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

26 October 2023, 9H00-17H00 CET (Hybrid: Madrid, Spain/Webex)

OUTCOMES

On 26 October, the group of National Competent Authorities on Pricing and Reimbursement and public healthcare payers (NCAPR) held a Plenary meeting in Madrid, Spain. The meeting started with some opening words from the co-chairs on behalf of the Spanish Presidency and DG SANTE.

Session 1 – Setting the strategic direction for EU-level cooperation on medicine pricing and reimbursement policies in the NCAPR

The session was introduced by *Sweden*, who wrapped up the priority areas and actions identified at the last Plenary meeting of the NCAPR. *Spain* continued with the session by stressing the **need to strengthen and structure NCAPR collaboration**. On behalf of the European Commission, *DG SANTE* gave a presentation on lessons learned and perspectives regarding EU health priorities. It also explained how financial support through a **Joint Action could support the NCAPR work**, serve its objectives and contribute to capacity-building within the participating national authorities.

Following this, a group discussion was held and the need for a solid framework of **governance**, clear **identity** for the group and producing **concrete deliverables** was stressed. Some members also proposed intensifying the dialogue with other authorities in the medicines lifecycle and their groups, as well as moving to a **two-tiered configuration** (strategic and technical). Concrete examples of specific activities that could be part of a Joint Action were shared. As the main outcome of the discussion and next step, it was concluded to reflect these views in a **non-paper** that will be discussed at the next Plenary.

Session 2 – Dealing with uncertainty: how can payers/buyers lead industry to produce robust and relevant evidence? Sharing solutions and experiences

The second session of the day focused on sharing different solutions and experiences on how payers/buyers can lead industry **to produce robust and relevant evidence supporting payers in their decisions**. *The EMA* presented the example of DARWIN, its pilots, and how it could help payers/buyers in their decision-making. Furthermore, *Karen Facey (RWE4Decisions)* shared examples and lessons on purposeful and effective post-launch evidence generation and *Spain* provided the concept of an uncertainty-based dynamic pricing system in development. Finally, *the Netherlands* elaborated on their experience on how to publicly communicate difficult reimbursement decisions.

NCAPR members then discussed how to **clearly communicate** evidence requirements and decisionmaking to the different stakeholders. Several examples of **risk-sharing agreements** were given, and the need to align HTA and P&R requirements was raised.

Session 3 – Overcoming the hurdles of initiating treatment optimisation studies and steering repurposing of medicines

After a debrief on the previous **June Plenary session** provided by *Slovenia, Prof. Dr. Gabe Sonke* (*Netherlands Cancer Institute*), explained how the <u>SONIA Trial</u>, a publicly-funded treatment

optimisation study in patients with advanced breast cancer, led to an important **decrease in both drug toxicity and expenditure**. Finally, on **steering drug repurposing**, *DG SANTE* presented some key aspects from the proposed Pharmaceutical Reform and *Spain* discussed the EMA/HMA <u>pilot</u> <u>supporting non-profit organisations and academia in drug repurposing</u>.

The **need for early treatment optimisation** studies to bridge the research gap between pre-approval development and post-approval use was highlighted once again. NCAPR members showed interest in discussing further how such studies could be initiated, **potentially through EU-funding and action**.

Conclusion – Next meetings

The meeting was closed by the *Spanish Secretary of State for Health, Ms Silvia Calzón Fernández*, who stressed the importance of addressing collectively the common access and affordability challenges payers and European patients face.

The co-chairs thanked all participants and noted the next meetings in 2023.