**January 12, 2025**

**New European legislation for Health Technology Assessment welcomed by the NCPE**

The NCPE has welcomed the introduction of new European legislation for Health Technology Assessment. The EU Health Technology Assessment Regulation (HTAR) comes into effect on January 12, 2025 enabling joint assessments of health technologies (medicinal products and medical devices) across EU Member States.

This significant development facilitates a new era of international collaboration in health technology assessment across the EU. Ireland will work with other individual EU States participating with them in joint assessments of new medicines and medical devices.

The assessment process involves working with pharmaceutical companies and medical device manufacturers as well as health agencies to assist in the journey to safely bringing new drugs and devices to the market in different European countries under a legislative framework.

The NCPE played a key role in preparations for the introduction of this new European legislation for Health Technology Assessment (HTA).

A European HTA Coordination Group chaired by Dr. Roisin Adams, Head of HTA Strategy and External Engagement for the NCPE will be the governance body with oversight for this legislative process. This joint way of working will be undertaken by two countries (joint) on behalf of the HTA Coordination group.

European colleagues worked collectively to establish the legislative and operational framework, necessary for efficient collaboration. Key milestones achieved during a two-year period included the adoption of five implementing acts and 15 procedural and guidance documents.

This combined effort also involved capacity-building activities, planning for joint work and supporting national preparedness for EU HTA implementation.

This year 25 Joint Clinical Assessments of medicinal products are expected of which 17 will be new active substances for the treatment of cancer and 8 advanced therapy medicinal products. The first products are due to be assessed in the coming months.

Additionally, it is planned to initiate five to seven Joint Scientific Consultations for medicinal products and one to three Joint Scientific Consultations for medical devices, starting in the second half of the 2025. Interested companies will be able to receive sound advice at these events.

Joint work will also include identification of emerging health technologies, through 'horizon scanning'

NCPE Ireland will continue playing one of the central roles in the joint European work, acting as an assessor or a co-assessor in the upcoming Joint Clinical Assessments in 2025. NCPE will also actively contribute to the Joint Scientific Consultations, providing early scientific advice on proposed clinical trials to pharmaceutical companies thereby enhancing the quality of future clinical evidence.

Policy makers from Ireland consider this an important step towards enhancing equity of access for technologies:

**Minister for Health Stephen Donnelly** said:
"Ireland has a long and well-developed system of health technology assessment as well as cross border working as an active partner in the Beneluxa and the International horizon scanning initiative. We consider that this way of working is highly beneficial to a small Member State such as Ireland in supporting equitable access to innovative and effective technologies for patients in Ireland.
The Health Technology Assessment Regulation is part of a broader suite of regulations that will be introduced across the European Union over the coming years. Collaborating with our European partners in the implementation of these regulations is a really important objective as we move towards Ireland's EU Presidency in 2026. "

**Professor Michael Barry, Consultant Clinical Pharmacologist and Director of the NCPE,** said:
"The NCPE has played a central role in the preparatory phases of this important regulation and will continue to actively collaborate with European HTA bodies. It is the first regulation for cross country health technology assessments in the world and represents an important milestone in ensuring decision makers at national level have the evidence needed to make value based decisions."

**Colm Henry, Chief Clinical Officer of the HSE,** said:
"The events of the past years have put considerable pressure on health systems and Ireland continues to experience these pressures. Providing innovative, effective and cost effective technologies to patients in Ireland is one of the measures required to ensure good outcomes for these patients.  The HSE welcomes this HTA Regulation as an enabler for decision makers to receive robust evidence in a timely way which will facilitate more equitable access."

https://ec.europa.eu/commission/presscorner/detail/en/ip_25_226