Pricing & Reimbursement in Italy
At a Glance

Although there is a national pricing and reimbursement process in Italy, each region controls their own budgets and formularies. Italy has pioneered risk-sharing agreements, employing them for over a decade. Manufacturers of expensive treatments, or those with uncertain benefits, should be prepared to negotiate on a payment-by-result or cost-sharing basis.

Key Considerations

- If therapeutic need, added value (compared to products already available) and quality of evidence are found to be high, the drug will be classed as innovative* and should be reimbursed by the regions.
- Regions may charge a copayment on Class A drugs, which were previously a small flat fee (~€3), but may now include a percentage of the drug price to encourage patients to select cheaper drugs if possible.
- Class C drugs are freely priced by the manufacturer**, but must be sold at 50% discount to hospitals.
- For hospital-only drugs, orphan drugs or drugs with exceptional therapeutic or social relevance, pricing/reimbursement negotiations can begin before marketing authorization and may take up to a maximum of 100 days.**
- In addition to cost effectiveness and risk-benefit ratio versus comparators, the CPR also considers the:
  - Financial impact on the national health system
  - Expected sale volumes
  - Prices and consumption in other European countries
- Italy employs varied MEAs. Since 2013, the number of MEA applications has increased, with payment-by-results and cost-sharing schemes dominating the market.
- The majority of the regions in Italy have a binding formulary, to which drugs need to be added in order to be prescribed. Five regions have formal HTA processes, while 13 conduct some HTA activity.

Pricing and Reimbursement Process

<table>
<thead>
<tr>
<th>Class</th>
<th>Reimbursement</th>
<th>Applicable drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>≥100%</td>
<td>Innovative, cost effective or essential drugs for chronic and serious diseases; can be limited to particular patients</td>
</tr>
<tr>
<td>H</td>
<td>≥100%</td>
<td>Drugs that are fully reimbursed, but can only be dispensed in hospitals and require specialist supervision</td>
</tr>
<tr>
<td>C</td>
<td>0%</td>
<td>Drugs without proven efficacy or with proven efficacy for minor diseases; over-the-counter products</td>
</tr>
</tbody>
</table>

In Practice

Managed entry agreements 2017

Presence of regional formulary and mean time to patient access following national decision (days)*

*First-in-class drugs are classified as innovative for a maximum of 36 months, and potentially innovative drugs can be measured after 18 months; **Price increases are only permitted in January of odd-numbered years; ***This means that drugs may be commercialized prior to receiving a classification from AIFA (automatically assigned Class “Cnn”) and may be reimbursed by some regions or paid for by patients directly.