



From: [REDACTED]
Sent: Wednesday, 16 December 2020 12:47
To: [REDACTED] (SANTE); [REDACTED] (SANTE)
Cc: [REDACTED] (SANTE); [REDACTED] (SANTE)
Subject: BTO meeting with EFPIA yesterday - also in view of our meeting with [REDACTED] in January

Meeting SANTE – EFPIA about inception impact assessment revision orphan/paediatric legislation (15 December 2020)

EFPIA: [REDACTED]
SANTE/ [REDACTED]

- SANTE introduced IIA and problems identified in the evaluation; IIA will run until 6 January 2021 and IA study will start in 2021
- EFPIA explained that EFPIA itself will respond to the IIA (Roadmap), but that members can/will also reply individually to the feedback mechanism.
- EFPIA also asked Dolon consultancy to assess the 4 options for orphans in the IIA and how they may influence investment decisions by companies (this report will not be published)
- EFPIA is preparing a paper on unmet medical need to better explain the different understandings around this concept, a 'mapping' and how unmet medical need is seen in different contexts. Following the completion of this paper, EFPIA plans to start an internal reflection on the specificities of unmet needs in the areas of rare diseases and medicines for children.
- According to EFPIA, there is no current [shared](#) definition of unmet medical need, therefore a multi-stakeholder discussion would be welcomed.
- Reference was also made to a legal analysis of unmet medical need that was drafted earlier this year.
- SANTE explained how unmet medical need will be further discussed in STAMP in 2021 (and discussions may also be opened to other stakeholders later in process).

END