

EMA Round Table Meeting with Stakeholders – 10 year Anniversary of the SME Office

27. November 2015, London

EU COPE Members (extract)



Feedback from past interaction with EMA

EUCOPE welcomes:

- The involvement of a broad range of industry stakeholders in particular also taking into account the needs of SMEs
- Transparency around meetings (invitations, participation, etc.) and policies
- Sharing of expert knowledge and administrative practice in EMA meetings
- Openness towards different industry stakeholders, patients and their specific needs
- In particular the help of the SME office is much appreciated

Regulatory & HTA: SME + mid-size pharma focus needed

- EUCOPE: 70+ members within 5 years → more than 75% are not represented in any other EU association → a growing innovative business segment
- **Small companies cannot leverage between various compounds – most of them have only one / a few products but are highly innovative!**
- **HTA and coordination is crucial:** Out of more than 86 new APIs launched in Germany since after 2010 (AMNOG) more than 10 % are from SMEs / our members → **especially SMEs need HTA coordination and parallel advice!**
- On the regulatory side procedures within EMA reflect SMEs needs (scientific advice, fee reductions, workshops ...)

Expectations from future interaction with the EMA

1. SME + mid-size pharma participation should be increased in pilots:

- Parallel Scientific Advice (high importance for SMEs – higher burden to deal with various HTA procedures for SMEs!)
- Adaptive Pathways /PRIME (Early Patient Access especially needed in rare diseases; reimbursement is crucial and therefore HTA involvement is important)

➤ Any final policy can only reflect SMEs needs if tested before!

2. Any policy should be checked for SME suitability (“SME Check“) such as:

- Transparency Policy (AtD applications are hard to deal with for SMEs with only product in the market – SME office support?)
- Medicines Shortages (small compounds / rare diseases / ...)

➤ Eucope will be there to help finding SMEs partners for those pilots!

EUCOPE

European Confederation of Pharmaceutical Entrepreneurs

Dr. Alexander Natz
Rue d'Arlon 50
1000 Brussels / Belgium
Tel. +32 2 503 6986
natz@eucope.org
www.eucope.org