EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

Brussels, 03.09.2019

[redacted]

NOTE TO THE FILE

Subject: **Internal GROW/D meeting on 01 July 2019 on the state-of-play of the implementation of the medical device Regulations**

[redacted]

Carlo Pettinelli (CP) – Director GROW/D

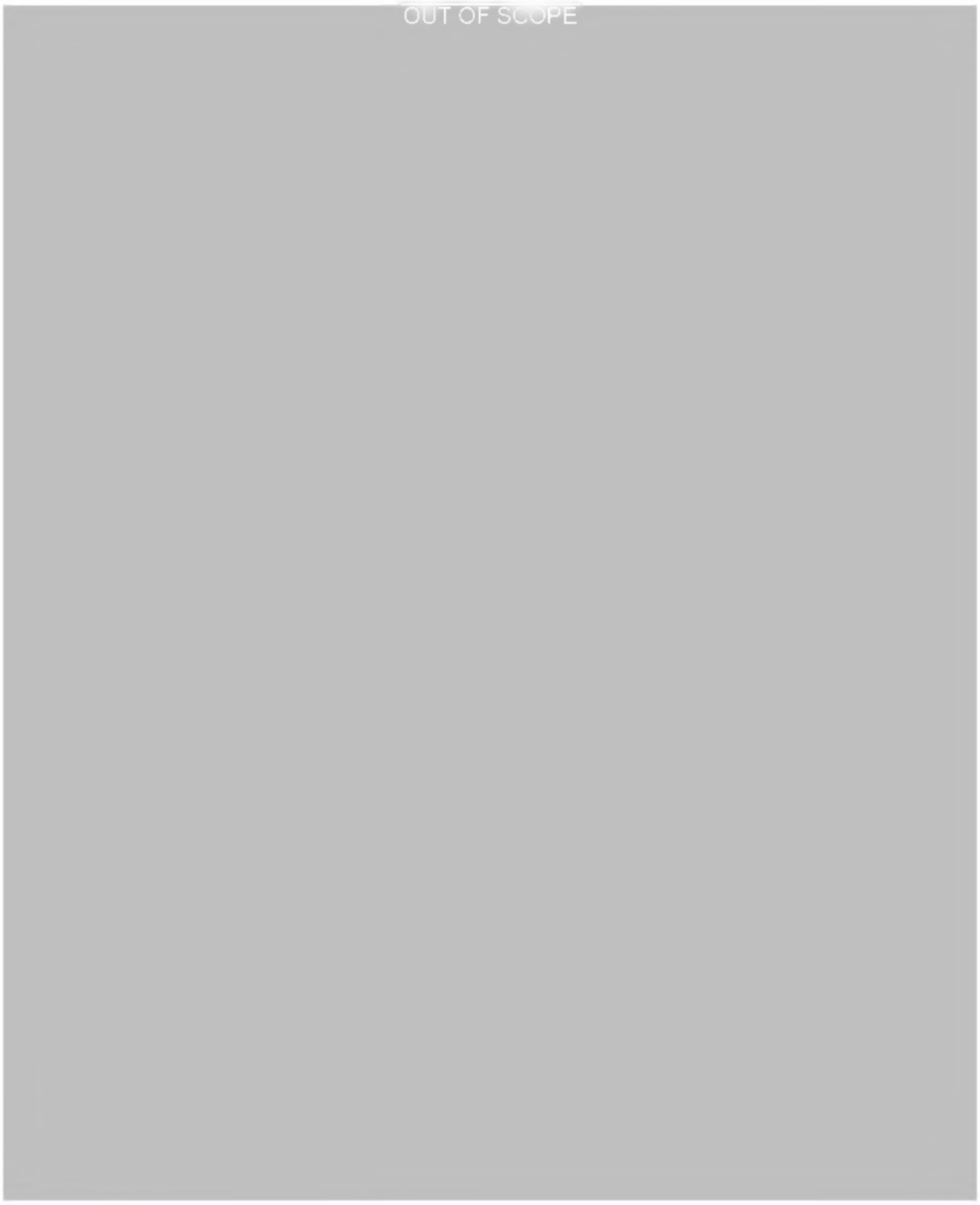
[redacted]

Points discussed

[redacted] OUT OF SCOPE

2) On Eudamed, it was noted that the document presented by the IT Unit of DG GROW to the MDCG of 20 June provided revised implementation timelines which were in contrast with the earlier planning communicated to D4 and presented to MS and stakeholders. In particular, the revised plan foresees several releases of parts of the databases across several years even until November 2022, while the scope of the first release was further restricted. It was agreed that a meeting should be urgently organised with Directorate R, in order to agree on a common granular schedule and verify the planning/monitoring tools used by the IT Unit. CP will take initiative to organise this meeting. As to the points of the rolling plan related to Eudamed, it was decided to indicate in the publicly available version that "certain modules" of the database might not be available by the application date. Moreover, certain information related to the state-of-play of Eudamed-related actions could be revised, where that information is made obsolete by the new planning presented by R3. This is the case of the release of the functional specifications, for which a new release is now foreseen in July 2019.

[redacted]


OUT OF SCOPE