15 September 2017
EMA/602747/2017
Corporate Stakeholders Department

Report of second EMA-EFPIA annual bilateral meeting

10 July 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

United Kingdom's withdrawal from the European Union - preparedness activities

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

Support for medicines development

- PRIME Initiative – EFPIA welcomed the recent stakeholder meeting held on 19 May to coincide with the first anniversary of PRIME (link to meeting report). It was noted that further dialogue with industry stakeholders on how the PRIME scheme could be improved based on experience is foreseen in industry stakeholder platform meetings. Proposals put forward by industry include a request for pre-submission interaction, an earlier entry point to the scheme independent of the size of the company, eligibility to be considered for products already authorised in the EEA that could address unmet medical need (e.g. new indications), and the possibility for a teleconference to debrief in the event of a negative outcome.
- Interplay with HTA and health systems – EMA provided an update on the revised , streamlined approach to engaging with HTAs (link to document).
- EMA provided an update on the work of the EMA-HMA big data task force which is exploring how big data can be seen in the regulatory context. The taskforce is currently working on a roadmap and a set of recommendations.
- IMI projects – EFPIA provided an overview of high level plans for IMI to 2020 and beyond. A public budget of about € 900 million will be matched by industry contributions for calls to be launched in the next 3 years.
- EU Paediatric legislation – publication of the EC report is awaited. EFPIA has also conducted a study looking at the impact from the industry's perspective.
- A number of proposals to address some of the current challenges with PIPs were discussed during the industry platform meeting in April (link to report). Further dialogue is expected during the course of follow-up R&D platform meetings in 2017-2018.

International Activity updates

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- ICH- Both parties welcomed the recent progress seen in ICH. EFPIA noted concerns with vaccines in emerging markets and were interested in exploring whether ICH would be a useful for a to address these. EMA considered that if the issues were of a technical nature, they could potentially be addressed at ICH.
- ICMRA – EMA provided a brief updated on ongoing work to align track and trace systems and asked EFPIA to nominate technical contacts to work with the Agency on this topic. 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).
- An exchange of views took place as to some of the practicalities for the implementation. EFPIA considered that a future workshop on EU-US MRA would be useful.
- EMA highlighted work ongoing to promote further use of the Article 58 procedure such as inclusion in the PRIME scheme, future rebranding and increased communication to raise awareness of the benefits. EMA would welcome feedback from EFPIA on what more can be done to increase uptake.

Implementation of recent legislation & IT telematics

- EMA provided brief updates on the status of the CT Portal and SPOR programmes. EFPIA highlighted the impact that the recent delays announced in these projects will have on industry and an exchange of views took place how to best address these concerns. Regular meetings scheduled between industry stakeholders and the EU Telematics Board provide an opportunity for dialogue and stakeholder input into all planned and ongoing EU telematics projects.

Shortages and availability of medicinal products

- EMA and HMA are finalising a reflection paper on availability and shortages of medicines. A workshop on the supply chain is also planned by regulators in Q4 of 2017

A.O.B.

- Regarding publication of clinical data (policy 0070) EFPIA welcomed the recent establishment of quarterly webinars to discuss aspects related to implementation of the policy and any planned updates to guidance documents.
- Further discussion on other topics related EMA's Industry Stakeholders' framework implementation and stakeholder event planning 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.