Meeting of the National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers (NCAPR) 30 March 2023, 9H00-16H45 CET
(Hybrid: Stockholm/Webex)

OUTCOMES

During the opening, the *Commission* thanked the Swedish Presidency for hosting the Plenary and referred to the progress made on the implementation of the NCAPR work plan since the previous meeting. It was noted that the group has evolved a lot since the adoption of the Strategy in 2020. **The *Commission* is committed to step up this cooperation** and further support information exchange, mutual learning and developing common tools for national policy-making, while fully respecting the competences of Member States in this area, **including through exploring the possibility of using EU4Health funds** to support joint projects on affordability of medicines.

Session 1 – Debrief of the NCAPR stakeholder event organised by the SE Presidency on 29 March

Making use of the physical presence of NCAPR members and participatory leadership techniques, small group discussions were held to reflect on the main take-aways from the stakeholder day organised by the SE Presidency on 29 March ("New legislative landscape for pharmaceuticals in the EU: How do we prepare?") and the role of patients in the P&R processes. The participants saw value in **continuing the dialogue** with stakeholders and reinforcing interaction with other actors, including patients, throughout the medicine lifecycle. Further work could be done in NCAPR to **share best practices for patient involvement and on developing proactive, strategic communication to the** general public, in particular on the difficulty of pricing and reimbursement decisions.

Session 2 – Willingness and ability to pay: what should we as payers (or buyers) be willing to pay for?

Different Member States shared their views on the challenges encountered when defining the limit of the willingness or ability to pay for certain novel medicines with high uncertainty. *Sweden* presented an analysis of how criteria such as sales volumes or number of patients could impact the acceptable cost for new medicines. They also presented some practical examples on the use of **follow-up data** and how this may lead to changes in decisions that were previously made under uncertainty. *Norway* added to this by noting the **challenges of uncertainty** and how the uncertainty around the decision is the true challenge, with the current level of uncertainty around the majority of decisions leaving little room to take additional risks in orphan medicines for instance. Giving practical examples, *Denmark* shared the rationale behind the negative reimbursement decision for a medicine whose price was concluded not be proportionate to its therapeutical value, and *France* presented their system of **safeguard clauses**.

ESIP urged the NCAPR members to speak up to ensure that affordability of medicines, and the bigger picture of the sustainability of social security would remain high on the political agenda. During the discussion, participants raised the **importance of data collection**, the use of **Management Entry Agreements** and **defining exit strategies upfront**. As a next step, DG SANTE will organise a workshop to exchange information on willingness-to-pay and ensure that the NCAPR receives an update of the DARWIN-EU initiative at a next meeting.

Session 3 – Impact of inflation in pricing, reimbursement and follow-up decisions

The session started with *IQVIA* giving a general introduction demonstrating the impact of the increased inflation. More importantly, the turbulent exchanges rates have greatly affected medicine pricing in non-euro markets. According to IQVIA, price increases should not be generalised, but rather targeted to area's with biggest risk of future shortages.

It was followed by the presentation of different national perspectives. *Portugal* highlighted the **challenges for policy makers with increasing expenditure** and presented its implemented measures to prevent shortages. *Spain* shared information on the **steep increase in the number of price increase applications**, a trend which is expected to continue. *Sweden* informed the group of its regulation of **price ceilings** which could be increased for groups of medicines that fulfil certain criteria.

Session 4 – What can be done to increase competition, also among patented drugs?

The session started with a presentation on the soon to be published *OECD* **health working paper on enhancing on-patent competition**, which will provide a review of pricing, coverage and procurement practices to map mechanisms promoting on-patent competition, as well as a quantitative analysis of on-patent competition using sales data for selected countries and therapeutic classes. *DG COMP* complemented this picture by giving an overview of the actions that can be undertaken under EU law to **tackle anti-competitive behaviour** of individual companies, but also noting the important role pricing and reimbursement authorities can play and what solutions could be further explored where there is market failure.

Norway, *Austria*, and *Hungary* then shared best practice examples on how to enhance competition in the on-patent area, including through **tendering, conditional reimbursement and price reductions** for follow-on medicine. *Denmark* closed the session with an update on the **International Horizon Scanning Initiative**.

During the discussion, several NCAPR members raised challenges experienced to encourage prescribing of preferred products. A solution suggested was to optimise the use of **formulary management,** for instance through preferential placement and including tiered benefits.

Key take-aways and next actions

In conclusion, participants called to **action** on reinforcing interaction with the different stakeholders, exploring best practices to involve patients and communicate about decision-making, as well as planning further workshops on willingness-to-pay.

Conclusions – Next steps

The co-chairs thanked the 65 participants from 23 Member States and Norway and noted the next meetings in 2023.