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HPRA MEDICAL DEVICES
NEWSLETTER

ISSUE 54

In this Issue

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 the COVID-19 infection.

During this period, please correspond with us by email using existing HPRA staff email 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

IVDR TRANSITION AND IMPLEMENTATION

On 14 October the European Commission published a proposed amendment to the *In Vitro* Diagnostic Medical Device Regulation 2017/746 (IVDR) that would allow for a more staggered approach to implementing the requirements. This progressive roll-out of requirements recognises the unprecedented challenges of the COVID-19 pandemic, which diverted resources from competent authorities, health institutions and economic operators towards managing the crisis. In their press release, the European Commission also acknowledged the serious shortage of notified body capacity, which has hindered manufacturers in completing their conformity assessment procedures.

This proposal is still subject to change and has to complete several steps before it is adopted. The proposal includes delays to the implementation of requirements regarding in-house manufacturing, changes to the transitional provisions for IVDs certified to Directive 98/79/EC (IVDD), and a longer grace period for IVDD devices to continue to be made available on the market.

While the proposed amendment to the IVDR is welcomed, the HPRA encourages our stakeholders to continue increasing their efforts with IVDR preparedness and implementation activities. Stakeholders should note that the proposed amendment is subject to change, and must be approved by both the European Council and European Parliament in order to be adopted. Furthermore, the proposed amendment does not postpone the IVDR in its entirety. Requirements such as those related to post-market surveillance, market surveillance, vigilance and registration will continue to apply from 26 May 2022.

In preparing for the IVDR, stakeholders should avail of the resources and guidance documents which have been published by the MDCG and the HPRA. The MDCG has published a number of documents related to the IVDR in 2021, which includes explanatory notes on IVDR codes, guidance on Article 16, and a Q&A document on the requirements relating to notified bodies. In addition to contributing to this work, the HPRA has also published a Reference List for Class A Manufacturers to further enable IVDR preparedness.

The regulatory network has been working to support stakeholders in their IVDR implementation. While the current number of IVDR notified

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Health Products Regulatory Authority

bodies remains low, a number of entities are progressing towards notification. Stakeholders are encouraged to refer to the NANDO database to identify notified bodies with a scope for their IVDs. In addition, expert panels for IVDs have been accepting submissions from notified bodies since September and ongoing consultations under the performance evaluation consultation procedure can be viewed here. The European Commission's expert panels on medical devices and in vitro diagnostic devices have recently published their first scientific opinion. This represents a significant step in effective IVDR implementation.

The HPRA will continue to work with stakeholders and other Member States to ensure effective IVDR implementation.

COVID-19 AND ANTIGEN TESTS

Rapid antigen tests for the detection of COVID-19 are classified as *in vitro* diagnostic medical devices (IVDs). These tests analyse a sample *in vitro* (outside the body) for the presence of the virus (i.e. an antigen).

As the competent authority for medical devices, the Health Products Regulatory Authority (HPRA) is responsible for the regulation of rapid antigen tests in Ireland. Rapid antigen tests placed on the Irish or European market are expected to conform to the requirements of the European *In Vitro* Diagnostic Medical Devices Directive 98/79/EC, as amended (IVDD). The IVDD requires that devices perform safely while achieving the purpose intended by the manufacturer.

Rapid antigen tests differ depending on the intended purpose. The intended purpose can include factors such as the setting in which the device is used, the intended user, the technology, the sample type and any other specifications outlined by the manufacturer. Generally, rapid antigen tests are either intended by the manufacturer to be used;

- in a professional setting by competently trained professionals,

or

- in the home environment by lay persons, also referred to as devices for self-testing.

You should check the labelling and instructions for use to determine the intended purpose of a rapid antigen test. If the test is designed and marketed by the manufacturer for use by professionals, it is not intended to be sold to members of the public for self-testing purposes. Rapid antigen tests intended for self-testing are required to undergo an independent assessment by a notified body on the suitability of the device design and instructions for lay persons. For this reason, these devices are suitable to be sold to members of the public. While the HPRA is the authority responsible for notified bodies and the competent authority for medical devices, the HPRA does not approve or certify medical devices for sale.

There are a number of checks to determine whether or not a rapid antigen test appears to conform to the IVDD and can be placed on the Irish market. You should start by examining the device and its label for the following:

- Make sure the device bears a **CE mark**;
- If the device is intended for self-testing, that fact must be clearly stated either on the label or on the instructions for use;
- As well as the CE mark, self-test devices must also have a **four-digit notified body number displayed** close to the CE mark. Devices not intended for self-test have a CE mark with no number displayed;

CE 0000

Self-tests have a CE logo and 4-digit Notified Body Number

- Make sure the device information is provided in the **English language**;
- For retailers, including pharmacies, verify with your supplier that the device has a **valid declaration of conformity**;
- For retailers, including pharmacies in the case of self-tests, verify with your supplier that the device has a valid **EC design-examination certificate from an EU-27 entity**;
- Check that the **manufacturer's contact details** are visible on the device label and instructions for use;
- Where the device manufacturer is located outside of the EU (including the United Kingdom), check that the name and address of the **European point of contact, known as the authorised representative**, is visible on the label and instructions for use.

If you are concerned about the regulatory compliance or safety of a device, contact your supplier and the HPRA at devices@hpra.ie.

You should check the HSE website for the latest public health advice and instructional videos on the use of rapid antigen tests for COVID-19.

Once a rapid antigen test is in conformity with the IVDD and is CE marked, it can be freely placed on the market. There is no requirement for a distributor or importer to be authorised or licenced by the HPRA in order to sell rapid antigen tests. The current regulatory requirements for rapid antigen tests will be impacted by the new legislative framework for IVDs, which will be in place following implementation of Regulation 2017/746 on *In Vitro* Diagnostic Devices (IVDR) in May 2022.

Further resources

Information on requirements and limitations of *In-Vitro* Diagnostic (IVDs) tests for SARS-CoV-2/Covid-19, including a HPRA brochure on self-test products are available on the HPRA website.

A Q&A on conformity assessment and performance in the context of COVID-19 tests was published by the European Commission.

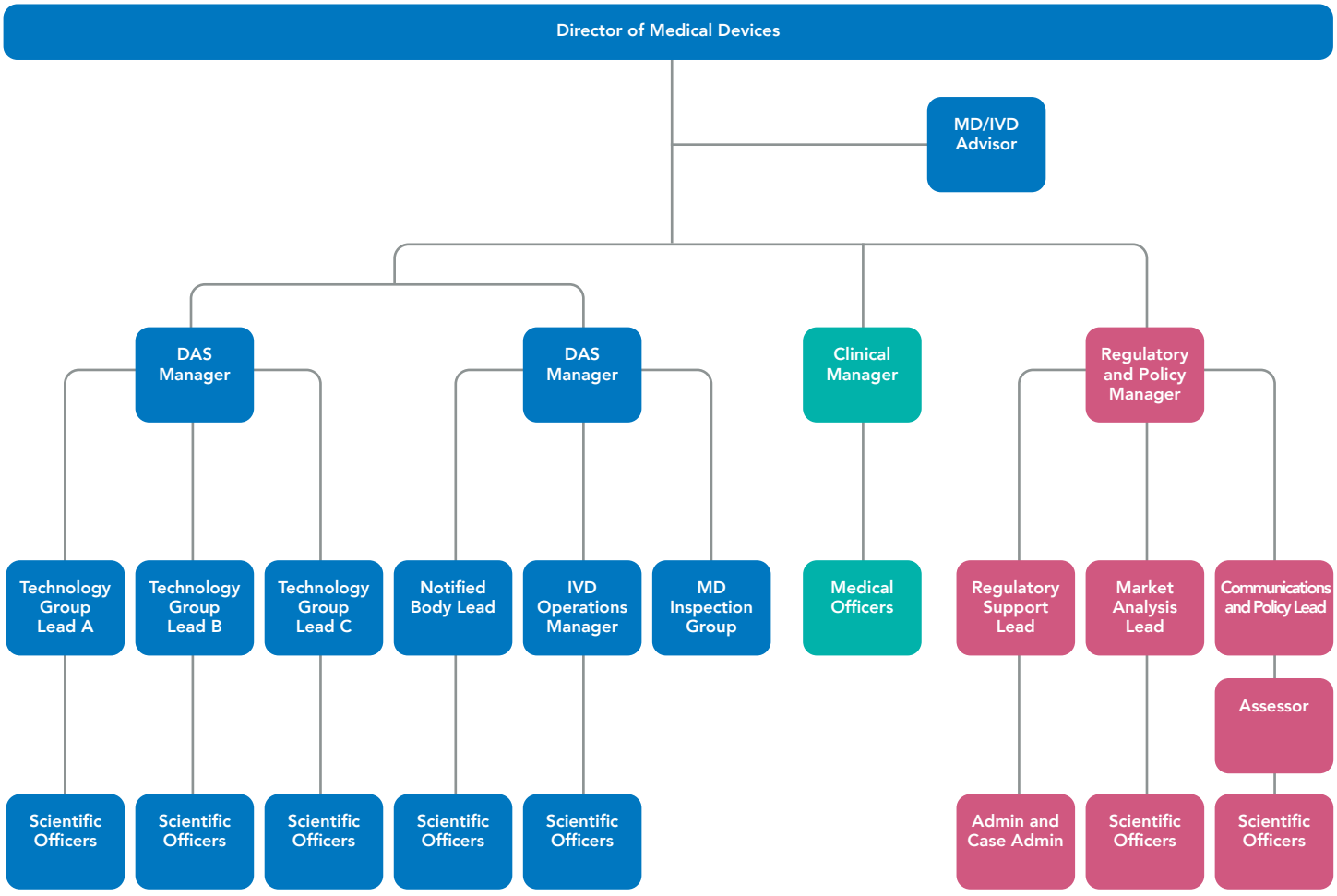
Review of Medical Device Compliance/Inspection Activities

In 2019, a number of medical device activities in the HPRA were consolidated from the Human Products Monitoring (HPM) and Human Products Authorisation and Registration (HPAR) departments to create one distinct Medical Devices department. The new department consisted of three sections – Device Assessment & Surveillance (DAS), Clinical, and Regulatory & Policy. As part of the organisational restructure, certain activities relating to medical devices remained within the remit of the Compliance department.

Earlier this year, the HPRA commenced a project to review the medical device activities being undertaken by the Compliance department. In particular, these activities included issuing certificates of free sale, notified body assessment support, inspections of manufacturers and other economic operators and the related planning and prioritisation associated with these activities.

As an outcome of this review, the inspection activities have transferred into a newly established Medical Devices Inspection team within the Assessment & Surveillance section of the Medical Devices Department. Certificates of free sale activities have transferred into the Regulatory Support team within the Regulatory & Policy section. In addition, the Regulatory Support team will provide administrative support for inspection activities and the associated planning.

By incorporating these activities into the Medical Devices Department, the HPRA has best positioned itself to support our stakeholders whilst continuing to maintain 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 continuing to work closely with all stakeholders in the future to ensure the ongoing supply of safe devices to patients in Ireland and the EU.



Eudamed Update

The European Commission has launched two more modules as part of the EUDAMED database development. The UDI/Devices Registration and NBs and Certificates modules are now available for use. Economic operators and notified bodies can start entering data on a voluntary basis. See here for public access to EUDAMED, and here for restricted access. Further information regarding this module is available on the European Commission's EUDAMED web page and on the system itself.

The HPRA recognises the voluntary registration module of Eudamed in the absence of a fully functional Eudamed. Once Eudamed is fully functional, this will become the mandatory registration system.

The HPRA is therefore requesting that manufacturers, authorised representatives, importers and system and procedure pack producers who are compliant with the Medical Device Regulation 2017/745 (MDR) voluntarily register their details and the details of their MDR-compliant devices on EUDAMED to meet the obligations set out in the Regulation. Details of legacy devices should also be registered where appropriate.

In addition, economic operators placing IVDR-compliant devices on the market before 26 May 2022 are also requested to use the voluntary EUDAMED system to fulfil their registration obligations.

More details regarding the MDR and IVDR registration requirements can be found on the HPRA website.

Certificates of Free Sale

Certificates of free sale are documents used in the registration of devices in third countries (i.e. countries outside the European Economic Area). They indicate that the devices listed are eligible for sale in the EU market. The Health Products Regulatory Authority (HPRA) currently issues certificates of free sale to economic operators that are established in Ireland.

To accommodate the provisions that are outlined in the Regulations regarding certificates of free sale and the transitional provisions that are applicable to some devices placed on the market in accordance with the Directives, the HPRA has recently made a number of changes to the application process including new contact points and two new application forms.

1. The *'Application for certificates for free sale (MDD medical devices, system and procedure packs, legacy devices)'* form should be used for
    - devices and system and procedure packs where the Declaration of Conformity has been drawn up before 26 May 2021 and the devices are placed on the market before 26 May 2021;
    - devices that are in conformance with the Medical Device Directives (MDD or AIMDD) and can continue to be placed on the market until 2024 in accordance with Article 120(3) of the MDR;
    - devices that are in conformance with the Medical Device Directives (MDD or AIMDD) but will be up classified under the MDR;
    - *In vitro* diagnostic medical devices that are in conformance with the IVDD.
2. *The 'Application for certificates for free sale (MDR compliant medical devices, system and procedure packs)'* form should be used for
    - Devices that are in conformance with the Regulation 2017/745 (MDR);
    - System and Procedure Packs that are in conformance with the Regulation 2017/745 (MDR).

All applications must be submitted electronically to devices@hpra.ie. Please note this new email address.

For more information, please see the Guide to Applications for Certificates of Free Sale for Medical Devices and the HPRA website.

Clinical Investigations – Process and Guidance Updates

There are three types of clinical investigation which are possible in Ireland as detailed in Article 62, 74 and 82 of the MDR. Statutory Instrument 261/2021, as amended, expands upon the Articles of the MDR to give clarity on areas such as the qualifications required of investigators, professionals entitled to provide medical care to subjects of clinical investigations, and the role of the national research ethics committee in clinical investigations. The HPRA's website has further information regarding these studies, and additionally we have developed a HPRA Guide to Clinical Investigations Carried Out In Ireland which stakeholders may avail of.

The MDCG has published a Q&A document (MDCG 2021-6) concerning clinical investigations. This guide has useful information relating to the regulatory pathway to follow for different types of clinical investigation, a description of what is considered burdensome or invasive for the purpose of post-market clinical follow-up (PMCF) investigations, and a description and examples of what are substantial modifications of a clinical investigation.

The MDCG has also published a guidance document (MDCG 2021-20) on how to issue a 'CIV-ID' number for clinical investigations via the Eudamed2 system. Eudamed2 is the European database which applies to the Medical Device Directives, however the use of the CIV-ID is an important way to track clinical investigations in Europe pending the new clinical investigation module of EUDAMED being developed for the MDR.

If you are preparing for a clinical investigation in Ireland, you are encouraged to contact devices@hpra.ie with any queries. The HPRA also offers preliminary meetings and pre-submission meetings to sponsors of clinical investigations in Ireland. Preliminary meetings provide a forum for HPRA clinical and technical assessors to meet with sponsors intending to develop a clinical investigation in Ireland in order to support regulatory awareness. Pre-submission meetings are available for sponsors who have prepared a clinical investigation and protocol. The meetings allow any outstanding aspects relating to a submission to be discussed prior to the submission.

The use of these processes is encouraged. Application forms and further information regarding this are available on our Clinical Investigations webpage.

HPRA Website Survey

We plan to redevelop the HPRA website as part of our new Strategic Plan for 2021 – 2025. As part of the initial planning process, we would like to ask you about your experience using the HPRA website. Your feedback will help us improve our online communications and deliver a better web experience for our stakeholders.

Completing all questions in the survey will take approximately five minutes. However, some questions are optional. All feedback from our website users is welcome and we would value as much information as you can provide.

You can complete the survey using this link: Website User Survey.

Survey responses are anonymous. The information collected in the survey will only be used to improve and develop our online communications.

HSE Webinar

The Health Service Executive (HSE) recently held an information briefing on MDR implementation, which was well-attended by both the public and private health sector. Representatives from the HPRA were in attendance and provided a broad overview of the MDR and the considerations specific to health institutions. A presentation was provided which covered areas such as in-house manufacturing, clinical investigations, traceability and the reprocessing of single-use devices. This was followed by a presentation from the HSE, highlighting their key considerations and policies related to these areas. Key messages for individual hospitals and health institutions were also highlighted by the HSE.

In order to ensure effective EUDR implementation, the HPRA has been engaging with stakeholders through a number of different fora. Strengthening collaboration with health services and health institutions represents an important component of the HPRA's strategic plan for 2021-2025. Further details on the event, including a recording and a copy of presenter slides, are available from hse.ie.

IPPOSI Workshop

IPPOSI is the Irish Platform for Patient Organisations, Science & Industry. It is an organisation which advocates for the important role that well-informed patients and carers can play in the design and implementation of patient-centred health research. Patients can also make valuable contributions towards future research and regulatory and ethical approval processes in Ireland. The HPRA has been involved for the past number of years in IPPOSI's Patient Education Programme. The programme has been created based on IPPOSI's continued involvement in, and partnership with, the European Patients Academy in Therapeutic Innovation (EUPATI). This year's programme is supported by the Health Research Board (HRB), with contributions from University College Dublin's Clinical Research Centre (UCD CRC), the HPRA, and Trinity College Dublin's Discipline of Pharmacology & Therapeutics, in association with the National Centre for Pharmacoeconomics (NCPE), and the Health Information and Quality Authority (HIQA).

The HPRA contributes to the programme's medical devices module and focused this year on the EU Device Regulations and the benefits that accompany the new regulatory framework for patients and the public. The module consisted of five online lessons, outlining the medical device regulatory framework and the role the HPRA plays as the national competent authority for medical devices in Ireland.

The module also included a virtual workshop which took place in July. The Director of the Medical Devices department, Dr Niall MacAleenan, provided an overview of the new regulatory framework as well as outlining the benefits it brings for patients. Participants were then given some clinical and vigilance scenarios, allowing them to discuss how to apply the principles previously covered in their online lessons including practical application of the online user reporting system. The workshop concluded by providing IPPOSI attendees with a short overview of the regulation of COVID-19 tests.

The medical devices module received very positive feedback from the participants and from IPPOSI directly. The HPRA values the engagement with patients and patient organisations, and will continue to engage with such stakeholders to both educate and deepen our understanding of patient perspectives and experiences in relation to medical devices. Further information on IPPOSI and their Patient Education Programme may be found on IPPOSI's website.

MDCG Classification Guidance

In October of this year, following several stakeholder consultations, the MDCG published MDCG 2021-24 (Guidance on classification of medical devices) to support manufacturers in their application of the MDR's classification system. This guide aims to help readers understand the purpose of risk-based classification, the key terminology and definitions used in Annex VIII and how to interpret and apply the classification rules.

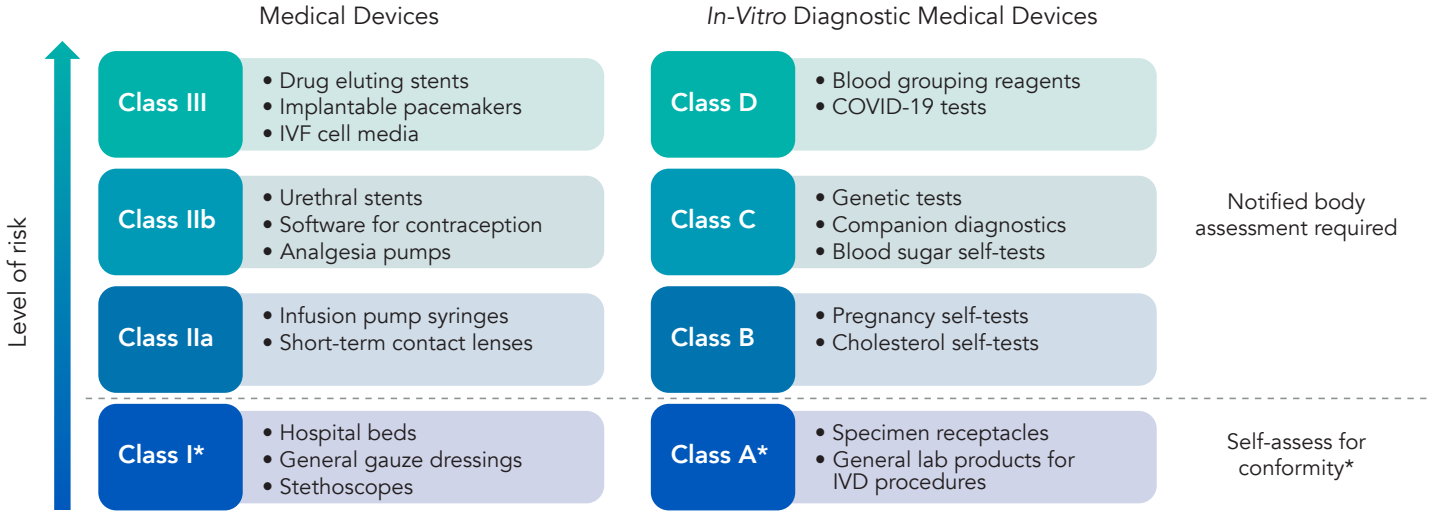
This guidance document also reminds manufacturers that irrespective of risk class, all devices must comply with certain MDR obligations. For example, all devices must meet their applicable general safety and performance requirements (Annex I), be subject to the reporting requirements under the medical device vigilance system, and must be CE marked (except custom-made devices and devices intended for clinical investigation). The guidance also reiterates that the involvement of a notified body in conformity assessment and the requirements surrounding conformity assessment itself are proportional to the risk class of a device.

The document, in part, focuses on key definitions and terms used in the application of the rules. Important terms relating to duration of use such as transient (less than 60 minutes), short term (between 60 minutes and 30 days) and long term (more than 30 days) are defined. Key terms relating to invasive and or implantable devices are also defined such as body orifice (any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma) and injured skin (an area of skin or a mucous membrane presenting a pathological change or change following disease, a wound or a scar). These definitions are essential in understanding and determining the most applicable rule for a given device. Further clarification is also provided for specific device types such as active medical devices, devices with a measuring function as well as systems and procedure packs.

MDCG 2021-24 also provides practical information on how to classify a medical device. It reminds manufacturers that it is the intended use and not the accidental use of a device which will determine its risk class. However, where the clinical use of a device changes over time with evolving clinical practice, this may result in a change to its intended use and may impact its classification. The guidance further clarifies that where several rules (or within the same classification rule, several sub-rules) apply to a device, the strictest rule and/or sub-rule resulting in the highest classification applies.

This MDCG guidance document provides an explanation of each rule and sub-rule, providing examples and outlining some practical considerations in their application. It is hoped that this section of the guidance will provide additional clarity to industry and notified bodies on the application of the 22 rules, and will help promote greater harmonisation within the system.

It is the manufacturer's responsibility to correctly qualify and classify their devices before placing them on the EU market. This guidance aims to help support innovation and industry while also fortifying the risk-based approach to conformity assessment and patient safety. The HPRA is continuing to work at an EU-level to promote greater harmonisation in this area and to develop borderline classification guidance that will accompany and complement MDCG 2021-24.



* Except for Class I reusable surgical instruments, Class I and Class A sterile devices and Class I devices with a measuring function; these require notified body assessment

MDCG Update

The Medical Devices Coordination Group (MDCG) met on 18 and 19 October to discuss MDR and IVDR implementation. The meeting on 18 October was a stakeholder session with a number of associations presenting on their experience of implementation to date. This included presentations from Medtech Europe, COCIR, AESGP and Biomed Alliance as well as Team NB. The meeting facilitated exchange of information on the implementation status of the Regulations. The Commission summarised the rationale for the need to introduce a proposal for a staggered transitional period for IVDR implementation based on device risk class. This rationale was based on challenges with notified body capacity, the 'up-classification' of many IVDs under the IVDR which require notified body oversight and the low numbers of manufacturers applying for certification. The need for a more progressive roll-out of requirements was identified as a high priority to ensure continued access to IVDs. While the proposal does not impact the date of application of the IVDR, it does propose an extension to the scope and timelines of transitional provisions. The Commission proposal represents some important changes for stakeholders, particularly with respect to Articles 110(2), 110(3), 110(4), 112 and 113(3). For a full overview of prospective changes, stakeholders can access the Commission's proposal here.

An update report on the MDCG task-force on transitional provisions ("legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC) was also provided. It was noted that the integration of the task-force report into MDCG guidance documentation is still ongoing. Additionally, a new MDCG Q&A guidance document concerning repackaging and relabelling activities under Article 16 of the MDR and IVDR was also endorsed by EU member states.

The EU Commission also provided an update on the development of EUDAMED. As of September, the actor registration, device registration and certificates registration modules are now live. Work is continuing on the vigilance, market surveillance and clinical investigations modules. It is expected that a minimum viable product of all modules will be available in 2024. The challenges with delays in EUDAMED development were acknowledged.

The MDCG also presented an update with respect to Notified Body designation under the MDR and the IVDR. 24 notified bodies are designated under the MDR and 30 applicant notified bodies are still in the process of being designated under the MDR. Concerning the IVDR, there are six notified bodies currently designated. In addition, the MDCG also endorsed a number of guidance documents during the October meeting which were recently published and are provided below.

The HPRA continues to work closely with the EU Commission and fellow EU member states to ensure a successful and harmonised application of the MDR and IVDR.

Recently Published Documents

Document/Update link	Document/Update Description	Publication Date
MDCG 2021-1 Rev.1 (updated document)	Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional	May 2021
MDCG 2021-7	Notice to manufacturers and authorised representatives on the impact of genetic variants on SARS-COV-2 *in vitro* diagnostic medical devices	May 2021
UDI Helpdesk	It helps the economic operators in the implementation of the requirements introduced by the new UDI system.	May 2021
MDCG 2021-08	Clinical investigation application/notification documents	May 2021
Public health: Stronger rules on medical devices	EU Commission Press release to mark the date of application of the MDR	May 2021
Q&A Release	Application of Regulation on Medical Devices – EU rules to ensure safety of medical devices	May 2021
Press release	Commission publishes information notice on the status of the EU-Switzerland Mutual Recognition Agreement for Medical Devices	May 2021

Document/Update link	Document/Update Description	Publication Date
MDCG 2021-09	MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers	May 2021
MDCG 2021-10	The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices	May 2021
MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)	May 2021
Joint implementation and preparedness plan for Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)	This Joint Implementation Plan is the result of a review by the MDCG including the relevant sub-groups with input from stakeholders. It has been endorsed in principle in the MDCG meeting of 28 May 2021. In addition to setting the priorities, the Plan will serve as a living document to monitor its implementation. The status and timelines of the items will be updated to reflect the progress of the work.	June 2021
MDCG 2021-11	Guidance on Implant Card – 'Device types'	June 2021
Q&A/Information document; European Medical Device Nomenclature (EMDN)	Questions and answers on the European Medical Device Nomenclature (EMDN) referred to in Article 23 of IVDR 2017/746 and Article 26 of MDR 2017/745	June 2021
MDCG 2021-13 rev.1	Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR	July 2021
List of opinions provided under the CECP	This page lists the opinions provided under the Clinical Evaluation Consultation Procedure (CECP, see Article 54 of Regulation (EU) 2017/745) by each thematic expert panel in the field of medical devices.	July 2021
MDCG 2021-13 rev.1	Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR	July 2021
MDCG 2021-14	Explanatory note on IVDR codes	July 2021
MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system	July 2021
MDCG 2021-20	Instructions for generating CIV-ID for MDR Clinical Investigations	July 2021
MDCG 2021-21	Guidance on performance evaluation of SARS-CoV-2 *in vitro* diagnostic medical devices	August 2021
MDCG 2021-22	Clarification on "first certification for that type of device" and corresponding procedures to be followed by notified bodies, in context of the consultation of the expert panel referred to in Article 48(6) of Regulation (EU) 2017/746	August 2021
MDCG 2021- 23	Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	August 2021
MDCG 2019-6 Rev3	Questions and answers: Requirements relating to notified bodies Revision 3	October 2021
MDCG 2021-24	Guidance on classification of medical devices	October 2021