

Europharm SMC feedback

Telma Costa
Head of Regulatory Affairs



Regulatory requirements and Scientific Advice

- Publication of standard information
 - Everybody knows where to find the information.....the rules, the regulations etc
 - Everything is well described and user friendly including Eudralex, SME newsletters and EMA website in general.
=>> EMA did a good job for having this well exposed ☺
- Scientific Advice
 - SMEs need more assistance because they don't know who to contact for scientific advice.
 - They should have a dedicated account manager, contact person (as for a bank account).
 - Although scientific advice is used for big issues SMEs need a more direct contact for regulatory day to day basic assistance.
- New Regulatory requirements
 - We would recommend the need for a prior assessment on the impact of implementation of new legislation and regulatory requirement in terms of finances and human resources.

Information, communication, networking, partnering

- Stakeholders meetings, dedicated email address etc....well appreciated !!
- Networking & Partnering => can be improved
 - In many cases SMEs need to find partners for sharing the costs: example PASS Study
 - It would be highly appreciated and very helpful if EMA could be a facilitator to organize the consortium by sending a formal request to identify companies working with the same specific molecule in order to bring the companies together.

International and National regulatory authorities

- EMA should work together with national agencies to organise workshops, training courses etc.... For example the Eudravigilance course should also be available at each national agency in order to reduce costs for SMEs.
- A closer interaction between EMA and National authorities would be highly appreciated in order to get more information on impact of European regulation at local level.

Funding and finance, Market access, competition, and globalisation

- Funding and Finance
 - SMEs should receive a free support and advice on funding and finance: which kind of programmes are available, which form to fill in etc.
 - A SME dedicated person would be very helpful.
- Market access, competition, and globalisation
 - SMEs look forward for further harmonisation: e.g.: the prescription statute should be a European decision etc....