While the results of the UK’s General Election have significantly increased the likelihood of a Withdrawal Agreement and resulting Transition Period, until a Withdrawal Agreement is agreed the HPRA is continuing to plan for a potential no-deal scenario and the impact this will have on the Medtech sector in Ireland. While the likelihood of a Transition Period is acknowledged, the UK will leave the European Union on January 31st with the Transition Period likely to end on 31st December 2020, therefore companies should ensure that they address any outstanding regulatory issues as soon as possible.

In accordance with the European Commission guidance document published in September, in the event of a no-deal scenario medical devices must be compliant with EU legislation by 31st January. Non-compliant devices after the withdrawal date cannot be placed on the EU-27 market. The HPRA has prepared a Brexit Preparedness Checklist as a quick-reference guide to assist economic operators prepare for Brexit.

We recommend that in order to ensure regulatory compliance, manufacturers plan for the following scenarios:

- Manufacturers with devices certified by UK notified bodies are encouraged to continue to work with EU-27 notified bodies to ensure devices are certified by a European notified body by 31st January;
- Manufacturers located in the UK and existing third country manufacturers, are required to designate an EU authorised representative in an EU-27 Member State in order to remain compliant with EU legislation;
- Authorised representatives for third country manufacturers located in the UK are required to establish in an EU-27 Member State in order to continue to place medical devices on the EU27 market;

1 The European Commission considers the current extension to the withdrawal date as sufficient time to achieve regulatory compliance and does not plan to adopt any further contingency measures.
Practical steps for manufacturers and authorised representatives located in Ireland

- Ensure you are registered with the HPRA as a Medical Device Economic Operator in Ireland. Please note that annual fees in accordance with SI 208/2018 are applicable to Economic Operators in Ireland. This SI is reviewed annually and is subject to a stakeholder consultation.

- Ensure you have registered your devices on the HPRA Medical Devices Extranet. The HPRA kindly requests that all devices (all IVDs and all classes of medical devices) impacted by Brexit are registered on our Extranet. This will greatly assist with device traceability and oversight during the transition process. Please note authorised representatives must register their organisation and are responsible for registering devices on behalf of the third country manufacturer.

- Ensure device labels are updated to include the details of the new EU-27 notified body or the authorised representative by 31st January. The HPRA acknowledges manufacturers are facing challenges in meeting this deadline. Should a manufacturer identify that it is not possible to update all device labels within this timeframe a labelling transition plan (.docx/PDF) should be submitted to the HPRA. The plan should provide a priority listing of device labels and documents requiring updates, a proposed timeframe for the completion of the label changes and a justification for the timeframe. In addition, the plan should specify how any complaints or incidents will be managed during the transition. The HPRA will review the plans submitted on a case-by-case basis.

Information for Distributors

In the event of a no-deal Brexit, commercial entities that currently operate as ‘distributors’ may become ‘importers’ if they are sourcing medical devices from the UK to be placed on the EU market. The HPRA encourages all distributors to assess their supply routes to determine whether their status will be affected after 31st January.

Where a distributor becomes an importer they will need to ensure they have the correct customs documentation in place to minimise potential delays at customs. For some entities this will mean additional documentation as well as additional tariffs depending on the medical device. The Revenue website have a number of useful resources as well as a Brexit checklist which may aid your Brexit preparations.

The HPRA will update the Medical Devices Brexit webpage as further information and guidance becomes available.

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. Audits, inspections and the issuance of certificates of free sale relating to medical devices will remain in the Compliance Department. We are delighted to announce that the new structure is now live. As outlined in the organogram in figure 1, the new department consists of three sections: Assessment & Surveillance, Regulatory & Policy and Clinical. A summary of the responsibilities of each section can be found below.

Assessment & Surveillance is responsible for both the vigilance and market surveillance activities relating to devices. To facilitate HPRAs oversight of the growing Medtech sector in Ireland devices have been

2 European Commission Q&A document, February 2019
categorised into three technology groups. Tech Group A has a focus on electronics, software and physics, while tech group B and C have a focus on mechanical engineering and materials respectively.

In addition, a specific IVD group has been created to support this growing sector, particularly during the implementation of new IVD Regulation in advance of the May 2022 application date.

A dedicated Notified Body team has also been created within the Assessment & Surveillance Section and is responsible for notified body designation and oversight to ensure the HPRA has the resource and expertise to fulfil our role as the Authority Responsible for Notified Bodies in Ireland.

The newly created Regulatory & Policy Section consists of three teams; Market Analysis, Communication & Policy and Regulatory Support.

Market Analysis is our data driven section. From tracking registration of different economic operators and investigating emerging technology trends, to analysing evolving safety issues and trends, the focus of this team is descriptive and analytical statistics. This will be achieved through the development of the systems and processes within the department. Market analysis ensures we capture metrics that will assist and support the identification of emerging or potential safety concerns and will assist with informing the focus of the organisation’s proactive surveillance activities.

The Communication & Policy team is primarily responsible for policy development both internally within the HPRA and also supports the Department of Health to inform national policy in line with new legislative developments such as the new Medical Devices Regulations. In addition, this team assists in department coordination, enhancing stakeholder engagement and medical devices communication initiatives.

The Regulatory Support team assist the work of all sections across the department and are the main contact point for stakeholder queries. The team has a key role in the management of registrations and our databases, and additionally provide support on our market surveillance operations.

The Clinical Section is responsible for clinical investigations for medical devices as well as performance studies for IVDs. They are also largely involved in compassionate use applications, inspections, incident management and assessment of applications and reports pertaining to clinical investigations. The clinical team work closely with the HPRAs innovation office and compliance department, in addition to other teams and sections within the medical device department.

Through this new restructure the HPRA will be better positioned to support our stakeholders throughout the medical device lifecycle, while maintaining a focus on public health and patient safety.

The HPRA would like to thank our stakeholders for their cooperation during this process, and we look forward to working closely with all of our stakeholders over the coming years to ensure safe devices are available to patients on the EU and Irish markets.

Figure 1
IPPOSI is the Irish Platform for Patient Organisations, Science & Industry. It is an organisation that advocates that well informed patients and carers have a key role to play in the design and implementation of patient-centred health research. Patients also have valuable contributions for future research, regulatory and ethical approval processes in Ireland. Over the past number of years, the HPRA has been involved in IPPOSI’s Patient Education Programme in Health Innovation. This education programme was conceived through IPPOSI’s experience within European Patients’ Academy on Therapeutic Innovation (EUPATI). The programme was developed in partnership with the University College Dublin Clinical Research Centre (UCD CRC), The Health Products Regulatory Authority (HPRA) and The Discipline of Pharmacology & Therapeutics, Trinity College Dublin, in association with the National Centre for Pharmaco-economics (NCPE) and the Health Information & Quality Authority (HIQA), and has had a strong focus on medicinal product regulations.

This year as part of the programme the HPRA introduced a medical device module. The module included six online lessons which detailed the medical device regulatory framework and the role of the HPRA as Competent Authority for medical devices in Ireland.

The module included a face-to-face workshop where specific aspects of the regulatory framework were discussed. The head of the Medical Device Department, Niall MacAleenan, provided an overview of the regulatory framework. A multi-disciplinary team from across the medical devices department facilitated workshop discussions on pre-market clinical investigations and post market surveillance. Our guest speaker Damien Kenny, a paediatric interventional cardiologist, from the Our Lady’s Hospital Crumlin, shared his experience of working within the medical devices regulatory framework, his interactions with the HPRA from a clinical perspective and the resulting positive impact on patients.

Throughout the sessions the important role that patients and patient associations play was highlighted, and the HPRA received very positive feedback from both the attendees and IPPOSI. The HPRA greatly values the opportunity of being involved in this initiative; it provides an opportunity for us to increase awareness amongst patient and patient advocates of the organisation and mechanisms to engage with the regulatory network and provide valuable input to its development. The programme also helped inform and develop our engagement with stakeholders, helping us obtain an understanding of what patient groups may perceive as the role of the regulator. These efforts should help understand the medical device regulatory framework and build trust and confidence in the regulatory system for medical devices.

Further information on IPPOSI and the Patient Education Programme in Health Innovation can be found on the IPPOSI website.
The Organisation for Professionals in Regulatory Affairs (TOPRA) held its annual symposium from the 30th of September to the 2nd of October at the Clayton Hotel in Dublin. The event attracted representatives from many European regulatory agencies as well as delegates from industry, healthcare, notified bodies, patient groups, and the media.

Two days were dedicated to medical device regulation, during which representatives from the HPRA played a central part in panel discussions and presentations. The Head of the Medical Devices Department, Niall MacAleenan, spoke on the forthcoming MDR/IVDR from the perspective of a competent authority (CA), with focus also on clinical evidence of medical devices and market surveillance. The EU Commission provided an update on implementation status and there were dedicated sessions on IVDR preparedness covering IVD clinical evidence, Notified Body designations and the HPRA perspective on IVDR implementation. A Brexit discussion panel concluded the event, where the importance of no-deal preparations was highlighted given the many uncertainties. Representatives from the HPRA were present to answer queries at our stand, and were actively engaged with attendees throughout the symposium. Information packs on the upcoming EUDR legislative changes and our Brexit Preparedness Checklist were in high demand, and are available online.

Colleagues from a range of backgrounds also presented on similar topics, and brought valued insight from the European Commission, European Medicines Agency, industry and healthcare.

The HPRA are delighted to have been able to contribute to this year’s TOPRA symposium. Our participation reflects our commitment to engage with our stakeholders and colleagues across Europe, to ensure industry are informed on implementation needs and developments.

On the 13th of November the HPRA’s Health Products Distributions Department (HPD) hosted a distributors information day on MDR, which was supported by the medical devices department. The principle aim of this meeting was to provide distributors with information on forthcoming inspections, provide information on the medical device regulatory systems, and address the concerns of this key stakeholder group.

The Medical Device’s Deputy Director opened the morning providing an introductory presentation on medical devices, after which the event was moderated and co-ordinated by the HPRA’s HPD Manager who was on board to help address questions in relation to inspection processes. Other topics presented on the day included an overview of the regulations, outlining the various steps that the distributors should be taking in order to be compliant with MDR before May 2020.

One of the HPRA’s HPD Inspectors presented on the distribution of medical devices and the inspection process, with reference to recent pilot inspections. Presentations included an overview of key obligations and considerations for distributors and a status update on implementation of the EU Device Regulations. The medical device assessment and surveillance manager closed off the session by presenting on post-market requirements. This included the responsibilities of a distributor with respect to reporting issues or incidents and timeframe for reporting these events.

There were many questions raised and active discussion around some of the more operational considerations in the supply chain. We would like to thank all the attendees for their active participation and the positive feedback submitted.
The European database on medical devices (EUDAMED) is intended to improve the transparency and coordination of information of medical devices on the European market. It will contain different modules on actors, UDI and devices, notified bodies and certificates, vigilance, clinical investigations, performance studies and market surveillance.

In October, the Commission concluded that it will only be possible to make EUDAMED operational once the entire system and its different modules have achieved full functionality and have been subjected to an independent audit.

As stated in a recent open letter to the Commission, the CAMD are offering its support to find legal, effective and operational solutions which are executable for all member states. As a member state and part of both the CAMD and the MDCG, we are working with our EU colleagues to identify solutions and monitor the progression of the MDR implementation.

While the transition provisions provide for such a delay, there remains some uncertainty around the impact such a delay will have on the provisions that are contingent on EUDAMED being in place. The EUDAMED delay will not impact the date of application of the MDR, providing guidance and ensuring an EU approach as an interim solution in the absence of EUDAMED is a key priority of the member states and the Commission. HPRA will continue to be engaged in these discussions and will provide further updates as they become clear. We expect further developments in this area as priority in the short term.

The Clinical Investigation and Evaluation Working Group (CIEWG) finalised a guide for manufacturers and notified bodies concerning the summary of safety and clinical performance (SSCP).

The SSCP is intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of implantable and Class III medical devices. The SSCP will be an important source of information for intended users of medical devices – both healthcare professionals and where relevant, for patients. The SSCP will be written by the manufacturer, validated by the notified body and published on the EUDAMED database which is under development.

This work was led by Sweden and Denmark and is the first guidance document published by the CIEWG for the Medical Device Regulation 2017/745. It is hoped that by providing an objective, public summary of clinical data for the first time, that the SSCP will support the goal of improving transparency as part of the revised regulatory framework.

The MDCG working groups are continuing to develop guidance in accordance with their individual work plans. The latest publications on guidance are available from the EU Commission’s webpage:

Recent guidance includes:
- Application of transitional provisions concerning validity of certificates issued in accordance to the directives.
- Qualification and classification of software.
- Person Responsible for Regulatory Compliance’ (PRRC)

In addition, the EU Commission has launched a communication campaign at the link below:

A number of factsheets have been developed to help key stakeholders understand the requirements for the new medical device and in vitro diagnostic regulations. In 2020, the HPRA will continue to work with our European colleagues to develop guidance related to both the MDR and IVDR.