies in the UK are overwhelmed with work. We are experiencing delays, confusion and a general lack of consistency in application of MDR. The new UK CA mark will add a further level of complication into a process that is already stressed/broken.

A10: *See Question 1.*

Q11: How much are Notified Bodies likely to charge? Or, will this be roughly the same as the fees charged for CE marking?

A11: *See Question 6.*

PROCESS AND DATA REQUIREMENTS

The technical requirements for compliance to the UKCA mark (or UK(NI) Mark) of products destined for the UK market is not detailed in the guidance. However as previously described, the regulation in force from the 1st January 2021 in the UK, will be the UK's transposition of the MDD/AIMDD and IVDD. With this in mind, it is expected that in order to affix the UKCA mark, compliance with this 2002 Statutory Instrument (as amended) is appropriate.

The technical files therefore prepared against the EU Directives will be applicable in the UK, at least in the short-term, until such time that the UKCA mark and EU CE mark diverge, when the EU MDR/IVDR complete their transition processes.

After the MDR/IVDR transition the UK CABs may need to demand a differently structured technical file to those required in the EU, when considering product destined for the UK market. For those products aiming for Northern Ireland however, the technical requirements will be those of the European Union regulations.

PROCESS AND DATA REQUIREMENTS FAQS

Q1: Where will ISO standards fit? Will these need to be specific BS ISO versions or will EN ISO still be valid?

A1: *There are no immediate plans to update the ISOs or ENs for January, so existing BS ISOs and BS ENs will continue to apply.*

Q2: Will discrete Technical Files be required or will MDD and then MDR Technical Files be considered an effective equivalent??

A2: *The conformity assessment process for the UK mark will mirror the process under the current Directives which have been transposed to UK law through the UK Medical Devices Regulations 2002. Therefore, the technical file requirements will be the same. The MHRA will consult with industry before making any changes.*

Q3: Has MHRA developed a gap analysis for comparing EU regulations with a new UK regulation for medical devices.

A3: *In developing the new UK regime, the MHRA will consider the MDR, IVDR and other international standards to develop a robust, world-leading regulatory regime for medical devices that prioritises patient safety.*

Q4: Will the new UK regulation for medical devices comply with International Medical Device Regulators Forum (IMDRF) guidance documents?

A4: *See question 3.*

Q5: Is there a standard template available for manufacturers of Class I medical devices to be able to self-declare their conformity against relevant parts of the UK regulation from 1st January 2021?

A5: *A Class I medical device or a general category IVD can bear the UKCA mark if the manufacturer declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of the Directive which apply to it.*

Q6: Do we know if there are any plans for the UK regulation to deviate from the EU MDR in the short term?

A6: *From 1st January 2021, requirements set out in MDD, IVDD and AIMDD (as transposed through MDR 2002) will continue to apply in GB. So, there will not be immediate significant changes for industry. For the UK's longer-term regulatory framework, the MHRA will consider the MDR, IVDR and other international standards to identify where our domestic regulatory framework to develop a robust, world-leading regulatory regime for medical devices that prioritises patient safety. The MHRA will consult with industry before making any changes.*

Q7: On the topic of EUDAMED, it seems that Northern Ireland will have access to this, but GB will not. Is there any way that GB can get access via Northern Ireland, at least to the data on vigilance?

A7: *Access to EUDAMED is a matter for negotiation with the EU and there are no further details at this stage.*

Q8: Is the MHRA anticipating to have access to EUDAMED from a post-market surveillance perspective?

A8: *See Question 7.*

Q9: Does the new MHRA guidance mean that the medical devices that are already CE registered and approved by a Notified Body in the EU need to be approved once again in UK by another regulatory body to gain the UKCA mark post Jan 2023?

A9: *Yes, and this Approved Body will need to be based on UK standards. To clarify the UKCA mark will be mandatory from 30th June 2023 in GB.*

Q10: Will the UKCA mark require substantially the same information as is required for CE marking, or will there be additional/different requirements?

A10: *See Question 6.*

Q11: Clinical Investigations after 31st December 2020:

1. **Ongoing multinational (GB and EU) studies: If CE mark obtained before 1st July 2023, GB will recognise the CE mark until then. Will the UKCA then need to be pursued with a UK CAB if placing on the market from 1st July 2023?**
2. **What will Serious Adverse Event (SAE) reporting to MHRA for GB and EU sites look like before MDR comes into force in May 2021 and MEDDEV guidance documents no longer apply?**
3. **Will new GB clinical investigation notifications need to follow UKCA route to market utilising a UK CAB and is further guidance is expected?**
4. **Will ongoing and new post-market studies after 21st May 2021 continue to follow MDD and will new post-market studies not need to be notified to MHRA?**

A11: *Any new clinical investigation and performance evaluation notifications from January must meet Directive requirements. Existing guidance will continue to apply.*

Manufacturers must continue to report SAEs to MHRA where the trial is taking place in the UK. The requirements would be the same as the MEDDEV requirements.

Requirements for post-market studies will continue to follow the requirements of the MDD/IVDD.

Q12: Clinical Investigations before 31st December 2020: if notified and letter of no objection obtained before 31st December 2020: What are the implications to conduct of the study after 1st January 2021? Will MDD apply or UKCA route to market?

A12: *Any Clinical Investigation or performance evaluation approved in the transition period will be applicable for UKCA marking. The requirements under the Directives will continue to apply to the study.*

Q13: Will post-market surveillance requirements follow EU MDR requirements, or directives requirements, especially in the case of Northern Ireland after May 2021?

A13: *Post-market requirements for medical devices, will continue be regulated according to the UK MDR 2002 (which transposes the EU MDD, IVDD and AIMDD) for devices placed on the GB market, including devices certified under the EU MDR or IVDR.*

For devices placed on the Northern Ireland market, post-market requirements will be regulated according to the UK MDR 2002, until the EU MDR and EU IVDR comes into force on 26th May 2021 and 26th May 2022 respectively. After these dates, MHRA will regulate devices according to MDR or IVDR requirements.

Q14: When will post-market surveillance requirements for the UK be confirmed? After May 2021, will GB follow 10/30day vigilance reporting timelines and Northern Ireland follow 10/15day vigilance reporting timelines? Where will vigilance expected to be submitted once EUDAMED is live if Northern Ireland follows CE marking?

A14: *See Question 13.*

Q15: After May 2021, where will MHRA expect field action notifications to be sent for both the GB and Northern Irish market, both before and after EUDAMED being live?

A15: *Current guidance will continue to apply. Therefore, where the manufacturer initiates a Field Safety Corrective Action, they should issue a notification to the Competent Authorities of all countries affected at the same time and also to the National Competent Authority responsible for the manufacturer. In cases where the UK is affected (including both GB and Northern Ireland), the MHRA would expect the manufacturer to notify the MHRA as the UK's standalone medicines and medical devices regulator.*

The MHRA will publish guidance in due course in relation to the implementation of the EU MDR and EU IVDR in Northern Ireland.

IMPORT/EXPORT/PLACING ON THE MARKET

Compliance with the UKCA mark is dependent on the issuance of certificates from a UK CAB. There will, at present, be no recognition of certificates issued by European Notified Bodies, which is not to say that future arrangements could allow for UK-CABs to re-issue certificates within their own organisation (i.e. no recognition of an EU-issued certificate from DEKRA by BSI-UK, but potentially allowance of BSI-UK to certify against BSI-NL audits).

IMPORT/EXPORT/PLACING ON THE MARKET FAQS

Q1: There are some overseas countries that will authorise market access only if the device complies already with either EU, USA or Japanese medical device regulations (e.g. Saudi Arabia). What steps are being taken to add the UK to that list of countries?

A1: *Market access arrangements are subject to new and continuity trade agreements being negotiated with individual jurisdictions by the Department for International Trade.*

Q2: Will devices placed on the GB market from 1st January 2021, on the basis of MDR recognition, require a GB Importer to be appointed who meets Article 13 MDR obligations?

A2: *The EU MDR and EU IVDR will fully apply in EU Member States from 26th May 2021 and 26th May 2022 respectively. As these regulations will not take effect until after the Transition Period with the EU has ended, they will not be retained EU law as described by the EU Withdrawal Agreement Act and will therefore not apply in GB. This means that the provisions contained within the EU MDR and EU IVDR will not be transposed into law in GB and will not be implemented in GB. The MHRA will recognise CE marked devices that have been certified according to the EU MDR and EU IVDR.*

The MHRA will consult in due course on any future changes to the role of the importer.

Q3: Will devices placed on the Northern Ireland market from 1st January 2021 on the basis of MDR recognition require a Northern Ireland Importer to be appointed who meets Article 13 MDR obligations?

A3: *The MDR and IVDR will apply in Northern Ireland from 26th May 2021, and 26th May 2022 respectively, in line with the EU's implementation timeline.*

Therefore, Northern Ireland Importers must meet the requirements of the MDR / IVDR from these dates.

Q4: Will transfers of devices from GB to the Northern Ireland market be considered placing on the EU market or making available on the EU market? i.e. Will an Northern Ireland importer or distributor require to be appointed in compliance with EU MDR?

A4: *Under the terms of the Northern Ireland Protocol, from 1st January 2021 the rules for placing medical devices on the Northern Ireland market will differ from those applicable to GB.*

Although the UKCA mark will need to be used in GB from 1st July 2023, a CE mark will continue to be needed for devices placed on the Northern Ireland market and EU rules will need to be met.

If you currently CE mark your device on the basis of self-certification, you will be able to continue to do so from 1st January 2021 for the purposes of the Northern Ireland market. From 1st January 2021, the results of mandatory conformity assessment carried out by UK Notified Bodies (Approved Bodies) will not be recognised by the EU. You will need to use an EU-recognised Notified Body to undertake any mandatory third-party conformity assessment in order to CE mark your device. This will allow it to circulate in the EU.

UK Notified Bodies will become UK Approved Bodies and will be able to conduct conformity assessments for the purposes of the Northern Ireland market. Where a device has been assessed by a UK Approved Body, the UK(NI) mark will accompany, but not replace, the CE mark. Products carrying both the CE mark and UK(NI) mark cannot be placed on the EU market.

These requirements will apply to any GB manufacturers placing their device on the Northern Ireland market.

Q5: After 30th June 2023, will devices to be placed on the GB market requiring the UKCA mark include legacy devices (previously marketed under CE recognition) or only devices that are introduced to the UK market for the first time after 30th June 2023?

A5: *The UKCA mark will be needed for all devices being placed on the GB market from 1st July 2023. Devices that have already been placed on the market will not be required to be re-labelled.*

Q6: Will Northern Ireland based manufacturers need to conform with UKCA marking requirements after 1st July 2023 in order to register devices with MHRA and to continue to market devices in GB or will the CE mark be sufficient?

A6: *See Question 4.*

Q7: Do we have to double register devices with MHRA that are sold in GB and Northern Ireland?

A7: *There will be no requirement to register with MHRA twice. The MHRA will provide further information on registration requirements in due course.*

Q8: Assuming manufacturers want to sell in the EU, Northern Ireland and GB, why would you want a UK(NI) mark? I do not understand why a device with a CE mark and UK(NI) mark cannot be sold in the EU. I assume the CE mark is coming from a EU based Notified Body?

A8: *The MHRA envisage that the CE UK(NI) mark would be used in cases where a manufacturer would like to place a device on the Northern Ireland market only, and they wish to use a UK Approved Body for the conformity assessment process. For example, an NHS hospital located in Northern Ireland who use a Notified Body in relation to sterilisation services for products to be used within the hospital, may want to continue using a UK Approved Body, rather than transferring to an EU Notified Body by 1st January 2021. The manufacturer (the hospital), would be able to apply a CE UK(NI) mark to these devices to ensure they can continue to place these devices on the market in Northern Ireland.*

Q9: What will the UKCA mark look like? We need this information as soon as possible to allow time for manufacturers to change their labels.

A9: *The guidance is available here.*

Q10: From a supply chain perspective, many companies have split their product release per country listings from EN ISO 3166 (Country Codes), which as we know lists United Kingdom as GB, Wales, Scotland and Northern Ireland. Will there be a EN ISO 3166 standard update to separate Northern Ireland?

A10: *Existing standards will continue to apply and the MHRA will issue guidance in the future, should this change.*

APPENDIX 1: REGULATORY CHECKLIST

1. Activities that are required prior to 1st January 2021

   a. Identification and contracting a European Union AR.

   b. Identification and contracting (if necessary) a UK RP, ensuring that they have the relevant experience and competence to cover their required role. This will be required by 1st January 2021 for Northern Ireland but only in line with registration grace periods for GB.

   c. Begin (if possible) discussions with a candidate UK CAB.

   d. Develop a strategy for how to register your product portfolio onto the MHRA's new database, including timings and working out possible costs.

   e. Consider whether the Northern Ireland Protocols will impact your products.

2. Activities that are required after 1st January 2021

   a. Start to register Class III, IIb (implantables), and List A IVDs before May 1st 2021.

   b. Start to register Class IIb, IIa, List B and self-test IVDs between 1st May and 1st September 2021.

   c. Start to register all other products before 1st January 2022.

   d. Determine technical requirements for product technical files, initially based on EU MDD (as transposed by UK Statutory Instruments).

   e. Register the UK RP if necessary. Depending on the product risks, use same timeframes and grace-periods.

   f. Develop a strategy that addresses label changes by 31st June 2023.

   g. Engage with a UK CAB, to determine timeframes, technical requirements, audit schedules and costs. Ensure that certificates to support UKCA mark will be available before 1st July 2023.

Activities that are required after 31st June 2023

   a. Ensure product on GB market is affixed with the UKCA Mark

APPENDIX 2: RESOURCES & REFERENCES

Guidance: Using the UKCA mark from 1 January 2021

Guidance: Conformity assessment bodies: change of status from 1 January 2021

Policy paper: Moving goods under the Northern Ireland Protocol

Placing manufactured goods on the market in Great Britain from 1 January 2021

Guidance: Regulating medical devices from 1 January 2021

The Medical Devices Regulations 2002

The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

Guidance: Register as a manufacturer to sell medical devices

APPENDIX 3: GLOSSARY

CABs - Conformity Assessment Bodies

HoTS - Harmonisation of Technical Standards

GMDN - Global Medical Devices Nomenclature

IMDRF - International Medical Device Regulators Forum

IVDD - In Vitro Diagnostic Medical Devices Directive

IVDR - In-Vitro Diagnostic Medical Device Regulation

MDD - Medical Device Directive

MDR - Medical Device Regulation

MHRA - Medicines and Healthcare products Regulatory Agency

MR - Mutual Recognition

PRRC - Person Responsible for Regulatory Compliance

REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals

RP - Responsible Person

RoHS - Restriction of Hazardous Substances

SAE - Serious Adverse Event

UKCA - UK Conformity Assessed

WEEE - Waste Electrical and Electronic Equipment

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