Questions and Answers on the progressive roll-out of the new In Vitro Diagnostic Medical Devices Regulation

Brussels, 14 October 2021

1. What is the *In Vitro* Diagnostic Medical Devices Regulation?

In vitro diagnostic medical devices are tests used on biological samples to determine the status of a person's health. There is a broad range of in vitro diagnostics (IVDs), from self-tests for pregnancy and blood glucose tests for diabetics, to sophisticated diagnoses performed in clinical laboratories. Other examples of IVDs are HIV tests or COVID-19 tests.

The In Vitro Diagnostic Medical Device Regulation (IVD Regulation) entered into force in May 2017 and becomes applicable on 26 May 2022. The IVD Regulation seeks to ensure a high level of public health and patient safety taking into account scientific progress, as well as smooth operation of the single market for these products. It was adopted together with the Medical Devices Regulation that is applicable since 26 May 2021.

The EU rules for placing medical devices on the market, including in vitro diagnostic medical devices, were created in the 1990s. To reflect the substantial technological and scientific progress in this sector over the last 20 years, the EU lawmakers updated the rules to improve the safety of medical devices, with a view to modernise the sector and to consolidate the EU's role as a global leader in this area.

The new rules contain a number of improvements, including:

- clear **obligations for economic operators** (manufacturers, importers, distributors), such as traceability of devices, registration of devices and as economic operator (for manufacturers and importers), and verification of correct labelling;
- introduction of a **risk-based classification system with 4 risk classes** of in vitro diagnostic medical devices: class A (low individual risk and low public health risk), class B (moderate individual risk and/or low public health risk), class C (high individual risk and/or moderate public health risk) and class D (high individual risk and high public health risk);
- **stricter control for high-risk in vitro diagnostic devices**via a new pre-market scrutiny mechanism with a pool of experts at EU level;
- reinforcement of the criteria for the designation and **oversight of notified bodies*** (a 'notified body' is an independent third party conformity assessment body) – more information below;
- **improved transparency**through a comprehensive EU database on medical devices (EUDAMED), parts of which will be publicly accessible – more information below;
- a **traceability system** based on a unique device identifier (UDI);
- **reinforced rules on clinical evidence and performance evaluation**, including an EU-wide coordinated procedure for authorising multi-centre performance studies;
- **strengthened post-market surveillance**requirements for manufacturers;
- **improved coordination** mechanisms between EU countries on vigilance and market surveillance;
- specific regime for **devices manufactured and used in the same health institution** ('in-house devices').

2. Why does the Commission propose longer transition periods?

Due to resources being diverted to addressing the COVID-19 pandemic and the substantial changes introduced by the IVD Regulation, Member States' authorities, health institutions, notified bodies and economic operators will not be ready to fully meet the requirements of the IVD Regulation at the date of application on 26 May 2022.

In particular, with only six notified bodies designated so far under the In Vitro Diagnostic Medical Device Regulation, there is a grave shortage of notified body capacity, making it difficult for manufacturers to conduct the legally required conformity assessment procedures in time. As the currently designated notified bodies are established in only three countries (Germany, France and the Netherlands), the situation is particularly problematic for SMEs established in other Member States, which have a tendency to apply to notified bodies in their own or neighbouring Member States.

If not addressed, this situation could lead to a significant disruption in the supply of a multitude o*f in vitro* diagnostic medical devices on the market both for health institutions and for the public.

Article 110 of the IVD Regulation provides for a transitional period until 26 May 2024 for in vitro diagnostic medical devices with a certificate issued by a notified body in accordance with the Directive on in vitro diagnostic medical devices prior to 26 May 2022. This transition period is extended by 1 year until May 2025. However, only devices that require a notified body certificate already under this Directive (around 8%) will benefit from this existing transitional provision.

In order to address the shortage of notified body capacity more broadly, the Commission proposes additional transitional periods for devices that have to undergo a conformity assessment involving notified bodies for the first time under the IVD Regulation. The proposal differentiates between risk classes, with a transition period until May 2025 for high risk devices (class D), until May 2026 for class C devices and until May 2027 for lower risk devise (class B and A sterile). This approach aims to balance the available notified body capacity with high level of public health protection.

3. Is the application of the entire Regulation postponed?

No. The general application date of the Regulation remains 26 May 2022. In particular, the IVD Regulation will apply in full from 26 May 2022 to CE marked in vitro diagnostic medical devices that do not require the involvement of a notified body (i.e. class A non-sterile devices which represent around 20% of the market) and to 'new' in vitro diagnostics (i.e. those not covered by a certificate or a manufacturer's declaration of conformity issued prior to 26 May 2022). Devices that are concerned by the additional transitional periods may make use of them only provided they satisfy certain conditions, notably that they continue to comply with the Directive and that there are no significant changes in their design and intended purpose.

Moreover, from that date the reinforced rules on vigilance and market surveillance will also apply to devices that benefit from the transitional periods.

4. Will the additional transitional periods compromise public health or patient safety?

No, on the contrary. The additional transitional periods are necessary to avoid disruption in the supply of essential in vitro diagnostic medical devices. Otherwise, the diagnosis of patients and their access to relevant health care could be at risk. It is estimated that around 70% of clinical decisions rely on in vitro diagnostic medical devices.**

Only those products that are on the market in accordance with the current Directive on in vitro diagnostics prior to 26 May 2022, and which are therefore deemed to be safe and performant, will benefit from the transitional periods. Brand-new in vitro diagnostic medical devices and products that have undergone a significant change in the design or its intended purpose will be subject to the new requirements.

Moreover, manufacturers will have to prepare for the certification procedures under the IVD Regulation as soon as possible. That means that they will have to adapt their quality management system, their products and their technical documentation, and apply to a notified body well before the end of the transition periods. In addition, the reinforced rules on vigilance and market surveillance of the IVD Regulation will apply from 26 May 2022 also to devices that benefit from the transitional periods.

5. What is the role of Notified Bodies?

Unlike medicinal products, medical devices, including in vitro diagnostic medical devices, are not subject to a pre-market authorisation by a regulatory authority. Instead, medium and high-risk devices are subject to a conformity assessment procedure involving an independent third party known as a 'notified body'.

Currently, under the Directive on in vitro diagnostics, only a relatively small number of high-risk in vitro diagnostic medical devices is subject to notified body control (about 8% of all in vitro diagnostics on the market). Under the IVD Regulation, around 80% of in vitro diagnostic medical devices will be under the control of notified bodies, the vast majority of them for the first time.***

Notified bodies are designated and monitored by the Member States and act under the control of the

national authorities. In 2013, joint assessments of Notified Bodies were introduced, with members from other Member States and the Commission involved in the designation procedure. Under the new framework, the successful experience of the joint assessments for designation of notified bodies is reinforced.

Under the new IVD Regulation, the notified bodies must also consult an independent panel of expert on certain high-risk devices before the final decision on the certification of the product is taken. This will help a notified body to make more informed decisions, drive innovation while preserving a high level of safety and performance of products.

6. Why are there so few Notified Bodies?

Notified bodies are in most cases private for-profit entities. Their establishment is therefore market-driven. Under the current Directive 98/79/EC on in vitro diagnostic medical devices, 18 notified bodies are designated (22 before the UK's withdrawal from the EU). So far, only 6 notified bodies have been designated under the IVD Regulation. 11 applications for designation are pending (October 2021). The IVD Regulation, like the Medical Device Regulation, has reinforced the criteria for the designation and oversight of notified bodies. While this is necessary for high level of safety and performance of devices, it also makes it more challenging for a candidate notified body to apply. Moreover, it is a challenge to identify and recruit personnel with specific qualifications required for notified body staff in the in vitro diagnostics sector.

Together with Member States' authorities and stakeholders, the Commission will closely monitor the situation on the market, including notified body capacity and preparedness of manufacturers to submit applications for certification, and consider measures to address shortage of notified body capacity.

7. Besides notified bodies, is the other necessary infrastructure in place to ensure application of the Regulation from May 2022?

Besides limited notified body capacity, all the other legal prerequisites for placing devices on the market are in place. The expert panels are the only legally obligatory component of the conformity assessment system of the highest risk (class D) devices in addition to the notified bodies. They are already operating and have started receiving submissions.

The IVD Regulation provides the possibility for other optional elements, for example to designate EU reference laboratories and to adopt common specifications. However, neither EU reference laboratories nor common specifications for IVDs are a pre-condition for the application of the IVD Regulation. It is possible to place devices on the market without them, after the assessment by the notified body and in some cases expert panel. For some less common class D devices it could be the case that there will be no EU reference laboratory as there may be no candidate laboratories. It may also be that there is insufficient scientific consensus in the field to produce common specifications for those less common class D devices. Such devices can nevertheless be legally placed on the market and made available to patients.

Even though they are not obligatory, it would be very helpful for the sector to have EU reference laboratories designated and common specifications available. The Commission is working on establishing the EU reference laboratories and adopting common specifications for 16 IVD types.

8. What is the state of play on the medical devices database, EUDAMED?

EUDAMED will provide an overview of all medical devices available in the European Union. It will be composed of six modules related to: actor registration, unique device identification (UDI) and device registration, notified bodies and certificates, clinical investigations and performance studies, vigilance and market surveillance. It will integrate different electronic systems with information about medical devices and related companies (e.g. manufacturers).

The development of EUDAMED is progressing, with first EUDAMED module on actor registration made available in December 2020. Since beginning of October 2021, the second and third modules are available, namely the module on UDI/device registration and the module on certificates and notified bodies, except for the mechanism for scrutiny and the clinical evaluation consultation procedure functionalities (CECP). The remaining modules as well as the functionalities for the mechanism for scrutiny and the CECP will be released when EUDAMED is fully functional.

The Commission is continuing to work in close cooperation with Member States on this highly complex project.

9. What are the rules for 'in-house devices'?

'In-house devices', also referred to as 'laboratory-developed tests' are manufactured and used within the same health institution. They are not marketed or transferred to other legal entities and do not

bear the CE marking. In-house devices developed in laboratories can be essential for the diagnosis and treatment, especially for rare diseases.

With the exception of the general safety and performance requirements laid down in Annex I of the IVD Regulation, in-house devices are exempted from the IVD Regulation, provided the health institution meets a number of conditions set out in Article 5(5) of the Regulation. Among other things, health institutions must have an appropriate quality management system, comply with the international standard setting out the quality and competence requirements for medical laboratories (EN ISO 15189) or other national provisions, and must justify that target patient group's specific needs cannot appropriately be met by an equivalent in vitro diagnostic medical device available on the market.

Since the outbreak of the pandemic, many health institutions, in particular hospitals, have had to focus their efforts on dealing with COVID-19. The Commission therefore proposes to defer the application of most of the conditions to be met by health institutions making in-house devices by 2 years until 26 May 2024. The requirement for the justification that there is no equivalent CE marked device available to meet the target patient group's specific needs is proposed to be deferred even further, until 26 May 2028, as the health institutions will need an overview of CE-marked in vitro diagnostic medical devices available on the market to comply with this requirement.

For more information

Press release

Medical Devices - New regulations

*EUROPA - European Commission - Growth - Regulatory policy - NANDO

**MedTech Europe Survey Report analysing the availability of *In vitro* Diagnostic Medical Devices (IVDs) in May 2022 when the new EU IVD Regulation applies, 8 September 2021 https://www.medtecheurope.org/resource-library/medtech-europe-survey-report-analysing-the-availability-of-in-vitro-diagnostic-medical-devices-ivds-in-may-2022-when-the-new-eu-ivd-regulation-applies/ (hereafter referred to as Medtech Europe Survey Report); Rohr U-P, Binder C, Dieterle T, Giusti F, Messina CGM, Toerien E, et al. (2016), *The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report.* PLoS ONE 11(3): e0149856. https://doi.org/10.1371/journal.pone.0149856.

***MedTech Europe Survey Report (see footnote 2).

QANDA/21/5210

Press contacts:

Stefan DE KEERSMAECKER (+32 2 298 46 80)
Darragh CASSIDY (+32 2 298 39 78)

General public inquiries: Europe Direct by phone 00 800 67 89 10 11 or by email