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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

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DIRECTORATE B AND EFPIA (EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS)
BTO 2 OCTOBER 2020 VIDEO-CALL ON PHARMACEUTICAL RELATED ISSUES

Meeting requested by EFPIA to have an update on ongoing activities related to pharmaceuticals and to inform of their own activities.

Pharmaceutical Strategy – EFPIA had concerns that the strategy might be focused only on access and availability. SANTE reassured that the strategy would be balanced with focus not only on access and affordability, but also innovation and international issues. The aim is to have a holistic approach covering elements such as research, innovation, new technologies, incentives, competition, regulatory efficiency but also unmet medical needs and availability. The pharmaceutical strategy communication will set the direction. The actions will be a mixture of legislative and non-legislative. The implementation will be done on the basis of evidence and only after evaluation and assessment of the options to address the issues identified.

Crisis preparedness – Mr Rys explained that there will be also a package of proposals for immediate response to health threats. The mandates of the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control will be strengthened as part of this package, following the experience of the coronavirus pandemic. Medium and longer term measures to increase preparedness and resilience including security of supply and management of shortages will be considered within the pharmaceutical strategy.

Environmental issues – EFPIA asked about the links of the pharmaceutical strategy and the Green Deal and the action on pharmaceuticals in the environment and if input was needed. SANTE explained that the pharmaceuticals in the environment would be part of the strategy, but some actions have already started as part of the implementation of the Commission communication on pharmaceuticals in the environment. More detailed actions will be considered in the implementation of the strategy and EFPIA can contribute then.

EFPIA's reply to Targeted Stakeholder Consultation pilot project market launch intentions – SANTE took note of the concerns raised and reassured EFPIA that they will be addressed in a subsequent version of the pilot project description (including concerns over confidentiality of information shared; level of granularity of the reasoning why a product is not launched). EFPIA supported greater transparency, referred to the need to

recognise the concerns raised by its members and to analyse all root causes. SANTE stressed the necessity to work collaboratively on this complex and multifactorial problem and to take proactive steps with the engagement of all stakeholders. This is a project of key importance for the pharmaceutical strategy and an opportunity to bring further transparency on access in a collaborative safe harbour environment.

Orphan and Paediatric medicines and unmet needs – EFPIA informed that they have commissioned a study on the impact of the incentives provided by Orphan Regulation and the number of new orphan products authorised. The study utilises a different methodology than the one of the study supporting the evaluation of the Orphan Regulation. The EFPIA study is planned to be published by beginning of November. Commission services will be invited to an event where this study will be presented.

Concerning the Paediatric Regulation, EFPIA stressed the importance of the Commission-EMA paediatric action plan and expressed hope that it can be continued. EFPIA will send a letter to SANTE and to EMA on the action plan and on the application of Article 46 of the Paediatric Regulation.

It was clarified that the ongoing work on the Orphan and Paediatric Regulations will not concern "other" unmet needs. A reflection on how to stimulate development in areas of unmet needs will be part of the pharmaceutical strategy. Following a question from SANTE, EFPIA gave an update on the industry fund created to support the development of novel antimicrobial products. EFPIA stressed that the fund in itself would not be sufficient and novel incentives would need to be put in place to support the creation of a pipeline of new products.

END

Participant: DG SANTE: Andrzej Rys (Director B), [redacted]

EFPIA: [redacted]