

**From:** [REDACTED] (SANTE)  
**Sent:** 25 January 2021 15:28  
**To:** [REDACTED] (SANTE); [REDACTED] (SANTE) [REDACTED] (SANTE);  
[REDACTED] (SANTE)  
**Cc:** [REDACTED] (SANTE)  
**Subject:** BTO meeting EFPIA 13 January 2021 about revision O/P legislation

**BTO Meeting with EFPIA on 13 January 2021 about inception impact assessment orphans/paediatrics**

**EFPIA:** [REDACTED]  
[REDACTED]  
**COM:** [REDACTED]

**Main points discussed:**

- Inception impact assessment (IIA): short introduction and explanation that it is not the aim of the revision to abolish the system of incentives.
- Options in IIA are about optimising the system (both for Industry and for patients/member states).
- There is however a tension in the system: products do not reach the market.
- Aim therefore is to see if we can close this gap, e.g. by better defining what an unmet medical need is for everyone (in a holistic approach).
- Important to explore what are the factors that can positively influence availability and access.
- How can areas of unmet medical need be promoted and how can we reward efforts of companies in these areas.
- In EFPIA's view, you cannot facilitate access through incentives.
- Indeed, many areas exist that ask for more attention (unmet medical need).
- However, limiting incentives will not help this (but the concept of novel incentives sounds interesting).
- As regards *paediatrics*, surprise from EFPIA side about the ideas around future revision of the paediatric legislation
- At the same time, EFPIA acknowledged that some of the unmet medical need has not been met.
- EFPIA welcomes the idea for novel rewards (that complement or replace the SPC).

**Next steps**

- Further discussions about unmet medical need will take place, both in area of orphans and paediatrics and in pharma in general.
- For the general discussion, we can already learn from the discussion in the area of orphans/paediatrics.
- COM will continue in STAMP, but will expand this group to other stakeholders.
- COM also wants to engage with HTA bodies and payers.
- COM is open to have similar follow-up meetings with EFPIA about unmet medical need in near future.

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END