Pricing and reimbursement in Italy: At a glance

The Italian healthcare system

- Italy's healthcare system is publicly funded through the National Health Service (NHS), with service delivery and budgeting delegated to regions and autonomous provinces (AP). While healthcare is decentralized, pricing and reimbursement (P&R) decisions for pharmaceuticals are centralized and governed by the Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA)[1]
- AIFA oversees the regulatory process, health technology assessments (HTA), pricing negotiations and reimbursement classifications. Within AIFA, the Scientific and Economic Commission (Commissione Scientifica ed Economica del Farmaco, CSE) evaluates both clinical and economic evidence, assesses the level of innovation, negotiates prices and participates in European Union Joint Clinical Assessment processes[2]

Pricing and reimbursement

Overall, products assessed for reimbursement by AIFA are classified into four categories[3]:

Class A: Essential medicines and medicines for chronic diseases, fully reimbursed for outpatient use

Class H: Hospital-administered medicines, fully reimbursed in a hospital setting

Class C: Non-reimbursed products, available for out-of-pocket purchase

Class C(nn): Non-negotiated products, pending or lacking pricing finalization

- When a product (Class A or H) is reimbursed nationally, it becomes eligible across the entire country, and the price set by AIFA applies across regions and APs; prices are revised every 24 months
- Formularies are defined at the regional or AP level, and inclusion in regional formularies depends on local budget constraints and decision-making
- Evaluation and negotiation proceedings are kept confidential and public access to HTA documents is usually limited
- Manufacturers can propose managed entry agreements (MEA), which is either performance- or financial-based; if accepted by AIFA, each MEA requires that the manufacturer keep a patient registry

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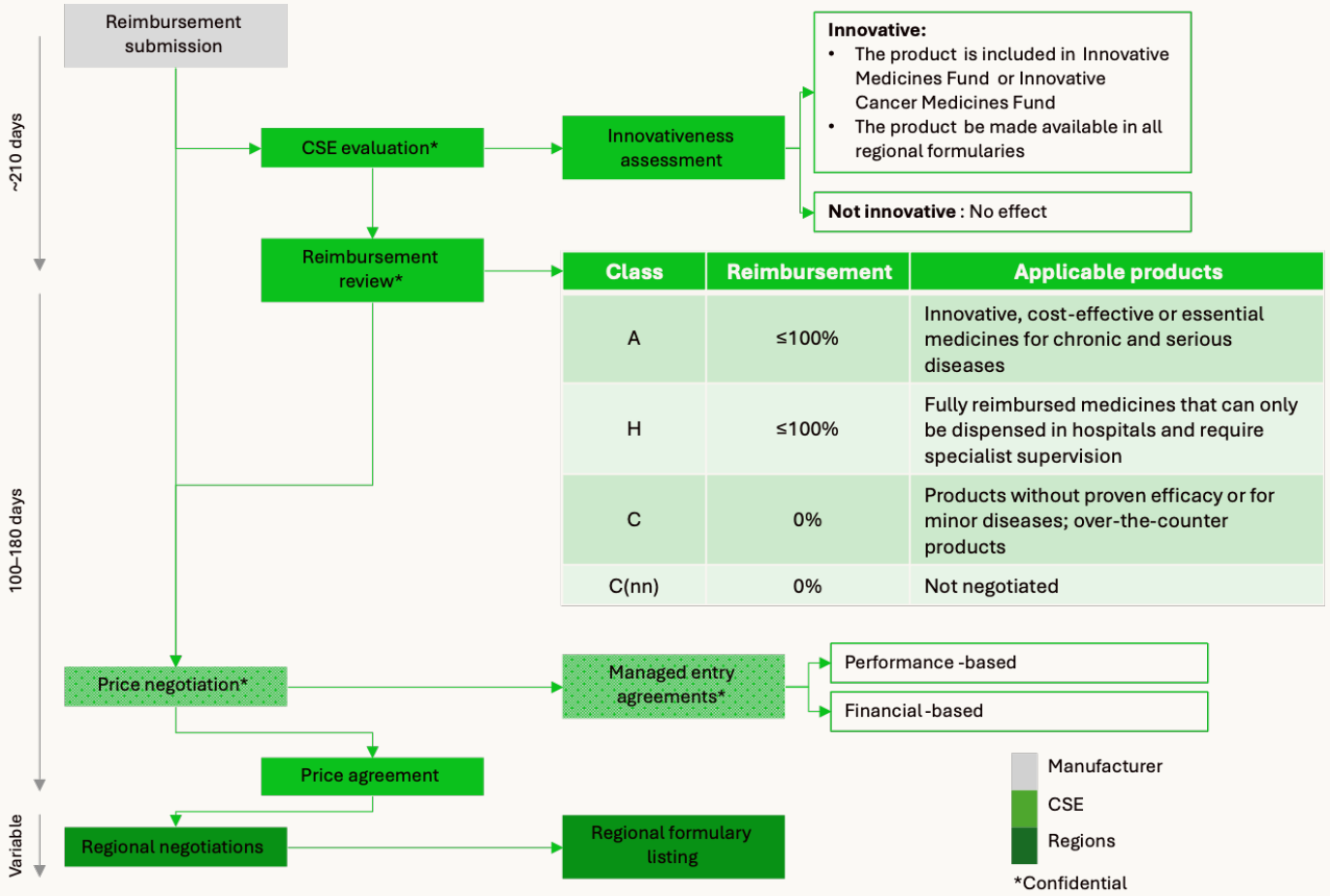
Access pathways

Several access pathways enable patients to receive innovative therapies even before formal marketing authorization.

- Off-label use is permitted under Law 648/1996 for novel drugs not yet approved for the indication of interest but that clearly demonstrate clinical efficacy and address significant unmet medical needs[4]
- Compassionate use programs, regulated by the Ministerial Decree of 07/09/2017, allow investigational drugs to be provided to patients with terminal or rare diseases lacking treatment options[5]
- For advanced therapies, AIFA may authorize the non-repetitive use of investigational advanced therapy medicinal products in hospitals for individual patients facing life-threatening conditions[6]
- Additionally, the 5% Fund supports access to orphan drugs, which is partially financed by a mandatory contribution from manufacturers equivalent to 5% of their expenditures on physician advertising[7]

Pricing and reimbursement processes in Italy

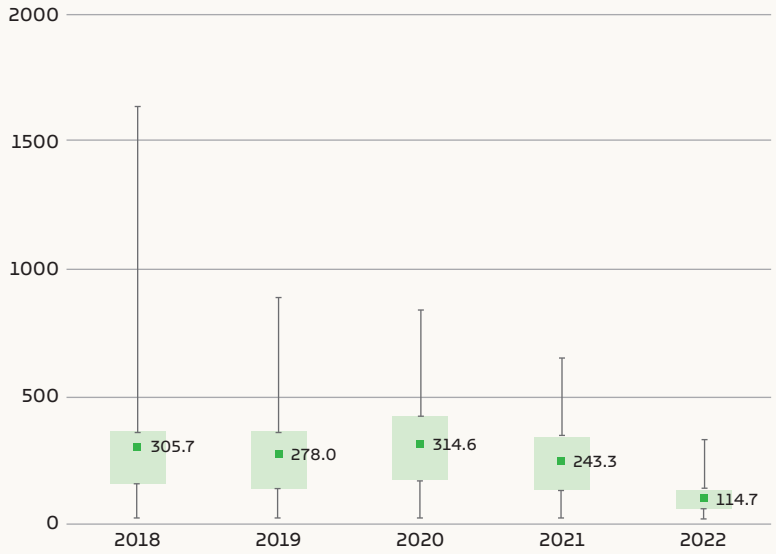


How do clinical and economic evidence inform P&R in Italy?

The evaluation of clinical evidence:

- Clinical evidence is the foundation for AIFA's assessment of new medicines. Manufacturers must submit a comprehensive reimbursement dossier that includes data from randomized clinical trials, comparative efficacy studies, safety data and real-world evidence (whenever available)
- The use of real-world evidence is accepted as useful to contextualize results, however it is secondary to evidence from clinical trials
- Products are evaluated within the proposed therapeutic positioning considering their added clinical value over existing treatments and whether they address unmet medical needs
- Evaluation reports are usually kept confidential[8]

Duration of AIFA evaluation procedures between 2018 and 2022, in days.



Source: AIFA. Rapporto sulle tempistiche delle procedure di prezzo e rimborso dei farmaci nel periodo gennaio 2018–2022. April 2023.

Innovation

- AIFA also assesses whether a product qualifies for **innovative status**, which allows for faster access to market and direct inclusion into regional formularies
- The level of innovation is mainly evaluated based on therapeutic needs, added therapeutic benefits and quality of the evidence provided; other factors include technological aspects of production, mechanism of action, route of administration and organizational implications. Products with strong pre-clinical and clinical proof-of-concept are usually favored. Products indicated for low/medium prevalence severe conditions are usually classified as innovative, while all antimicrobials listed by the World Health Organization (AWaRe list) are considered innovative.[9] For each assessment performed, a report on therapeutic innovativeness may be published[10]
- Innovative status automatically allows for inclusion in regional formularies and direct access to reimbursement through the €1.3-billion Innovative Drugs Fund (Fondo Farmaci Innovativi) and grants an exemption from some financial obligations. Such innovative status lasts for 36 months for first-in-class products, and for a residual period in case of follower products
- While it allows for faster and easier market access, it is worth stressing that innovative status has a negligible impact on pricing[11]

The evaluation of economic evidence

- All reimbursement submissions must include a budget impact analysis and a cost-effectiveness, cost-utility or cost-minimization analysis[12]
- Economic evaluations should strictly adhere to internationally recognized guidelines. However, a pre-specified value framework for medicines price setting is missing, and a willingness-to-pay threshold is not pre-defined[13]
- Pricing negotiations following an economic evaluation are usually informed by the quality of evidence, the reimbursement prices in other EU countries and the availability of other treatment options for the same indication[14]

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