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/

Subject: BTO - Pharmaceutical Strategy meeting - Meeting with European

Patients Forum (EPF) 26 July 2020

Pharma strategy overview

Commissioner Kyriakides mentioned that the Commission intends to publish the strategy by end of 2020. The Commissioner also presented the strategy's objectives, timeline and process and urged CPME to participate in the ongoing public consultation (roadmap and questionnaire). She also invited CPME to take part in the online stakeholder workshop on 14-15 July.

EPF Welcomes the published roadmap (especially equal access to medicines) and that the strategy takes into consideration whole lifecycle of medicines and mentioned it will respond to the consultation. EPF input will engage on 3 out of 4 objectives of the roadmap (not manufacturing as this is more technical and not the primary focus of patient advocacy activities).

Covid, vaccines, APIs and shortages

The Commissioner noted that the pandemic has amplified the challenges that needed to be addressed in the new Strategy. The Commissioner outlined the elements of the EU4Health initiative and its different strands which indicate a paradigm shift in EU Health policy which is now more ambitious than ever. The crisis accentuated the challenges and highlighted that we're not out of the woods yet, we need more Europe in health and EU4Health is a testament to that. The Commissioner asked EPF if they have feedback from their survey on Covid-19 on patients and expressed her concern about patients not following their treatments due to the crisis, an issue the Commission is following closely. The Commissioner also mentioned plans to diversify in APIs, study on shortages and called the EPF to help the Commission in identifying critical APIs for patients.

EPF agreed that the Covid-19 pandemic is far from over and that a more European approach is indeed needed. This is why it welcomes the EC focus on healthcare which relates to Europe's future itself and believes that it's an opportunity for the EU to prove its value to citizens. The EPF congress of 2020 focuses on shortages (especially for antibiotics and cancer medicines) and it is good to see that Commission took this priority on-board. EPF is ready to be contacted by Commission contractor on the shortages study to provide input.

Innovation, Access, affordability

Commissioner Kyriakides mentioned that the strategy will focus on affordability related to health systems and look for better ways to coordinate actions at national level and EU level. The Commissioner welcomed the EPF paper on value on pricing of innovative medicines and confirmed her participation to the EPF launch event scheduled on 1/7. The Commissioner also welcomed EPF support on the HTA proposal on which the Commission will work together with DE presidency. The Commissioner also called for EPF input on the Orphan and Paediatric legislation evaluation which will be published in the summer. The DG asked EPF to think about how they see the digital perspective and how to not alienate patients that are not digital savvy.

EPF supports access to medicines for all patients (in 2016 it developed a definition of access based on Availability, Affordability, Adequacy Appropriateness, Accessibility). The strategy will remove some of the barriers to access and EPF welcomes the recognition of challenges on affordability (which is not a problem for all medicines). EPF mentioned that granting access to life saving medication should not be the privilege of rich only countries alone. EPF supports the review of incentives-obligations and believes that finding the right balance is key (balance does not lie at the same place for all products). EPF supports achieving more transparency and reaching definitions for "unmet medical need", "added therapeutic value" where a patients perspectives is a must. Innovation for unmet needs means better products that make difference in patients life. We should upstream patient involvement in research (Eg using IMI) including in early stages in clinical trials (which today don't measure quality of life and patient endpoints we should fix that before we come to the regulatory assessment stage). On affordability, EPF supports a better value assessment cost effectiveness P&R procurement. Innovative procurement (EU procurement for EU products is a big step - hand in hand with EU level HTA). As innovation is not always aligned to the needs of patients the solution is to involve patients early on to understand real value of innovation. Pricing is important as EPF recognises that a fair price is needed (which doesn't necessarily mean cheap). Getting the right medicine at right moment important, too late means financial waste, and that therapy is not as useful. Lack of access has complex reasons (market failures, marketing strategies), small countries are particularly vulnerable. EPF believes that the mechanism of parallel import is concerning and creates many problems. MS should move away from increasing patient co-payments to decrease costs. They support patient involvement in defining prices.

EU State of health companion report is positive and data needed (EPF is available to help).

Closing the Commissioner mentioned that we want to have a dialogue with EPF and also want the mental health aspect taken into account. Regular engagement with stakeholders and in online event. We shouldn't be talking about patients but with patients.

ENDS.

Participants:	EPF:
	Commission: Commissioner Kyriakides, Giorgos Rossides,
	(CAB Kyriakides).
	(DG SANTE).