AT A GLANCE

Although there is a national pricing and reimbursement process in Italy, regions control 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.
If therapeutic need and value 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 authorisation, and may take up to a maximum of 100 days***.

For completeness, we provide a table summarising the processes.

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### 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 in the hospital setting 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>

### KEY CONSIDERATIONS

- If therapeutic need and value and quality of evidence are found to be high, the drug will be classed as innovative.
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### IN PRACTICE

- For hospital-only drugs, orphan drugs or drugs with exceptional therapeutic or social relevance, pricing/reimbursement negotiations can begin before marketing authorisation, and may take up to a maximum of 100 days.
- In addition to cost effectiveness and risk-benefit ratio vs comparators, CPR also considers the:
  - Financial impact on the national health system
  - Expected sale volumes
  - Prices and consumption in other European countries

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AIFA=Agenzia Italiana del Farmaco; CPR=Comitato Prezzi e Rimborso; CTS=Commissione Tecnico Scientifica; HTA=Health Technology Assessment


*First-in-class drugs are classified as innovative for a maximum of 36 months, potentially innovative drugs can be reassessed after 18 months; **The price must be the same across the country and can only be increased every two years in line with inflation; ***This means that drugs may be commercialised prior to receiving a classification from AIFA (automatically assigned Class “Cnn”) and may be reimbursed by some regions or paid for by patients directly.
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