SUMMARY REPORT

'The Value and Pricing of Innovative Medicines' Launch Event

1 July 2020

On 1 July 2020, the European Patients' Forum published its position paper on **'The Value and Pricing of Innovative Medicines.'** In the context of current political priorities on ensuring access to affordable medicines and a forthcoming new Pharmaceutical Strategy for Europe, the paper contributes EPF's perspective as a cross-disease umbrella patient organisation to the EU-level and international debate on prices and value of innovative medicines, building on our core principles of 2016.

EPF presented this paper during an event which took place virtually on 1 July from 15h to17h. The event was moderated by EPF President Marco Greco, co-hosted by MEPs Kateřina Konečná, Tomislav Sokol and Tiemo Wölken and featured a keynote speech from European Commissioner for Health and Food Safety, Stella Kyriakides.

Below you will find a summary of the event.

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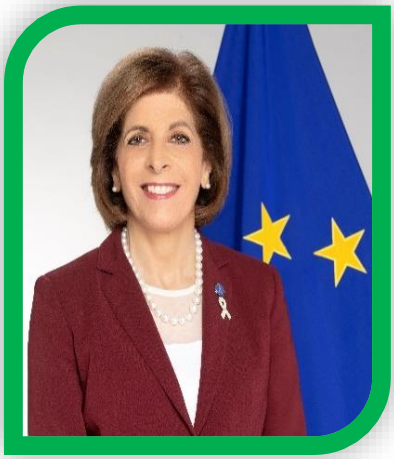
WELCOME & INTRODUCTORY REMARKS

Marco Greco, President, European Patients' Forum

Moderator Marco Greco began by thanking all participants and panellists joining the event for such a relevant paper and event for the organisation. In the context of current political priorities on ensuring access to affordable medicines and a forthcoming new Pharmaceutical Strategy for Europe, he pointed out that the paper contributes EPF's perspective as a cross-disease umbrella patient organisation to the EU-level and international debate on prices and value of innovative medicines, building on earlier work including the "core principles" from 2016.

KEYNOTE ADDRESS



Stella Kyriakides, European Commissioner for Health and Food Safety

Commissioner Kyriakides acknowledged and reiterated the importance of a strong collective patient voice in Europe. Patients must have a seat at the table, and this will be considered in the new EU Pharmaceutical Strategy. She addressed that the pandemic has certainly amplified the weaknesses of the healthcare systems and has galvanized us to act to ensure timely and affordable access to medicines. She closed by stressing the need for the continued involvement, collaboration and dialogue with EPF and patient organisations as the Commission moves forward with its EU4Health Programme.

"Despite near-universal health coverage, European patients still have limited access to innovative medicines and treatments. We must do more to address this vital issue."

REMARKS FROM MEPS

Kateřina Konečná MEP, Group of the European United Left - Nordic Green Left, Czech Republic

MEP Konečná acknowledged that the COVID-19 pandemic has caused us to re-address several items we have ignored over the past years. There are several interesting files currently open at Parliament like Medicines Shortages and the new EU4Health programme that will address shortages and pricing.

"EU citizens are now more than ever in favour of doing more and better for health and it is something we should take as an opportunity."

Tomislav Sokol MEP, Group of the European People's Party (EPP), Croatia

MEP Sokol spoke of the importance of these discussions surrounding innovative medicines are absolutely crucial to ensuring that unmet medical needs are addressed and solved across the continent.

"EU does not have a health competence because it did not used to be a priority. Now it is. Joint procurement could also be useful to reduce the price of medicines. There are still many unmet needs but there is so much the EU can do"

Tiemo Wölken MEP, Group of the Progressive Alliance of Socialists and Democrats, Germany

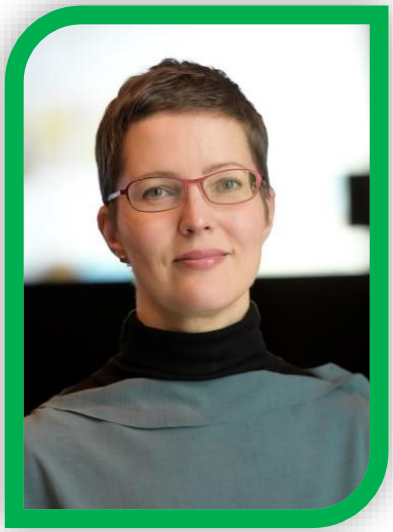
MEP Wölken discussed the threats to access and affordability for EU patients as well as the sustainability of the system.

"EU actions in the field of pharmaceuticals and medical devices have to shift the focus to help Member States ensure fair prices so that all their citizens can access the pharmaceuticals they need. Although we need new incentives for the pharmaceutical industry, we cannot get to the stage where one the one side we use public funding in order

to incentivise pharmaceutical companies and on the other side let them charge high prices in order to make profit. The EU research and innovation programme currently does not attach sufficient upstream safeguards or conditions to public funding to ensure the accessibility, availability and affordability of medical products that result from public investment. This needs to change. Most importantly, patients must be included throughout the entire process."

PRESENTATION OF PAPER

Kaisa Immonen, Director of Policy, European Patients' Forum



Ms Immonen began by stating that access to healthcare is a fundamental right – but not yet reality for many patients. There is a need to talk about prices and value now because of a need for change prompted by lack of access and concerns about sustainability. Medicines must be available at a fair, reasonable and sustainable price for all patients in a timely way. Evidence shows that timely and accurate diagnosis, treatment and follow-up care save lives, improve health, quality of life and ultimately, benefit society.

EPF believes that the added value of the medicine for patients must be a strong factor when considering a "fair" price, combined with other factors such as the costs of R&D and investments plus affordability for the healthcare system. Differential pricing has potential to improve access in lower-income countries, and for that reason should be further explored as a political strategy. Unequal access to medicines persists and goes against the EU Charter on FR, EU Treaties & EU values of equity & solidarity.

EPF calls for transparency from all parties. Industry should be more transparent about its costs of developing a medicine: national authorities should be more transparent about their decisions, how these are made, what criteria are used, and who is involved in the process.

Ultimately, to advance discussions on pricing, value and access, it is necessary to agree a common definition of key concepts, including innovation, unmet need and added therapeutic value. Patient perspectives are crucial in defining true innovation and ensuring new medicines serve to benefit public health. She stressed that industry and academic researchers should ensure that meaningful patient involvement is embedded in the R&D process from the start.

Ms Immonen finished by presenting key recommendations in the paper and concluded that ensuring speedier access to new and more effective medicines is patients' top concern. Ultimately, patient organisations should be included in finding solutions, as partners when designing studies on access barriers and in developing measures for access across the EU.

PANEL DISCUSSION

Moderator Marco Greco opened the floor to the three co-hosting MEPs, as well as the three other panellists: Sylvain Giraud, Head of Unit on Medical products, European Commission; Sibylle Reichert, Executive Director, The International Association of Mutual Benefit Societies (AIM):;and Andy Powrie-Smith, Executive Director of Communications and Partnerships, European Federation of Pharmaceutical Industries and Associations (EFPIA).

Tomislav Sokol MEP, Group of the European People's Party (EPP)

MEP Sokol reiterated that joint procurement has proved effective for member states during the pandemic. He discussed how he advocated for better cross-border healthcare initiatives for pricing so that patients do not have to travel to have access to affordable healthcare. He mentioned European HTA and the need for clear and transparent criteria, which was mentioned in the paper. He also mentioned the transparency directive, which was drafted 30 years ago and needed updating. He closed by noting that the patient perspective is crucial and that MEPs need to listen more to the people. Mr Sokol will give his full support to helping EPF drive its message further in Parliament.

Kateřina Konečná MEP, Group of the European United Left - Nordic Green Left

MEP Konečná was brief in her comments, essentially echoing the importance of the patient perspective and voice, highlighting that the focus must remain on patients, rather than legislators. She mentioned there are a number of papers open in Parliament at the moment that require further support to change EU healthcare in an equitable and sustainable fashion, all for benefits of the patient.

Tiemo Wölken MEP, Group of the Progressive Alliance of Socialists and Democrats

MEP Wölken reiterated MEP Konečná's statement regarding the focus on patients and referred to his earlier statements. He later came back on the panel to discuss HTA, and how it is a vital link to bring health innovation to patients but there remains an urgent need to establish a more clear understanding of value at the EU level.

Sylvain Giraud, Head of Unit on Medical products, European Commission

Mr Giraud said that the paper presents an insightful take on the matter and is quite comprehensive. He acknowledged that the paper comes at an opportune moment as the Commission is consulting on the preparation for the EU Pharma Strategy, as affordability is one of the key dimensions to be considered under the strategy. He added that meetings have begun to be organized with national authorities on pricing and reimbursement to provide a forum to exchange ideas and views as well as articulate their own positions. He closed by stating that he is grateful for the input thus far and looking forward to further dialogue for the benefit of the EU Pharma Strategy.

Sibylle Reichert, Executive Director, The International Association of Mutual Benefit Societies (AIM)

Ms Reichert began by introducing AIM and then delved into analysis of the paper, reiterating the importance of patient perspective and how several core principles and recommendations cover topics of interest to AIM. She presented AIM's Fair Pricing Model, which works to create one EU price for every new drug registered at EMA level. She highlighted that fair prices are part of the new EU Pharmaceuticals Strategy. Reichert advocated for ensuring access to affordable medicines for all – including the fair prices, ensuring supply of medicines for patients across Europe and getting the therapies that health systems need on the market. She closed by stressing the need to harness the challenge of real-world data for better pharmaceuticals.

Andy Powrie-Smith, Executive Director of Communications and Partnerships, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Mr Powrie-Smith argued that industry has been a leader in sharing clinical trial data, and noted EFPIA's sunshine policies for disclosing relationships with doctors. He acknowledged the need for more transparency including how industry develops and assesses its ideas of value. Powrie-Smith reiterated industry's opposition to sharing R&D costs based on practicalities, specifically giving the wrong incentives to ROI. He closed by stating that there is a need to rebuild the research ecosystem.

CLOSING

EPF President Marco Greco closed by thanking all panellists and participants for attending the virtual launch as well as the EPF team for their efforts behind the paper. It is only a first step for a long dialogue that he hopes will bring fruitful outputs in the near future. He closed by stating that this is a relevant and essential topic, especially when all stakeholders are heavily involved for a greater and sustainable health system.