

From: [REDACTED]
Sent: mardi 15 septembre 2020 17:59
To: [REDACTED] (SANTÉ)
Cc: [REDACTED]
Subject: BTO: Meeting with EUCOPE on O/P revision and Pharma strategy - 14 September 2020

Dear [REDACTED]

Please see our BTO from the meeting with EUCOPE yesterday.

It was quite a fruitful meeting, a lot of homework for EUCOPE!

They will come back to us in October with the outcomes of their brainstorming on the possible solutions for the O&P revision.

Thank you,
O&P and Pharma Strategy Teams

Meeting with EUCOPE on O/P revision and Pharma strategy - 14 September 2020

EUCOPE: [REDACTED]
[REDACTED] (Alexion)

SANTÉ: [REDACTED]
[REDACTED]

Evaluation of orphan and paediatric legislation

EUCOPE

- Follow-up to the Evaluation of the Orphan Regulation will be followed closely within EUCOPE.
- The Orphan Regulation has delivered concrete results. A follow-up should build on this positive result and on the objectives of the legislation.
- Main finding: 95% of rare diseases have no treatment
- Leveraging real world evidence is important. Regulatory flexibilities are also needed.
- Collaboration around European Reference Networks has been a success story.
- Affordability: changing the Orphan Regulation will have no impact on this. Complementary measures are needed outside the scope of the Orphan Regulation (pricing being a national competence).
- Current level of pharmaceutical incentives should be maintained.

- Working group has been set up, with external (multiple) stakeholders.
- As regards this new "Expert group on orphan drug incentives": multi-disciplinary, joint reflection process, approx. 30 participants in this group. Expert group will have (smaller) focus groups.
- Three main topics for this group: 1) optimisation of incentives framework (what kind of incentives most valuable); 2) looking into regulatory pathway (increased accessibility also in view of developments in science); 3) bring tools and incentives to Europe that are not here yet (e.g. in US) for development of orphan medicinal products.
- Expert group should come up with recommendations by the end of this year.
- More convergence needed as regards risk-benefit assessment and more alignment between evidence generation at EMA level and national decisions (including use of Real World Evidence between HTA bodies).

Action: EUCOPE will come back to SANTE with the preliminary results of the work of the Expert group on orphan drug incentives already in October.

Pharmaceutical strategy

SANTE analysed the objectives of the strategy and thanked EUCOPE for their comments to the Roadmap and asked EUCOPE what actions they would like to see in the Communication in terms of the objectives mentioned.

EUCOPE

- Lessons learned from Covid should be taken into account.
- Include actions that look into the root causes for shortages not just in crisis.
- Look into ways of integrating in the authorisation process the value of post launch evidence generation.
- Give emphasis on Europe as part of the word that innovation in pharma takes place.
- Reduce dependency on generics manufactured in China/India
- Joint procurement is not a cost containment tool in itself
- Build on the positive effect of ERNs (extrapolate lessons from O/P to other meds)

EUCOPE mentioned that the trans-border healthcare directive will help European patients travel to centres of excellence for care. They also mentioned that an Expert group on RWE for regulatory decisions is established by the Belgian INAMI. Recommendation from that group will be presented on 10 November in a conference on the European Health Data space which is organised in collaboration with the DE presidency. (EUCOPE will send more information). EUCOPE also enquired on the interlinkage of strategy and O/P revision and asked to maintain the current level of incentives, and find a way to define with all stakeholders unmet needs innovation and value.

