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**Contacting the HPRA**
The vast majority of HPRA staff are currently working remotely. This is in line with Government advice aiming to slow down the spread of COVID-19. During this period, please correspond with us by e-mail using existing HPRA staff e-mail contacts or via the devices mailboxes:
- Medical Device Adverse Incident Reporting, information regarding serious risk, falsified devices and any issue regarding device safety: devicesafety@hpra.ie
- Medical Device Registration and other queries: devices@hpra.ie

**Brexit Preparations**

On Friday 31 January 2020, the UK left the European Union on the basis of the Withdrawal Agreement. As a result, the UK is no longer an EU Member State and is now considered a "third" country.

With the entry into force of the Withdrawal Agreement, negotiations are now focused on reaching an agreement on the future relations between both parties. These negotiations are taking place during the transition period, which is due to last until 31 December 2020. This transition period could have been extended for 12 or 24 months. The deadline to request an extension was 30 June. However, the UK did not request such an extension. During the transition period, not much has changed for the EU’s MedTech sector. The UK remains within the EU single market and customs union and all EU rules, policies and legislation currently still apply for the duration of the transition period. The UK is, however, no longer able to take part in EU Institutions’ discussions and decisions. This includes the work carried out by the working groups of the EU Medical Device Coordination Group.

The outcome of the ongoing negotiations between the EU and the UK will shape future relations and will help determine how medical devices in Britain and Northern Ireland are regulated.
This will also have an impact on economic operators based in the EU-27 who have close ties to these regions. While a number of rounds of negotiations have taken place, both face-to-face and virtually, significant divergences remain between both parties. In the absence of a deal on trade, the UK would fall back on basic World Trade Organisation (WTO) terms, which would mean that tariffs on goods and border checks would be introduced from 1 January 2021.

The Brexit trade negotiations have continued and both parties have indicated their intent to intensify talks over the coming weeks. Currently, October is viewed as the deadline to reach a deal to allow both parties to ratify the agreement before the end of the year.

The HPRA would encourage all stakeholders to be aware of the regulatory steps required to remain in compliance with EU medical device legislation and to be aware that steps similar to the Brexit no-deal planning may be required. Any manufacturer located in a third country is required to designate an EU-27 authorised representative. Authorised representatives must accept to undertake this role and act on behalf of the manufacturer, for example, when liaising with competent authorities. Manufacturers established in the UK will be required to designate an authorised representative in an EU-27 Member State if they wish to continue placing CE-marked medical devices on the EU market. Designated authorised representatives located in the UK will be required to relocate to an EU-27 Member State.

Economic operators, such as EU distributors, are also affected and may take on the obligations and responsibilities of an importer if bringing in devices from the UK. The HPRA is encouraging all Irish distributors to review their supply chain to assess if they now have additional regulatory responsibilities. To assist stakeholders with their planning, the HPRA has developed a Brexit Transition Period Checklist.

The Department of Business, Enterprise and Innovation also has a Brexit Preparedness checklist, which you can find here. We encourage all stakeholders to once again, prepare for the possibility of a no-deal and plan accordingly.

The European Commission has issued a number of stakeholder notices on how to prepare for the end of the transition period. This includes recently published notices on Trademarks and Design and Good Laboratory Practices. Both documents are available on the Commission website here. In addition to the publication of new guidance documents for stakeholders, the Commission has revised and consolidated the 2018 stakeholder notice and the 2019 FAQ document. The consolidated notice was published on 13 March and is available here. The Commission has also published a specific Communication on readiness at the end of the transition period. The HPRA would encourage all stakeholders to become familiar with this Communication.

COVID-19 Updates

IVD Testing

The HPRA Call to Stakeholders

Stakeholders (manufacturers, distributors, commercial entities) are asked not to supply IVD tests for Covid-19 to the Irish market that are not in line with the national testing strategy.

As the regulator for medical devices and in vitro diagnostic medical devices (IVDs) in Ireland, the HPRA is a member of the National Public Health Emergency Team (NPHET) which co-ordinates the management of and response to COVID-19 in Ireland.

COVID-19 – Risks of Testing Outside the National Testing Strategy

The HPRA is aware of several commercial tests for COVID-19 on offer in Ireland. The HPRA is concerned that these tests are not in line with the national testing strategy. The HPRA is asking suppliers and manufacturers not to supply COVID-19 tests that are not in line with the national testing strategy, in particular any lateral flow antibody tests.

Lateral Flow Antibody Tests

Further to the publication of the HIQA HTA report, a NPHET subgroup on Diagnostic Testing Approaches was established and this group has issued a Strategic Framework Document. It includes the following recommendation (#8) to restrict these tests to research only:

NPHET has noted and accepts the recommendation from the WHO that the use of point-of-care (POC)/near patient lateral flow immunassays (LFIA) or immunochromatographic antibody tests (ICT) is currently not recommended in any setting other than for research. Evidence supporting their use for specific indications is required before any further recommendation can be made. In the interim, use of these tests may undermine the public health response to COVID-19.

In due course, the national testing strategy may change. Any future changes to the national testing strategy as directed by NPHET will also be communicated to healthcare professionals, members of the public and industry stakeholders.
Like most in the medical device sector, notified bodies had to alter their plans and operations when international restrictions on the movement of people and social distancing measures were introduced in March. May 2020 was going to be a significant milestone for many in the sector, particularly notified bodies who had achieved designation and notification to the new Medical Device Regulation (MDR). However, with the decision to defer the full application of the MDR until 26 May 2021, notified bodies can now dedicate time and resources to the COVID-19 health crisis.

Notified bodies assess the conformity of higher-risk medical devices before they can be placed on the European market. The assessment procedure commonly involves a detailed review of relevant documentation and records that support the design, validation and clinical benefit of the medical devices. Such documentation is reviewed as part of a product file review. This acts as a component of the overall conformity assessment of the medical device. In addition, depending on the conformity assessment route selected by the manufacturer, it is very common for an on-site audit to take place at the manufacturer’s premises to allow the notified body to assess the quality management system under which the medical device is manufactured. These on-site audits became impossible to perform when international travel restrictions and social distancing requirements were implemented. In response to this, the European Commission and the Notified Body Operations (NBO) Working Group developed guidance and put allowances in place for notified bodies to perform remote audits so as to ensure an uninterrupted supply of safe and effective medical devices. Notified bodies and manufacturers had to adapt quickly to ensure appropriate ICT systems and logistics were in place to facilitate remote auditing. Remote audits have now become common across the notified body system in the continued management and oversight of medical devices that are placed on the market under the medical devices Directives.

Another outcome from the postponement of the MDR was the requirement for notified bodies to continue their operations under the Directives for a further 12 months. In instances where the notification and designation of notified bodies under the Medical Devices Directive 93/42/EEC (MDD) and the Active Implantable Medical Devices Directive 90/385/EEC (AIMD) expires prior to 26 May 2021, a re-designation is required to maintain the notified body’s ability to continue oversight of MDD and AIMD certificates. Currently, remote audits cannot be used for MDR/IVDR notified body designations.

On account of the travel restrictions, it was not considered feasible to arrange for joint assessments to be scheduled for re-designations, as required under Implementing Regulation 920/2013. As a result, a new Implementing Regulation was agreed to allow for this change in approach and supporting guidance was developed within the NBO working group.

Remote Inspections – Process Changes

In light of travel restrictions and the risk to public health posed by the COVID-19 pandemic, the HPRA has initiated a process to conduct inspections remotely.

The feasibility of conducting a remote inspection will be determined on a case-by-case basis. Manufacturers will be notified in advance of the remote inspection in the same manner as that which exists for an on-site inspection. The process will, in general, follow a similar format to that of an on-site inspection and will commence with an opening meeting and conclude with a closing meeting via teleconference or alternative communication platform. The communication platform will be particularly important to facilitate the smooth running of the inspection. Manufacturers will be requested to propose a suitable method of telecommunications, and this will be agreed with the Inspector in advance of the inspection.

The process will require electronic copies of documents and other information to be provided to the Inspector for review. Consideration should be given to the use of platforms that provide for live sharing of documents and videos, in addition to the use of cameras to allow for a virtual review of physical facilities and equipment, where applicable. To avoid delays during remote inspection, manufacturers will be requested to make certain documentation available before the inspection begins. This documentation will be specified in the notification of inspection sent to the company.

It will typically consist of electronic copies of quality system procedures and lists of quality records such as non-conformances, complaints, and change controls.

In certain circumstances, a remote inspection alone may not be sufficient to enable a decision to be made regarding the company’s level of compliance and a follow-up on-site inspection may be required when circumstances permit. If a follow-up on-site inspection is required, it will focus on areas of the site that could not be inspected remotely and/or areas requiring further follow-up resulting from the remote inspection.

Further information on the conduct of remote inspections of manufacturers may be requested from inspect@hpra.ie.
As we progress through the roadmap for reopening society and business during the COVID-19 pandemic, temperature measurement systems may be considered as one mitigation tool against the spread of the virus by identifying people who have elevated temperatures.

Routine temperature measurement of individuals plays a key role in healthcare. To account for this, a wide variety of temperature measurement devices are available on the market.

**Thermometers**

The mercury thermometer, which is no longer in use, is perhaps the most well-known of these devices. More advanced devices, such as digital and infrared thermometers, have become common-place in many homes and healthcare settings.

- Digital thermometers are placed in direct contact with the body (such as under the tongue, or in the ear) and use a sensor within the device to determine the temperature.
- Non-contact infrared thermometers are pointed at the body (usually the forehead), detect infrared radiation (heat energy) emitted from the body and correlate this with a temperature reading.

Thermometers typically qualify as medical devices in accordance with the Medical Device Directive 93/42/EEC (MDD). When the intended use is to directly diagnose or monitor a vital physiological process, i.e. a person’s temperature, in accordance with the classification rules, a thermometer is a Class IIa medical device. Please note a thermometer that does not make medical claims and is intended for non-medical purposes, such as use in manufacturing, cooking etc., does not qualify as a medical device.

Medical thermometers placed on the market or put into service in Ireland must fulfil the regulatory requirements outlined in the MDD. When purchasing a medical thermometer either for personal/professional use or for retail purposes, there are a number of factors to keep in mind. The HPRA’s Information Notice “Caution when Purchasing Thermometers” highlights key recommendations including the need to:

- Always ensure there is a CE mark accompanied by a four-digit notified body number visible on the device/packaging and instructions for use.
- Check that the manufacturer contact details are available on the device/packaging and instructions for use. Where the manufacturer is based outside of the EU, make sure there are contact details of a European-based point of contact, known as the authorised representative, visible on the device/packaging and instructions for use.
- Retailers purchasing thermometers should also request a copy of the Declaration of Conformity and Notified Body Certificate. These documents should be in the name of the manufacturer and reference the Medical Device Directive 93/42/EEC.
- Check the device information is supplied in the English language. Always purchase devices from a reputable source.

If these requirements are not met, the performance and safety of the thermometer cannot be guaranteed. Currently, there are a number of thermometers being recalled as they do not comply with the requirements mentioned above.

**Thermal Cameras**

Infrared technology also forms the basis of thermal cameras, which display an image of the surface and overlay colours to illustrate temperature differences.

Thermal cameras that are intended to be placed on the market to perform temperature readings on individuals or to perform a thermal screening for infectious disease also qualify as a Class IIa medical device and are required to fulfil regulatory requirements as detailed in the MDD.

Where a manufacturer places a thermal camera on the market without claiming an intended medical purpose or making medical claims, the product will not be classified as a medical device.

The HPRA has published guidance documentation for distributors of medical devices on our website. However, if you suspect that a medical device is non-compliant, report it to the HPRA by e-mailing devicesafety@hpra.ie
COVID-19 has placed unprecedented and unexpected pressures on economic operators, notified bodies, and competent authorities. On 17 April 2020, the European Parliament adopted the amending Regulation 2020/561, allowing for a 12-month deferral to the MDR. As a result, the MDR will become fully applicable from 26 May 2021. The introduction of this amending Regulation does not affect the provisions set out in the MDR, such as the timelines for including the UDI on the device labels or the transitional provisions set out in Article 120. This means devices with a MDD notified body certificate or Class I device up-classified under the MDR classification rules can continue to be placed on the market until 2024. The MDR vigilance reporting timelines, post-market surveillance requirements and registration requirements will apply to these devices from May 2021. In addition, the derogation allowing MDR compliant devices to be placed on the market before the date of application of the MDR will continue to apply.

The HPRA will continue to support our stakeholders with the implementation of the MDR and acknowledges the significant effort made by economic operators to be MDR compliant by 26 May 2020. Below is an update from the CIE Working Group and a list of recently published EU Guidance documents that can assist stakeholders with implementation.

**CIE Working Group Update**

The Clinical Investigation and Evaluation Working Group held a meeting on the 16-17 March 2020 by teleconference. A number of documents were finalised and endorsed by the Medical Device Co-ordination Group (MDCG), which are relevant to the implementation of the Medical Device Regulation. These include:

- A guidance and template on safety reporting in clinical investigations;
- Post-Market Clinical Follow-up (PMCF) plan and evaluation report templates;
- Guidance on sufficient clinical evidence for legacy devices;

The CIE Working Group is also working to finalise a template Clinical Evaluation Assessment Report (CEAR) template.
### EU MDR Guidance Published From March 2020

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All documents are available on the European Commission [webpage](https://www.europe.europa.eu).  

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### MDCG Guidance for Drug-Device Combinations

The European Commission’s Medical Device Coordination Group (MDCG) recently published a guidance document on transitional provisions for consultations on devices incorporating a substance which may be considered a medicinal product and which has an action ancillary to that of the device. This guidance also covers devices manufactured using transmissible spongiform encephalopathy (TSE) susceptible animal tissues. The guidance outlines the differences between Regulation 2017/745 on medical devices (MDR) and Directive 93/42/EC on medical devices (MDD), Directive 90/385/EEC on active implantable medical devices (AIMDD) and consultation requirements for devices transitioning from MDD to MDR.

In accordance with the MDR, medical devices incorporating an ancillary substance that could be considered a medicinal product should undergo a consultation by a medicinal products/medicines authority or the European Medicines Agency (EMA) using a similar process to that which is in place for the MDD and AIMDD. Some changes include a 210-day timeframe for the competent authority or the EMA to provide an opinion for initial consultations, a 60-day timeframe for supplementary consultations and the stipulation that notified bodies may not issue a certificate if the opinion is unfavourable.

Under an initial consultation, notified bodies must submit the full documentation to the medicinal products/medicines authority. This documentation should include the previous opinion for the ancillary substance and a consolidated list of changes. Notified bodies must also include a declaration stating whether there were changes made pertaining to the ancillary substance, the notified body's assessment of the product or whether only administrative changes were made.

This guidance also includes information on devices manufactured using TSE susceptible animal tissues. For devices incorporating these tissues, notified bodies must carry out a consultation via their competent authority with other competent authorities and the Commission. This requirement remains unchanged from the MDD.
Manufacturer Incident Report (MIR) Q&A

On 19 May 2020, the European Commission published a Q&A document regarding the implementation of the new Manufacturer Incident Report (MIR) Form. Use of the new MIR form has been mandatory since January 2020. The publication of this Q&A document is intended to help manufacturers adapt their IT systems by indicating the main changes introduced compared to the previous MIR form and by answering typical IT questions in the form of an Annex in the document. This is the first version of the Q&A document and it will be complemented in due course with further information relating to the transition to the MDR/IVDR Regulation and to the new EUDAMED database. The document can be found on the Commission’s website.

PSUR Guidance Document

In February, a workshop was held in Brussels with representatives from industry, Notified Bodies and competent authorities to advance the development of two documents: a PSUR Guidance Document and a PSUR Form Template for Manufacturer. A new structure for the document was agreed and drafting committees were established for each of the sections (see the table below). The HPRA is involved in the drafting of section one of part 1: Objective of the PSUR.

The draft documents have been progressed through a number of teleconferences. It is anticipated that the group may be able to advance the text further during another teleconference in advance of the meeting of the Post-Market Surveillance and Vigilance Working Group (PMSV WG) on 28-29 September. It is envisaged that agreement will be reached on the consolidated text of the guidance document at the PMSV WG.

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Additional Vigilance Updates

- **IMDRF Codes**
  - Published in June 2019 – 12 month transition June 2020. These codes are now mandatory.
- **Annex E Clinical signs, symptoms, and conditions and Health impact (Annex F)**
  - Published in April 2020 – 12 month transition April 2021
- **Annex G (component codes)**
  - Published on 20 April 2020. It will be mandatory for manufacturers to include these codes in MIRs following a 12 month transition period