Questions and Answers on in vitro diagnostics and the European Database on Medical Devices (EUDAMED)

Brussels, 23 January 2024

1. **What rules apply to *In Vitro* Diagnostic Medical Devices?**

In vitro diagnostic medical devices (IVDs) are **tests used on biological samples to determine the status of a person's health**. There is a broad range of IVDs, from self-tests for pregnancy or COVID-19 to blood glucose tests for diabetics.

The EU rules for placing medical devices on the market, including IVDs, were established in the 1990s. **In 2017, the rules were updated** to improve patient safety, reflect scientific progress, modernise the sector and consolidate the EU's role as a global leader in this area.

The new In Vitro Diagnostic Medical Device Regulation (IVD Regulation) entered into force in May 2017 and has been applicable since 26 May 2022. It was adopted together with the Medical Devices Regulation that has been applicable since 26 May 2021.

The new rules contain important improvements, including:

- Clear **obligations for economic operators** (manufacturers, importers, distributors) to ensure the traceability of devices, for example through registration of devices and economic operators (for manufacturers and importers) in a database, EUDAMED, and correct labelling;
- introduction of a **risk-based classification system for IVDs, with 4 risk classes**:
  - 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 controls for high-risk *in vitro* diagnostic devices** via a new pre-market scrutiny mechanism with a pool of experts at EU level;
- **oversight of notified bodies** (a 'notified body' is an independent third-party body that assesses the conformity of medical devises with the applicable safety requirements) and revised criteria for the designation of such bodies;
- **more important role for notified bodies in the conformity assessment of IVDs in a way that is proportionate to the device risk class;**
- **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 the new proposal?**

The aim of the proposal is to **ensure availability of safe devices, essential for healthcare systems, and protect patient care**. The latest available data shows that a high number of IVDs currently on the market has not factored in the new rules (nor has been replaced by other devices), meaning that those devices would no longer be available. The number of devices which have not

factored in the new rules and are not expected to transition in time is particularly high for high risk IVDs (class D). These include important tests detecting infections in the context of blood transfusions or organ donations.

The Commission is **therefore proposing** to extend the transition periods **to give manufacturers and notified bodies more time** to complete the necessary conformity assessment procedures. This extension will be subject to conditions and therefore safeguard the high level of requirements set out by the legislation and protect public health.

The Commission also proposes measures to enable and accelerate a **gradual roll out of EUDAMED**, a database that will contain information about all medical devices and IVDs placed on the EU market. The mandatory use of finalised parts of EUDAMED will support all key players in the implementation of the regulatory framework and enhance transparency for the public.

The proposal also introduces a requirement for **manufacturers to give prior notice to authorities, as well as to distributors or health institutions, if they foresee the interruption of supply** of IVDs or medical devices, which would pose risks to patient care. This measure would enable healthcare systems to have more time to take action to safeguard patient care (See question 8).

3. **What are the <u>current</u> transition periods for the IVD Regulation?**

The IVD Regulation initially stipulated that the sector had until 26 May 2022, to adapt to the new rules.

In October 2021, however, in the middle of the COVID-19 pandemic, it became clear that Member States, health institutions and economic operators were **not ready** to apply the Regulation as from that date. The Commission therefore proposed a progressive or staggered roll-out of the rules of the Regulation.

The current transition periods range from 26 May 2025 for high risk IVDs to 26 May 2027 for lower risk IVDs. Certain provisions for devices manufactured and used in health institutions, would have to apply as from 26 May 2028.

With today's proposal, the Commission is revising these transition dates in order to balance the readiness of the sector with high level of public health protection.

4. **What are the <u>new</u> transition periods proposed by the Commission for IVDs?**

The proposed new transition periods will **depend on the type of device**, specifically its risk class under the IVD Regulation. There will be:

- a shorter transition period for **high risk** IVDs (31 December 2027) and
- longer periods for medium and **lower risk** IVDs (31 December 2028 and 31 December 2029 respectively).

The Commission has also proposed postponing the application of one of the requirements for devices manufactured and used in health institutions (notably the requirements to show that there is no alternative and equivalent commercial device on the market). This requirement is postponed to 26 May 2030. This gives health institutions more time to first have an overview of available IVDs on the market.

5. **Under what conditions do the new transition periods apply?**

Only 'legacy devices', meaning devices covered by a certificate or declaration of conformity issued under the previous legal framework (notably Directive 98/79/EC), may benefit from the extended transition periods if they fulfil the following conditions:

- they continue to comply with the rules in force when they were placed on the market for the first time;
- there are **no significant changes** in the design or intended purpose of the devices;
- the devices do **not present an unacceptable risk to the health or safety** of patients, users or other persons, or to other aspects of the protection of public health;
- no later than 26 May 2025, the manufacturer puts in place a **quality management system** compliant with the IVD Regulation;
- for devices requiring an assessment by a notified body, the manufacturer submits an **application to the notified body to transfer the device to the IVD Regulation** by 26 May 2025 (class D), 2026 (class C) or 2027 (class B and A sterile IVDs). The manufacturer and the

notified body sign a written agreement to proceed with conformity assessment shortly after those dates.

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

No, on the contrary, longer transition periods help ensuring that **essential devices continue to be available** to patients. In addition, the application of the extended transition periods will be subject to several conditions, to ensure that **only safe devices will benefit** from this additional time, as long as manufacturers have already taken steps to factor in the IVD Regulation.

7. **What other actions is the Commission taking to ensure availability of medical devices and *in vitro* diagnostics?**

The Commission has already taken several actions to ensure the availability of medical devices and IVDs. This includes measures to **increase the capacity of notified bodies and to enhance the preparedness of manufacturers**. The Commission also provides **financial support** for such actions under the EU4Health programme and is working together with competent authorities of Member States in the **Medical Device Coordination Group** (MDCG) to further help the sector in their efforts to comply with the new rules.

Specifically for devices intended for small patient populations like children or persons with a rare disease ("**orphan devices**") a **new guidance**, is being developed. The guidance is expected to **significantly help the certification of existing orphan devices** in accordance with the MDR/IVDR, by addressing the specific challenges of clinical evidence requirements for these types of devices.

Finally, the Commission will start already in 2024 preparatory work for a **targeted evaluation of the legislation**. The evaluation should assess in particular the impact of the legislation on the availability of devices, especially devices responding to special needs such as "orphan devices", and the development of innovative devices in Europe. Special attention in the assessment may also be given to costs and administrative burdens stemming from the implementation of legislation, especially for SMEs.

8. **Why is the Commission proposing to introduce a mechanism of prior notice by manufacturers in case of disruption of supply of certain medical devices and IVDs?**

To ensure availability of devices, Member State authorities and healthcare providers need to know in advance whether devices will be discontinued, and whether such discontinuation may pose a risk to patients or public health.

The Commission is therefore proposing that manufacturers provide this information to competent authorities, as well as distributors and healthcare providers. They have to provide this information six months in advance, so that national authorities and healthcare providers have enough time to consider mitigating measures to ensure patient safety and a high level of public health.

9. **What is EUDAMED?**

Eudamed is an essential element of the medical device regulatory framework and is a major step forward in ensuring traceability and transparency in medical devices. It is created to register **all medical devices placed on the European Union market**, thereby offering a broad and detailed overview of the devices available on the EU market.

It has **six modules,** covering:

- actor registration,
- unique device identification (UDI) and device registration,
- notified bodies and certificates,
- clinical investigations and performance studies,
- post-market surveillance and vigilance, and
- market surveillance.

Currently, the first three of the six modules are available for voluntary use (actor registration; UDI and device registration; notified bodies and certificates). Two other modules (market surveillance; post-market surveillance and vigilance) are expected to be completed in 2024. The module covering clinical investigation/performance study will not be completed before Q3 2026.

10. **Why is the Commission proposing a gradual roll-out of the medical devices database,**

EUDAMED?

EUDAMED is key for the effective and efficient implementation of the Medical Device Regulation and IVD Regulation. It helps Member States authorities and the Commission monitor the market.

Under the current provisions, the use of EUDAMED will only become mandatory when **all modules** function correctly.

However, it would be important to speed up the mandatory use of modules which are already available and functioning correctly. The Commission is therefore proposing to allow the gradual implementation of EUDAMED modules as soon as they have been audited and declared functional.

This will allow the mandatory use of several modules to start from end 2025.

The procedural aspects for the declaration of functionality of the modules (e.g. independent audit, publication of notices of functionality) of EUDAMED will remain unchanged.

For more information

Press release

Factsheet

Medical Devices - New regulations

QANDA/24/347

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