

# HPRA MEDICAL DEVICES

## NEWSLETTER

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**46**

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## New Regulations on medical devices and *in-vitro* diagnostic medical devices agreed at European level



On 7th March 2017 the European Council adopted two new Regulations on medical devices and *in-vitro* diagnostic. In June 2016, these proposals were agreed at political level between the three relevant European institutions – the European Council, the European Parliament and the European Commission.

This political agreement reached during the Dutch Presidency of the European Council allows the law making process to enter its final phase with the formal adoption and publication of the Regulations in the *Official Journal of the European Union* (OJ). The HPRA anticipates that this publication will occur during quarter 2 of 2017, probably in April. The legal texts enter into force 20 days after publication in the OJ with a staggered transition period with some aspects

becoming legally binding after 6 months and full application of the Regulation on medical devices after 3 years and full application of the Regulation on *in-vitro* diagnostics after 5 years. The legislation now being in the form of a Regulation, rather than a Directive, means that the EU law is directly applicable at national level without requiring transposition through specific national legislation. This should allow for greater legal certainty and prevent variation in the approach taken or in the rules that are applied across EU Member States.



(pictured) The European Council Working Party on Pharmaceuticals and Medical Devices who achieved political agreement on the Regulations with the European Commission and Parliament during the Dutch Presidency of the European Union in June 2016.

The Regulations represent a significant development in the existing European regulatory system for medical devices. The original Directives having now been in place for over 25 years have been successful in regulating a vast array of medical device products. However, the legislation required significant update to account for increasing numbers and complexity of medical device technologies. In addition, the level of detail and definition of requirements within the existing Directives needed to be increased to ensure a consistent approach is taken across Europe to applying the legal requirements effectively.

The two new Regulations which will each comprise over 400 pages of legal text provide much greater clarity and definition of the requirements, procedures and systems involved in the regulatory framework for medical devices. Nevertheless, the key principles of the regulatory framework remain the same but have been significantly evolved to add clarity, definition, strengthened legal provisions, enhanced assessment procedures and to account for the exponential growth in medical device technologies.

The new Regulations will provide a secure, consistent regulatory framework which will enhance public health across Europe by ensuring that medical devices available on the market are safe, perform and afford benefits to the public, to patients and to healthcare systems. The new Regulations will also help to encourage

the innovation and development of new medical technologies which will allow patients and healthcare users access to new state of the art diagnostic and therapeutic alternatives. The Regulations will help ensure that new products are subject to robust controls during their development, are allowed access to the market at the right time. The new Regulations will allow for appropriate monitoring on an ongoing basis to detect any safety or performance issues. This regulatory system therefore also brings benefit to innovators of new devices and medical device manufacturers by providing a secure, consistent environment that fosters scientific development of new and innovative technologies. In Europe, the medical technologies sector year after year has the highest level of new product innovation based on the numbers of patent applications filed at EU level and it is anticipated that the new Regulations will further this.

The new Regulations have taken a long time to negotiate and agree at European level. These Regulations were proposed by the European Commission and published in September 2012 and through the course of the negotiations have been developed and amended significantly by the European Council and European Parliament. Throughout the negotiations the HPRA has provided significant levels of support to the Department of Health (DoH) as the national policy maker on medical devices. This included providing support throughout the Irish Presidency of the European Council back in

2013. The HPRA represented the Irish position along with the DoH at the European Council's Working Party on Pharmaceuticals and Medical Devices which met almost 100 times over the four and a half years of negotiation. The time taken reflects the level of complexity, the technical nature of the Regulations and also the importance placed upon the sector by the European institutions.

Over the last number of months as the texts are finalised and are translated into all European languages the HPRA has been conducting detailed planning for implementation of the new Regulations at national level. The HPRA also has been working closely with other European authorities and the European Commission as part of an implementation taskforce established by the Competent Authorities for Medical Devices (CAMD) network. This taskforce's objective is: to identify priorities for implementation at European and national level; to coordinate on implementation and avoid duplication; to provide a forum for developing a common understanding and consistent approach to implementation across Europe and to provide a platform for engagement and dialogue with relevant stakeholders on implementation. The HPRA hope that our participation in this work will help to ensure an effective, consistent and timely implementation across Europe. The HPRA is also a member of the Executive of the CAMD. Further details of the CAMD can be found at [www.camd-europe.eu](http://www.camd-europe.eu).



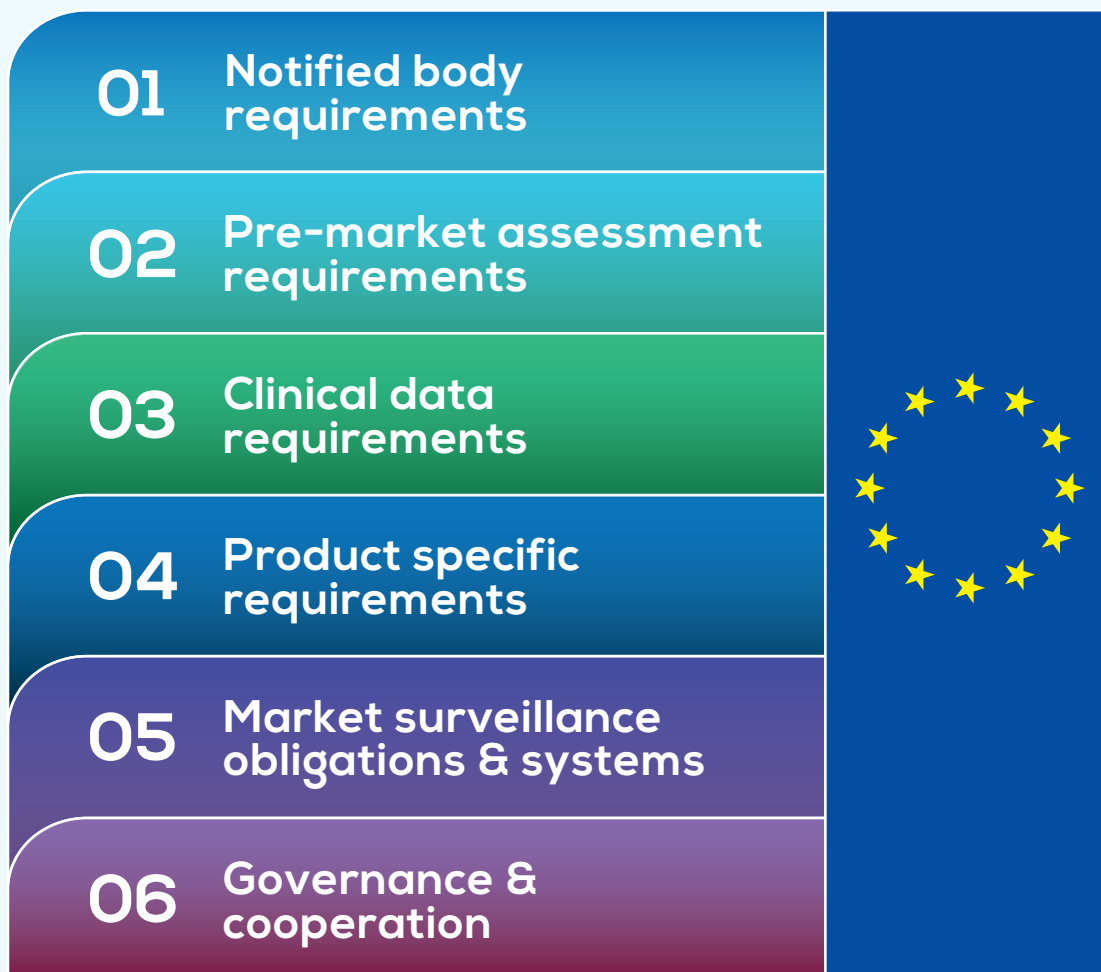
# Key aspects of the new Regulations on medical devices and *in-vitro* diagnostics

The new Regulations on medical devices and *in-vitro* diagnostics represent a significant, development and strengthening of the existing regulatory system for medical devices in Europe. The existing principles and fundamental components of the regulatory system are retained but each element is strengthened and better defined in these two new Regulations. These improvements are made based

on experience of implementing the existing Directives since the mid-1990s and to address identified gaps or weaknesses in the existing system in light of technological and regulatory developments in the medical technology sector. The Regulations have also been developed in line with experience of implementing the EU Commission's 2012 Joint Plan for immediate action on medical devices,

which has resulted in a step-change improvement in the EU regulatory system for devices.

The HPRA believe that these improvements will allow for an effective, consistent and robust regulatory framework for medical devices across Europe and will afford the public appropriate levels of health protection to safe and effective medical devices.



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Each of the foundations of the system have been significantly strengthened:

### **1. Improved performance of notified bodies for medical devices**

The new Regulations significantly increases the definition and clarity in the requirements that a certification organisation must have to become a notified body for medical devices. The Regulations also build on experience of the EU joint assessment scheme for designation of notified bodies which provides for an independent EU level assessment of candidate notified bodies. The new Regulations also place very specific obligations on national authorities to continue to monitor the performance of notified bodies based in their territory on an ongoing basis. These elements make the requirements and standards for notified bodies more consistent and will help ensure that their ongoing oversight by authorities is effective. This will lead to further improvements in the consistency, transparency and performance of notified bodies across the EU.

### **2. Clearer requirements for clinical data on medical devices and its assessment**

The new Regulations increase clarity on the requirements for clinical data for medical devices, in particular those of the highest risk and improves the mechanisms for the assessment of clinical data throughout the lifecycle of a medical device. The requirements for clinical studies (investigations) of medical devices are significantly enhanced and include many specific provisions to ensure that people enrolled in clinical studies are appropriately protected. Further and increased emphasis is put in place on the need to gather and evaluate clinical data to demonstrate the safety and performance of a medical device on an ongoing basis. Increased clarity is added about how clinical data from predicate or equivalent devices can be used as part of clinical dossiers. In addition, across the Regulations a huge amount more clinical data will be available on medical devices to the public and to healthcare professionals. These Regulations

will drive improvements in both the quantity and quality of clinical data available for medical devices.

### **3. More specific product requirements**

The new Regulations place greater emphasis and increase the possibilities to develop specific criteria and specifications for high risk medical devices. This may be of particular relevance in defining clinical data criteria and specifications to ascertain the performance and safety of a medical device. Clarifying the requirements for medical devices, in addition to existing technical standards, will afford better protection to public health and help ensure medical devices available are safe and effective. Clarity in the requirements and expectations will also allow for a great deal more consistency and predictability in the assessment of medical devices which results in a fairer, more secure system for manufacturers and device innovators.

### **4. Improved pre-market assessment of high risk devices**

The new Regulations provides for additional pre-market scrutiny of the highest risk medical devices by an independent expert panel operating on behalf of the European regulatory system. These devices can also be selected for review based on specific clinical concerns or emerging safety issues with similar devices. The independent panels who will complete these assessments will also be available to provide advice to manufacturers and innovators on the requirements for their device early in the development process.

In addition, the provisions relating to the routine assessment of medical devices by notified bodies are clarified and in particular in relation to their assessment of clinical data presented to demonstrate the safety and performance of a device.

### **5. Enhanced provisions for market surveillance**

The new Regulations further define and develop the requirements for the continued surveillance of

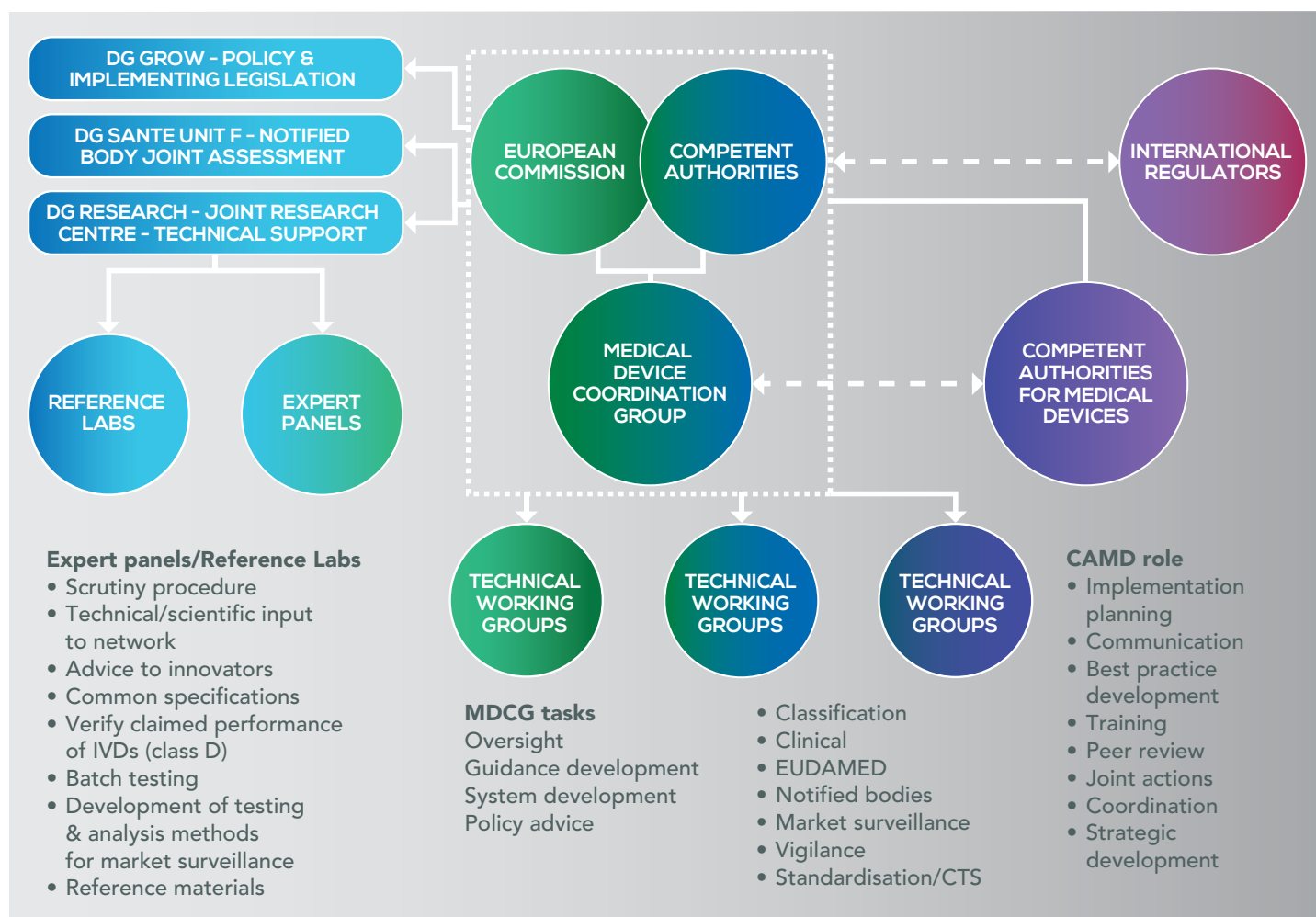
medical devices on the market place both by manufacturers and by regulatory authorities. Manufacturer's obligations in relation to operating effective post-market surveillance of their medical devices are greatly clarified as is the need to continuously update risk analysis and clinical documents. The Regulations place specific obligations on regulatory authorities in relation to ensure effective market surveillance systems are in place at national and European level. This includes increased assessment of compliance of devices, increased provisions for sampling and testing of devices and greater legal powers to address non-compliant products.

In addition, the new Regulations increase the definitions and provisions relating to the reporting and assessment of adverse incidents (vigilance). Additional reporting obligations are defined for manufacturers of high risk devices including the compilation of Periodic Safety Update Reports (PSURs). Specific obligations are placed on authorities regarding the assessment and coordination of vigilance issues.

### **6. Governance, coordination and cooperation**

To help achieve all of these improvements and ensure an effective regulatory system is implemented, the Regulations have specific requirements and structures defined to provide for governance and coordination of the system. Throughout the Regulations the national authorities are required to work closely together in a coordinated fashion and in conjunction with the European Commission. The European Commission's role and functions in coordinating the system has also been significantly enhanced with obligations for the provision of administrative, scientific and technical coordination of the system. The HPRA anticipate that this will include support from the policy unit in DG Grow D4, DG Santé Unit F (Food and Veterinary Organisation) and the DG Joint Research Centre.





Graphic: Potential EU governance model for device regulation as per new Regulations (©HPRA)

In addition to the improvement across these range of fundamental aspects of the regulatory system for devices other significant developments and improvements have been made, including but not limited to:

- **Requirements for every economic operator** involved in the medical device sector are clearly defined. The new Regulations place very specific obligations on operators throughout the supply chain, including distributors and importers, of a medical device to help ensure that products placed on the EU market are compliant and that any issues are addressed as effectively as possible. Increased information will be available about economic operators to identify their role in the supply chain. A detailed series of specific obligations and requirements are defined for medical device manufacturers including an overview of the components to include in their obligatory quality system.
- The new Regulations require that each device must have a **unique identifier**. This will allow for clear information on all of the devices available on the European market place and the ability to identify all of the manufacturers and other economic operators responsible for them. These details will be contained within a centralised European database which the public and healthcare professionals will also be able to access information on. These requirements will also enhance the traceability of devices in the event that a device needs to be modified or recalled from the market.
- The new Regulations will also have a **broader scope** and include more products which have previously not been regulated as medical devices. In particular, the legislation will regulate invasive and **implanted devices used for aesthetic** and cosmetic purposes such as dermal fillers and coloured contact lenses.

The aim of the legislation is to try to ensure these devices are as safe as possible and that people are aware of the risks associated with using such devices.

The **Regulation on *in-vitro* diagnostic (IVD)** devices has many Regulation on medical devices but system changes and other IVD specific changes will have important implications and changes for that product sector. These include, but are not limited to:

- **Classification system** – the IVD Regulation introduces a rules-based classification system for IVDs. IVDs will now be classified into four different classes based on risk from class A (low) to class D (high). This will mean that regulation and assessment for each class of device can be tailored accordingly.

- **Changes to conformity assessment procedures** – IVDs will now be subject to conformity assessment based on the classification of the device. Classes B-D IVDs will all require assessment and certification by a notified body for medical devices (appropriately designated for IVDs) prior to being placed on the market. This represents a significant change in the system today where many IVDs are self-declared devices rather than being assessed by a notified body.
- **Performance evaluation and clinical data requirements** – the requirements for performance evaluation of IVDs are defined in much greater detail in the new Regulations. Specific requirements are also defined in relation to the use of clinical data for IVDs and the conduct of clinical performance studies.
- **Changes to requirements for in house manufacturing of IVDs** – under the existing legislation IVDs which are manufactured within a healthcare institution and for use within that health institution are exempted from the Directive. Such tests may be developed due to the lack of a commercially available alternative e.g. for rare diseases. The new Regulation will place specific requirements on 'in-house' IVDs and the healthcare institutions which manufacture them.

## HPRA information day on medical devices – November 2016



Pictured: Medical Devices Information Day, 18th November 2016.

On 18th November 2016, the HPRA hosted an information day on medical devices for medical device manufacturers based in Ireland. The day provided the HPRA with an opportunity to provide an overview of the anticipated requirements in the new EU Regulations and to highlight the expected implications that these will have for medical device manufacturers.

Throughout the next number of years the HPRA will arrange a series of information forums and workshops to communicate the new Regulations and

their implications to targeted groups of stakeholders. This 2016 information day was seen as the first of those events.

The day was over-subscribed with over 200 people securing places to attend. The meeting was opened officially by Minister Corcoran-Kennedy, the Minister of State for Health Promotion at the DoH who spoke about the importance of medical devices and the Regulations for Ireland. The meeting also was addressed by MEP Mairead McGuinness, Vice-President of the

European Parliament who played a leading role in the discussions of these Regulations at the Parliament. Lorraine Nolan, Chief Executive of the HPRA provided an overview of the implications of the new Regulations on the authority's activities and its strategic development. Overview presentations were then made by the HPRA and by a representative from industry to headline the key changes in the new Regulations and provide advice on how to plan and prepare for their implementation.



John Brennan (Director Regulations & Industrial Policy, Medtech Europe) and Wilf Higgins (ACMD Chair, HPRA Board Member) at the HPRA's medical device information day 2016



Pictured (L to R): MEP Mairead McGuinness (MEP Ireland Midlands/ Northwest. Vice President of the European Parliament), Minister Corcoran-Kennedy (Minister for Health Promotion, Department of Health) and Lorraine Nolan (Chief Executive, HPRA).

In the sessions that followed, the HPRA devices team provided detailed information on various specific aspects of the new legislation in particular highlighting: responsibilities for economic operators, changes to conformity assessment & classification, post-market surveillance & vigilance requirements and market surveillance by authorities.

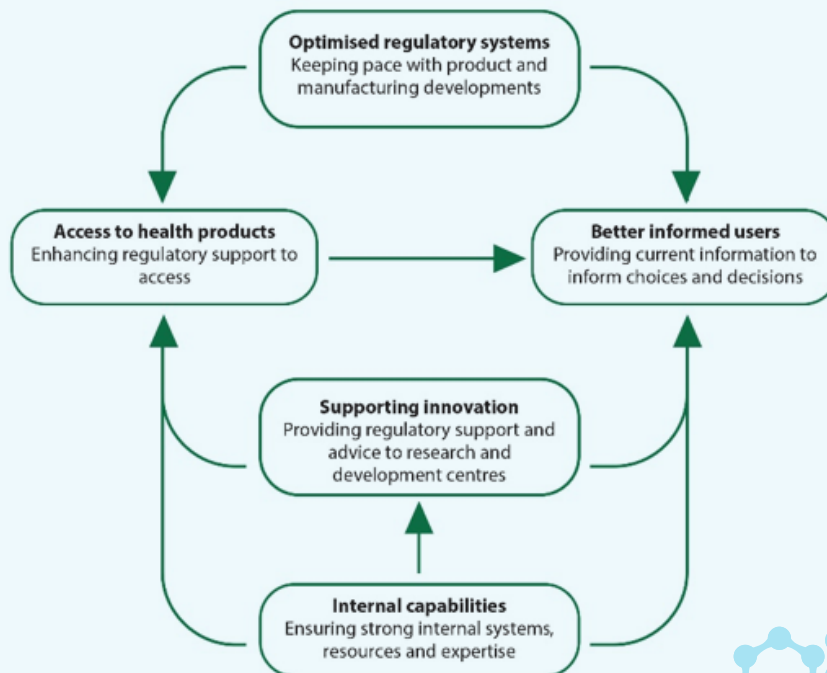
Specific presentations were made on unique device identification (UDI) and on the proposed European database on medical devices by invited speakers

Dr. Andy Crosbie (Medicines and Healthcare products Regulatory Agency, UK) and Dr. Matthias Neumann (Federal Ministry for Health, Germany).

In the afternoon, parallel sessions were held to provide detailed information on the Regulations new requirements was for clinical data and for *in-vitro* diagnostic devices.

This information the starting point in the HPRA's communication of the new EU Regulations on medical devices. It allowed an opportunity

for presentation of the anticipated content of the Regulations rather than detailed information and guidance on implementation. To support the implementation over the next number of years the HPRA intends to hold a series of targeted information sessions and workshops to ensure the new regulatory requirements are clearly communicated and implemented effectively.



Graphic: HPRA strategic plan 2016-2020



# Medical device fees

From January 1, 2017 the HPRA will introduce fees at national level to cover the cost of all of its medical device regulatory activities in accordance with SI 602 of 2016.

Previously the HPRA has been funded directly from the exchequer apart from some transaction based fees associated directly with a specific service, for example applications for clinical investigations, requests for classification, designation as notified bodies, registration of self-declared medical devices and issuance of certificates of free sale.

However, the primary activities conducted by the HPRA arise from market surveillance and vigilance activities which are a central component of our functions and responsibilities and cannot be readily

linked to a specific transaction. To be effective, market surveillance involves the monitoring of the safety and performance of a medical device on the market place throughout its lifecycle. Robust market surveillance is fundamental to the medical devices regulatory system and is essential to ensure that public health is protected across Europe. In addition, surveillance enables an environment for safe and timely innovation and market access for new technologies and a secure marketplace in which companies can flourish without exposure to unfair competition from disreputable or poorly regulated companies and notified bodies.

The new EU Regulations on medical devices makes specific provision for Member States to levy fees at national

level on the basis of full cost recovery for all of the activities associated with the regulation of medical devices. The Commission will require that Member States inform them of fees to be introduced and make the structure and level publicly available on request.

The HPRA has engaged in dialogue with affected stakeholders over the last number of years, in particular the medical device industry both at national and European level. This resulted in the HPRA's consultation on medical device fees in 2015 which informed the final model proposed to the Department of Health. The HPRA has committed to review medical devices fees on an ongoing basis as part of our annual fee consultation. Full details can be found on our website.

## Transitioning to the new legislation

The new Regulations on medical devices will result in significant improvements and developments of the regulatory system for medical devices and *in-vitro* diagnostic devices. Nevertheless the Regulations are highly complex and require a transition period to be implemented fully by manufacturers, notified bodies, regulatory authorities and all of the other operators affected by them.

The HPRA anticipate that the Regulations will be formally adopted and published in April 2017. The Regulations will enter into force 20 days after this publication, likely sometime in May 2017. To allow time for transition to the new requirements the Regulations will become fully applicable over a period of 3 years for

the Medical Device Regulation and 5 years for the IVD Regulation. This means that the Regulations will not be fully legally binding until 2020 and 2022 respectively.

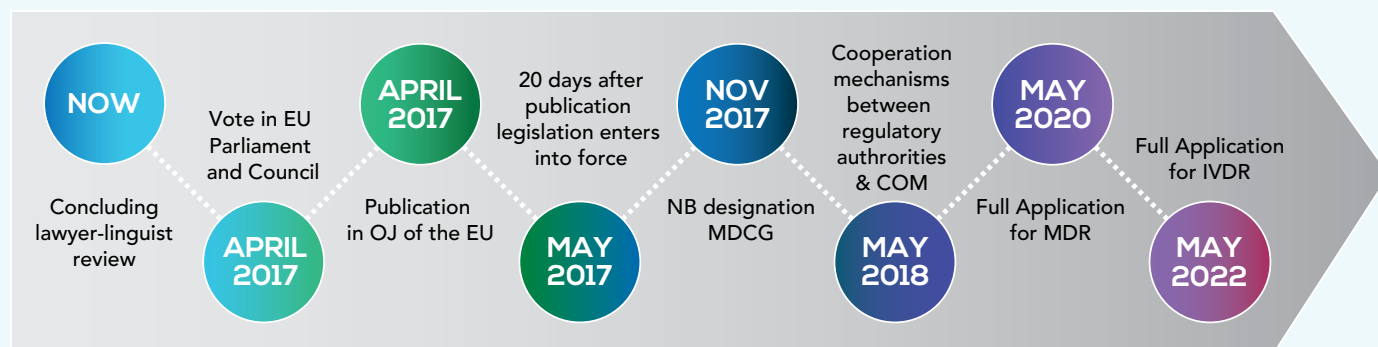
The transition period envisaged is staggered so this means that some provisions become fully applicable and legally binding over the 3-5 year transition periods envisaged. For instance, the requirements for designation of notified bodies for medical devices become applicable 6 months after entry into force, which means based on the above timeline that they will be binding from November 2017. Notified bodies when designated to the new legislation, may issue certificates to the new Regulations before 2020 if

a manufacturer requests them to do so and the notified body is satisfied that the devices comply with the new requirements.

It is critical that notified bodies, manufacturers and other economic operators relevant to medical devices are aware of the new EU Regulations. Start now, if you haven't already, to plan for this to ensure that your product complies with the new Requirements in time. While the two Regulations will not be fully applicable until 2020 and 2022 respectively there will be a significant lead time required to ensure that procedures, systems, documentation and products are all developed appropriately to ensure that they comply with the new requirements.



## Transitioning to the new legislation



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**OJ** Official Journal of the European Union  
**NB** Notified body

**MDCG** Medical Device Coordination Group  
**COM** European Commission

**MDR** Medical Device Regulation  
**IVDR** In-vitro Diagnostic Regulation

The HPRA are in the process of drafting a detailed implementation plan for the two Regulations. We will continue to work closely with the DoH to ensure that the Regulations are implemented effectively and that the legal, resource and system requirements are all put in place at national level. A central component to this implementation

plan is on the HPRA's engagement with relevant stakeholders to clearly communicate the requirements of these new Regulations and ensure they are correctly understood and implemented on time. The HPRA is committed to working closely with affected stakeholders on implementation and will continue

our regular dialogue with the industry and trade associations in Ireland.

The HPRA welcome questions and are happy to discuss the new requirements. Further information on implementation of the new Regulations for medical devices can be found on the HPRA website [www.hpra.ie](http://www.hpra.ie).

## New Innovation Office and Innovation Day to support the development of novel health products and technologies



The HPRA has recently established an innovation office to foster and support innovation in the life sciences sector.

The goal of the HPRA's Innovation Office is to provide regulatory advice and assistance to those developing novel health products or technologies. Ensuring that regulatory factors are considered early in the development process will help to ensure that innovators have a clear understanding of the regulatory pathway that would apply to their novel products of

technologies and support a timely trajectory from product concept to market access and through to patient use.

Ireland is ranked as the seventh most innovative economy globally. This HPRA initiative will add to a number of existing programmes and supports already in place at a national level to further develop our world leading position. As part of its activities to support innovation, the HPRA has commenced an outreach programme

with higher education institutes and research centres, and a horizon scanning group has been established within the HPRA to ensure that the HPRA's knowledge base keeps pace with life sciences innovation worldwide.

The Innovation Office will be focused on directly assisting innovators to understand and comply with EU and national regulations when developing novel health products or new approaches for manufacturing or testing of such products. It will be of

interest to those involved in the early development of innovative health products or technologies and queries can be submitted in respect of initial research and design, formulation, testing, clinical studies or manufacture. The Innovation Office will be a dedicated centre providing individuals, academics, SMEs, medical device and pharmaceutical companies, and other groups with an initial point of contact and access to regulatory information and advice.

A confidential online query service is available and will be managed by a team of experienced regulatory experts. Those who require regulatory support or further information should use the [online enquiry form](#) or e-mail the Innovation Office at [innovationoffice@hpra.ie](mailto:innovationoffice@hpra.ie). The HPRA

has also developed a [dedicated section on its website](#) and published an [information leaflet](#) with details of the support and advice that is available through the Innovation Office.

#### ***HPRA Innovation Day***

Following on from the successful launch of the innovation office, the HPRA will host an innovation day on Thursday 25th May in the O'Reilly Hall in UCD.

The objective of this event is to create awareness of the support and guidance offered by the HPRA and others to facilitate innovation within the health products sector. Anyone who is involved in or considering developing an innovative health product or technology is invited to attend.

The agenda for the day will include include an overview of the recently established HPRA innovation office and other HPRA initiatives to support innovation for medical devices and other types of health products and activities within the HPRA's remit. The agenda will also include speakers from other organisations who promote innovation and presentations from innovators who have experience in developing novel health products. The event will provide an excellent opportunity for networking and information sharing.

Further information in relation to the HPRA Innovation Day including details on how to register for the day are available on the [HPRA website](#).

