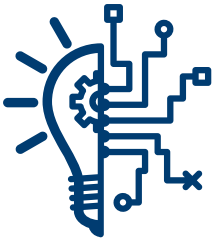
EUCOPE

European Confederation of Pharmaceutical Entrepreneurs AISBL

The New EU HTA Procedure



The **complexity of current HTA processes** across Member States require significant administrative and financial resources and time from developers and can cause access delays.

The EU HTA procedure must lead to sufficient harmonisation of existing methodologies and wide uptake of joint EU HTA reports to avoid the risk of additional clinical assessments being demanded at Member State level. **The aim should be to prevent the duplication of work, reduce burdens and increase the predictability for all involved stakeholders.**

EUCOPE's PRIORITIES FOR THE EU HTA REGULATION:

1. **Joint Scientific Consultation must be offered to all developers**
2. **A flexible methodology is needed that reflects the specificities of Orphan Medicinal Products (OMPs) and Advanced Therapy Medicinal Products (ATMPs)**
3. **There must be procedures for resolving the issue of multiple and competing comparator requests from the Assessors**
4. **The procedure must ensure the broad involvement of relevant stakeholders**
5. **A transparent and balanced selection of experts for rare disease and specialised technologies is necessary**

#EUHTAPriorities