22 February 2016
EMA/80132/2016
Corporate Stakeholders Department

Report of first EMA-European Generic Association (EGA) Annual bilateral meeting

27 January 2016, 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

EGA Regulatory Efficiency Report 2015

- Proposals made by the EGA in their 2015 report (link) to promote use of the centralised procedure by generic/biosimilar applicants/manufacturers. Increasing flexibility in the centralised optional scope for generics' access, naming policy for duplicates, and usage patents in the cross border health care setting were discussed.
- An update on international activities relevant for generic medicinal products was provided, as published on 26 January 2016 in the European Commission's (DG-Trade) technical paper (link) for TTIP.
- EMA provided a general update on telematics support and the road map to transition to ISO-IDMP followed by a discussion on the potential for variation simplification in the mid to long term.

Biosimilar activities update

- Both parties exchanged views on their current positions regarding Biosimilar naming and labelling.

Global supply chain

- EGA emphasised the importance of strong global supply chain (inter-)links in the generic/biosimilar field. EGA will organise a Workshop in India in May and a representative of the Agency has agreed to participate.
- Update and next steps further to the EMA multi-stakeholders workshop on "Developing a proactive approach to the prevention of medicines shortages due to manufacturing and quality problems" held at EMA on 9th October 2015 were briefly presented.

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MAHs compliance with PRAC recommendations for updating the product information of Centrally Authorised Products

- A presentation was made by EMA on a recent survey and process improvements (publication of translations since January 2015 and transition to concurrent submission of variations since July 2015) that will facilitate the submission of variations to update the product information of Centrally Authorised Products to comply with PRAC recommendations in the context of signal detection.

Framework for interaction between the European Medicines Agency and industry stakeholders

- EGA introduced EGA Staff and their respective roles and responsibilities together with upcoming EGA initiatives and conferences foreseen for 2016.
- An update on the implementation of the "Framework for interaction between the European Medicines Agency and industry stakeholders" was provided. Stakeholders' eligibility criteria have been drafted and will be circulated to Industry Stakeholders for comments. The EMA is also finalising an overarching stakeholder's management framework together with the 1st Industry stakeholder's annual report. Finally, EGA was informed of EMA's intention to launch an initial MAA survey in 2016.

Participants List

EMA	
Zaide Frias, **Chair**	Head of Human Medicines Research and Development Support
Marie-Hélène Pinheiro, **Co-Chair**	Industry Stakeholder Liaison, Corporate Stakeholders
Melanie Carr	Head of Corporate Stakeholders
Ana Rodriguez Sanchez Beato	Head of Clinical and Non-Clinical Compliance
Emer Cooke	Head of International Affairs
Patrick Costello	Scientific Administrator, Manufacturing and Compliance office
Brendan Cuddy	Head of Manufacturing and Quality Compliance
Georgy Genov	Head of Signal Management
Iordanis Gravanis	Evaluation Procedures C, Procedure Management and Committees Support
Ana Hidalgo-Simon	Head of Specialised Scientific Disciplines
Francisco Penaranda Fernandez	Head of Business Data and Analytics
Cherif Radhouane	Head of Telematics Office
Sonia Ribeiro	Head of Regulatory Affairs Office
Alexios Skarlatos	Head of Labelling Review and Standards
Aniello Santoro	Scientific Administrator
Matthias Sennwitz	CMD(h) Secretariat
Camille Vleminckx	Scientific Officer, Oncology, Haematology and Diagnostics

European Commission	
Sebastien Goux	D-5, DG SANTE

EGA	
Adrian van den Hoven	Director General
Beata Stepniewska	Deputy Director General, Head of Regulatory Affairs
Julie Maréchal Jamil	Director, Biosimilars Policy & Science
Koen Nauwelaerts	Quality and Regulatory Manager