ITALY

AIFA- Italian Medicines Agency

AUTHORISATION

EMA OR AIFA

Task: decision on authorisation. In Italy marketing authorisation takes place at the same time as the Reimbursement decision.

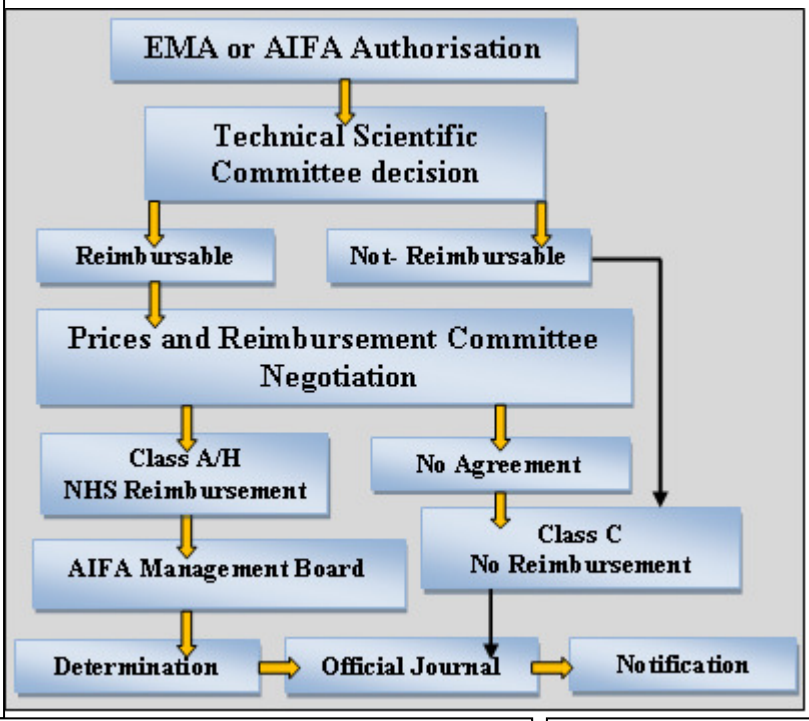
Criteria: quality, safety and efficacy have to be evaluated for a marketing authorisation (Directive 2001/83/EC), Law 219/2006.

PRICING AND REIMBURSEMENT

AIFA

Task:

Since 2004 a negotiation procedure for all medicines reimbursed by NHS has been introduced (Law 326/2003 art.33). Price negotiations represent the ex factory price to the NHS. The negotiation on price determination and reimbursement decision are managed by the Committee for Pricing and Reimbursement (CPR) and the Technical Scientific Committee (CTS). The current reimbursement medicine classification is: Class A (totally reimbursed by the NHS) and Class C (not reimbursed by the NHS).



AIFA

Criteria:

- therapeutic value and impact on target population,
- other country international prices,
- pharmaceutical expenditure ceiling planning,,
- budget impact,
- cost/efficacy and pharmacoeconomic analysis

(according to CIPE Deliberation n. 3/2001).

PRICING AND REIMBURSEMENT AT REGIONAL LEVEL

OUT - PATIENT

According to AIFA decision, all medicines listed on the National Pharmaceutical Formulary (NPF) are harmoniously managed by all Regions. The out-patient pharmaceutical pricing is established according to the maximum reference price of NHS purchase through the community pharmacies channel. In order to guarantee a balance in medicine distribution and cost containment , all Regions have adopted the pharmaceutical "Direct Distribution", which is carried out by two different channels: Distribution of reimbursed medicines to patients by hospitals (e.g. first cycle of therapy at patient's discharged or specialised out-patient visits) and "Distribuzione per Conto", which is a distribution of reimbursed medicines to patients through the community pharmacy channel. Those medicines are purchased by the Region and distributed by the pharmacy according to shared stipulations.

Planning indicators: (Law n.122/2010) established by AIFA in accordance with Ministry of Health and Ministry of Economics. Tables comparing out patient pharmaceutical consumption and expenditure in each Region for the following therapy classes: A02BC (PPI), C09 (AGENTS ACTING ON THE RENIN-ANGIOTENSIN-SYSTEM), C10AA (HMG CoA reduct. inh.), N06AB (SSRI). The following ratio indicators have been produced:

- A02BC (off patent) / on total A02BC
- C09A / on total C09A+ C09C
- C09B / on total C09B + C09D
- C09CA01 (Losartan off patent) / on total C09CA
- C10AA (off patent) / on total C10AA
- N06AB (off patent) / on the total N06AB

IN - PATIENT

In-patient pharmaceutical pricing is negotiated by AIFA, but Pharmaceutical Companies must grant rebates to hospitals according to those medicines listed on the Hospital Pharmaceutical Formulary (HPF). Tenders may be provided at Regional level, or may be directly managed by hospitals bargaining their own rebates (Law 264/74, art.9). Some Regions adopt their own Formulary, which may include a limited list of medicines. Some other Regions do not have their own Formulary so they adopt all medicines authorised at National level. The HPF is part of the Regional Hospital Pharmaceutical Formulary (RHPF) and the National Pharmaceutical Formulary (NPF).

All medicines distributed within the in-patient sector, both Class A-(H/OSP) and Class C-(SOP-OTC) are 100% reimbursed by the NHS.