

From: [REDACTED] (SANTE)
Sent: vendredi 25 septembre 2020 13:04
To: BUCHER Anne (SANTE); GALLINA Sandra (SANTE); RYS Andrzej Jan (SANTE); HUDSON Matthew (SANTE); RYAN John-F (SANTE)
Cc: [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED]
[REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE);
[REDACTED] (SANTE); [REDACTED] (DEVCO); [REDACTED]
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(SANTE); [REDACTED] (SANTE); [REDACTED]
(SANTE); [REDACTED] (SANTE); [REDACTED]
[REDACTED] (SANTE)
Subject: BTO: Head of Cabinet meeting with the European Association of Bioindustries (EUROPABIO) - 24 September 2020

Dear all,
Please find below, for your information, the minutes of the meeting between EUROPABIO and CAB on the Pharma strategy which took place yesterday.
Kind regards,

BTO - Head of Cabinet meeting with the European Association of Bioindustries (EUROPABIO) - 24 September 2020

Presence

EUROPABIO: [REDACTED]
CAB/SANTE: Giorgos Rossides, Annukka Ojala, Karolina Herbout-Borczak, [REDACTED], [REDACTED]

EUROPABIO: Expressed its appreciation for the cooperation with Commission on dealing with of Covid shortages and supply of remdesivir. It reiterated its goal to make the life sciences sector part of the strategy to make the EU one of the leading regions in the world to attract investment and maintain the right ecosystem to address healthcare needs. The objective of the meeting was to hear how the Commission's thinking on the Pharmaceutical Strategy had developed since roadmap and after the consultation.

CAB: Thanked EUROPABIO for their cooperation on bringing remdesivir to the market and mentioned that the Pharmaceutical Strategy is a key priority. Its objective is dual 1) delivery outcomes for patients (access, affordability and meeting unmet needs). 2) ensure that pharma industry remains a global leader. In this respect we must provide smart incentives to companies to invest in the EU and stay, supply and tackle the dependency. We are analysing the consultation input and will use it to create a framework which will allow future proofing and ensure a regulatory environment which doesn't create legislative burden. CAB also welcomed that the EUROPABIO document on life sciences is convergent to current thinking and asked about EUROPABIO's expectations.

Innovation

EUROPABIO The strategy must have a strong focus on innovation as a growth engine and ensure the EU's competitiveness against the US and China. We must give the right signal that we are encouraging investments through IP stability (longevity and predictability of the framework). **CAB**: noted that innovation should serve the needs of patients and stressed that it is important to have a strong IP rights system and smart incentives that encourages R&D and delivers products at affordable price.

Supply chain and global resilience

EUROPABIO mentioned that 80% of available medicines in EU originate in Europe. We must make sure the single market is working and keeping the flow of medicines.

CAB mentioned that we should look at Covid lessons. We know that ecosystem has to deliver outcomes even under conditions of stress. In the SOTEU address the President mentioned the strengthening of the EMA role and ECDC. EMA has shown its flexibility in the crisis, we must make some of these learnings permanent. We also need a more European system on HTA.

GMOs

EUROPABIO asked if the EC sees any changes as regards **GMOs** given the learnings of Covid.

CAB mentioned the specific characteristics of medicines for human use and indicated that the challenges of the application of GMOs rules to human medicines will be assessed as part of the pharma strategy.

Incentives

EUROPABIO asked if it would be possible to clarify what measures are considered, legislation with non-legislative instruments?

CAB replied that different approaches are being examined. A unitary SPC procedure could be part of the solution.

Manufacturing in EU

EUROPABIO noted the complexity of the manufacturing of biologicals such as ATMPs and stressed the benefits for society of attracting manufacturing of high-value products to the EU (highly qualified jobs, economic development). It noted that EU should not repeat what happen with generics (by focusing only on prices and neglecting other benefits, manufacturing has moved elsewhere). According to EUROPABIO the following can help to bring back manufacturing: a quality of workforce, link with universities, a favourable fiscal regime and regulatory environment (predictability/certainty), access to customers, capital intensive investments.

CAB: Noted the suggestions.

Access and affordability

EUROPABIO mentioned that the role of EMA is crucial in terms of acceleration the assessment times and cooperation with agencies (the cooperation we saw in Covid should be continued). Accelerated access also relates to the HTA debate and the efficiency of the EU regulatory system (average time for assessment of MAAs in EMA is 423 days in EU vs 300+ in US). Shorter assessment timelines will lead to earlier access. It reiterated that the IP front needs to be stable because if you reduce IP rights or introduce obligations this will inevitably inhibit access.

CAB noted the comment but maintained that a balance needs to be found between access and incentives. It also asked EUROPABIO to come back with proposals in areas other than Pharma which would be beneficial for the competitiveness of the sector.

ENDS

