European Commission

Public Health

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Designation of EU reference laboratories for high-risk in vitro diagnostic medical devices

On 5 December 2023, the European Commission adopted an implementing act designating 5 EU reference laboratories (EURLs) in the field of in vitro diagnostic medical devices (IVDs). These EURLs will be involved in conformity assessment of high-risk (class D) IVDs as well as carry out certain advisory tasks. The designated EURLs together cover the following categories of class D IVDs:

- Hepatitis and retroviruses
- Herpesviruses
- Bacterial agents
- Respiratory viruses that cause life-threatening diseases

The implementing act includes transitional arrangements to allow the EURLs to form a network and harmonise their working methods, and for manufacturers and notified bodies to adapt their processes to include EURL testing. The EURLs are expected to take up their tasks in conformity assessment of devices on 1 October 2024.

The act includes provisions to minimise disruption to ongoing conformity assessment processes. In particular, only new applications submitted to notified bodies after the end of the transition period will be subject to performance verification by the EURLs. On the other hand, batch testing of devices already CE-marked under Regulation (EU) 2017/746 will begin after the end of the transitional period to ensure appropriate control of those IVDs.

Background on EURLs

EU reference laboratories in the field of IVDs are designated to perform important tasks outlined in Article 100 of Regulation (EU) 2017/746. EURLs verify the performance of class D devices and compliance with common specifications and they perform batch testing of class D devices in response to requests by notified bodies.

EURLs can also provide scientific and technical assistance to the European Commission, the Medical Device Coordination Group (MDCG), Member States and notified bodies in relation to the implementation of Regulation (EU) 2017/746. EURLs can also provide scientific advice regarding the state of the art, contribute to the development of appropriate testing and analysis methods, common specifications and international standards. The laboratories provide recommendations on suitable reference materials and reference measurement procedures. They can collaborate wih notified bodies in the development of best practices for the performance of conformity assessment procedures. EURLs also set up and manage a network of national reference laboratories, where those exist, and publish a list of the participating national reference laboratories and their respective tasks.

EU reference laboratories must form a network to coordinate and harmonise their working methods as regards testing and assessments.

Selection procedure for the EURLs

The European Commission's Joint Research Centre (JRC) was entrusted by DG Health and Food Safety (DG SANTE) to coordinate the selection procedure for the EURLs.

In July 2022, a call for EURL applications was sent to Member States in 8 categories of class D devices: hepatitis and retroviruses, herpesviruses, bacterial agents, arboviruses, respiratory viruses that cause life-threatening diseases, haemorrhagic fever and other biosafety level 4 viruses, parasites and blood grouping. Interested laboratories had until January 2023 to submit their applications to their Member State.

The selection took place in two steps. First, Member States verified and documented whether the candidate laboratories in their country complied with the selection criteria. Following this, Member States submitted 8 applications for further consideration by the European Commission. To oversee this process, the JRC established a European Commission Selection Board comprising Commission services, the European Centre for Disease Prevention and Control (ECDC), and the European Medicines Agency (EMA). The Selection Board reviewed the verification conducted across Member States and assessed the candidate laboratories' capacity for performance verification and batch testing. After careful consideration, the Selection Board shortlisted 5 laboratories for designation based on their capacities and compliance with the selection criteria.

Details

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