In this Issue

Section 1 - Process Development
- Notified Body designation 2
- New Device Legislation and Aesthetic Products 3
- Vigilance Reporting 4

Section 2 - Guidance
- HPRA Guidance on standalone software and apps for manufacturers and users 4
- Distributors 5

Section 3 - EU Cooperation
- CAMD Implementation Taskforce- Roadmap 5
- CAMD Transitional Sub Group 7
- EU Meeting Updates 7
- HPRA Information Day 2018 9
- Further information 9

HPRA Industry Survey: Impact of Brexit on the Medtech sector in Ireland

As the negotiations for the UK to leave the European Union continue, the HPRA is asking economic operators to share their views on the potential impact of Brexit on the Medtech sector in Ireland and particularly on the supply chain. A priority for the HPRA, working with all stakeholders, is to ensure the availability and continued uninterrupted supply of critical use medical devices and in vitro diagnostic medical devices in Ireland. The survey can be accessed through the HPRA website.

HPRA Medical Devices Information Day
in Galway on 23 May 2018

Visit the HPRA website to register.
Please see full details on page 9.
SECTION 1 - PROCESS DEVELOPMENTS

“Notified Body Designation – The Process is Underway”

The two new EU Device Regulations1 (EUDR) entered into force in May 2017 and the first significant milestone in the transition to the new regulations was reached with commencement of the designation process for conformity assessment bodies under the new EUDR across Europe.

Now that the designation process is underway, designating authorities, such as the HPRA in Ireland, are progressing applications through the established process which is outlined on the EU Commission website.

The HPRA has been preparing for this new process and continues to provide updates, guidance and support as all stakeholders engage in this effort to enhance the European notified body system. Guidance on the application process is also available on the HPRA website.

The joint assessment of notified bodies was introduced in response to the PIP breast implant crises and was made mandatory through Implementing Regulation 920/2013. This process has been responsible for the significant improvement in the standard of notified bodies across Europe and the process has been incorporated in the new EUDR ensuring further enhancement, consistency and transparency in the performance of notified bodies.

Implementing Regulation 920/2013 did not directly address in vitro diagnostic (IVD) medical devices and therefore notified bodies certifying IVDs will need to apply for designation in accordance with the IVDR, the scope of which has increased due to the new risk based classification rules and new conformity assessment procedures mandated within the regulation.

For this reason the most significant impact of the new EUDR is in the IVD sector where now 80% of IVDs will require oversight by a notified body. The transition period of five years for the IVDR was agreed based on these substantive changes to the IVD regulatory requirements.

The first on-site assessments of applicants are scheduled for later this year. The Commission in conjunction with the Medical Device Coordination Group (MDCG) will appoint joint assessment teams comprising of experts from the Commission and Member States. The final designation decision of the National Designating Authority is made subject to the outcome of the on-site assessment and satisfactory corrections of non-conformities identified throughout the designation process. The timeline for the designation decision will be dependent on how long it takes the applicant to address any non-conformities and for consensus to be reached by all involved parties of the assessment team.

It is envisaged that from the point of application to the point of designation, the process will take a minimum of 18 months. Updates regarding the progress of applicants should be requested directly from the conformity assessment bodies involved. The HPRA encourages manufacturers to engage with existing notified bodies regarding the transition process to the new Regulations to ensure certifications can be maintained for current CE marked devices and to ensure that the notified body system in general has sufficient capacity to account for any increased certification demands going forward given the transition timelines involved.

Further information and guidance on the new EUDR is available through the HPRA website. The EU Commission website and the NBOG website also publishes the latest European guidance information being developed through the European network.

For any prospective conformity assessment bodies who wish to apply to the HPRA for designation, all details regarding the application process and associated documents are also included through our website.

Any questions regarding the notified body designation processes can be addressed to us through our email devices@hpra.ie

---

1 Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices
New Device Legislation and Aesthetic Products

The new EUDR has a broader scope that the current Directives and will cover groups of products frequently used for aesthetic purposes which may not have a medical purpose. The aim of the legislation is to try to ensure these products are as safe as possible within their intended use and ensure that the risks associated with using such products are addressed.

These groups of products are similar to medical devices in terms of functionality and risk profile. Examples of aesthetic products that will be within the scope of the medical devices regulation are listed below.

<table>
<thead>
<tr>
<th>Table 1: Examples of aesthetic products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liposuction equipment</td>
</tr>
<tr>
<td>Coloured contact lenses</td>
</tr>
<tr>
<td>Dermal fillers</td>
</tr>
<tr>
<td>Collagen implants</td>
</tr>
<tr>
<td>Laser hair removal equipment</td>
</tr>
<tr>
<td>Skin resurfacing equipment</td>
</tr>
<tr>
<td>Tattoo removal equipment</td>
</tr>
</tbody>
</table>

Note: tattooing and piercing products are excluded from the list

Six groups of aesthetic products have been identified and are listed in Annex XVI of the MDR. The European Commission may amend this list to include additional groups of devices when it is deemed necessary to protect the health and safety of product users or other persons. A justification for the inclusion of new aesthetic products shall take into consideration the similarities between a device with an intended medical purpose placed on the market and a product without an intended medical purpose in respect of their characteristics and risks.

It is important that economic operators and beauty professionals are familiar with the six groups of products that will fall under the MDR and any new responsibilities they may need to fulfil under the new Regulation. For example, if you are sourcing a product online from outside the European Union you could be taking on the role of the importer and will be subject to the legal obligations for importers that are set out in the MDR.

The Commission is currently drafting the necessary technical and/or clinical requirements that provide a means of complying with the legal obligations applicable to a device. These requirements are known as Common Specifications (CS) and examine the application of risk management and where necessary clinical evaluation regarding safety, which should be adopted before May 2020.

The MDR requirements regarding the reporting of incidents will also apply to Annex XVI products. Customers should be advised to report any incidents or problems relating to the use of an aesthetic product or concerns regarding the safety of the product to the Competent Authority (e.g. the HPRA) and to the manufacturer of the product. Customers should also report the problem to their healthcare provider. Suspected incidents or complaints may also be reported to the importer or the distributor of a product. This information is then shared with the product manufacturer.

Any incident which has occurred during use of the product which might lead to or might have led to an impact on health of the user or others should be reported directly to the manufacturer. Under the MDR manufacturers are required to establish and maintain a post market surveillance and vigilance system. As part of this system there is a requirement to report serious incidents to the Competent Authority (e.g. the HPRA.)

To assist in a smooth transition to the new requirements of the MDR, a three year transitional period was agreed. This means the MDR will be fully applicable by May 2020. The requirements of the MDR will only apply to aesthetic products once the Commission has adopted the necessary Common Specifications (CS). For example, manufacturers of the six groups of aesthetic products will have to demonstrate the conformity of these products and these products will have to bear a CE mark. Where a product may have both a medical and non-medical intended purpose it should fulfil both the requirements applicable to devices with, and to devices without, an intended medical purpose.

---

Vigilance Reporting

The new Regulations set out specific requirements for manufacturers to establish and maintain a post market surveillance and vigilance system. As part of their system there is a requirement to report serious incidents and Field Safety Corrective Actions to the relevant Competent Authority (the HPRA in Ireland) through the centralised database. As a general rule, the time period for reporting shall take account of the severity of the incident (See figure below). It is important to note that the time frame for reporting serious incidents has been reduced compared to that specified in the European Commission guidelines on a medical devices vigilance system. If after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, the manufacturer should submit a report within the timeframes required as set out in the figure below. Medical device users are also encouraged to report incidents. Suspected incidents or complaints may also be reported to the importer or the distributor of the device. This information shall be shared with the manufacturer of the device.

Time frames for reporting serious incidents

- **Serious incidents**
  - Immediately after the manufacturer has established a reasonably possible causal relationship.
  - Not later than 15 days after awareness of the serious incident

- **Unanticipated serious deterioration in state of health**
  - Immediately after establishing or suspecting a causal relationship between device / serious incident
  - Not later than 10 days after date of awareness of the serious incident

- **Serious Public Health Threat**
  - Immediately but not later than 2 days after awareness of this threat


SECTION 2- GUIDANCE

HPRA Guidance on standalone software and apps for manufacturers and users

Standalone software including apps play an important role in the delivery of healthcare. For example, they may be used to control or monitor the performance of medical devices remotely, for patient management activities, or as an aid for treatment planning. Advances in mobile technology in recent years, such as smart phones and tablets, have seen a large increase in the use of mobile applications both within healthcare facilities, community settings and in patients’ homes.

Standalone software including apps may be considered a medical device in its own right when it is intended for a medical purpose that meets the definition of a medical device, as defined in S.I. No. 252 of 1994. Depending on the specific intended purpose, standalone software may qualify as an IVD medical device or an AIMD, in which case S.I. No. 304 of 2001 or S.I. No 253 of 1994 apply respectively.
Not all standalone software used in healthcare are medical devices. For example, apps for general health and wellbeing that record lifestyle habits such as smoking and exercise are generally not considered as medical devices.

The HPRA works to ensure that only medical devices, including standalone software and apps, that are compliant with the relevant legislation can be placed on the Irish and European market. In June 2017 the HPRA issued a “Guide to Placing Medical Device Standalone Software on the Market”. The purpose of this document is to provide a general overview of the regulatory process involved in placing a medical device on the market for manufacturers and to provide additional guidance that is specifically relevant to standalone software.

The HPRA has also published an Information Notice for Mobile Applications in Healthcare that have a medical purpose to highlight the requirements of such apps under the relevant medical device legislation. Both of these publications can be found under ‘Standalone software and applications’ in the medical devices section of the HPRA website. As the use of medical device standalone software and mobile apps in healthcare continues to develop the HPRA may publish further guidance in this area.

HPRA Guide for Distributors of Medical Devices

Following a consultation period with Industry, the HPRA ‘Guide for Distributors of Medical Devices’ has been published. The guidance document outlines the obligations for distributors as specified in Regulation (EU) 2017/745 on medical devices (MDR) and Regulation 2017/746 on in vitro diagnostic devices (IVDR). The document also provides supplementary guidance that can be used by distributors to achieve compliance with the requirements of the Regulations. The MDR and IVDR have staggered transitional periods and the obligations for distributors of medical devices will apply from May 2020 for the MDR and from May 2022 for the IVDR. Distributors should perform a gap analysis of their current systems against the requirements of the Regulations. They should ascertain what processes or systems need to be modified to meet their obligations and commence a project plan to ensure compliance by May 2020 or May 2022 as applicable. The Guidance document can be found on our website. Queries relating to the guidance document can be sent to compliance@hpра.ie.

SECTION 3 - EU COOPERATION

CAMD Implementation Taskforce

The importance of a consistent and harmonised approach in interpretation of the Regulations across the European network is key to ensuring an effective implementation of the regulations and in securing confidence in the regulatory framework. To coincide with the adoption of the two new EU Device Regulations (EUDR), the Competent Authorities for Medical Devices (CAMD) Executive Group recommended the establishment of an implementation taskforce to facilitate collaboration and cooperation within the medical devices network during the implementation phase of the new Regulations.

The taskforce was established in early 2017 in preparation for adoption of the new EUDRs and initial membership included representatives from Austria, Belgium, France, Germany, The Netherlands, Sweden, Switzerland, UK and Ireland and the Commission. The Phase I objectives of the taskforce were to:
- help identify key issues that require clarification between authorities to ensure a uniform interpretation of the requirements and expectations of key provisions;
- help identify key issues that require clarification for all stakeholder groups to ensure consistency in the application of the regulations;
- help identify the need for guidance for stakeholder groups in terms of the interpretations of the relevant provisions; and
- optimise resources, minimise duplication of work across the network, cooperate and collaborate in the implementation phase in reaching consensus, drafting guidance and developing processes between authorities and stakeholders.
In delivering on the taskforce objectives a number of workshops were held at the CAMD meetings in Amsterdam in June 2016 and in Bratislava in October 2016. These workshops helped identify the key implementation challenges for each technical work stream identified. As an output from that exercise, the CAMD implementation taskforce has developed a priority listing to help identify the key issues to be addressed and a recommendation on where it may best be addressed as part of the implementation phase. Following the workshops these priorities were circulated for initial endorsement by the whole CAMD network, and the Working Group Chairs, which will be responsible for meeting several of these priorities. Following CAMD endorsement, the taskforce, in collaboration with the Commission, initiated a formal engagement exercise with European stakeholders with the aim of using the priorities as the basis for the development of a single European ‘roadmap’ for implementation. The feedback from stakeholders has been integrated into the roadmap and represents a collaborative needs analysis for effective implementation.

The roadmap is now publicly available on the CAMD website www.camd-europe.eu and will be updated regularly as implementation progresses. There are currently eight technical areas or work streams where priorities are identified for implementation as follows:
- Clinical Evaluation and Investigation/
  Performance Evaluation and Performance Studies
- Scope and Classification
- Notified Bodies and Conformity Assessment
- Post-Market Surveillance and Vigilance
- Eudamed and UDI
- Market Surveillance
- IVD Specific Issues
- Over-arching issues

Recommendations identifying where the work may best fit are made within the roadmap and it will be up to each working group to map out the project plan and timeframes to deliver on the items listed. Stakeholders will be involved and kept updated on the progress of work items identified through the working groups and also through ongoing engagement with the Commission and CAMD.

The taskforce membership has grown since its establishment to also include representatives from Denmark, Greece, Italy, Spain and Slovenia. The implementation taskforce has received a mandate from the CAMD network to continue to Phase II and is tasked with ongoing maintenance of the roadmap, to establish a facilitative liaison role with the working groups and to communicate with the authorities and stakeholders on the challenges, experience and best practise for implementation.

---

**Eight work streams for implementation**

<table>
<thead>
<tr>
<th></th>
<th>Clinical evaluation &amp; investigation (MD); Performance evaluation &amp; Performance studies (IVD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Scope &amp; Classification</td>
</tr>
<tr>
<td>2</td>
<td>Notified Bodies &amp; Conformity Assessment</td>
</tr>
<tr>
<td>3</td>
<td>Post-market surveillance &amp; vigilance for MD &amp; IVD</td>
</tr>
<tr>
<td>4</td>
<td>Eudamed &amp; UDI</td>
</tr>
<tr>
<td>5</td>
<td>Market surveillance</td>
</tr>
<tr>
<td>6</td>
<td>IVD specific issues</td>
</tr>
<tr>
<td>7</td>
<td>Over-arching issues</td>
</tr>
</tbody>
</table>

---

CAMD members in Tallinn, November 2017
Following the entry into force of the new medical device Regulations in May 2017 the CAMD established a new Sub Group. This Sub Group provides competent authorities with a platform to identify and discuss any potential inconsistency in the interpretation and application of the new Regulations specifically focussing on the transition-related provisions, such as certificate validity and derogations to timelines set out in both the MDR and IVDR.

The TSG has issued recommendations on the interpretation of these transitional provisions and derogations in the form of a FAQ document. Both the MDR and IVDR FAQ documents have been published on the CAMD website. Both documents will be updated continuously throughout the implementation process.

**EU Meeting Updates**

**IVD Technical group (IVTDG)**

The current focus of the IVDTG is on the key changes introduced by the IVD Regulation, IVDR (2017/746) published in May 2017. There is a 5 year transition period for IVDs with full application by 2022.

A subgroup of the IVD Technical group (IVDTG) has been established to develop guidance on the classification of in-vitro diagnostic medical devices under Regulation 2017/746/EU. The group is led by the French Competent Authority ANSM with participation from Ireland, Switzerland, Austria, Croatia, Belgium, the Netherlands, Finland and UK. Notified Bodies, Industry and the European Commission are also represented on the group. Under the IVDR, the classification system has changed significantly from what is currently in place under the IVD Directive (98/79/EC). Annex VIII of the IVDR outlines a risk based rules system for IVDs resulting in four new risk classes; Class D (highest risk) to Class A (lowest risk). It is anticipated that the guidance will be available later this year.

Discussions are also ongoing regarding the requirements for IVDs under the IVDR. The HPRA is represented from both the CIE WG and IVDTG perspectives in this subgroup.

During 2017 the IVDTG also provided input to the development of designation codes for Notified Bodies which were required to be in place in advance of 26th November 2017 to allow for designation of notified bodies under the IVDR. Approximately 80-90% of IVDs will be subject to review by a Notified Body to some degree for the conformity assessment process under the IVDR. This has a significant impact on the workload for Notified Bodies involved in the conformity assessment of IVDs.

The expansion of the scope of the IVDR to include genetic tests and companion diagnostics also presents certain challenges and the need for guidance in particular for companion diagnostics has been identified as another priority for the group. Work has also commenced on the designation of EU Reference Laboratories (EURLs) under the IVDR.

**Clinical Investigation and Evaluation Working Group (CIEWG)**

The CIEWG meeting took place over two days in Brussels on the 9th and 10th November 2017. This meeting of CIEWG focussed on the work programme and priorities for the CIEWG, especially in light of the publication of the Medical Device Regulation 745/2017 (MDR).

The focus of the CIEWG meeting was the clinical aspects of the MDR and the Competent Authority for Medical Devices (CAMD) Groups implementation roadmap for the MDR.

As an outcome of this meeting, a number of subgroups involving competent authorities and stakeholders have been formed. The focus of these subgroups will be:

1. A clinical subgroup which will focus on developing guidance relating to equivalence, sufficient clinical data and legacy products.
2. Summary of safety and clinical performance (SSCP) guidance.
3. A subgroup to work on the clinical aspects of the MDR Eudamed database and developing a number of templates, detailed in the MDR.

The CIEWG has also established a joint taskforce with the IVD Technical Group to work together to develop guidance relevant to the In Vitro Diagnostic Regulation 746/2017. Terms of reference for each of these activities, including deliverables and timelines have been developed by agreement and consensus.

An update from the Eudamed working group chair was given and the input needed from the CIEWG was outlined in terms of developing priorities and the functional specifications of the database.

The European Society of Cardiology presented a case concerning clinical data collected from a compassionate
use programme, which appeared to be used to support conformity assessment. The approach of European Competent Authorities to compassionate use applications and initiatives to achieve greater collaboration were also discussed.

MEDDEV 2.7/1 revision 4 and the application of this guidance was discussed. The Commission made it clear that revision 4 of this guidance is the current gold standard. A full gap analysis between MDR and revision 4 is not needed at present. However certain aspects such as equivalence and sufficient clinical evidence, as relevant to the MDR, will be further described in supplementary guidance.

The CIEWG has also established a teleconference for Competent Authorities to discuss clinical investigation applications. A pilot initiative was agreed to be very helpful to Authorities and it was agreed amongst the CIEWG Authority members that it would take place on a monthly basis going forward. The aim of this teleconference is to discuss issues relating to clinical investigations, however in light of the need for greater communication with respect to MDR implementation, this will also be facilitated by regular updates to the CIE teleconference.

MDEG Vigilance

Two meetings of the MD Expert Group on Vigilance were held since the last ACMG meeting. Both meetings were held in Brussels, one on the 20th and 21st March 2017 and the second on the 6th and 7th November 2017. The first day of both meetings involved a closed session attended by Member States and the European Commission with the second day of the meeting also attended by representatives of the medical devices industry.

A significant focus of the work of MD Expert Group on Vigilance over the past year has been on the development of the Manufacturers Incident Report (MIR) form. This work is very close to completion, the final draft document was agreed during the groups meeting in early November 2017 has since been endorsed by MDCG. Work will now commence on the development of IT processes to support the use of the form.

In parallel to this, representatives from the vigilance working group have been activity involved in the IMDRF working group that have been developing adverse event terminology and coding. Two sets of codes; device problem codes and investigation codes have been developed to date. These codes have been integrated in to the new MIR form.

Progress has also been made on a number of Device Specific Guidance for vigilance reporting, breast implants, cardiac implantable electronic devices and insulin infusion devices documents. It is anticipated that advance drafts will be presented at the next meeting.

Work has commenced on the next revision of the MEDDEV 2.12.1 (current rev 8). The next revision will include the outputs from the trending taskforce, the coordination taskforce (chaired by IE) and the taskforce looking at the Field Safety Notice template. An initial draft has been prepared and will be discussed in further detail at the next meeting when it is anticipated that the work on the FSN template will be complete. In parallel, a taskforce, chaired by IE, focused on developing a guideline to outline the roles, responsibilities, composition and activities of vigilance taskforces further clarified the scope of its work.

A group composed of competent authorities has been set up to examine the industry proposal to develop a standard Periodic Summary Report spreadsheet for the reporting of multiple incidents. It is envisaged that the group will have an advanced template and a reporting mechanism/ system proposal ready for the next 2018 meeting.

Work has continued on the examination of the Periodic Safety Update Reports requirement as outlined in the Medical Device Regulation. A working group composed of competent authorities and industry are currently developing a guidance document in advance of developing a template. When the work has progressed further, before finalising the guidance document, the group will consult with the other relevant groups involved in market surveillance.

The working group have also considered the vigilance requirements of EUDAMED in the context of the Medical Device Regulation and the corresponding nomenclatures/coding that will assist going forward.

The topic of trending and signal detection of vigilance data has been discussed on several occasions. The JRC provided feedback on the recent Signal Detection Meeting that they held in ISPRA. National experiences of trending vigilance data were shared and potential data quality issues were examined. Member States were encouraged to start considering the topic and the requirements. It was noted that the requirements would be very important in the development of EUDAMED.

Updates were provided on the IMDRF NCAR Exchange. Member States were encouraged to engage in the NCAR exchange programme.

COEN Working Group

The COEN WG met in April and October 2017. In the April meeting the group discussed the proposed changes to the procedure for use of the COEN2 form amongst member states such that COEN2 forms shall only be sent to affected member states. There was general consensus to this approach that will be incorporated to the procedure for COENs that is to be drafted and distributed by the Chair. The role of the COEN WG under the MDR/IVDR was also briefly discussed. The Chair gave a presentation on the outcome of Joint action project on reprocessing of reusable medical devices (JA2014) that was completed in early 2017. Further discussions will occur to look at a coordinated approach for follow up on non-compliant manufacturers. Developments in the area of harmonised standards were discussed.

At the COEN WG meeting in October 2017 discussions were focused on preparing for work items relevant to the implementation of the new legislation, and closer cooperation between MS in the areas of market surveillance plans and with the MDCG and other working groups.
HPRA Information Day 2018

An information day on medical devices and in vitro diagnostic medical devices will be hosted by the Health Products Regulatory Authority (HPRA) on the 23rd May 2018 in the Galmont Hotel (formerly the Radisson Blu) in Galway. The objective of the day will be to provide an overview of the implications and interpretation of the new EU device regulations for manufacturers and other economic operators.

Further details on the agenda and registering for the event is available here. Any queries in relation to the event should be addressed to events@hpra.ie

Stakeholders attending the Information Day are invited to submit questions upon registration.

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 or eudr@hpra.ie

Stakeholders wishing to receive legislative updates including regular communication on the new Regulations can sign up by emailing eudr@hpra.ie

This is one in a series of information leaflets that you can get from the HPRA and from our website: www.hpra.ie.