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HPRA MEDICAL DEVICES
NEWSLETTER

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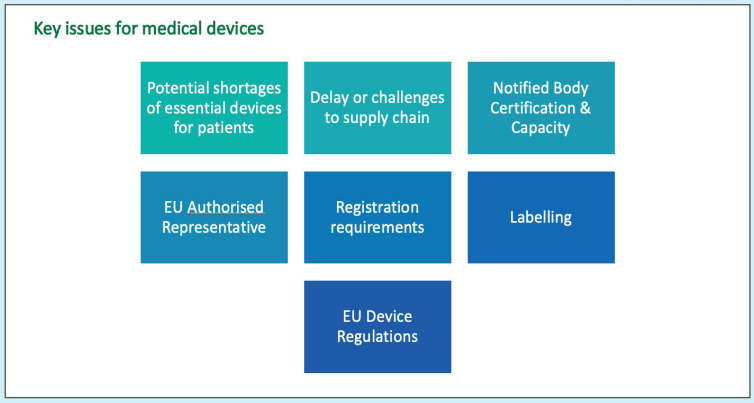
HPRA Brexit Preparations



The HPRA's strategic objective in regard to Brexit is to protect public health by supporting the continued supply of health products, including medical devices. The HPRA has been planning for Brexit for the past two years to ensure the organisation and the regulated sector are sufficiently prepared to manage the regulatory challenges presented by the UK's departure from the European Union. Our focus from the outset has been planning for all possible scenarios. We have been working closely with the Department of Health and Health Service Executive to plan for all possible scenarios including identifying the steps necessary to address and mitigate the potential negative impact on health care delivery.

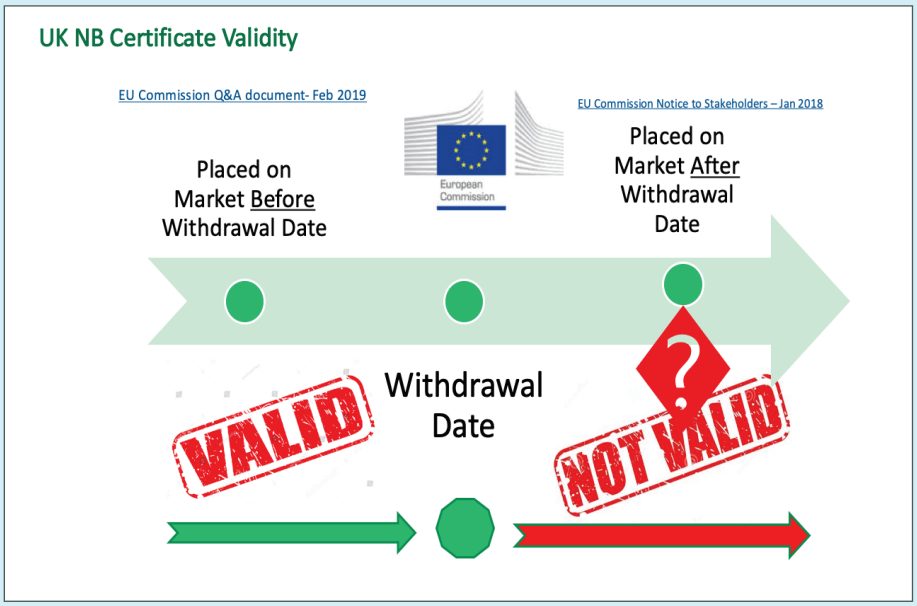
On 11th April 2019, the European Council reached an agreement with the United Kingdom to extend Article 50 until 31st October 2019. In the event that the UK has not ratified the Withdrawal Agreement by this date then the UK will become a third country and all EU primary and secondary legislation will cease to apply on 1st November 2019.

In the event that the UK ratifies the Withdrawal Agreement in advance of 31st October 2019 an orderly withdrawal will take place on the first day of the month following the completion of the ratification procedures.

The UK's exit from the European Union has the potential for significant implications on the Medtech sector in Ireland. Although the eventual outcome of the ongoing discussions in relation to the UK withdrawal from the EU is unknown, the HPRA would like to highlight the requirements relating to two key issues:

- Validity of UK notified body certificates;
- Impact on EU economic operators.

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority



No-Deal - Validity of UK Notified Body Certificates

The Commission's notice for stakeholders (January 2018) highlights the status of UK notified bodies and the certificates they have issued. In the event of a no-deal, UK notified bodies will no longer be considered EU notified bodies and will be removed from the EU database of New Approach Notified and Designated Organisations (NANDO). As a consequence, UK notified bodies will no longer be able to carry out EU conformity assessments nor issue EU certificates.

The Commission Q&A document (February 2019) further clarifies the impact of a 'no-deal' Brexit on UK issued certificates. The document outlines the steps manufacturers or their authorised representatives must take to continue to access the EU 27 market (in this context the EU market means the European market of the 27 remaining Member States) in the event of a no deal withdrawal. For devices certified by a UK Notified Body, the options include either applying for a new certificate from a EU27 notified body or arranging a transfer of certificates to a EU27 notified body or a relocated 'UK' notified body.

No-Deal - Impact on Economic Operators

As outlined in both Commission documents[1] a manufacturer, authorised representative or importer established in the UK will no longer be considered a European economic operator in the event of a no deal withdrawal. From the withdrawal date, manufacturers based outside of the EU will have to designate an EU authorised representative located within the EU-27 to continue to access the EU 27 market. The EU 27 authorised representative will act on behalf of a manufacturer located in a third country and will fulfil certain regulatory functions. The labelling requirements will also be impacted in that an EU 27 Authorised Representative and Notified Body, where applicable, will need to be included on all devices placed on the market after the withdrawal date.

In addition economic operators, such as distributors established within the EU27, may be directly affected as they may be considered an importer if they are placing a device from the UK, which will be considered a third country after the withdrawal, on the EU market under European products legislation[2].

Distributors should become familiar with the specific importer obligations and assess how their status as an EU economic operator may be affected.

We recommend that all economic operators become familiar with the requirements set out in both EU Commission documents referenced in this article. Further information on the impact of Brexit for the Irish Medtech Sector is available from our website.

In the case of economic operators establishing in Ireland as a result of Brexit, further information on how to register devices and organisations with the HPRA can be found on the HPRA's website. Any questions relating to Brexit can be sent to devices@hpra.ie. The HPRA would also encourage stakeholders who have identified examples of challenges or potential device shortages they will face as a result of the UK exit from the EU to contact us at the same email address.

1 Notice to Stakeholders withdrawal of the United Kingdom and EU rules in the field of industrial products, Questions and Answers relating to the United Kingdom's withdrawal for the European Union with regards to Industrial products.

2 Regulation 765/2008

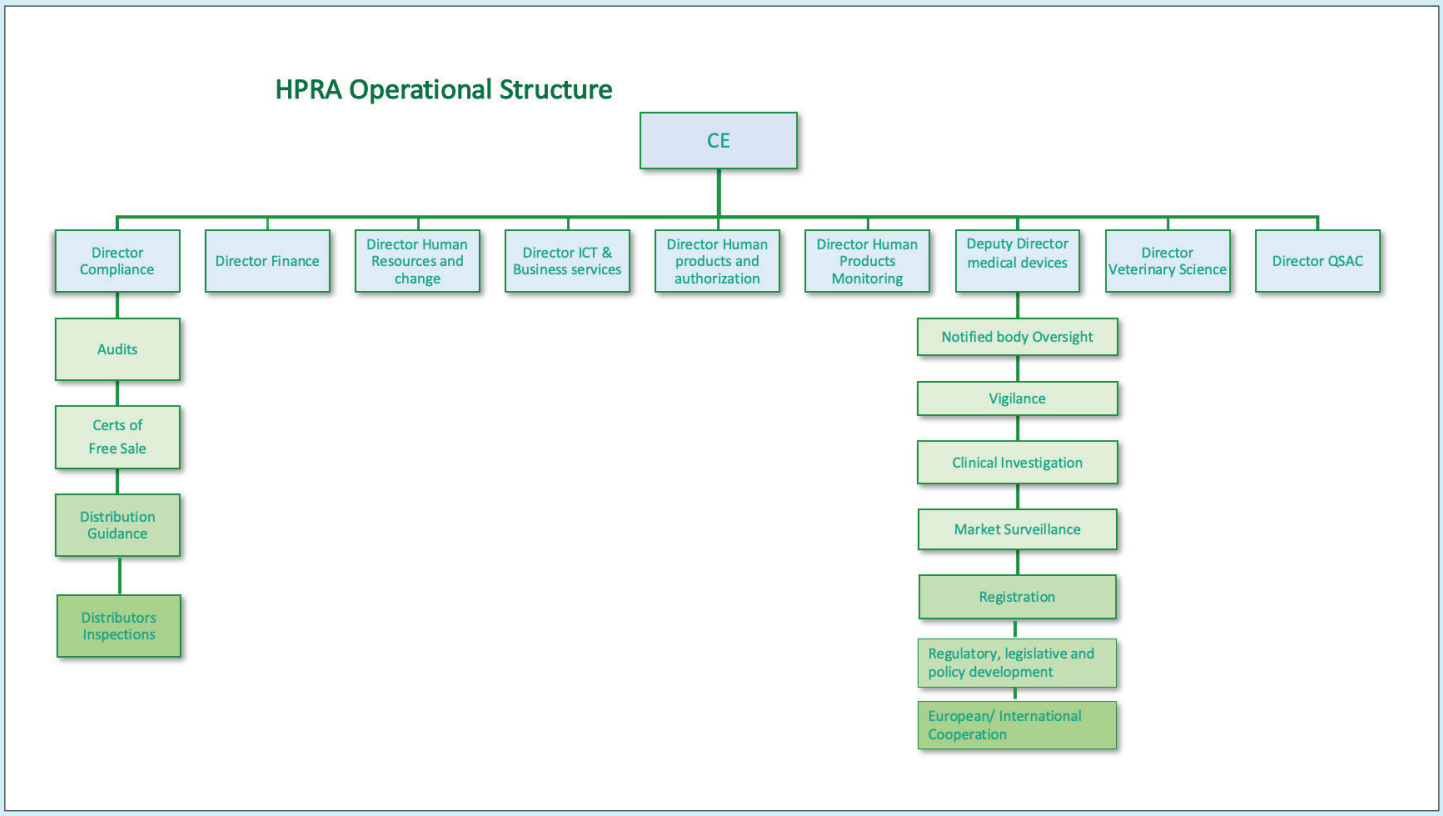
Medical Devices Department Restructure

Historically medical devices activities in the HPRA were divided across three Departments: Human Products and Authorisation (HPAR), Human Products Monitoring (HPM) and Compliance. At the beginning of 2018 the HPRA decided to create a single Medical Devices Department by bringing the device activities of HPAR and HPM together by initiating a restructure project. The purpose of the re-structure project is to identify a structure that best positions us to effectively and efficiently deliver on our medical device regulatory remit of protecting public health now and into the future. In delivering on our regulatory remit we look to ensuring processes are effective and efficient and that we can demonstrate to our stakeholders how we afford protection of public health and ensure information is available to the public on medical devices regulatory activities. In addition, we look to ensure that medical devices on the Irish and European market are safe and effective, while providing an environment where new diagnostic and therapeutic technologies can be innovated affording patients and health systems new options.

The new Medical Devices Department will be responsible for all device activities related to notified body designation and oversight, vigilance, clinical investigations/ performance studies for IVDs, and market surveillance activities including registration. In addition, this department will also be responsible for the regulatory and policy developments relating to medical devices as well as the HPRA's participation in both European and International cooperation initiatives (CAMD, IMDRF etc). This departmental restructure will have no impact on the services provided by the HPRA and any change in contact points will be communicated in advance.

Audits and inspections and the issuance of certificates of free sale, relating to medical devices will remain in the Compliance Department.

The HPRA expects the medical device department restructure and change to be finalised by the end of Q3 2019 and would like to thank stakeholders for their cooperation during this process.



HPRA Registration Requirements

Current Medical Device Directives

The current Medical Devices and *In-Vitro* Diagnostics Directives[3] require economic operators such as manufacturers, or their authorised representatives, to register with the Competent Authority in the Member State where they have their registered place of business. This requirement has been transposed into Irish national legislation[4] and requires registration with the HPRA as the Competent Authority for medical devices. In addition to organisation registration, certain categories of devices should also be registered with the HPRA prior to being placed on the market. Both organisation and device registration can be completed online through the HPRA's extranet.

- Who needs to register their organisation with the HPRA?

Manufacturers* or their authorised representatives established in Ireland and placing devices on the market for the categories of devices listed below must register with the HPRA:

Table 1
Class I devices- sterile devices, devices with a measuring function, fully refurbished devices;
Custom-made devices including any Class I devices such as dental crowns and active implantable devices;
System and Procedure Packs*
In-vitro diagnostic medical devices

Please note:

* Own Brand Labellers for the categories of devices listed above are required to comply with the registration requirements.

* Sterilisation organisations responsible for sterilising system and procedure packs for the purpose of placing such devices on the market are also required to comply with the registration requirements.

Organisations registering with the HPRA will need to provide details regarding the organisation's size, contact point for regulatory purposes, information on any third country manufacturers being represented by an EU Authorised Representative amongst others. Further details on the requirements are available in our guidance document for registration. Information on the applicable fees can also be found on the HPRA website.

Once the economic operator has an organisation registered the organisation will then be able to access the Medical Devices Extranet to electronically submit the appropriate information relating to the devices which fall into the categories listed in the table above. All device information must be entered correctly prior to placing the devices on the market. A unique device registration number will be assigned by the HPRA to each registered device on the Extranet. Due to the impact of Brexit, organisations registering in Ireland as a direct impact of Brexit, are asked to inform us directly before registering devices through the extranet.

Registration under the new EU Device Regulations

The new EU Device Regulations (EUDR)[5] entered into force in May 2017. The Medical Devices Regulation has a three year transition period and is fully applicable from 26th May 2020. The *In-Vitro* Diagnostic Medical Device Regulation has a five year transition period and is fully applicable from 26 May 2022.

One of the fundamental pillars of the new EUDR is the centralised European database, Eudamed, which is currently being developed by the EU Commission. Eudamed will facilitate access to information on devices and economic operators and will lead to improved device traceability and identification.

Registration under EUDR will require registration of Economic Operators, including manufacturers, authorised representatives and importers with the centralised European database. Once an economic operator has registered, their details will be verified by their National Competent Authority and a Single Registration Number (SRN) will be generated by Eudamed and provided to the economic operator. The new Eudamed database is expected to be functional by the date of application of the MDR. Until such time as the Eudamed registration module is fully functional the provisions set out in the current Directives shall apply, i.e. registration at national level will be required.

Both of the new Regulations contain a derogation which allows MDR or IVDR compliant devices to be placed on the market before the respective date of application of each Regulation. If you intend on registering medical devices compliant with the new Regulations during the transition period please contact deviceregister@hpra.ie.

The HPRA is currently undertaking a project to upgrade our Extranet. In the meantime, we are asking Economic Operators to facilitate us in providing additional information on their activities through our Economic Operator Database portal. Further Guidance on registration under the new Regulations will be provided in due course.

3 Article 14 of Directive 93/42/EEC and Article 10 of Directive 98/79/EEC

4 MDR Article 105, Regulation 14 of S.I. 252/1994 and Regulation 10 of S.I 304/2001

5 Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)

Implementation of the EU Device Regulations

EU Cooperation

Medical Devices Coordination Group (MDCG)

The new EU Device Regulations established the Medical Devices Coordination Group (MDCG) in November 2017. The MDCG is made up of Member States' experts and is chaired by the Commission. The nominated experts represent their Competent Authority (HPRA in Ireland).

The terms of reference for the MDCG outlines the tasks and roles, membership and operation of the group and is published along with the Rules of Procedure on the EU Commission's website. Each Member State nominates one expert for medical devices and one for IVDs or alternatively, one expert can be nominated as both the medical devices and IVD expert. Nominations to this group are based on the expert's role and expertise in medical devices and IVDs. Alternate experts are also nominated in both fields. HPRA has nominated experts and alternatives for both medical devices and IVDs.

The MDCG tasks and responsibilities are set out in both of the new Regulations[6]. Some of the responsibilities of the MDCG are summarised below to illustrate what will be required of the HPRA's MDCG experts.

Competent authorities' coordination

The MDCG assists Member States' competent authorities in a number of activities such as determining the classification and regulatory status of a device and supporting the competent authorities of the Member States in their coordination activities in other areas such as clinical investigations and vigilance and market surveillance.

Designation of Notified Bodies

All designation applications from conformity assessment bodies are transmitted from the Authority Responsible for Notified Bodies to the EU Commission and are shared with the MDCG.

The MDCG will issue a recommendation on the designation application which should be taken into consideration by the Authority Responsible for Notified Bodies. During this designation process both Member States and the Commission have the opportunity to raise an objection to the designation. Any objection is brought before the MDCG which will consult with the relevant parties before providing its opinion. If the Designating Authority decides not to follow the MDCG recommendation a justification for the decision must be provided.

EUDAMED

The MDCG's role in the development of EUDAMED, includes review and input into the system's functional specification. Once these specifications have been fulfilled the Commission will inform the MDCG and a notice will be published in the Official Journal of the European Union.

The Commission have adopted a phased approach to the development of Eudamed. It is expected that the Registration and UDI modules will be functional next year by the date of application of MDR.

Harmonised implementation

The MDCG also contributes to harmonised administrative practice in Member States such as the development of guidance aimed at ensuring effective and harmonised implementation of both Regulations. This harmonised approach to implementation is further set out in the Commission's MDR/IVDR Implementation Rolling Plan. The plan identifies the essential implementing acts, actions and guidance which needs to be developed by the Commission and/or MDCG during the transitional period. This plan is updated quarterly and provides information on the expected timelines for implementation as well as an update on the state-of-play. This rolling plan should be read in conjunction with the CAMD's MDR/IVDR Roadmap.

Examples of the guidance developed to date are Listed in Table 2. Further information can be found on the Commission website.

Table 2

Topic	Publication Title
UDI	- *MDCG guiding principles for issuing entities rules on basic UDI-DI;* - *Guidance on basic UDI-DI and changes to UDI-DI;* - *UDI assignment to medical device software.*
Eudamed	- *Timelines for registration of device data elements in EUDAMED;* - *Registration of legacy devices in EUDAMED.*
Notified Bodies	- *Best practice guidance on designation and notification of conformity assess-ment bodies;* - *Guidance on content of the certificates, voluntary certificate transfers;* - *Best practice guidance on the information required for personnel involved in conformity assessment*
Vigilance	- *New MIR form published in January 2019. Following a one year transition pe-riod the form will become mandatory on 1st January 2020.*

6 MDR Article 105, IVDR Article 99

Stakeholder Participation

As part of the MDCG's terms of references stakeholders such as organisations representing the medical device industry, healthcare professionals, patients and consumers, notified bodies and laboratories at a European level may attend MDCG meetings as an observer and may take part in the discussions.

The MDCG also holds a number of Stakeholder Days the most recent took place on 14th February 2019 in Brussels.

The MDCG meets on a regular basis. The most recent meeting took place on 9th & 10th April. Minutes of the MDCG meetings are published on the Register of the Commission Expert Groups – which is a website available to the public.

New EU Working Groups

The MDCG has 11 working groups listed below. The Working Groups are composed of representatives of competent authorities who are experts in the particular policy area. The HPRA will participate in each of these groups.

MDCG Working Group Structure:

1. Notified Body Oversight (NBO) - Provides assistance to the MDCG on issues related to notified bodies designation and conformity assessments. The group aims to be effective and consistent in the application and implementation of the new Regulations. In addition, this group prepares draft best practice documents and template forms relating to designating authorities and notified body activities.
2. Standards Working Group - Provides assistant to the MDCG in relation to the standardisation in the medical devices field of the new IVDR and MDR. In particular, the group addresses any issues such as safety issues identified in harmonisation standards and proposes solutions. In addition, the group supports establishing a coordinated and more effective cooperation with the European and international standardisation organisations, in particular in the context of the International Medical Device Regulators Forum (IMDRF). It contributes to the development of proposals for standardisation requests to the European Standardisation Organisations.
3. Clinical Investigation and Evaluation (CIE) - Provides assistance to the MDCG on issues relating to clinical investigations and evaluations of medical devices under the new Regulation. This group develops guidance document which are presented to the MDCG for endorsement.
4. Post-Market Surveillance and Vigilance (PMSV) - Provides assistance to the MDCG on issues related to post market surveillance, which include incident reporting and vigilance. This group coordinates the vigilance activities of Member State using various systems and tools, for example, the group has a forum for sharing suspected safety signals and trends which have been detected. Guidance documents drafted by the group are presented to the MDCG for endorsement.
5. Market Surveillance - Assists the MDCG developing a coordinated approach to market surveillance activities. This coordination includes development and maintenance of the framework for the European market surveillance programme. In addition, this group assists in analysing the application and implementation of the general safety and performance requirements of the Regulations as well as the general obligations of the economic operators with regards to products that do not require notified body oversight.
6. Borderline & Classification - This group advises the MDCG on issues relating to the qualification and classification of a product as a medical device, as products without an intended medical purpose in accordance with Annex XVI of the MDR or as an IVD under the new EU Regulations. The group provides a forum for competent authorities to exchange of information and coordinate national practices regarding the qualification and classification of medical devices.
7. New Technologies - Assists the MDCG on issues that relate to the new and emerging forms of technologies such as cyber security, software and apps. This group provides solutions and recommendations in accordance with the MDR and IVDR.
8. Unique Device Identifier (UDI) - Assists the MDCG on all the issues related to the introduction and operation of the unique identification system. Provides advice on all matters related to device identification and traceability, for example the implementation of relevant provisions of MDR implant cards.
9. International Matters - Monitors international trends on any medical device issues. The group also coordinates the development of common positions of EU Member States on harmonised topics for discussion within the International Medical Devices Regulators Forum (IMDRF). Recommendations from the other working groups are considered when developing EU positions.
10. *In-Vitro* Diagnostics (IVDs) - Provides assistance to the MDCG on all IVD specific issues. In particular, the group develops and promotes homogenous application and implementation of the new Regulation.

Further information

If you have any questions about the regulation of medical devices, or queries about any particular products, please e-mail devices@hpra.ie.

Further information is also available on our website: www.hpra.ie. Information on the Regulations is also published on the EU Commissions website.

HPRA
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Health Products Regulatory Authority

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