WHITEPAPER

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New Possibilities, Everyday

IVDR - Latest EUDAMED Options for Manufacturers

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According to IVDR, EUDAMED will not fully functional by the date of application of the IVDR (26 May 2022). Hence the obligations and requirements in the IVDR that relate to EUDAMED shall apply from the date corresponding to six months after the date of publication of the notice of full functionality of EUDAMED. Until EUDAMED is fully functional, the IVDR stipulates that the corresponding provisions that will continue to apply for the purpose of meeting the obligations lay down in the provisions of IVDR regarding the exchange of information. In addition IVDR clarifies that on registration of devices, and the registration of certificates will start to apply 24 months after the date of publication of the notice.

During the absence of EUDAMED or until the EUDAMED becomes fully functional, The harmonized administrative practices and alternative technical solutionsfor the exchange of information provides guidance to Member States and other relevant parties on the application of certain IVDR provisions and to meet their obligations effectively while minimizing any potential additional burden on the parties concerned.

ALTERNATIVE TECHNICAL SOLUTIONS

1. Application for performance studies:

Sponsors of a performance study shall enter and submit an application to the Member States in which the performance study is to be conducted along with the documentation. The application must be submitted by electronic system which generates Union-wide unique singleidentification number for the performance study, which shall be used for all relevant communication in relation to performance study.If any change occurring in relation to the documentation the sponsor shall update the relevant data in the electronic system and make that change to the documentation clearly identifiable. If the concerned Member State finds that the performance study applied for does not fall within the scope of IVDR Regulation or that the application is not complete, it shall inform the sponsor and shall set a time limitto comment or to completethe application through electronic system.

- The application for performance study should take place via the respective national procedures applicable to performance studies.
- The update and notification of the relevant information should take place via the respective national procedures applicable to performance studies.
- A list of national contact points for submission should be published on the Commission website.
- The new performance study application form developed under the IVDR framework may be considered at national level to the extent possible.

Performance studies regarding devices bearing the CE marking

The device which already bears the CE marking and where the performance study would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic system.

- The notification should take place via the respective national procedures applicable to performance studies.

2. Substantial modifications to performance studies

If a sponsor intends to introduce modifications to a performance study that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the data generated by the study, it shall notify, within one week, by means of the electronic systemtothe Member State(s) in which the performance study is being or is to be conducted of the reasons for and the nature of those modifications. The sponsor shall include an updated version of the relevant documentation and changes to the relevant documentation shall be clearly identifiable.

- The notification should take place via the respective national procedures applicable to performance studies.

3. Information from the sponsor at the end of a performance study or in the event of a temporary halt or early termination

If the performance study has temporarily halted or has terminated earlyby the sponsorshall inform to the Member State within 15 daysthrough the electronic system by providing a justification. In the event that the sponsor has temporarily halted or terminated early the performance study on safety grounds, it shall inform all Member States within 24 hours.Irrespective of the outcome of the performance study the sponsor shall submit to the Member States a clinical investigation report. The performance study report shall be submitted along with summary that is easily understandable to the intended user. The report and summary shall be submitted by the sponsor, if it is not possible to submit the performance study report within one year of the end of the investigation, it shall be submitted as soon as it is available. The performance study plan shall specify when the results of the performance study are going to be available, together with a justification.

- The communication of the relevant information should take place via the respective national procedures applicable to performance studies.
- The upload of the relevant information should take place via the respective national procedures applicable to performance studies.

4. Coordinated assessment procedure for performance studies

The sponsor of a performance study to be conducted in more than one Member State may submit, for a single application that is transmitted electronically to all Member States.

Where the conclusion of the coordinating Member State concerning the area of coordinated assessment is that the conduct of the performance study is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of all Member States concerned. A Member State concerned may only disagree with the conclusion of the coordinating Member State concerning the area of coordinated assessment on the following grounds:

a) When it considers that participation in the performance study would lead to a subject receiving treatment inferior to that received in normal clinical practice in that Member State concerned;

b) Infringement of national law; or

c) Considerations as regards subject safety and data reliability and robustness submitted. Where one of the Member States concerned disagrees with the conclusion shall communicate its disagreement, together with a detailed justification, through the electronic system to the Commission, to all other Member States concerned and to the sponsor.

Each concerned Member State shall notify the sponsor through the electronic system as to whether the performance study is authorised, or subject to conditionsor whether authorisation has been refused.

Notification shall be done by way of one single decision within five days of the transmissionby the coordinating Member State of the final assessment report. Where an authorisation of a performance study is subject to conditions, those conditions may only be such that, by their nature, they cannot be fulfilled at the time of that authorisation.

Any substantial modifications shall be notified to the Member States by electronic system. Any assessment as to whether there are grounds for disagreement shall be carried out under the direction of the coordinating Member State, except for substantial modifications which shall be assessed separately by each Member State concerned.

- The procedure is mandatory as of 27 May 2029. Prior to that, the application of the procedure is voluntary as decided by the Member States willing to participate.
- In the absence of EUDAMED, the coordinated assessment procedure will not be possible.

5. Recording and reporting of adverse events that occur during performance studies

The sponsor shall report through the electronic systemwithout delay to all Member States in which the performance study is being conducted about any serious adverse event that has a causal relationship with the device, the comparator or the investigation procedure or where such causal relationship is reasonably possible or if any device deficiency that might have led to a serious adverse event if appropriate action had not been taken. The period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial report that is incomplete followed up by a complete report. Upon request by any Member Statethe sponsor shall provide all information in which the clinical investigation is being conducted.

The sponsor shall also report to the Member States in which the performance study is beingconducted any event that occurred in third countries in which a performance study is performed under the same clinical investigation plan as the one applying to a clinical investigation by the electronic system.

In the case if the sponsor has used the single application of a performance study, the sponsor shall report any event by electronic system. Upon receipt, this report shall be transmitted electronically to all Member States in which the performance study is being conducted. The Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether to modify, suspend or terminate the performance study or whether to revoke the authorisation for that performance study. The Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.

- The reporting should take place via the respective national procedures applicable to Performance studies.

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