EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

Brussels
SANTE.DDG1.B.5[redacted]/vt(2020)6212382

Subject: **BTO - Meeting with The European Consumer Organisation (BEUC) on the Pharmaceutical Strategy – 8 October 2020**

Participants: **SANTE:** [redacted]

BEUC: [redacted]

SANTE presented the objectives, state-of-play, and plans for implementation of the strategy, stressing that it will include actions that will be initiated in the short and medium term (next 3 years) but will aim to create a policy that is long-term and fit for purpose for the next 20 years. There will be separate consultation process in the implementation phase.

On funding BEUC emphasised the need for pull incentives for unmet need, noting that more conditionality on funding is required linked to affordability (especially in case of antibiotics, orphan medicines), and that regulators must pilot alternative approaches to funding. Consumers/patients representatives should be involved more in the activities in research and innovation, for example by being represented in the panels of the research and innovation open days. Consensus is needed on basic concepts such as unmet needs.

On shortages: **BEUC** asked if the expansion of EMA mandate will include powers on shortages. They consider there is a need for the review of pharmaceutical legislation to tackle availability (obligations for marketing authorization holders), prevention plans and push for diversification. **SANTE** mentioned that the strategy will focus on the root causes and that information is needed before policy choices are made. The study on shortages focuses on definitions and tools for monitoring shortages and it will inform possible actions. On dependency the aim is to have a structured dialogue, to strike balances with state aid, trade etc. More data is needed before actions can be brought forward, but data availability and quality is improving.

On affordability BEUC called for transparency of prices and medicines costs. They are finalising a position paper on transparency of research costs. The EURIPID survey could be expanded if there is interest in pricing transparency. BEUC asked about revision of the transparency directive. SANTE mentioned we are aware of calls to revise the transparency directive, actions are already ongoing on transparency on a voluntary basis. There are already studies: IQVIA Study, shortages root causes study.

On health technology assessment BEUC is keen on having the proposal adopted and had pressed DE Presidency on this. They asked what can be done to unblock the situation. **SANTE**: explained that it is a good proposal and that only links can be made, but it is not in the Commission's control, but remain optimistic for the outcome.

On the vaccine strategy BEUC considered that there is a need for quick compensation scheme in case of adverse effects. They noted that some companies had requested the product information with their vaccine be in one language across the EU but mentioned these measures should be temporary/proportionate. There should always be a possibility for access to information in the local language. They called for transparency of the contracts and fair pricing. They stressed that the scientific assessment should be robust because if there was a loss of confidence in COVID vaccination this could impact attitudes to vaccination in general. **SANTE** mentioned the Product Information flexibility already exists, the waiver on printable information at moment of delivery is not total, there will be no compromises on information for use. In any case the derogations are made temporarily for the benefit of patients and to accelerate availability as much as possible. The EMA Emergency Task Force for rolling review is in place to enable the Commission accelerated procedure for authorisation on the basis of assessment / evidence. Monitoring enhanced vaccines monitoring platform: we will not cut down on evidence requirements for robust assessments.

BEUC asked about the interaction of the pharmaceutical strategy with the European Health Data space. **SANTE** explained that health data for secondary use by regulators and industry for development and monitoring of medicines as well as regulatory decision-making will include these issues and regulators' access to the health data.