Meeting of the National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers (NCAPR)

22 June 2023, 9H00-17H15 CET
(Hybrid: Brussels/Webex)

OUTCOMES

After the opening words of the Swedish Presidency and the Commission, a quick debrief was given on the recent Willingness-to-pay workshop and joint OECD-EURIPID webinar on *"understanding access to medicines by turning data into knowledge"*.

Session 1 – Participatory session on common challenges for affordability and access to medical products

Through small group discussions, the group reflected on *"what will be new/remaining common challenges for affordability and access to medical products"*, considering also the work that has been conducted in the past years and the legislative proposals currently on the table. A large array of topics were brought forward, both in the shorter- and longer-term. They spanned from the need to **increase collaboration and having a stronger political voice**; to having **payment models fit for purpose**; moving from a supply- to a **demand-driven market addressing UMN**; **communicating more efficiently on decision-making** and the uncertainties surrounding those; **ensuring budget sustainability and competition**; adapting and preparing for a **changing legal landscape** (HTA-R, Pharma Reform); as well as many others.

Session 2 – Information session on Commission legislative proposals

Sandra Gallina, Director-General of DG SANTE, gave a keynote speech on the **Pharmaceutical Reform** underlining how key and central the NCAPR group had become to address the numerous challenges with affordability of medicines. Ms Gallina presented the proposed reform of the EU pharmaceutical legislation underlining its potential to promote timely and equal access to a continuous supply of safe, effective and affordable medicines that meet the medical needs of patients across the EU. She also stressed that legislation will not be the tool to solve all challenges and the reform also refers to the importance of complementing non-legislative measures. DG Gallina stressed the Commission's commitment in this respect to strengthen the support to the NCAPR cooperation.

Following this, DG GROW colleagues from the Intangible Economy unit gave two presentations: one on the **SPC (Supplementary Protection Certificates) reform**, which aims to create a more efficient and predictable framework, reducing the costs and increasing legal certainty and transparency for both innovators and generic makers, without removing national procedures nor modifying the substance of the current SPC regime; the other on the **EU compulsory licensing mechanism,** which will build on EU crisis mechanisms and ensure appropriate territorial reach to cover cross-border supply chains. It was made clear that this mechanism can serve only as an alternative in crisis times when voluntary agreements do not work.

Session 3 – Treatment optimisation of medicines

The session was introduced by Denis Lacombe, CEO of EORTC (European Organisation for Research and Treatment of Cancer). He explained the need for and gave an overview of **treatment optimisation studies**, discussing potential **benefits in terms of patient safety/outcomes and costs savings**. In particular, he referred to the recently established **EMA Cancer Medicines Forum**, which will discuss

the uptake of academic work in the wider context of regulatory decision-making in oncology, and propose a strategy for treatment optimisation. Overall, he very much stressed the urgent need to re-engineer the continuum of drug development and access.

Momir Radulovic from the Slovenian Medicines and Medical Devices Agency built further on this by sharing possible policy options to overcome the hurdles of initiating such treatment optimisation studies, including the **facilitation of clinical evidence generation and ensuring adequate (public) funding**. He highlighted how cancer care's sustainability is challenged by drug expenditures, requiring innovation to curtail drug costs in the absence of systemic change. Strategies to identify safe, efficacious and cost-conscious regimens extracting the maximum value from expensive therapies include clinical research into de-escalation of dosage, treatment duration and administration frequency. *The Commission* also came in to explain how the pharma reform includes new provisions to give the opportunity to regulators to ask for post-authorisation data and also to take into account data generated by other parties than the Marketing Authorisation Holder.

Session 4 – Co-creation of future NCAPR priorities and actions

The group built further on the strategic issues and challenges identified in the morning, translating the most important and relevant ones into concrete actions with tangible outcomes. This included proposals on **evidence generation and addressing uncertainty; collaboration and joining forces in negotiations; Unmet Medical Needs and demand-driven systems; adapting and preparing for a changing legal landscape; and ensuring budget sustainability through competition.** These proposals will be further discussed and taken up within the group.

Conclusions – Next steps

The co-chairs thanked the more than 40 participants from 22 Member States and noted the next meetings in 2023.