

Cabinet Kyriakides:

The Cabinet welcomed the dialogue and explained the main pillars of the strategy, highlighting the fact that access is one of several pillars. The input of industry is important and EFPIA was invited to participate actively. The wish for a high-level forum was noted. Cabinet informed the different outreach activities of the Commission in the coming months, both through bilateral meetings and workshops and the public consultation. However, the Commission would also further consider alternative ways for engaging with stakeholders.

2. Orphan and paediatrics evaluation (including Incentives and AMR)

EFPIA:

O/P evaluation: The current framework has delivered not just in terms of O/P products but also has created an ecosystem around these products. Incentives are an important pillar of this framework and should not be opened. EFPIA is awaiting the outcome of the evaluation and engaging with patient groups to possibly make joint proposals. O/P is not an area which is inherently commercially attractive, changing the incentives will not change that fact. EFPIA inquired about expected timeline.

On **AMR** Industry is working on its new proposal i.e. fund that will support the clinical development of antimicrobials (funding other companies) and will permit to bring new molecules on the market (EFPIA will send the proposal). It is important to work together with MS in order to create further incentives/ correct market conditions after the marketing authorisation process.

Cabinet Kyriakides/SANTE:

The importance of the orphan/paediatric evaluation was recognised. The evaluation goes beyond only the incentives into performance of regulations. It looks at whether the system has delivered in terms of research and access to market, definition of diseases and diagnosis. All these will define the way forward not just incentives. The publication of the SWD for the evaluation is foreseen for July and subsequently information about next steps will be published. Specific meeting with EFPIA on orphan/paediatrics might be scheduled in September.

3. HTA

EFPIA:

- EFPIA reiterated its support to the file, acknowledged the delay of the negotiation due to the COVID-19 but expressed concerns on the non-visibility of the HTA proposal in the Trio presidency programme and current discussions on future of cooperation in Health. Asked whether the EC was deprioritising the file and if there is a plan B for HTA. EFPIA underlined that the COVID crises showed that cooperation at EU level on assessment of evidence is essential. Linked the agreement on the HTA proposal as an important pre-requisite for the discussion on the pharma strategy, in particular as the pharma strategy in the view of EFPIA has strong focus on access. It was also questioned how Member States could discuss access related issues in the context of the pharma strategy without being able to agree on the HTA proposal. EFPIA considers important quick adoption of the HTA proposal to contribute to facilitate access.

Cabinet Kyriakides/SANTE:

The cabinet stressed that there is no plan B for the HTA proposal. The Commission, remains committed to the adoption of the HTA Proposal which is an important deliverable and linked to the objectives outlined in Commissioner's mission letter. The Commission had reassurance from German Presidency that they will deal with the file but with the COVID crisis they had to reshuffle their priorities and they

might need to deal with more urgent files. While the Commission will raise the importance of progressing the negotiation on the file during ministerial meetings, any support/outreach would be welcome.

4. Conclusion

Cabinet appreciated the direct exchanges with EFPIA. This interaction is important for the Pharma Strategy as well as for other important legislative files (e.g. HTA). A meeting with Commissioner Kyriakides on the pharma strategy is already foreseen for July (and a preparatory call may be organised beforehand). In addition, a further meeting on orphan/paediatrics might take place after the summer.

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