edma DIAGNOSTICS FOR HEALTH

Position Paper

HEALTH TECHNOLOGY ASSESSMENT FOR IVDS IN THE CONTEXT OF MARKET ACCESS

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EDMA, the European Diagnostic Manufacturers Association, welcomes the opportunity to bring forward its position regarding health technology assessment (HTA) applied to in vitro diagnostics (IVDs). EDMA would like to comment on several points of significant importance that are needed to ensure equitable patient access to IVDs and to treatment in Europe. This position delineates EDMA's vision for the future of HTA for IVDs in the context of Europe's market access environment.

- In vitro diagnostics play a key role in guiding and enabling decision-making for health and appropriate healthcare, while also contributing to the sustainability of health systems.
- Acknowledging this role, access to IVDs should follow transparent and predictable processes within EU Member States.

Regarding access to IVDs at EU Member State level, EDMA calls for:

- Market access processes that are suitable for the specificities of IVD technologies. These processes need to allow for the value of IVDs for patient management to be shown, including:
    - Transparency and clarity of criteria and data requirements for decision making on IVDs; and
    - Appropriate timelines for market access decisions.
- Incentives that will further drive innovation and continuously improve care.

Taking into account general aspects of HTA at EU Member States and EU level, EDMA is certain that:

- If an HTA on IVDs is requested, the HTA should be performed in order to inform a decision point through a "fit-for-purpose" approach. Such an approach should be:
    - Linked to a decision about coverage, reimbursement, funding and/or use;
    - Well adapted to the specifics of the technology under assessment; and
    - Using appropriate and specific methodologies based on available quality evidence, and developed in cooperation with relevant stakeholders.
- A timely dialogue involving manufacturers should be an integral part of the HTA process.

Regarding specific HTAs conducted at EU Member States or EU level, EDMA requests that:

- Relevant stakeholders including industry, be involved in all parts of the HTA process in order to:
    - Meet decision-makers' expectations;
    - Answer questions;
    - Share knowledge about the technology under assessment;
    - Identify unmet needs in existing healthcare pathways;
    - Help to define patient populations, interventions, comparators and outcomes;
    - Provide information about the availability of data; and
    - Provide information about patients' and providers' preferences.

- EDMA calls for a more explicit disclosure of value judgments within the process of assessment and within the appraisal.

Regarding HTA at EU level, EDMA feels that

- The scientific European HTA network – EUnetHTA[i] – needs to be of value for decision-makers and other stakeholders. This implies using EUnetHTA outputs in a timely manner within concrete assessments and appraisals of technologies, as well as applying its methodologies/guidelines and joint infrastructure at the Member State level.

- Transparency, efficiency and overall knowledge of HTA in Europe will increase by allowing the general public timely access to the EUnetHTA databases on planned and on-going projects, as well as on evidence gaps and HTA research protocols.

Regarding HTA at the European strategic level, EDMA believes that:

- The EU Network of Health Technology Assessment (HTAN[ii]) could play a beneficial role for sustainable healthcare in Europe. Via early involvement and assessments that consistently apply a fit-for-purpose approach, HTAN could address decision-makers' needs.

- Appropriate mechanisms for patient access to IVDs, and thus appropriate healthcare decisions, have a significant potential for improving the health of European citizens.

  For further information, please contact:

  EDMA HTA Secretariat
  +32 2 300 96 47
  HTA@edma-ivd.eu

[i] EUnetHTA is the European Network for Health Technology Assessment, a scientific and technical Joint Action of national and regional HTA agencies, co –funded by the Health Programme of the European Commission. www.EUnetHTA.eu

[ii] HTAN is the Health Technology Assessment Network, a voluntary strategic Network of Ministries of Health or competent authorities responsible for HTA, appointed by Member States, set up under Article 15 of the Directive on the application of patients' rights in cross-border healthcare 2011/24.
http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm