EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

Brussels, 28.11.2019

[redacted]

NOTE FOR THE FILE

Subject: **State of play of the implementation of the new Medical Device Regulations**

[redacted]
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1.3. The implementation of the new framework

The implementation of the new Regulations is a huge challenge for all stakeholders. OUT OF SCOPE he setting-up of the Eudamed database are the main challenges.

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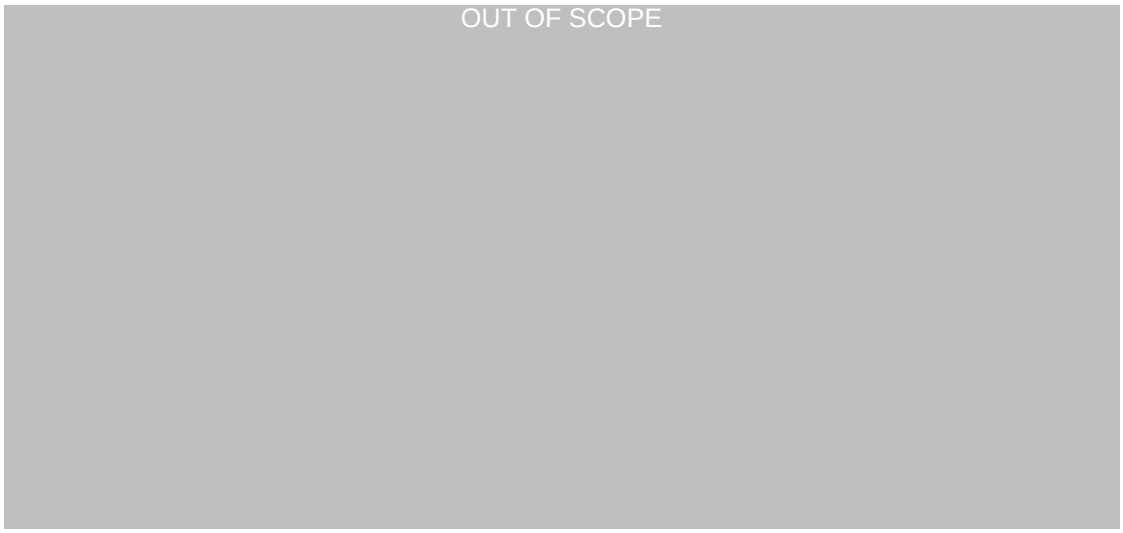
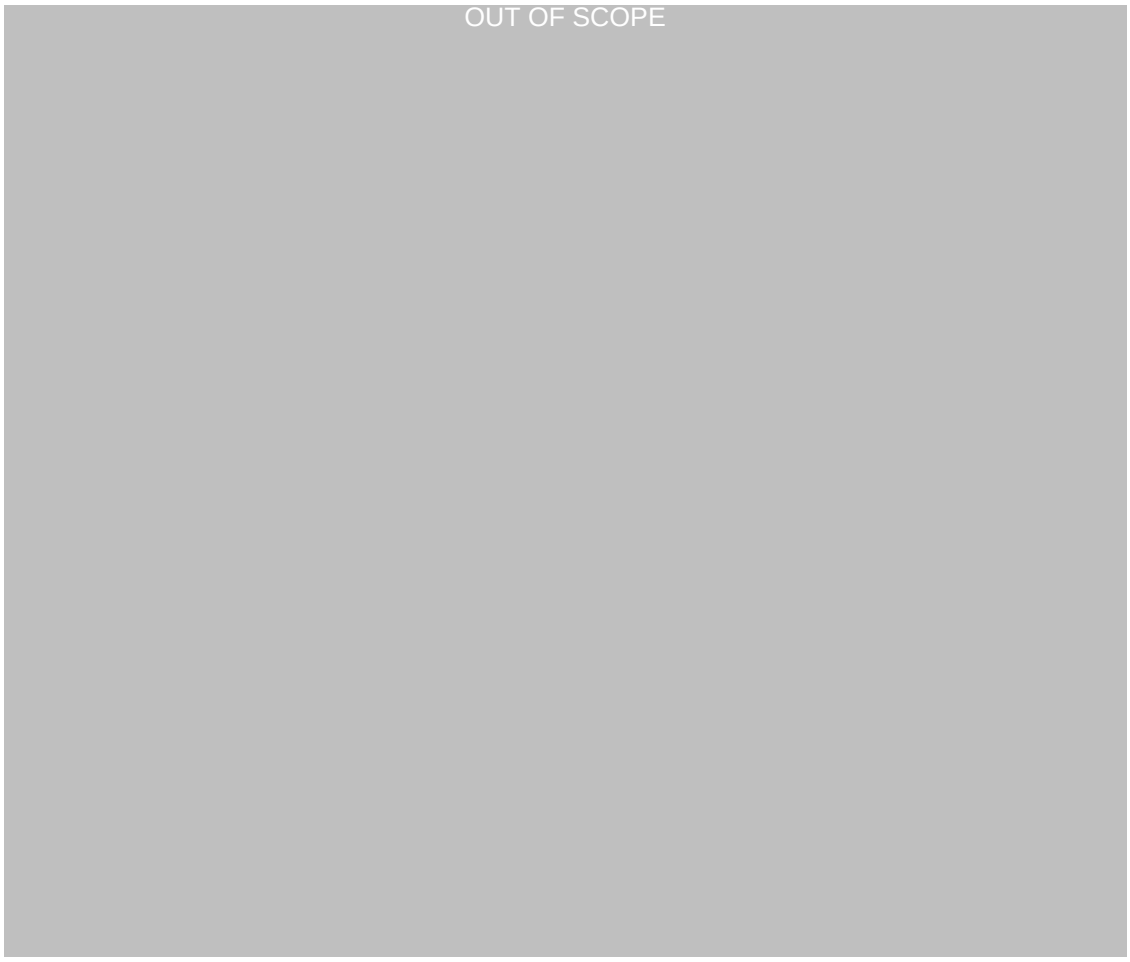


With regard to the future Eudamed database, in October 2019, the Commission has informed the Member States and the public that, despite the crucial modules (including registration of devices, operators and certificates) being ready for deployment in 2020, the establishment of the database will suffer a two-year delay (to 2022). From a legal point of view, the procedure for the validation of Eudamed can be activated only when the database is fully deployed.



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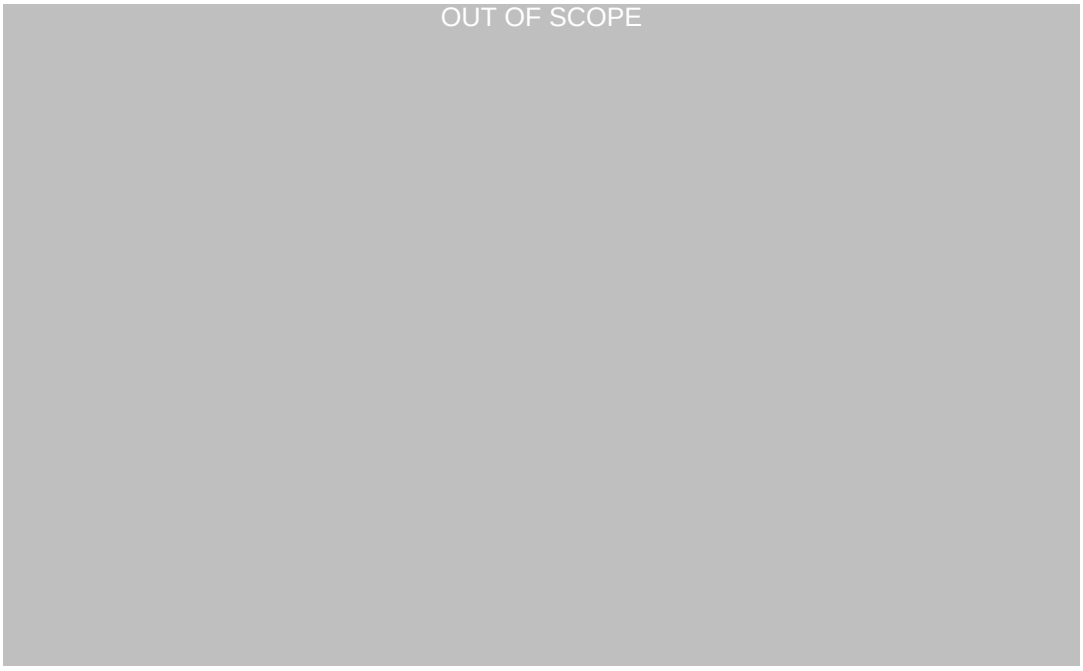

3.1.2. Eudamed

The delay of the database does not impact the application of the new Regulations as such. The two Regulations already foresee an alternative plan in relation to the exchange of information in the absence of the Eudamed database. In practice, the relevant obligations of the Regulation which are related to Eudamed shall continue to generally apply, while the exchange means/tools should be the ones set under the Current Directives. The new rules on registration of device and certificates are instead delayed until the database is available.

The Commission and Member States are currently working together on the practical details of this alternative plan. The Commission in particular is working on first guidance which is intended to clarify in detail, notably to operators, the practical consequences of the Eudamed postponement. Moreover, the Commission, in order to support harmonisation of practices during the interim period, intends i) to release one of the Eudamed modules related to actor registration already by May 2020, which would allow such function on a voluntary basis, and ii) to make certain adaptations to the already existing EU database on devices.

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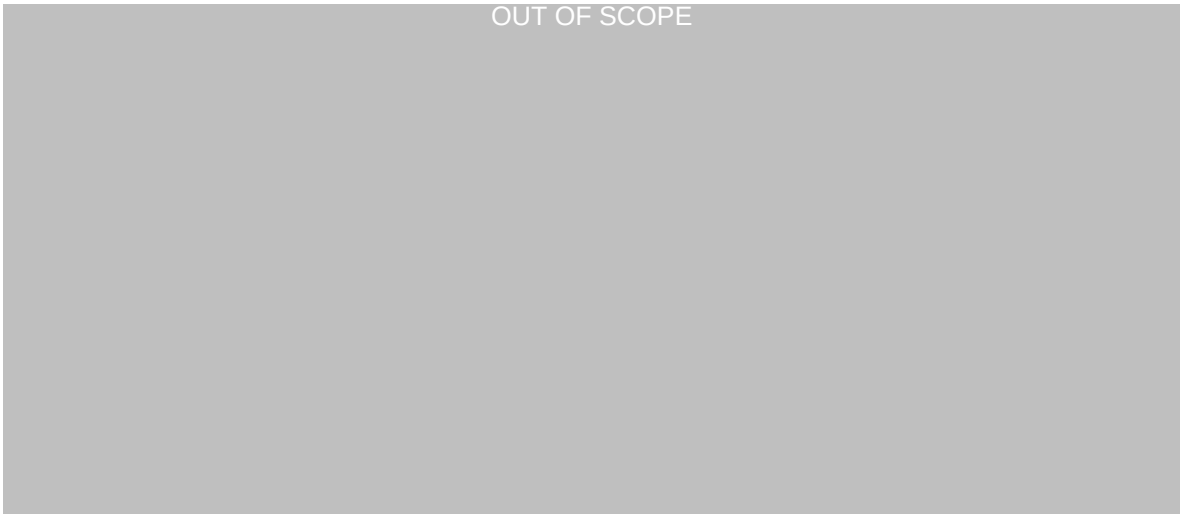

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4. PROPOSED LINE TO TAKE

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- OUT OF SCOPE Eudamed are certainly two of the key challenges:

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  - On the Eudamed database, in October 2019, the Commission has informed that the project will suffer a two-year postponement: from 2020 to 2022. The two Regulations already foresee an alternative plan in the absence of the Eudamed database. The Commission and Member States are currently working together to elaborate the practical details of the alternative plan. The Commission also intends to deliver on a voluntary basis a module on actor registration and make some adjustments to the already existing database on medical devices for procedures and exchange of information during the interim period.

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