

# HTACG

MEMBER STATE COORDINATION GROUP  
ON HEALTH TECHNOLOGY ASSESSMENT



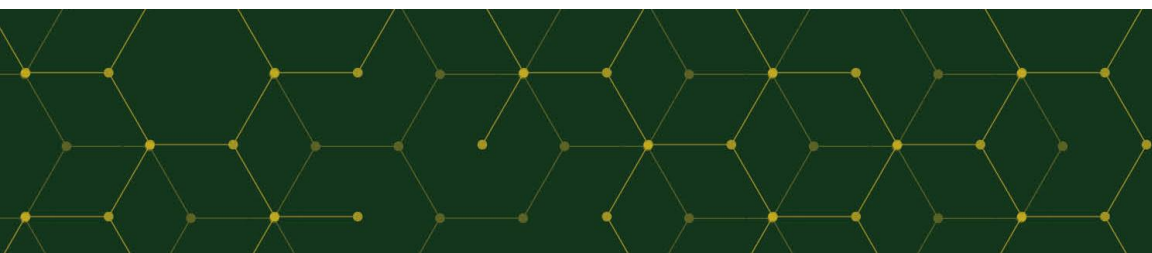
## Impact of the EU HTA Regulation on Innovation and what lies beyond 2025

Roisin Adams, Chair of the Member State  
HTACG

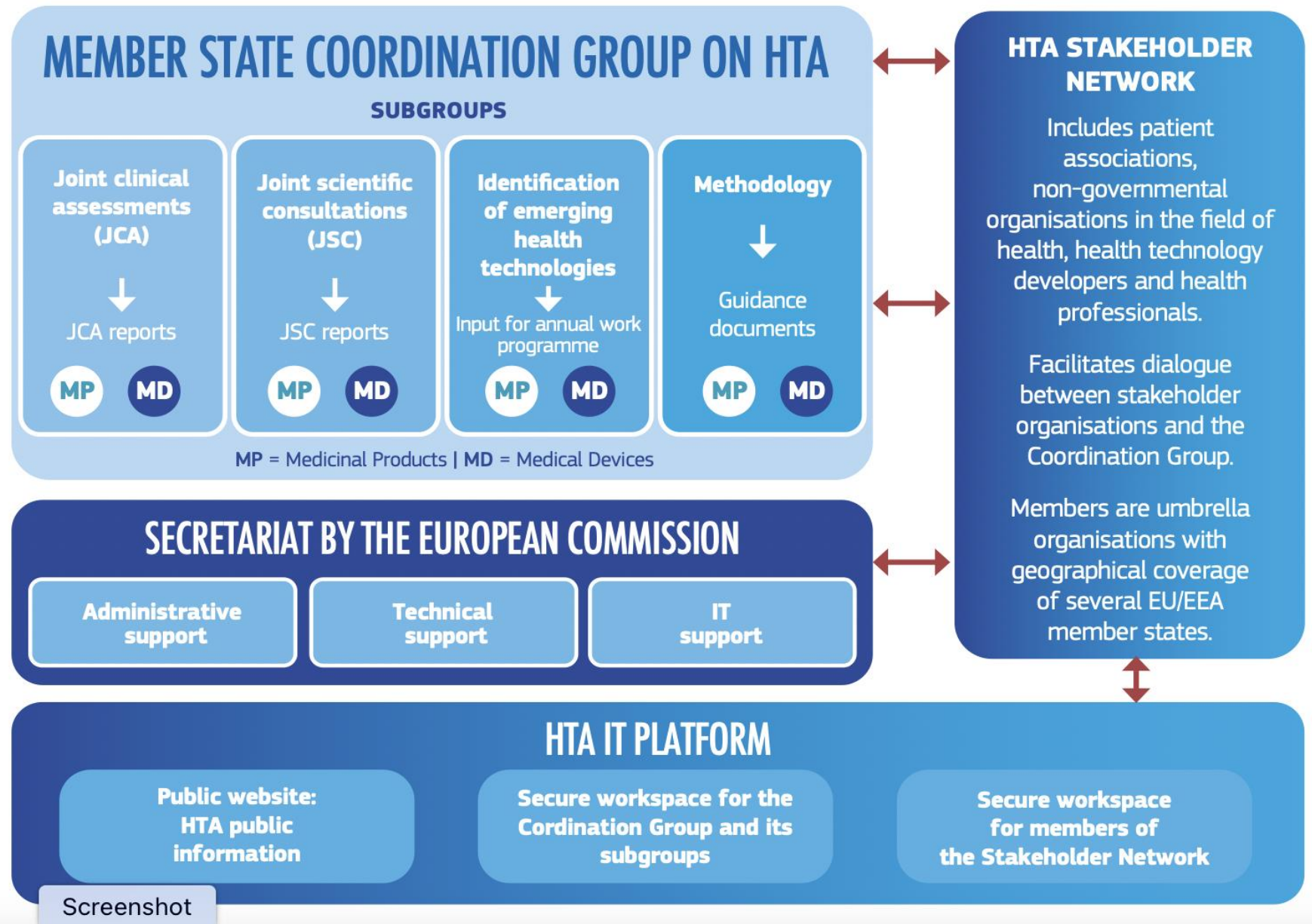
23 April 2024

# Why do we need HTA Regulation (EU) 2021/2282?

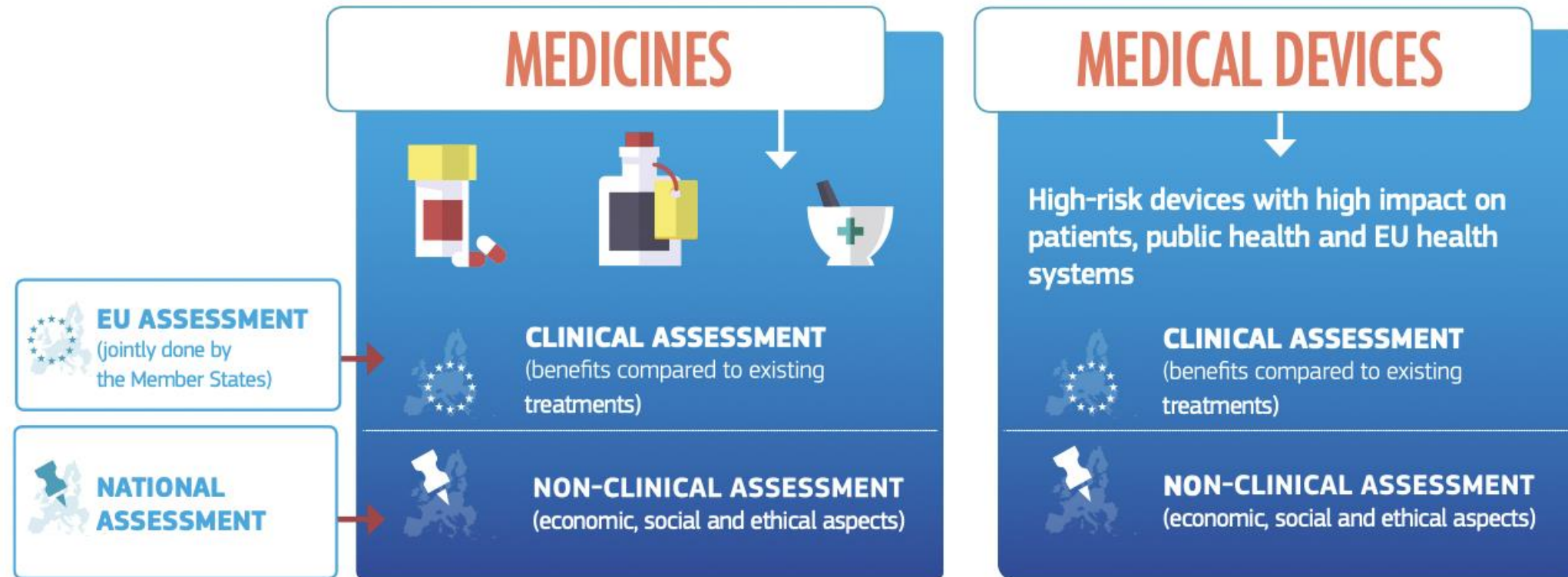
- Unequal access to medicines for patients in Europe
- Diverse HTA processes
- Duplication of processes
- Challenging evidence dossiers



# GOVERNANCE STRUCTURE

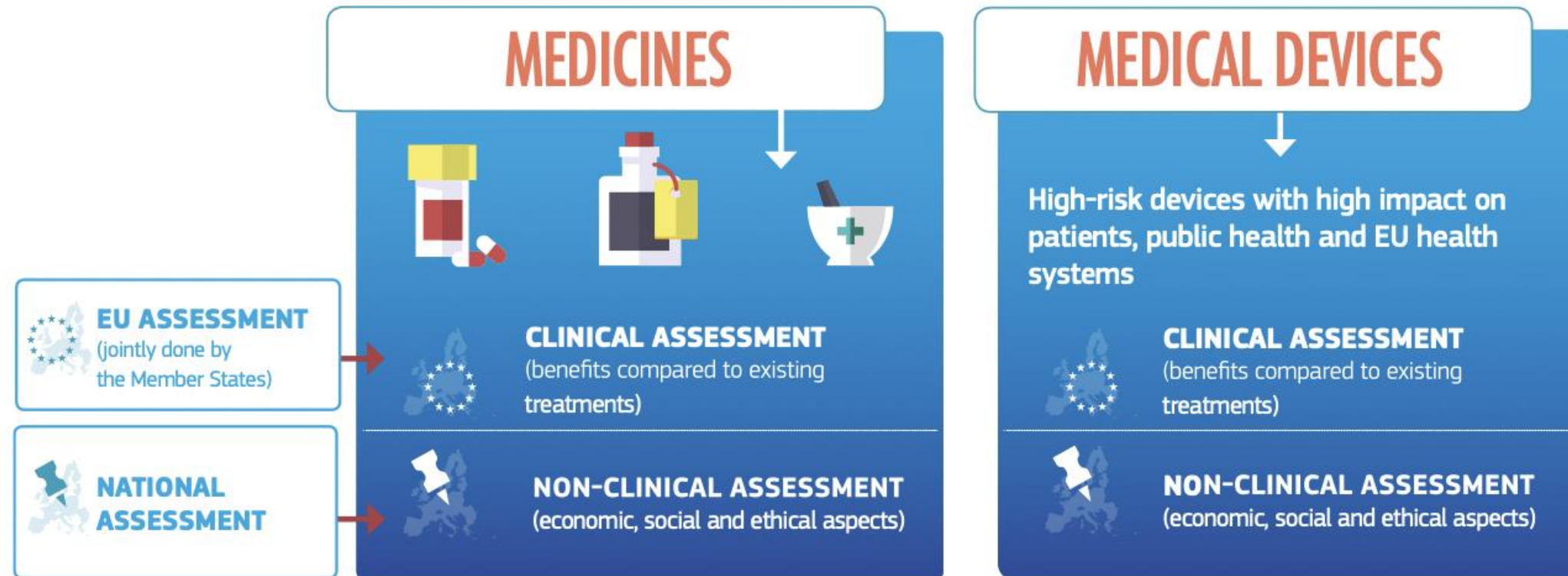


# WHAT WILL BE ASSESSED AT EU AND AT NATIONAL LEVEL?



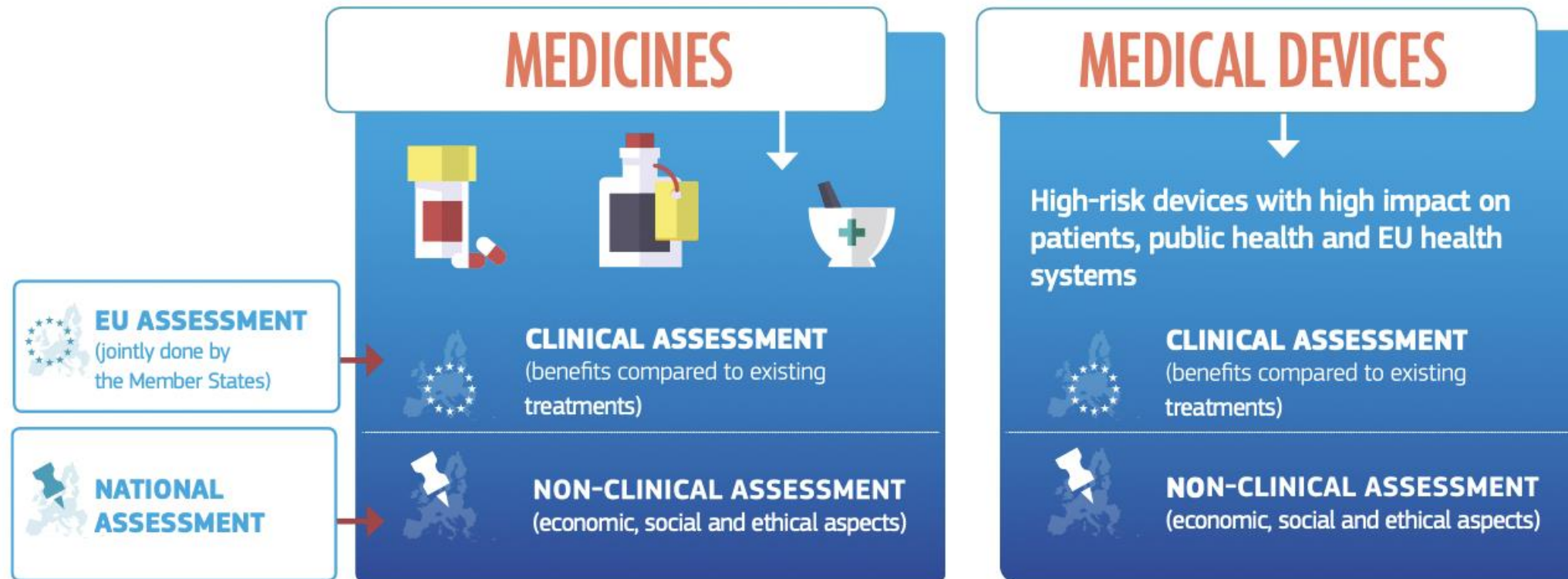


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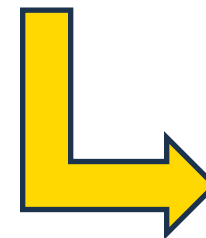


Oncology Medicines and ATMPs  
12<sup>th</sup> January 2025

# WHAT WILL BE ASSESSED AT EU AND AT NATIONAL LEVEL?



Oncology Medicines and ATMPs  
12<sup>th</sup> January 2025



New Indications, extended indications if JCA complete on new indication

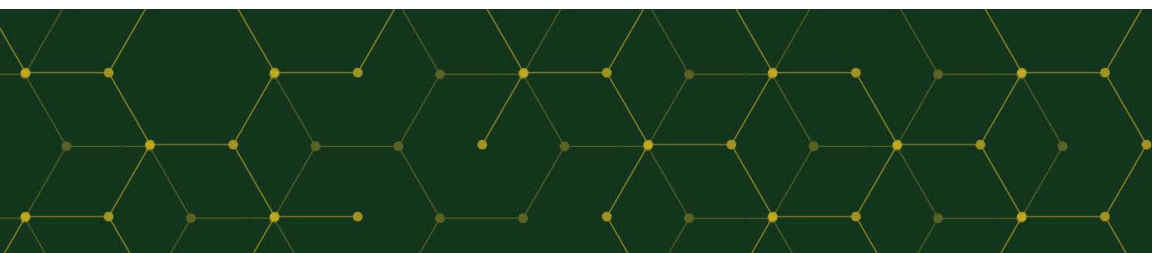
# Whats next?

## HTA CG:

- Scientific Guidance and procedures

## European Commission: Implementing Acts

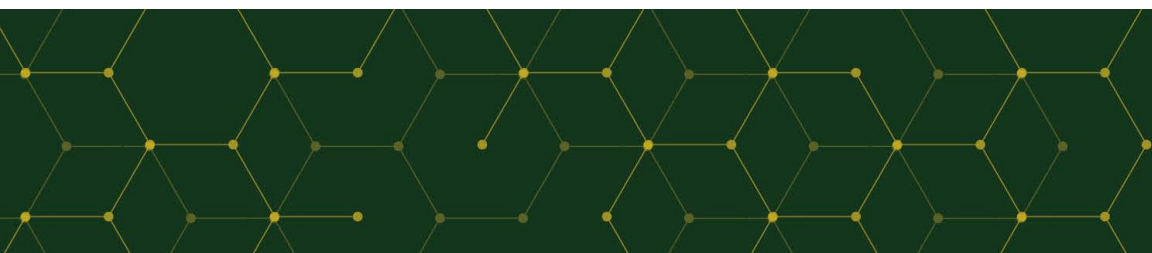
- JCA for Medicinal Products almost complete
- Conflict of Interest and EMA data sharing
- JSC for Medicinal Products
- JCA and JSC for Medical Devices



# Member State Implementation

Input to EU HTA:

- Local Organisation for EU HTA (e.g. Greek HTA Committee)
- Assessors, training, local scope.
- Local legislation.





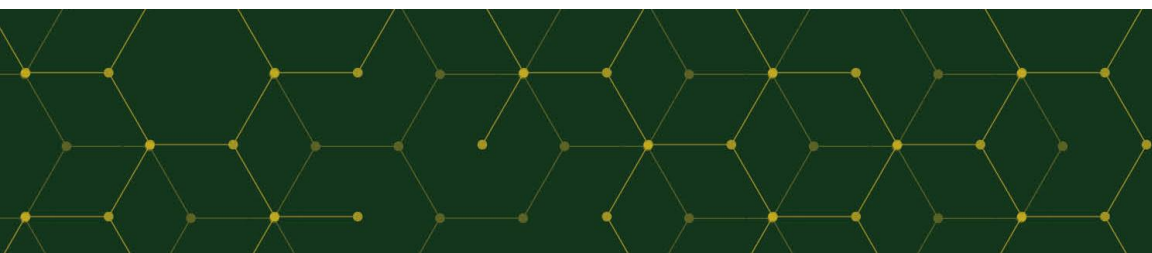
# Member State Implementation

## Input to EU HTA:

- Local Organisation for EU HTA (e.g. Greek HTA Committee)
- Assessors, training, local scope.
- Local legislation.

## Outputs of EU HTA:

- How can JCA be used efficiently?
- Do processes need to be adapted?



# Beyond 2025?

2026 – Medical Devices

2028 – all orphan medicines

2030 – all other medicines



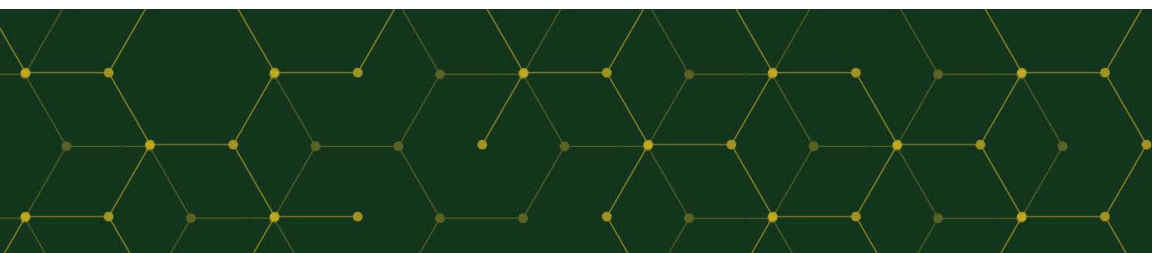
# Beyond 2025?

2026 – Medical Devices

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- ✓ **EU HTA informing decision frameworks across EU.**
- ✓ **Faster and more equal access to effective innovative medicines.**
- ✓ **Robust, inclusive & resourced EU HTA System**



# HTA CG

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Thank you

[https://health.ec.europa.eu/health-technology-assessment\\_en](https://health.ec.europa.eu/health-technology-assessment_en)