From: (SANTE) Sent: vendredi 19 février 2021 12:28 To: (SANTE) Cc: (SANTE); (SANTE) BTO - Second meeting of the Healthcare and Pharmaceuticals Working Group Subject: - CEPS can you please register the below and add it in EMT? Dear In ARES INFO to B4 and B5. and on some specific points made on AMR and HERA and the resources shared by MSD in the chat for their info. Many thanks *** BTO - Second meeting of the Healthcare and Pharmaceuticals Working Group (Centre for European Policy Studies) 18 February 2021 **Participants** (AmCham EU), (MSD), (SANTE) (OECD)

Presentation by SANTE on the pharmaceutical strategy and by OECD on the challenges in pharmaceutical policy: Unpacking the tension between incentivizing R&D investment and ensuring affordability.

Pharmaceutical incentives and innovation

A definition or criteria of unmet medical needs can guide the focus of incentives. An agreement on that is unmet needs in the different stages of medicines lifecycle could create more favourable conditions for medicines considered as meeting unmet medical need.

Call for strong push incentives from the Commission to private sector stakeholders collaboration. Industry called for a strong public funding programme and partnerships to innovate in areas of need. The provision of a EHDS and reduction in the regulatory system is positive. Trust legitimacy and understanding of operatiors and subjects to EHDS is important for its success.

AMR and market failures

Industry mentions that current system doesn't work, companies that launch new antimicrobials go bankrupt.

Call for a new market model (Netflix type system for AMR) so as to minimise risk of development of new antimicrobials.

New clinical practice models could also help research effective ways to reduce AMR. Withdrawals of old antimicrobials.

Price transparency and cost reduction

OECD and EC stressed need for price transparency and need to avoid paying twice. Possible links of full incentives to public service obligations.

Call to move away from winner takes all public procurement as it is a system that may reduce prices in the short term but reduces competition in the long term.

Covid-19 learnings

Call for risk sharing shown in crisis like with APAs to continue on "normal" times. HERA and the new HERA incubator are examples of how the system can prepare for new threats. Options on the responsibilities and form of HERA are on the table the could be some room to use it beyond simple crisis preparedness to support development of medicines for specific urgent need like for antimicrobials.

Information shared in chat by MSD representative:

(1) MSD "Pharmaceutical Policy Passport", which is a lay-language overview of the fundamentals and various issues being debated about pharmaceutical policy. https://www.efpia.eu/news-events/the-efpia-view/blog-articles/msd-policy-passport-on-pharmaceutical-innovation-guest-blog/ (2) On antimicrobial resistance, see MSD Global Action Plan on AMR for potential policy recommendations https://www.msdresponsibility.com/wp-content/uploads/2018/07/MSD_Global-Antimicrobial-Reisitance-Action-Plan_2018-1.pdf See also our editorial on AMR: https://www.msd.com/stories/addressing-antibiotic-resistance-is-more-critical-than-ever/ (3) MSD position on the various themes that the EU Pharmaceutical Strategy focuses on. https://www.dropbox.com/s/bdwwr32oymr5h23/MSD%20POSITION%20ON%20PHARMA%20STRATEGY%20SURVEY%20-%20FINAL_sec.pdf?dl=0

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