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From: [redacted] (SANTE)
Sent: 08 July 2020 09:59
To: BUCHER Anne (SANTE); GALLINA Sandra (SANTE); RYS Andrzej Jan (SANTE); HUDSON Matthew (SANTE); RYAN John-F (SANTE)
Cc: [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (DEVCO); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE)
Subject: BTO - Meeting between Commissioner Kyriakides and EFPIA on Pharma Strategy - 3 July 2020

Dear all,
Please find below, for your information, the minutes of the 4th out of 10 bilaterals of the Commissioner with stakeholders on the Pharma strategy.
Kind regards,
[redacted]

BTO - Pharmaceutical Strategy meeting - Meeting with EFPIA 3 July 2020

<u>Participants</u>
EFPIA: [redacted]
Commission: Commissioner Kyriakides, Giorgos Rossides, Karolina Herbout-Borczak, Anne Mueller, Christiana Solomonidou (CAB Kyriakides). [redacted] (SANTE [redacted], [redacted] (SANTE [redacted], [redacted] (SANTE [redacted]).

Summary
The EFPIA generally supports the objectives under the strategy with an emphasis on innovation and having a stable legislative environment for investment. It believes that most actions are possible within the current framework and that the existing system of incentives should not be weakened. It believes that the EU should draw on lessons from the crisis to shorten authorisation review times by EMA (not only in crises) and follow through on its proposals on HTA. EFPIA stands ready to work with the

Commission, stakeholders and Member States preferably in a "high level forum". The Commissioner stressed that the strategy is holistic and focuses on providing the right incentives for patient centred innovation. Opening the legislation is an option and the Commission is ready to engage regularly with all stakeholders in the context of bilateral meetings and the existing fora.

Regulatory framework

EFPIA: The EU can be a leading hub for innovation but access also relates to delays in procedures of regulatory approvals where the EU could do better compared to the FDA, China and others. Approvals can be supported by artificial intelligence (AI) and modelling. Digital developments will challenge the current framework. EFPIA welcomes EMA's intention to accelerate approval in times of need and encourages the Commission and EMA to apply similar principles in the "business as usual" scenarios, referring to faster approval times in other regions. To do this the Commission does not need to open the legislation. On the other hand, a stable and predictable framework is important. EFPIA considers opening the legislation may destabilise the sector and decrease investments.

Commission: The EU has proven that when needed we can go faster (example of remdesivir). A stable regulatory framework is important but we must be open-minded when looking at solutions and not be afraid to improve legislation if we see a need for it. The roadmap outlines the challenges, which are also opportunities to achieve a more patient centred system. The strategy will examine ways of simplifying procedures and possibility of integrating a system of rolling review of medicines. It is important to have a system that creates trust that the assessments made are accurate and robust. A core aim of the strategy is to examine how to integrate promising methods, AI modelling and to provide for efficiency in legislation. The opening or not of legislation should not be the focus of the discourse now, but rather how to look at the opportunities and challenges in critical way.

Shortages, accessibility, HTA

EFPIA: A definition of medical need is required. EFPIA has conducted a comprehensive analysis based on evidence, the pillars of the solution require a sustainable HTA framework as a strong basis.

The Commission must act as a broker for dialogue. To achieve these objectives a "high level forum" is needed to co-create stakeholder solutions on access and mitigation of shortages.

Commission: A regular engagement with stakeholders is important and it will continue (e. g. bilateral meetings, an online workshop on the strategy on 14-15 July, meetings of the Pharmaceutical Committee). The Commission is not planning to establish a "high level forum" for the moment, but it is something it could consider in the future.

Incentives framework

EFPIA: The EU must safeguard the incentives and rewards framework. Opening the legislation (e.g. for orphan and paediatrics medicines) risks weakening the system of incentives and investment in the field. Access will not be fixed by reviewing incentives. This should be addressed separately in an appropriate forum. AMR relates to push and pull incentives, which are very important (industry is planning a global fund on AMR).

Commissioner: The Commission has some preliminary ideas on the strengths and limits of the current legislation and welcomes all perspectives including on legislative or non-legislative actions. The problems of innovation in antimicrobials is recognised, we must look at the current business model and how it works. The Commission will consider this in the strategy. The evaluation of Orphan and Paediatric legislation will be published this summer.

Competitiveness – Covid preparedness

EFPIA: EU should support industrial sustainable capacity for projects and develop health emergency countermeasures from vaccines to diagnostics. R&D manufacturing requires long-term investments from EU and Member States. There must also be an opportunity for discussion on conflicting policy choices ("trade-offs"). For example there is a counterbalance between outsourcing of production cost versus bringing back APIs to the EU. Resilience cannot be achieved by reshoring only. Member States must join forces for a policy framework and incentives that support a strong and innovative pharmaceutical sector.
Commissioner: The EU must be a global leader. The EU4Health programme aims to strengthen resilience of health systems and provide a robust health data structure. We are still learning from the pandemic and these learnings will feed into the pharmaceutical strategy. A Vaccine strategy was published mid June. No lowering of our quality/efficacy standards should be accepted and a coordinated way of response in crisis and public health emergencies is needed. Competitiveness involves a lot of policies: industrial strategy, green deal and others. This holistic approach to incentives and innovation will be in the heart of the strategy.

END