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GRUPPO ISPOR ROMA FOR FUTURE

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Attuazione del Nuovo Regolamento Europeo sull'Health Technology Assessment e applicazione del JCA: i primi sei mesi di implementazione e prossimi passi

Sharing Experiences: Italian perspective

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Disclaimer

The views and opinions expressed in this presentation are my own and should not be understood or quoted as being made on behalf of or reflecting the position of Madrigal Pharmaceuticals.

Early implementation challenges at EU level: No Agreement on Multi-Comparator Indications

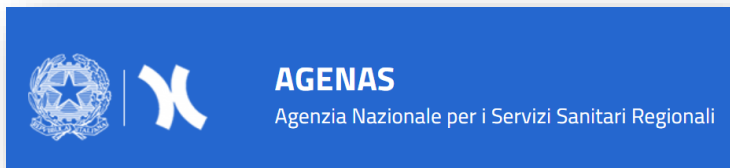
STORY - Thursday, 22 May 2025 - 15:41 GMT

No agreement between EU states on treating multi-comparator indications in PICO during HTA, says coordinator

BERLIN, 22 May (APM) - The number of population, intervention, comparator, outcome (PICO) based on the designated comparators is not regulated since the EU countries did not agree on how to approach indications with many comparators, Beate Wieseler, chair of the EU HTA subgroup on methodology and procedure, said on Thursday.

AIFA and AGENAS played a significant role in EUnetHTA

- Leadership in Work Packages (e.g. Evidence Generation & National Implementation)
- Participation in Joint Clinical Assessments: JCAs during EUnetHTA Joint Action 3, which spanned from 2016 to 2021
- Engagement in Early Dialogues and Parallel Scientific Advice: AIFA was the third most involved agency from 2010 to 2015



Tafuri G et al., Br J Clin Pharmacol 2018

AIFA reports the process of enhancing capacity and aligning competencies for HTA-R is underway



Editorial

Agenzia Italiana del Farmaco (AIFA): Developments and Strategy in a Transitioning European HTA Landscape

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J. Mark. Access Health Policy 2025

- ❑ *“Harmonization will ensure efficiency, consistency and quality of HTA & faster patient access”*
- ❑ *“However, national autonomy needs to be maintained in non-clinical assessment, e.g. cost-effectiveness, epidemiology and health care specificities”*
- ❑ *“AIFA is in a process of **increasing capacity and targeting competency profiles** to actively prepare for the upcoming changes and challenges”*

AIFA's actions with potential to contribute to HTA-R implementation

- ❑ Increased transparency on HTA decision-making: reports on the innovative status in the public domain
- ❑ AIFA released its Regulation for the Scientific-Economic Committee in May 2024, which references JCA-related activities



The screenshot shows the AIFA (Italian Medicines Agency) website. The header is blue with the AIFA logo and the text 'Italian Medicines Agency'. Below the header, there is a navigation bar with links: 'home', 'Pricing and reimbursement', 'Economic evaluations', and 'Technical and scientific reports'. The main content area is titled 'Report tecnico-scientifici per specialità medicinale'. The text below the title states: 'In questa sezione vengono pubblicati i report tecnici su nuovi medicinali innovativi di particolare interesse da parte del SSN, relativamente alla prima indicazione terapeutica ammessa al rimborso, e per i quali sono disponibili dati economico-sanitari sufficienti e verificabili da parte dell'Agenzia (es. modello di costo-efficacia su file Excel aperto e modificabile), utili alla compilazione di tutte le sezioni.'

Innovative drug list

An updated list of medicines is available which, according to the Scientific-Technical Committee, meet the requirement of **full or conditional therapeutic innovation**, pursuant to Article 10, paragraph 2 of Law no. 189/2012, as defined by Article 1, paragraph 1, of the State-Regions Agreement of 18 November 2010 (Rep. Atti n.197/CSR).

The list contains the innovative products to be made **immediately available to patients**, even without formal inclusion in the regional hospital therapeutic schedules.

The reference to the inclusion in the list is published in the Official Gazette for each individual specialty, relating to the indication reimbursed by the National Health Service.

This list also includes the details of the products having access to the **Fund for innovative oncological and non-oncological medicines** (Article 1, paragraphs 402, 403 and 404, of the Law 11 December 2016, no. 232 and subsequent amendments).

The above list includes the **assessment reports for recognition of innovation**, by therapeutic indication, in accordance with the provisions of AIFA Resolution no. 1535/2017.

Reports are also published of medicines that have obtained negative results in the innovation assessment.

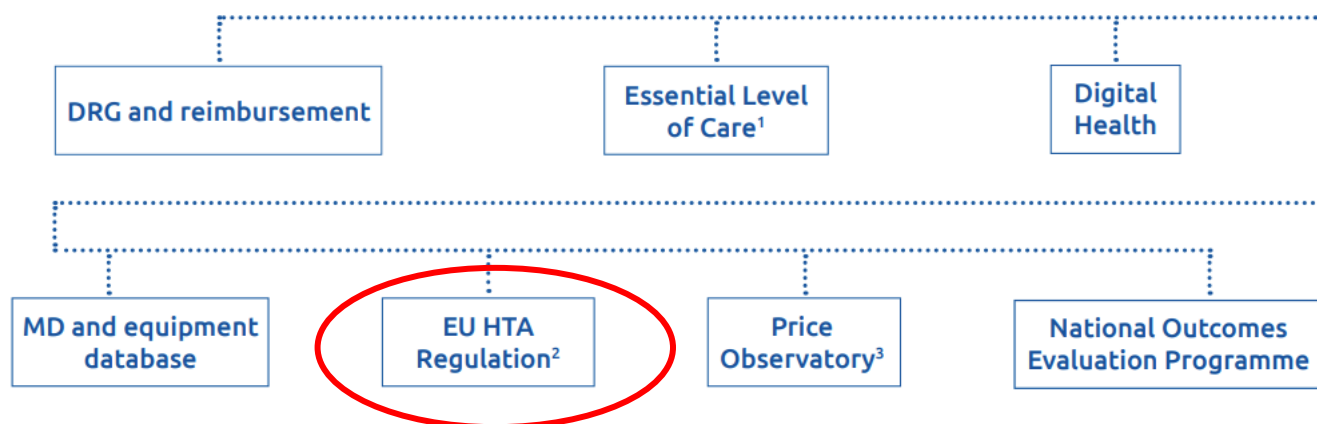
[Innovative medicinal - April 2025 \[0.07 Mb\].\[QDS\] >](#)



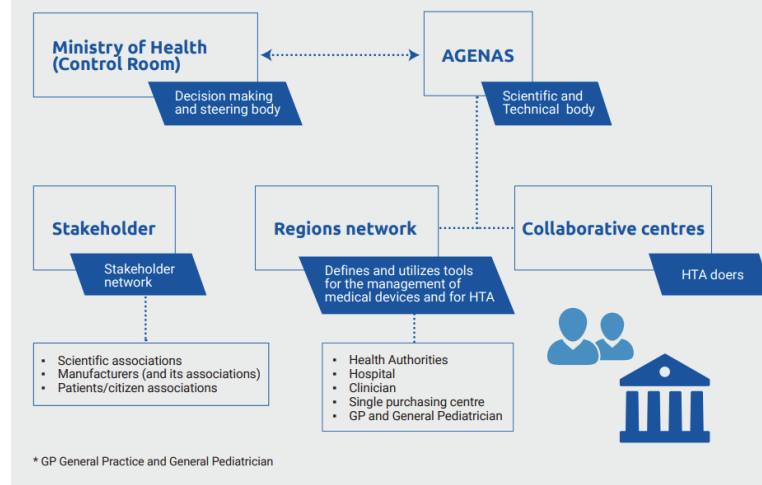
AGENAS continues to foster HTA capacity building at the national and regional levels



Integration area with the PNHTA 2023-2025



Governance Structure of the PNHTA 2023-2025



What needs to be addressed

- ❑ No guidance has been released on how AIFA is planning to leverage the EU JCA report in the national Pricing & Reimbursement process
- ❑ Strengthen the Agency's **internal organization** in view of the HTA Regulation
- ❑ Ensure **integration** between JCAs and **regional/national decision-making**
- ❑ Need for greater **inter-agency coordination** (AIFA, AGENAS, Regions, Ministry of Health, ISS)
- ❑ Stakeholder engagement: importance of **early involvement of patients, clinicians and industry**



The HTA-R recognizes the importance of regional contributions to health technology assessments

Regions play a key role in the EU's health technology assessment framework in terms of **assessment, implementation and adaptation** of JCAs and contribution to the HTA-R **governance**

Where Member States conduct HTAs at national or regional level for health technologies that have been assessed at Union level, they should consider the joint clinical assessment reports at that level. In that regard, especially taking into account that different timing can apply for national HTA decisions, Member States should be able to take into account information, data, analyses and other evidence that were not part of the joint clinical assessment at Union level. The HTA conducted at national or regional level on a health technology that has been assessed at Union level should be made available to the Coordination Group.



3. The members of the Coordination Group shall designate their national or regional authorities and bodies as members of subgroups of the Coordination Group. The members of the Coordination Group may designate more than one member to a subgroup, including the member of the Coordination Group, without prejudice to the rule that each Member State shall have one vote. The members of the subgroup shall appoint their representatives, who shall have the appropriate HTA expertise, in the subgroups on an *ad hoc* or permanent basis and inform the Commission of their appointment and any subsequent changes. Where there is a need for specific knowledge, members of the subgroup may appoint more than one representative.

Coordination among national and regional institutions is key to ensure alignment with JCAs

- ❑ JCAs can support regional healthcare planning and provide greater transparency into how health technologies are assessed
- ❑ Risk of fragmentation at the regional level if a coordinated, centralized approach is not adopted
- ❑ AIFA and Regional HTA bodies may select different comparators within those identified in the joint EU PICO
- ❑ This lack of alignment may undermine consistency in national decision-making and pricing processes



Conclusions

- ❑ Italy has shown commitment to the EU HTA process, with active participation in EUnetHTA and early JCA activities

- ❑ Several key challenges remain to ensure effective implementation:
 - Strengthening technical and methodological capacity
 - Advancing internal reorganization within AIFA to meet HTA-R requirements
 - Ensuring coordination between national and regional institutions
 - Promoting structured and continuous stakeholder engagement

- ❑ The coming months will be critical to consolidate progress and align national processes with the EU JCAs

