22 February 2017
EMA/52182/2017

Report of second EMA- AESGP annual bilateral meeting

11 January 2017, European Medicines Agency

Objectives of the meeting

To provide an annual opportunity for EMA to engage individual industry stakeholder associations in dialogue on key areas of mutual interest, to share information, exchange views and enhance the EMA understanding of the needs and expectations of its stakeholders.

Topics addressed at the meeting

AESGP Self-Care agenda and priorities

- AESGP Self-Care Agenda 2020 and priorities framework was presented. The focus is on proposals for non-prescription medicines improvements within the existing legislative framework. Establishing evidence-based policies, enhancing cooperation between stakeholders, creating more incentives for innovative self-care, reducing administrative burden, using procedures for market access efficiently and a risk-based implementation of rules are amongst other proposals made by AESGP to achieve its objectives.

Centralised procedure & non-prescription medicines: taking stock of the last 10 years and the way forward

- EMA provided an update on 10 years of "switching" legal status to non-prescription for centralised and nationally authorised medicinal products, acknowledging the limited use of the centralised route over that period i.e. only 7 "switches" applications were submitted centrally. For the vast majority of medicines the change of legal status is done at national level. A brief summary of the incentive of Article 74a of directive 2001//83/EC was also briefly discussed together with future procedural and stakeholder engagement proposals.
- AESGP highlighted their support for the centralised route as the path to innovation of the self-care sector given a number of centrally authorised medicines could give rise to innovative switches. AESGP also shared their reflections on centralised "non-prescription" medicines challenges, benefits and ideas for changes. Amongst existing challenges, the generation of "OTC experience" without prior approval was highlighted. A staggered approval mechanism and recognition of a new methodological approach to aid the benefit-risk assessment of non-prescription medicines recognising the benefit of access were presented as ideas for changes.
- EMA presented a proposal for a multi-stakeholder Scientific Advice for OTC switch. Further information will be published shortly.

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Linking SPOR implementation and optimisation of regulatory processes

- EMA gave an overview of SPOR/ISO-IDMP rationale, objectives, benefits development and timelines update – see presentation.
- The perspective of AESGP on SPOR/ISO-IDMP implementation and potential for regulatory process optimisation to drive quality data generation, regulatory process simplification and global alignment was discussed. The importance of ensuring stakeholder (Regulators (EMA and NCAs) and Industry) awareness, and engagement, through effective and timely communication was highlighted.
  In particular the need for timely communication of any amendments in project timelines was flagged as a critical point for Industry to mobilise resources and budget within their organisations.
- AESGP emphasised the importance of EU telematics tools to enable the objective of regulatory process optimisation within EU network and in that respect welcomed the creation of the HMA-EMA Regulatory Optimisation Group to interconnect the many telematics initiatives and multidisciplinary process overview across the network to foster simplification and optimisation in terms of process management and resources.

Framework for interaction with the industry

- AESGP gave positive feedback on their cross Agency-AESGP interactions over the past couple of years and on the role of the industry liaison as facilitator. Suggestions for further optimisation were shared and will continue to be discussed post-meeting.

Participants List

EMA	
Marie-Helene Pinheiro	Industry Stakeholder Liaison, Corporate Stakeholders ***(Chair)***
Nathalie Bere	Patients liaison Officer
Michael Berntgen	Head of Product Development Scientific Support
Radhouane Cherif	Head of Telematics Office
Alberto Ganan Jimenez	Head of Evaluation Procedures D
Evdokia Korakianiti	Head of Procedure Management
Laura Liebers	Regulatory Affairs Officer
Viola Macolic Sarinic	Senior Scientific Advice Officer, Scientific Advice
Francisco Penaranda	Head of Business Data and Analytics
Irene Rager	Head of Evaluation Procedure E
Sonia Ribeiro	Head of Regulatory Affairs
Tania Teixeira	Head of Evaluation Procedures F
AESGP	
Hubertus Cranz	Director General, AESGP
Christelle Anquez-Traxler	Regulatory and Scientific Affairs Manager, AESGP
Christine Eising	Bayer Consumer Care
Aurelie Farfaro	GSK CHC
Mark Griffith	Johnson & Johnson
Gabriella Grippaudo	Pfizer
Bruno Mabboux	PGT Healthcare
Sabrina Pradeau	HRA Pharma