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Corporate Stakeholders Department

Report of first EMA-EuropaBio annual bilateral meeting

09 June 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

EuropaBio priorities for 2017-2018

- EuropaBio priorities for 2017-2018 focus on fostering innovation of Bio-industry in Europe and patients access through maintenance of EU frameworks and incentives, multi-stakeholder interaction and collaboration. Orphan medicinal products, Advanced Therapy Medicinal Products (ATMPs) and biosimilar medicinal products were amongst the products type used to illustrate the priority areas.

United Kingdom's withdrawal from the European Union preparedness activities

- EMA and EuropaBio provided a brief update on ongoing preparedness activities.

New paradigms in medicines' development

- EuropaBio presented case studies of innovative drug developments highlighting new progressing paradigms with unprecedented speed of scientific development and complexity focusing on products targeting areas where there is high unmet medical need and disease progression. In the context of new business models for global developments, factors which facilitate rapid knowledge generation and innovation of pharma industry, it is critical that multi-stakeholder engagement (including regulators, HTAs and payers) is established at an early stage, in a continuous manner during life-cycle development (pre- and post-marketing) and is as much as possible, aligned with international requirements.
- EMA provided an update on the PRIME scheme, accelerated assessment tools, conditional marketing authorisation and EMA-HTA collaboration, all identified as key EU regulatory tools to stimulate and foster innovation.

Industry utilisation of "Big Data"

- A presentation from EuropaBio was made on the ways "Big-Data" are being utilised by industry in medicines development and where it may play a role in supporting regulatory decision making

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from an industry perspective. It was highlighted that the terminology of "Big Data" may vary in meaning from quantitative (large in terms of heterogeneous large data sources (structured or unstructured), data itself or people) to descriptive e.g. gene sequencing. Therefore its regulatory usage as evidence source or generation may also vary and its full potential use still remains to be discovered. Hence, the research, data gathering mechanisms, methods and analytical tools being developed.

In this context industry participants shared a few examples of "Big-Data" usage, including claims databases and electronic medical records, social media, population health survey data, prescribing databases. All this data is intended to facilitate the understanding of disease burden, treatment patterns, as well as patients' behaviour and product performance, genetic profiling etc.

This presentation was followed by an update on the HMA-EMA joint Task force on Big Data activities given by EMA (see presentation) and the priorities of the EMA and network engagement.

Future of mutual recognition of inspections and approvals and EMA – FDA cooperation

- EMA updated industry participants on the EU-US Mutual recognition Agreement (post- and pre-approval inspections, inspection outside the territory) with regard to the scope of the MRA, the proposed MRA process in term of assessment and joint audit programme, and the upcoming key timelines (i.e. entry into force on 1st November 2017 with 8 Member states and by 15th July 2019, all EU MSs are expected to be recognised). See presentation for more details.
- Exchange of views took place as to some of the practicalities for the implementation and a call for more transparency and detailed guidance was highlighted.

Update on EMA Industry Stakeholders activities

- Further discussion in the context of EMA's Industry Stakeholders' framework implementation was postponed.
- It was highlighted that in view of the EMA post-UK referendum outcome preparedness and EMA Business Continuity Planning (BCP), some changes to existing plans for interaction will have to be considered in 2018.