

**From:** [REDACTED] (SANTÉ)  
**To:** BUCHER Anne (SANTÉ); [REDACTED] (SANTÉ)  
**Cc:** RYS Andrzej Jan (SANTÉ); [REDACTED] (SANTÉ); [REDACTED] (SANTÉ); [REDACTED] (SANTÉ); [REDACTED] (SANTÉ); [REDACTED] (SANTÉ); SEYCHELL Martin (SANTÉ); [REDACTED] (SANTÉ); [REDACTED] (SANTÉ); [REDACTED] (SANTÉ); [REDACTED] (SANTÉ); [REDACTED] (SANTÉ); [REDACTED] (SANTÉ)  
**Subject:** RE: Minutes of meeting with EFPIA on 5 June 2020  
**Date:** vendredi 5 juin 2020 18:18:23

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Dear Anne,

Please find below the minutes of the meeting we had this morning with EFPIA as validated by Andrzej and colleagues present. We will register them as per standard procedure.

Kind regards,

[REDACTED]

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Meeting with EFPIA 5 June 2020

**EFPIA:**

[REDACTED], [REDACTED]  
[REDACTED], [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

**SANTÉ:** Anne Bucher, Andrzej Rys, [REDACTED], [REDACTED], [REDACTED], F [REDACTED]  
[REDACTED], [REDACTED], [REDACTED]

## 1. Pharma strategy

**EFPIA:**

Would like to see an engagement at a **high level forum** (COM, MS and stakeholders) which would discuss particularly access to issues. This is considered an urgent issue for EFPIA and should the Commission not be prepared to organise such a discussion EFPIA would then, “as a plan B” go ahead on its own to set up such a forum (EFPIA claims this would have the support of DE presidency). The CEOs meeting didn’t happen due to Covid, but the message from them would have been the same: that an open conversation on access is urgently needed.

**HTA:** EFPIA considers there is misalignment of evidence in decision making, HTA can contribute to access/availability. EFPIA inquired about the current standstill and timetable on this file and informed that it will have a meeting with services on this on 12 June. **Roadmap:** EFPIA welcomed the roadmap publication and elements (specifically API reliance, data, use of RWE) and inquired about the connection with other initiatives e.g. the industrial strategy. It also asked if repurposing is something that can be envisaged in the strategy.

**SANTÉ:**

On a **high level forum** SANTE replied that it does not foresee the establishment of a permanent high level forum at this stage. The Commission speaks to all the stakeholder and MS on access. The consultation process of the strategy has opened and will give the opportunity for discussion in a stakeholder workshop in July on targeted questions regarding the strategy. The consultation process, can also include discussions in an enlarged pharma committee and the Commissioner is already planning bilateral meetings with targeted stakeholders. It should be noted that more technical discussions will take place during the implementation of the Communication. Commission wants to build up on good cooperation and there will be ample opportunity to get the right people around the table on these consultations.

**HTA:** DE presidency will not discontinue the file but will not prioritise it as it will give precedence to Covid lessons learned. Mandatory use of assessment and the role of the Commission are some of the hot points. There is support from the ENVI committee, but reactivation of file will come more under the PT presidency.

**Roadmap:** This is a Commission strategy, so the output is common. The Commission is engaging with all relevant DGs and will focus its contacts with certain DGs to propose specific actions (RTD, CNECT ENV, COMP GROW). With GROW there is already close cooperation on API dependency. Repurposing is something that can come out of the strategy indeed.

## **2. Incentives and access (incl. orphan & pediatrics evaluation, AMR)**

### **EFPIA:**

**Incentives:** Intellectual property status holds a key role to innovation. IP is not a barrier but rather an incentive and prerequisite for innovation. The review of incentives on O/P can create a roll back on IP which will have an impact on EU competitiveness for innovation given the rising global competition.

On **AMR** low sales contribute to insufficient revenues. EFPIA acknowledged that there are already effective push incentives (e.g. IMI), however there is an urgent need for pull incentives. 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.

**O/P evaluation:** The current framework has delivered not just in terms of O/P products but also an 88% increase in clinical trials in the EU alone and has created an ecosystem around these products. Access is important, also research is needed, lack of basic epidemiological data, screening diagnosis on O/P diseases contributes to access issues. Changing incentives doesn't have a predictable impact on access. There is an urgent need to have a conversation with all stakeholders and MS on access models (links to high level forum). EFPIA is already engaging with patient groups to possibly make joint proposals. O/P is not an area which is inherently commercially attractive, changing the incentives won't change that fact. EFPIA inquired about expected timeline.

**Use of RWD/complex clinical trials:** Innovative clinical trial design can be addressed within current framework. Is there a technical platform to hold these discussions?

### **SANTE:**

**O/P evaluation:** Incentives help research but access is the issue and this is the message the Commission receives from MS. The evaluation goes beyond the incentives into

performance of regulations, and whether the system has delivered in terms of research and access to market, definition of diseases, diagnosis also recognized. All these will define the way forward not just incentives. Incentives do not always lead to innovation for all areas. That's why we need to see how we can spark innovation in areas that are not served yet. Pharmaceutical strategy will give an opportunity to have this urgent discussion. A mix of legislative & non-legislative action as well as wider action (beyond pharma) will provide the solutions. SANTE has been working with GROW on incentives (see relevant study) and discussion has started on how incentives can make available the products to patients. Timing depends on internal processes. We expect publication beginning of July.

**Incentives for AMR**, COVID has prioritized the issue of AMR. We need to go beyond classical incentives which should be coupled with public health obligations. Commission is open to options and would welcome ideas (perhaps a federated fund for research). AMR is a different case than O/P because there is no market (antimicrobial developed for the shelf/restricted use).

END