

**From:** [REDACTED] (SANTE)  
**Sent:** vendredi 11 septembre 2020 11:06  
**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};  
(SANTE); [REDACTED] {SANTÉ}; [REDACTED]  
[REDACTED] {SANTÉ}; [REDACTED] (SANTE);  
{SANTÉ} [REDACTED] (SANTE), [REDACTED] (SANTE);  
[SANTÉ]; [REDACTED] (SANTE); Sante;  
CONSULT-B5

**Subject:** BTO - Pharmaceutical Strategy meeting - Meeting with the European Public Health Alliance on 10 September 2020

Dear all,

Please find below, for your information, the minutes of the 9<sup>th</sup> out of 10 bilateral of the Commissioner with stakeholders on the Pharma strategy.

Kind regards,

**BTO - Pharmaceutical Strategy meeting - Meeting with the European Public Health Alliance on 10 September 2020**

## Participants

**EPHA:** [REDACTED] Universal Access and Affordable Medicines) and [REDACTED] European Alliance [REDACTED] (project run by EPHA)

**Commission:** Commissioner Stella Kyriakides, (CAB Kyriakides). [REDACTED] (DG SANTE).

**Introduction:** Commissioner Kyriakides opened the meeting by providing an overview of the current epidemiological situation and referred to several initiatives carried out by the Commission to help Member States deal with the COVID-19 outbreak. Such activities include among others joint procurements and negotiations with vaccine-producing companies. Commissioner Kyriakides presented the state of play of the preparation for the Pharmaceutical strategy, the different consultation activities (feedback on roadmap, public consultation, workshop) and called for EPHA's active participation throughout the process. She also informed that the evaluation of the orphan and paediatric legislation has been finalised and that the Commission considers a revision of the legislation. EPHA welcomed the objectives of the strategy and particularly the prominent role of access to medicines and enhancing their affordability, and pointed to the role of the Commission in ensuring a better coordination between Member States. EPHA congratulated DG SANTE for the "excellent work" on designing a comprehensive and well targeted questionnaire for the public consultation, to which EPHA will reply.

**Incentives and access:** EPHA welcomes that the strategy will examine the system of incentives, in line with the results of the evaluation of the orphan and paediatric legislation. Even in an area like orphan and paediatric medicines, where incentives are stronger than for other types of medicines, there is weak market launch and access falls behind. The Pharmaceutical strategy needs to look into patent law and the granting of exclusivities, which are needed for innovation but should not distort competition. Incentives should not over compensate and should enable meaningful innovation and competition that works.

**Orphan and paediatric legislation:** EPHA supports introducing a withdrawal clause in cases where protection is abused. It also supports revision of article 8(2) of the orphans legislation with the introduction of a definition of “excessive profit” and “sufficient profit”. It also supports a review of disease prevalence criteria.

**Shortages:** EPHA welcomes the study on root causes of shortages and calls for reinforcing the obligations of market authorisation holders and for considering sanctions in cases of non-compliance. EPHA supports better monitoring, prevention and management plans for shortages. EPHA agrees with the goal of diversification of sources of active pharmaceutical ingredients (APIs) and medicines, and considers that public tendering needs to abolish ‘winner takes it all’ practices as they lead to established products being pulled out of the market.

**Antimicrobial resistance (AMR):** EPHA is driving the debate together with the EP. EPHA thanked the Commissioner for participating in the MEP Interest Group on AMR launch event. EPHA noted that industry used the problem of AMR to seek more incentives, but EU policy must make sure that the principles of affordability and access are respected. Non-market based solutions can be part of the actions on AMR.

**Affordability:** EPHA mentioned that transparency is key. The Commission should look at the cost of market exclusivities and their impact on affordability and availability. Member States should use their joint-leverage vis-a-vis companies in terms of pricing. SANTE mentioned that the strategy will give more opportunity to Member States to talk to each other on issues of their competence and look for action that provide value for money to health systems.

**Covid-19 vaccines and therapeutics:** EPHA considers that the Commission’s deals with companies on vaccines is already a success since it has helped Member States to speak with one voice. EPHA calls for more transparency on the negotiation process and welcomed DG SANTE’s presentation in the EP in this respect. EPHA (also expressing the view of the European Patients Forum) calls for clinical trials data transparency for Covid-19 vaccines and therapeutics and welcomes that agencies will uphold higher standards.

**Health technology assessments:** EPHA strongly support the file, as it is beneficial for patients. Commissioner Kyriakides mentioned that this file is now in the hands of the co-legislators, and the Commission will do its utmost to get it through.

**EU4Health:** The Commissioner mentioned that the Commission has proposed an ambitious EU4Health programme which, even with a reduced budget, remains an

important advancement. She invited EPHA to get involved in the implementation of the programme. EPHA shares the disappointment on the reduction of the budget and stands ready to contribute to its implementation.

**Public support to biomedical R&D:** EPHA called SANTE to put pressure on DG RTD for more research on biomedical R&D. SANTE should press for a more important role of Public Private Partnerships like IHI (Innovative Health Initiative), but also to Public - Public partnerships on AMR. EPHA also supports more funding, from RTD and the European Investment Bank, on bringing new antibiotics to the market. More generally, for all the funding of health activities EPHA would like to see a prioritization of actions taking into account the public interest. EPHA would welcome more structured and regular dialogue with the stakeholders on prioritization of actions and on the implementation and evaluation of the projects.

ENDS.