



EUROPEAN PUBLIC HEALTH ASSOCIATION (EUPHA) STATEMENT ON THE PROPOSAL FOR A REGULATION ON HEALTH TECHNOLOGY ASSESSMENT OF THE EUROPEAN COMMISSION

19 February 2018

EUPHA welcomes the publication of the European Commission's "Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU":

EUPHA believes that this proposal forms a sound basis for Health Technology Assessment (HTA) processes to be implemented in all Member States of the European Union. It gives Member States the responsibility to lead the process and safeguards a long-term and sustainable cooperation by setting up a permanent structure.

EUPHA notes that the proposal seeks to reinforce the European Commission's intention to support the process scientifically, administratively and by providing an IT platform.

Therefore, the implementation of the HTA regulation at EU level could represent an important step in facilitating the provision of good quality, transparent and timely information for the subsequent decision-making process at Member State level.

Notably, the proposal provides for "early dialogues" with health technology developers and for "horizon scanning" as a governance tool to drive innovation.

EUPHA welcomes the concept of stimulating Member States to engage in voluntary cooperation at European Union level for issues beyond the regulation, which could be of benefit for Member States to collaborate on.

EUPHA additionally welcomes the institution of a stakeholder network by the European Commission but emphasises that this stakeholder network should be actively involved not simply informed by the Coordination Group and with the participation not limited to *ad hoc* meetings.

EUPHA has some concerns about the interactions between the Coordination Group and regulatory bodies (EMA and national regulatory and HTA bodies). These should be carefully and transparently monitored.

Furthermore, the timing of the Joint Clinical Assessment (JCA) is a crucial issue, if the JCA is to be most useful in subsequent decision-making process.

EUPHA believes that the new approach to "horizon scanning" should go beyond the EuroScan initiative and attention must be paid to analyse the way in which this could

impact the important recent multilateral agreements among groups of Member States (e.g. BeNeLuxA initiative, Valletta Technical Committee)

EUPHA calls for absolute transparency in the whole HTA process. This requires robust policies on conflicts of interest that regulate the involvement of individuals and organizations

About the Proposal

On January 31st 2018, the European Commission released a legislative proposal for a regulation on HTA to reinforce cooperation amongst Member States https://ec.europa.eu/health/technology_assessment/eu_cooperation_en

The proposal comes after almost two decades of voluntary cooperation in this area, the adoption of the Cross-border Healthcare Directive (2011/24/EU), of which Article 15 will be amended, and a wide stakeholders' and citizens' consultation acknowledging the usefulness of HTA (98%) and agreeing that EU cooperation on HTA should continue beyond 2020 (87%).

The proposed Regulation on (HTA) covers new medicines, approved medicines on new therapeutic indications, certain classes of medical devices and *in vitro* diagnostic medical devices, providing the basis for permanent and sustainable cooperation at the EU level in the form of JCAs in these areas.

Member States will be able to use common HTA tools, methodologies and procedures across the EU, working together in four main areas: 1) on JCAs, focusing on the most innovative health technologies with the most Union-wide and public health potential impact; 2) on joint scientific consultations (JSCs), whereby developers can seek advice from HTA authorities; 3) on horizon scanning activities for emerging health technologies to identify promising technologies early; and 4) on continuing voluntary cooperation in other areas.

Individual Member States will continue to be responsible for assessing non-clinical (e.g. economic, organizational, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

The JCA, limited to medicines and certain classes of medical devices, will be implemented progressively. The regulation establishes a requirement of mandatory use of the JCA report and no repetition of the assessment in the Member State's overall HTA process.

Health technology developers can make a request to the Coordination Group for a JSC ("early dialogues").

The Coordination Group has the mandate to carry out an annual study on the identification of emerging health technology ("horizon scanning").

Member States can continue to cooperate on voluntary basis at Union-level on other than the scoped for health technology, non-clinical assessments, collaborative assessments on medical devices not selected for a JCA.

The activity will be led by Member States through the Coordination Group: the Members of the Coordination Group will be designated by Member States among their designated national authorities and HTA bodies. Member States can designate more than one representative, but where a vote is necessary there shall be one vote per Member State. Under the authority of the Coordination Group, a number of sub-groups can be appointed. The EU Commission will support the work of the Coordination Group and sub-groups by providing scientific, administrative and IT support. The Commission shall establish a

stakeholder network through an open call for application and a selection of suitable organizations.

Background Information about EUPHA

EUPHA (European Public Health Association) is an umbrella organisation for public health associations and institutes in Europe. EUPHA was founded in 1992 by 15 members (12 countries). EUPHA now has 79 members from 46 countries. EUPHA is an international, multidisciplinary, scientific organisation, bringing together around 19'000 public health experts for professional exchange and collaboration throughout Europe. EUPHA has been selected by DG SANTE to be a Member of the HTA Network Stakeholder Pool.