EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels, 5 March 2021
SANTE.DDG1.B.5/AR/am(2021)1819316

BTO - Pharmaceutical Strategy meeting - Meeting with European Consumer Organisation (BEUC) 30 June 2020

Participants

BEUC: [redacted] (BEUC [redacted]), [redacted]

Commission: Commissioner Kyriakides, Giorgos Rossides, [redacted], [redacted] (CAB Kyriakides). [redacted] (DG SANTE).

Commissioner Kyriakides opened the meeting by providing an overview of COVID-19, the EU4Health Programme and the Pharmaceutical strategy. The Commissioner informed BEUC of the different consultation activities (feedback on roadmap, public consultation, workshop) and called for their active participation throughout the process.

BEUC congratulated the Commissioner for EU4Health and the launch of the Pharmaceutical strategy. Access to medicines is one of BEUC's five main priorities. Unmet needs, shortages and affordability are other issues of concern. BEUC shared its full support to an EU level pharmaceutical strategy and its wish to contribute constructively.

Safety and efficacy

BEUC considers that more focus - than currently in the Roadmap - should be given to the importance of strong evidence on safety and efficacy. According to BEUC, a large number of medicines lack efficacy, and, in some cases, are unsafe (in addition to being expensive).

Commissioner Kyriakides was very keen to learn more. According to two studies by BEUC's German and Belgian members, which have tested thousands of medicines, 11% of the medicines they assessed (about 6.500 in total) had a questionable benefit. BEUC will share those studies.

SANTE indicated that the examination of evidence on safety and efficacy is part of the benefit/risk assessment of medicines. The assessment procedure follows a common approach shared by regulators and scientists in the relevant EMA committee and following EC decision for authorisation.

BEUC considers also that consumer expectations are insufficiently reflected in the results of clinical trials. BEUC suggested that observational studies should be increased in order to complement - not replace - clinical trials. BEUC suggests more emphasis in the strategy on better evidence and end points important to patients e.g. Quality of Life. BEUC linked stronger evidence with Health Technology Assessment (HTA) and added therapeutic value. BEUC considers that Pharmacovigilance should be continuously improved.

BEUC considers that the pharmaceutical strategy should include these elements, and, also, take the activities of EMA under the EMA/HMA strategy into account under the broader topic of governance.

R&D on unmet needs

BEUC considers that identifying unmet need priorities should be done with the participation of stakeholders from the demand side also. BEUC advocated for including representatives of civil society in priority setting e.g. under the Innovative Medicines Initiative (IMI). BEUC indicated that this would be a strong signal in favour of inclusiveness. BEUC indicated it struggled to be involved. BEUC has a call scheduled with RTD (Mr Pacquet).

R&D will be important in the roll out of the strategy. R&D funding should, according to BEUC, be conditioned by public return and affordability. BEUC indicated it welcomes turning non-exclusive licensing into common practice for all medicine and vaccines supported by research funds.

Affordability and pricing

BEUC considered that prices are out of normal ranges. BEUC calls for making generics more available. Generics are safe drugs and BEUC notes the existence of fake news on generics. BEUC considers that SANTE, in cooperation with COMP, should address anticompetitive prices in the pharmaceutical sector. BEUC is in favour of promoting

additional competition for Orphan drugs. According to BEUC, a better balance between incentives and accessibility is needed, and so is a fair system for patients with rare diseases.

The Commissioner indicated that the evaluation of the orphan and paediatric legislation will be published this summer. The Commissioner indicated this is a priority file and called for BEUC's views on follow-up actions, referring to feedback on the upcoming Inception Impact Assessment.

BEUC called for more transparency on pricing – a national competence - both from companies and governments, including for the purpose of public accountability. Information sharing between member states is, in that respect, crucial. BEUC considers that negotiating pricing at EU level would reduce costs for citizens and for social security systems overall. **BEUC** referred to the relevance and usefulness of Euripid in the area of pricing transparency. It called for further support, including under the EU4Health programme. **SANTE** noted that.

SANTE indicated it will seek for opportunities to address the topic while paying due regard to national sensitivities.

SANTE also indicated that improving pricing transparency is a cross policy effort, working with RTD, linking research funding and incentives with obligations. The case of orphan and paediatrics provides an example.

Shortages

BEUC called for improved transparency and a stronger role for the EU. Stockpiling during the COVID-10 pandemic makes the case for further resilience. BEUC called for a permanent system at EU level, with a stronger coordination role for EMA.

SANTE noted that and referred to the importance of agencies network coordination.

Closing the **Commissioner** indicated that this was the start of an ongoing consultation process and thanked BEUC for raising the various points.

ENDS.