

From: [REDACTED] (SANTE)
Sent: lundi 25 janvier 2021 14:43
To: [REDACTED] (SANTE)
Cc: [REDACTED] (SANTE)
Subject: BTO meetings in October '20 with AmCham and [REDACTED] out of scope

EuropaBio OMP Working Group/AmCham EU's Healthcare Committee

SANTE/B.5 joined [REDACTED] out of scope **/AmCham's EU Healthcare Committee** on October 29 to present the main findings of the evaluation of the orphan and paediatric legislation.

out of scope

Main comments received from members of AmCham

- How can there be 'overcompensation' if at the same time Europe wants to incentivize R&D on field of orphans?
- Has the Evaluation been conducted too early, also in view of number of orphan authorizations and designations now accelerating since a couple of years?
- Further research needed about national policies (tax, special funds, faster assessment) in relation to access (external factors)
- Are European health systems ready to take onboard products addressing unmet medical needs in the future?
- Would the Commission be ready to set up a 'Pharmaceutical Forum'?
- How will challenges in the field of AMR be addressed, and how can the EU add value there? Would transferable exclusivities provide an option to incentivize new classes of antibiotics?

[REDACTED] (B.5 - [REDACTED])

END