ITALY

Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

Total population: 60,359,546
GDP per capita: 41,626 USD
Health Care Sector: NHS
Health Care Expenditure per capita: 3,428 USD
Pharmaceutical spending per capita: 601 USD

New medicine

AUTHORISATION

European Medicines Agency (EMA) for Centralized procedure

OR

Italian Drugs Agency (AIFA) for
- National procedure
- Mutual recognition and decentralized authorization procedure

In consultation with

Technical Scientific Commission (CTS) with the co-operation of experts belonging to the National Institute of Health (ISS) and of other experts of well-known experience belonging to the Italian academic and health community

Task: Decision on authorization
Criteria: quality, safety and efficacy have to be evaluated for a marketing authorization (Directive 2001/83/EC), Law 219/2006.

Marketing authorization (Autorizzazione all'immissione in commercio, AIC)

PRICING – EX FACTORY LEVEL

Balduzzi Decree – 13 sept 2012, n°158 : C-Non Negotiated (CNN) – those drugs that obtained the AIC through the centralized, mutual recognition, decentralized and national procedure as well as of parallel import, **are automatically classified into the C-NN group waiting for the Company to present a possible request for different classification and price negotiation through an ad-hoc dossier** (CIPE resolution of 1 Feb 2001, n°3)

AIFA and its technical-advisory commissions are responsible for the definition of the reimbursement and supply regime for all authorized medicines as well as the negotiation with the pharmaceutical companies of the prices of those medicines charged to the NHS

Several examples of Management Entry Agreements (MEAs)

Reimbursable pharmaceuticals (Class A/H)

Price is set through **a contracting process** between **AIFA** and **pharmaceutical Companies**.
The contracting process is made of 4 steps:

1. The Company presents price & reimbursement request by submitting a dossier to AIFA. The request has to follow the Guidelines published by the Agency;
2. The Scientific Technical Commitee (CTS) expresses a binding opinion on the therapeutic value of the drug, its *place in therapy* and supply regime, as well as its eventual innovativeness;
3. The Pricing and Reimbursement Commitee (CPR) evaluates the dossier and, when necessary, convenes the Company for the negotiation;
4. In case of positive opinion on the reimbursement, the negotiation result is submitted to AIFA Board of Directors for the definitive assessment

AIFA decides the allocation

The request for classification is contextual to negotiation. Negotiation is foundamental for the drugs' disbursement by the NHS

Non - Reimbursable pharmaceuticals (Class C)

Free pricing by pharmaceutical companies

Class C drugs can be sold to the citizens either against the presentation of a medical prescription
(Class C with prescription) or directly dispensed without prescription

Price negotiation criteria
(CIPE resolution of 1 Feb 2001, n°3):
- Positive ratio/cost efficacy
- Risk/benefit ratio
- Economic impact assesment on NHS
- Cost of the therapy more favorable than products
- Estimate of the market shares that can be acquired
- Comparison with prices and consumptions of other EU countries

II-patient (H): pharma company must grant rebates (at least 50%) to hospitals for those medicines listed on the Hospital Pharma Formulary (HPF)

Tenders

Positive opinion o the drug by CTS at regional and local health authority level before hospital use
[VETO POSSIBILITY]

Results are published in the **Official Journal of the Italian Republic (Gazzetta Ufficiale)**

Th only regulatory provision applicable to non-reimbursable medicinal products must be traced in article 13 of the RD 03/03/1927 which provided for the right of the pharmacist for a margin not less than 25% of the price to the public

PRICING – WHOLESALE & PHARMACY LEVEL

WHOLESALER	Maximum margin of PRP net is 3%	Law n. 662/96, modified by the law n. 122/2010
PHARMACIES	Maximum margin of PRP net is 30.35%. Pharmacy claw-back linked to pharmacy turnover and medicine price.	

+ VAT: **10%**

AIFA carries out a monitoring action on prescription-only medIcines, verifying compliance with two conditions:
-the price of the medicine can be increased every two years (in odd years);
-the increase cannot exceed the programmed inflation

By 2008, the price of **not-prescription medicines** at all price levels is totally free. AIC's holder is obliged to communicate to AIFA the increasing variations over the maximum ex-factory price applied to distribution

REIMBURSEMENT

IN-PATIENT (Class H)	OUT-PATIENT (Class A)
Positive list	Hospital Pharmaceutical formulary
-No patient copayment for medicines dispensed in hospital -Most medicines, included into the HPF are part of the National reimbursement list (class A), but the HPF may also include some not reimbursed medicines (class C), according to the Hospital specialization	- Patient **fixed co-payment ("ticket")** and **prescription fee** (it changes/exists or not according to the region) -**Exceptions** from co-payment for particular social groups, pregnant women, aged etc.

Reference Price System ATC 5

100% reimbursement

But… authorities can decide to put restrictions in place for certain products or product classes, which are known as "note AIFA"

*A fund for **innovative medicines** & a fund for **innovative cancer medicines**, 500 million endowment each, have been established in 2017 (Legge di bilancio).*
*Innovativeness criteria: **medical need**, **added therapeutic value** and **quality of evidence**. Innovativeness and benefits have a maximum duration of 36 months*

For more information please visit the site of the Italian Drugs Agency (AIFA) at https://www.aifa.gov.it/ or scan the QR code