

Dear members of the MDCG,

Dear members of the CAMD Transition Sub Group,

As mentioned at the last MDCG meeting on 1<sup>st</sup> October, the draft EUDAMED Implementing Act prepared by GROW.D4, presented during the 20 June MDCG meeting, is currently being revised by the Commission's services, including the Legal Service.

It has emerged from extensive discussion on the draft Implementing Act, that there is the risk that the progressive entry into operation of EUDAMED functional specifications provided therein could not be entirely compliant with Recital 9, Article 34 and Art 123(3) of Regulation (EU) 2017/745 (MDR).

In particular, the analysis made by the Commission services concluded that, in order to ensure full legal compliance with the Regulation, only when the Commission has verified that EUDAMED has achieved full functionality on the basis of an independent audit on all functional specifications covering the entire EUDAMED electronic systems, the Commission will be entitled to publish a notice to that effect in the OJ, in accordance with Article 34 of the MDR.

This conclusion entails several consequences. Notwithstanding the advancement in the development of the EUDAMED systems, the previously discussed option to make operational only parts of the EUDAMED electronic systems before full functionality of all EUDAMED electronic systems is achieved would not be suitable.

Consequently, the notice mentioned in Article 34(3) of the MDR will only be issued after the MDR date of application, i.e. after 26 May 2020. This represents a possibility which has been explicitly foreseen by the legislator, who has therefore also provided for specific effects resulting from this scenario.

In this situation, the Commission and the competent authorities of the EU Member States are called to discuss the practical arrangement that will be required in this context. In particular, as the EUDAMED-related obligations in the MDR will not apply on 26 May 2020, the Commission and the competent authorities of the EU Member States will need to identify the provisions of Directives 90/385/EEC and 93/42/EEC that will remain applicable and discuss the practical steps to be implemented ahead of that date.

The attached document provides a first overview of the MDR provisions that govern the consequences of the publication of the Article 34 notice after 26 May 2020.

We look forward to your feedback, notably with respect to the upcoming meeting of the CAMD Transition Sub Group on November 7, and we remain available for any questions and clarifications.

This situation does not affect in any way the current EUDAMED development planning and the ongoing continuous. Intensive efforts on the technical advancement of the systems development will be maintained.

The postponement of the entry into operation of EUDAMED will give more time to users to prepare for the new EUDAMED electronic systems until the Article 34 notice is published.