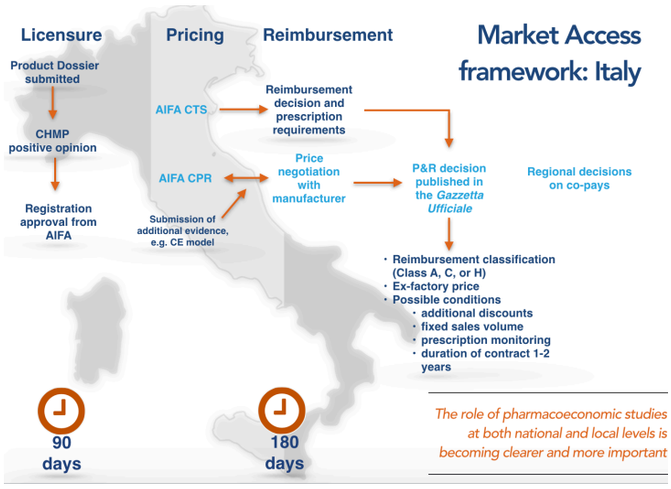
Market Access Decision Makers



By the Numbers

- 3rd biggest pharmaceutical market in Europe
- Population: 60.8 million
- GDP per capita: USD $29,957
- Health spending: 9.2% of GDP
  - ~ public: 75.6%
  - ~ private & cash: 24.4%
- Life expectancy at birth: 82.6
- Median age: 43.8
- NEET: 22% (youth not in education, employment, or training)
- Elderly population (65+): 22.4%
- Top causes of death: ischemic heart diseases, cerebrovascular diseases, cancer

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Market Access

- Longest time to market in EU5: Average time between licensure and access is longer than planned (1 year on average) and is increased due to regional discussions
- The degree of innovation assigned at the end of the HTA process determines the reimbursement situation (inclusion in the PFN)
- Reimbursed products are categorized as Class H or Class A (Class A: essential products for chronic diseases and fully reimbursed by NHS, Class H: only fully reimbursed in the hospital)
- PFN is updated every 6-12 months
- Regions can apply additional restrictions in terms of authorized prescribers and access to patients
- Co-payments in place (except for the elderly and citizens with low income)

Pricing

- The price is negotiated with CPR (under AIFA) after inclusion in the PFN
- Negotiations are conducted in line with the HTA result
- 21 different regions can decide on different price levels
- External reference pricing is used as a supportive tool to provide insight into negotiation
- The reference basket includes France, Germany, Spain and the UK and potentially some other European countries
- Mandatory external and internal (by the creation of groups based on active substance) reference pricing implemented for generics and off-patent originals in order to set the maximum reimbursed price

HTA

- Used for each product's inclusion in the PFN
- Conducted by CTS (under AIFA)
- Seriousness of the disease, availability of similar therapies and additional benefits in comparison with the comparator are evaluated
- Cost effectiveness and budget impact are used
- After the HTA evaluation, a degree of innovation is assigned to the new technology
- Some regions conduct additional HTA to provide recommendations on the use of new products

Access to Innovation

- Early access programs in use for innovative products which are: authorized abroad but not in Italy, have not yet received an authorization but have undergone clinical trials, or to be used off- label
- Free pricing is in place for such products
- Other market access agreements for innovative products include paybacks for non-respondent patients (P4P), conditional treatment continuation and price volume agreements

Regulatory and IP

- Market authorization granted by EMA or AIFA
- 20 years of patent protection
- 8 + 2 + 1 years of data exclusivity

Although Italy has a strong domestic pharmaceutical industry; cost containment measures, lack of transparency, regulatory hurdles and a long time to market slow down new drug's access to the market, which is further affected by the unstable investment atmosphere brought by the economic crisis

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We are here to support your market access and pricing needs.
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