EU HTA Regulations (HTA-R) in Motion: Italy's Path Forward

ISPOR Forum

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Presentation outline

- How AIFA committees have worked so far
- How the CSE may (could?) function
- How HTA-R/JCA could be integrated into the work of the CSE
- What critical issues are envisaged

Market Access of drugs in Italy

NATIONAL LEVEL

AGENZIA ITALIANA DEL FARMACO

National Access

- **HTA place in therapy**
- **Reimbursement status and Pricing**
- **Innovation degree**
- **Approval conditions (MEAs, PVAs, …)**

REGIONAL LEVEL

19 Regions
2 APs

Regional Drug Access

- **Regional Formularies (PTOR, PTP)**
- **Regional Tender/s**
- **Identification of Prescribing Centres**
- **Regional Guidelines**

LOCAL LEVEL

Local Health
Units/Hospitals

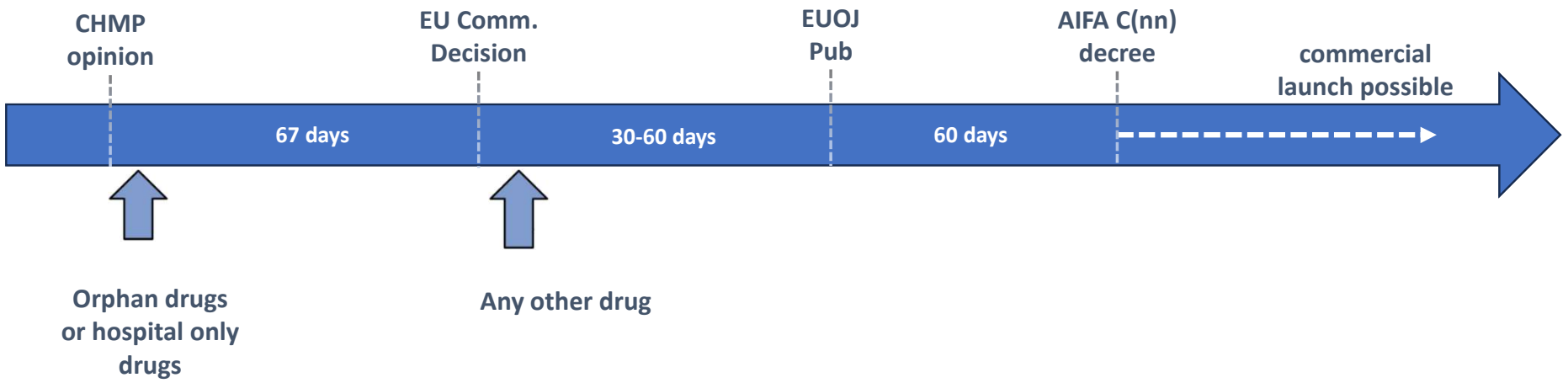
Local Access

- **Local Formularies (PTAV, PTO)**
- **Healthcare planning and delivery**
- **Local prescribers and budget holders**

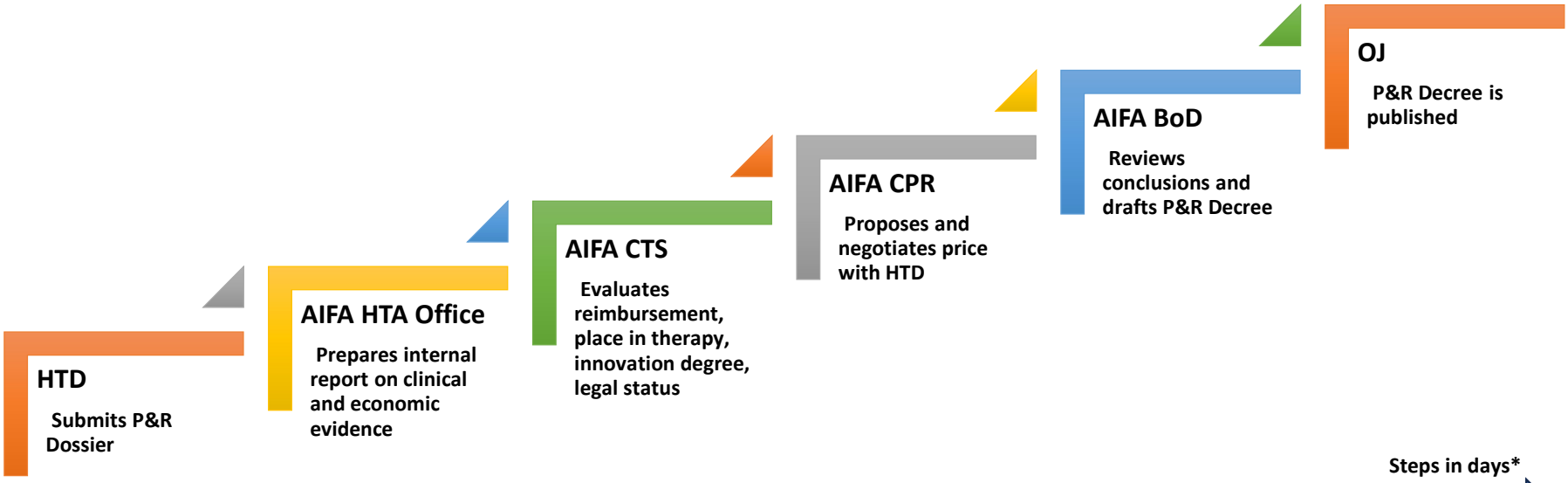
AP = Autonomous Provinces

P&R - submission timelines

For products approved through the EMA Centralised procedure



P&R- process and average timelines

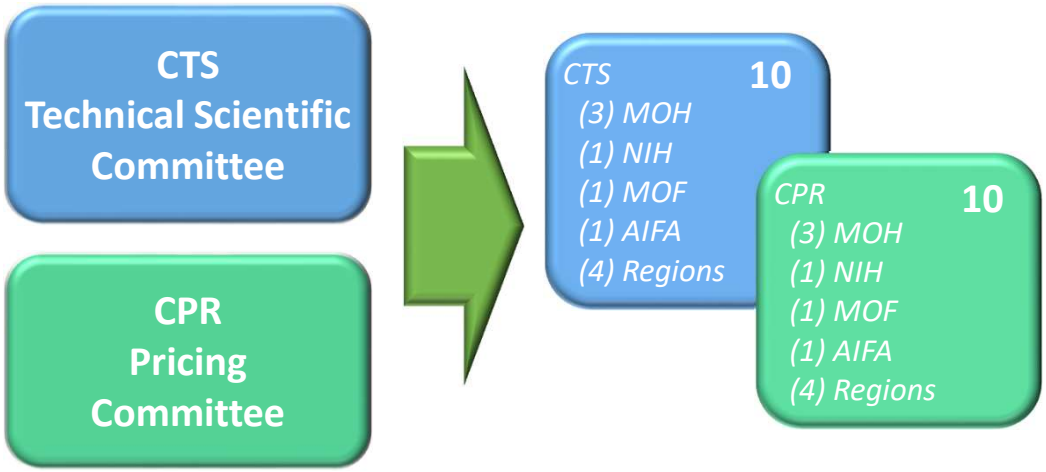


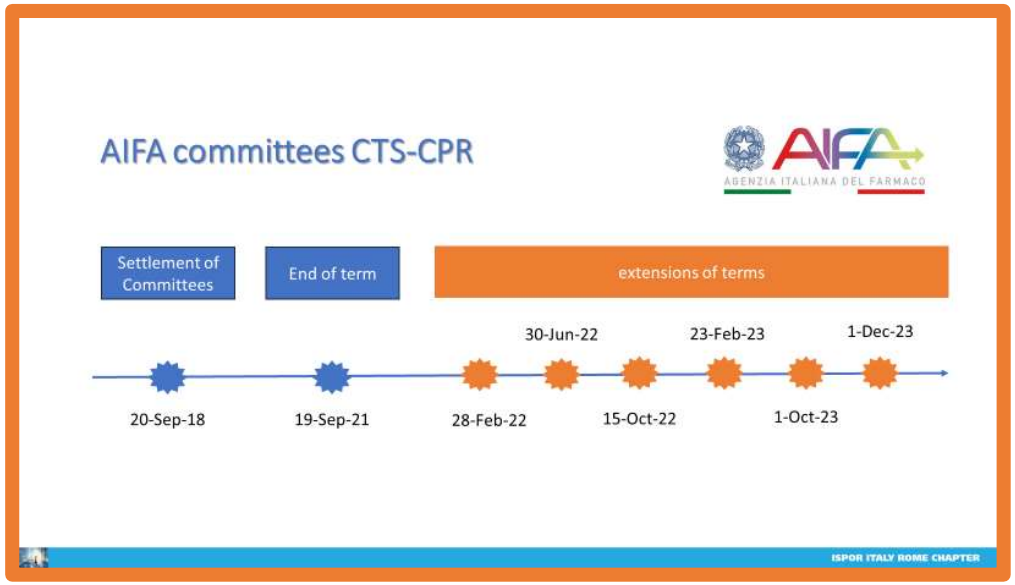
	Steps in days*					Total in months*
(N=171) All reimbursed	start	143 d	65 d	113 d	43 d	41 d	13.3
(N=71) Oncology	start	132 d	66 d	92 d	41 d	41 d	12.2
(N=61) ODD	start	120 d	71 d	140 d	42 d	37 d	13.5
(N=6) ATMP	start	93 d	139 d	137 d	35 d	25 d	14.1

*Data from PHARMALEX Italy proprietary database. Products submitted/approved 2018-2023. Updated 10-NOV-2023

HTD = Health Technology Developer; CTS = Technical Scientific Committee; CPR = Pricing Committee; ODD Orphan Drug Definition

AIFA Committees





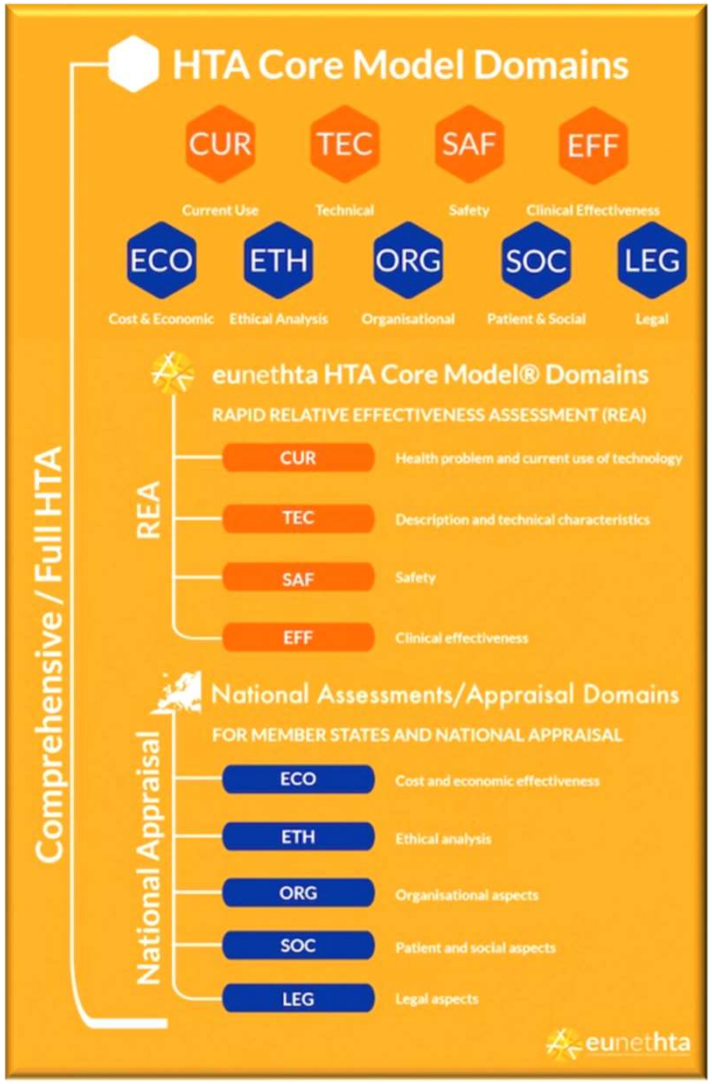
[Price and Negotiation Decree DM 02.08.2019 GU185 24-07-2020]

The Scientific Technical Committee (STC) of AIFA (...) expresses its opinion in particular **on the clinical value** of the drug and the **added therapeutic value vs. the drugs indicated as comparator reference drugs** (...).

If needed, in order to ensure **greater appropriateness of use** or to identify specific areas of use, the CTS **may introduce limitations** to reimbursement.

The negotiation procedure is considered negatively concluded (…) in the event that the outcome of the aforementioned evaluation does not reveal **clinical superiority** of the drug under negotiation with **respect to the comparator(s) identified by the CTS** and the company does not reformulate a proposal that configures a therapy cost **equal to or lower** vs. the comparators.

CPR also issues **binding opinion on request for innovation rating** (which influences the pricing discussion with CPR).



HTA-R/JCA

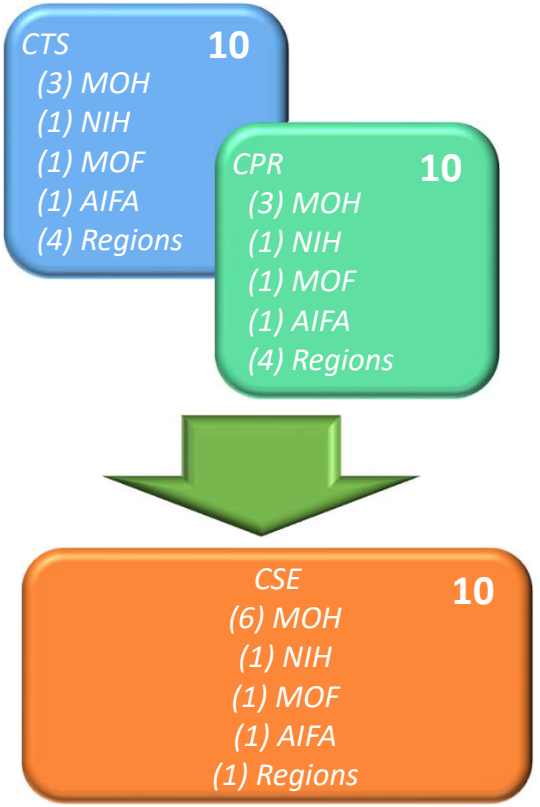
Member States only

The HTA-R/JCA clearly prescribes that the REA domains are allocated to the EU HTA process, whilst the other 5 domains remain within local national appraisal responsibility.

Now, looking at the role and responsibilities of the CTS it seems very appropriate to draw the conclusion that HTA-R/JCA will (would?) superimpose on the mandate of the current CTS.

The new Scientific and Economic committee (CSE)

- The **CSE will perform the functions previously attributed to CTS & CPR**.
- It makes its determinations with autonomy on the technical-scientific and healthcare level and also carries out technical-scientific advisory activities.
- The **CSE is appointed by decree of the Ministry of Health**
- and is composed of 10 members, including
  - (…) **six members appointed by the Health Ministry** among persons of proven and documented national and international technical-scientific expertise, with at least five years spent in the field of drug evaluation and in the field of drug pricing methodology, health-economics (…).
- The non-executive members serve 3-year terms, renewable consecutively for 1 term.
- Each non-executive member of the committee is entitled to a gross annual allowance of € 25,000



REF: https://www.quotidianosanita.it/allegati/allegato1681747218.pdf

CSE and HTA-R

- **How the new CSE will work, still to be defined:**
  - Will the process be structured/organized into 2 separate activities (clinical & economic appraisal)?
  - Or will there be a single-comprehensive appraisal?
- The main feature of HTA-R/JCA will be the PICO definition
- According to the Regulation, every MS Authority will contribute to PICO definition
- **so potentially HTA-R/JCA could significantly simplify the work of the CSE, by providing the "raw material" (data analysis) for scientific appraisal, based on pre-agreed PICOs and leaving more room for the pricing and economics negotiation.**

REF: https://www.quotidianosanita.it/allegati/allegato1681747218.pdf

Critical issues

- Put an end to the current uncertainty that influences time-to-market and availability of innovation and potential cures to patients.
- Rapid appointment of the CSE members and start of the new appraisal process
- Ability/willingness of AIFA/CSE to contribute to the HTA-R/JCA process to have local PICOs considered and addressed in the HTA-R process.
- Modify the organization to include knowledge/expertise specific to the new HTA-R/JCA topics (i.e. MAIC, ITC, NMA, …)
- Notwithstanding the consideration that in any case the new regulation will be effective only for newly registered EMA drugs (Jan 2025 onwards) and therefore a significant number of AIFA procedures will still have to be handled under the current approach.

Take-away

- In a highly regulated pharmaceutical marketplace like Italy, decisions from MOH, AIFA and their accompanying experts and teams, are still awaited to better understand what will be the effect of the HTA Regulation on P&R of pharmaceuticals, in Italy.

Thank you for your attention!