26 September 2016
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Corporate Stakeholders Department

Report of first EMA-EFPIA annual bilateral meeting

16 September 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

Support for medicines development and market access

- EMA provided an update on recent experience with EMA's "PRIME" initiative which was launched earlier this year. It was noted that a stakeholder meeting on PRIME will be organised by EMA in Q1 2017 once one year of experience has been gained with the scheme.
- The recently published report from the Adaptive Pathways pilot was discussed. It was noted that a multi-stakeholders workshop on Adaptive Pathways will be held at EMA on the 8th December 2016 to discuss the learnings from the pilot and next steps. Discussions around the various development support mechanisms and regulatory tools for EMA early access to medicines took place with reference to the published overview of "Development support and regulatory tools for early access to medicines (EMA/531801/2015)".
- In the context of the ongoing EC review into the experience with Orphan and Paediatric incentives for medicines development, industry shared their views in response to the consultation.
- Exchange of views regarding on-going implementing Commission legislative documents took place.
- Finally a discussion took place on EMA-HTAs interaction early in development and the importance for industry of joint advice.

Implementation of recent legislation & IT telematics

- Both parties exchanged views on experience and challenges relating to the development of databases further to the implementation of falsified medicines, pharmacovigilance and clinical trial legislation. The high level business specifications and potential benefits and opportunities were discussed, as well as the involved partners/stakeholders, data standards and interdependencies. These discussions will continue to be coordinated through existing "technical fora" with all relevant

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stakeholders, namely Member states, European Commission, EMA and Industry, where and as relevant.

International Activity updates

- Both parties welcome the new ICH Reform and are looking forward to the extension of its membership, to facilitate global standard development and convergence, where and as appropriate. EFPIA highlighted potential challenges in maintaining efficiency and flexibility around such expansion but acknowledged the added benefits this may bring on topics such as scientific manufacturing standards, and regulatory capacity.
- At the end of the meeting, EMA and EFPIA briefly discussed their recent engagement with emerging regulatory authorities. EMA also provided an update on ICMRA activities.

Interaction between the European Medicines Agency and industry stakeholders, namely EFPIA

- The implementation of the eligibility criteria for industry stakeholder associations and the launch of the application process (application form) for direct involvement in EMA activities were highlighted.
- Further discussion on EMA and EFPIA specific Industry Stakeholders' framework implementation will take place prior to the next annual meeting bilateral which is expected to take place around the same period in 2017.

Participants List

EMA	
Guido Rasi	Executive Director
Melanie Carr, **Chair**	Head of Stakeholders and Communication *ad interim,* Head of Corporate Stakeholders
Marie-Hélène Pinheiro	Industry Stakeholder Liaison, Corporate Stakeholders
Enrica Alteri	Head of Human Medicines Research & Development Support
Peter Arlett	Head of Pharmacovigilance & Epidemiology
Michael Berntgen	Head of Product Development Scientific Support
Stefan Blixen-Finecke	Head of Head of Planning, Architecture and Quality *ad interim*
Francesca Cerreta	Scientific Advice
Emer Cooke	Head of International Affairs
Hans-Georg Eichler	Senior Medical Officer
Zaide Frias	Head of Human Medicines Evaluation
Jordi Llinares Garcia	Head of Scientific & Regulatory Management
Riccardo Luigetti	Principal International Affairs Officer
Stefano Marino	Head of Legal Department
Esther Martinez	Manufacturing and Quality Compliance
Jane Moseley	Scientific Advice
Francisco Fernandez Penaranda	Head of Business Data & Analytics
Cherif Radhouane	Head of Head of Telematics
Agnes Saint-Raymond	Head of Portfolio Board
Fergus Sweeney	Head of Inspections, Human Medicines Pharmacovigilance & Committees
Spiros Vamvakas	Head of Scientific Advice

EFPIA	
Richard Bergström	Director General
Sini Eskola	Director Regulatory Affairs
Pär Tellner	Director, Team Leader, Regulatory Affairs
Salah-dine Chibout	Member of IMI Board and Chair, EFPIA Innovative Medicines WG
Sue Forda	Chair, EFPIA Adaptive Models Priority WG
Edith Frenoy	Director HTA/REA
David Jefferys	EFPIA European Regulatory Expert WG