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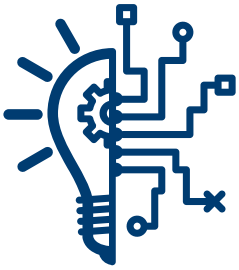
The New EU HTA Procedure



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 that accounts for the specificities of Orphan Medicinal Products (OMPs) and Advanced Therapy Medicinal Products (ATMPs)**
3. **Procedures for resolving multiple and competing comparator requests**
4. **Ensure the broad involvement of relevant stakeholders**
5. **A transparent and balanced selection of experts**

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On the EU's General Pharmaceutical Legislation

EUCOPE sees the review as an opportunity to build a **future-proofed pharmaceutical framework** that **supports access to innovative therapies** and **builds an internationally competitive environment** that continues to promote research and development in Europe, which in turn allows the marketing of new technologies that reach patients.

EUCOPE's vision on how to improve the legislative framework:

1. **Build a future-proof regulatory framework** to support the assessment and access to innovative technologies.

2. **Maintain a robust and predictable incentive framework** to continue encouraging innovation and the development of novel health technologies.

3. **Update the legislative framework** to ensure that the EU remains competitive on the international stage, encouraging the development, research and launch of therapies in the EU.

"The revision of the pharmaceutical legislative framework must be strengthened, accounting for hurdles faced by small and mid-sized pharmaceutical companies so that it can promote sustainable financing and the continued research and development of new technologies."

Alexander Natz
Secretary General

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On the European Health Data Space (EHDS)

Reflections: EUCOPE sees the review as an opportunity to build a **future-proofed pharmaceutical framework** that **supports access to innovative therapies** and **builds an internationally competitive environment** that continues to promote research and development in Europe, which in turn allows the marketing of new technologies that reach patients.

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On the Proposal for an Artificial Intelligence (AI) Act

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