ESIP Press release

Public healthcare payers welcome the formal adoption of the HTA Regulation by the EU Parliament and Council

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The European Social Insurance Platform (ESIP), representing public healthcare payers across the Union and in Switzerland, welcomes the formal adoption of the health technology assessment (HTA) Regulation by the EU Council and Parliament.

"Since the publication of the legislative proposal, we have encouraged efforts to develop a permanent and sustainable framework for joint clinical assessment of health technologies, including both medicines and medical devices. This mechanism is an essential tool to support Member States to make evidence-based decisions on pricing and reimbursement of health technologies" said Ilka Wölfle, ESIP president.

Public healthcare payers support the establishment of a permanent and sustainable structure for EU cooperation on HTA

Since the launch of joint initiatives on HTA, ESIP has been a long-standing supporter of cooperation in this field: several ESIP members actively contributed to EUnetHTA and its underlying joint actions, while ESIP participated in the HTA stakeholder network. ESIP will closely follow activities led by the new EUnetHTA21 consortium, towards the full implementation of the Regulation. Against this background, **consensus was found among ESIP Members on the need for a more permanent, harmonised and sustainable structure for cooperation at European level**, replacing and improving the current project-based approach.

We welcome a permanent structure that avoids duplication, allowing at the same time a certain level of flexibility

The scope of joint clinical assessment has been extensively debated by institutional actors. A similar discussion took place among ESIP Members. While the Regulation aims at avoiding duplication of efforts, ESIP supports a certain level of flexibility with view to complementary clinical assessment, allowing for adaptations to national requirements. A mitigation of the binding effect of the assessment on Member States is overall welcome, bearing in mind the differences among national health systems in terms of comparators, patient populations, clinical pathways, endpoints etc. **We believe that the Regulation marks a first, promising step towards strengthened cooperation and coordination on HTA at EU level in the future**.

We welcome a permanent structure that provides added value for decision-making processes

Harmonising clinical assessments of health technologies will have an impact on pricing and reimbursement (P&R) decisions at national level. In fact, **payers are the principal end users of HTA at national level**, where both clinical and economic assessments of health technologies are key to the decisions taken by P&R authorities. Hence, joint **HTA should provide national P&R institutions with high level evidence**, especially for new (conditional) pricing and reimbursement mechanisms for advanced health technologies.

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Stakeholder involvement in joint health technology assessment is crucial and should be carefully defined

Stakeholder involvement is essential. In particular, **collaboration between regulators, HTA bodies and healthcare payers**, especially on evidence requirements, facilitates patient access and **should be promoted from the early stages of health technology development** and throughout the product life-cycle.

We welcome the establishment of a **stakeholder network** to support the work of the Coordination Group and we look forward to being involved as representatives of healthcare payers. At the same time, we welcome provisions aimed at managing conflict of interest in joint scientific work: **strict conditions should apply to the selection of external experts to avoid conflict of interest** that could result from early involvement of stakeholders and undue interference with the independent scientific process (e.g. during the preparation of the draft joint clinical assessment report). Stakeholders should be given instead the opportunity to comment on a finalised draft assessment.

Find previous ESIP position documents on the proposal for a Regulation on Health Technology Assessment here. We will continue to develop our positions during the implementation process and we look forward to providing our input into the preparation of implementing and delegated acts.

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