

ITALY

Rational use of medicines in the in- and out-patient sector

Educational strategies (not exhaustive):

- ⇒ Information campaigns directed at the general public via media, web and social network (e.g. Rational use of Antibiotics, Use of Generics, etc.)
- ⇒ AIFA editorial activities targeted at health care professionals (e.g. Use of pharmaceuticals for children and pregnant women, National annual report on the use of pharmaceuticals), available also on web site
- ⇒ Regional and/or Local Health Units (ASL) monitoring and auditing of GPs prescribing activities to contain public pharmaceutical expenditure below the ceiling provided by Law No. 405/2001
- ⇒ The National Guidelines Programme, (PNLG) – provides clinical and clinical-organisational guidelines, and a database collecting national and international guidelines (available at <http://www.pnlg.it>)

Managerial strategies (not exhaustive):

- ⇒ Internal Reference Price List for the out-patient sector
- ⇒ List of substitution for the out-patient sector
- ⇒ AIFA Monitoring Registries
- ⇒ Direct Distribution in public health centres or out-patient pharmacies of:
 - the first cycle of therapy upon hospital discharge and during out-patient follow-up for guaranteeing therapeutic continuity and monitoring
 - high cost medicines, through centralised discounted purchase and financial agreements with wholesalers and out-patient pharmacies for distribution to patients
- ⇒ Pharmaceutical formularies at regional/ hospital level

Economic strategies (not exhaustive):

- ⇒ Pharmaceutical budgets for in-/out-patient expenditure
- ⇒ Outcome-based Managed Entry Agreements (Risk sharing and Payment by results) for pharmaceuticals with high uncertainties in clinical and cost-effectiveness profile and in order to:
 - evaluate the utilisation in clinical practice (effectiveness)
 - collect epidemiologic data
 - get information on the safety profile
 - collect ex-post evaluation about missing knowledge
- ⇒ Financial incentives for pharmacists: as an incentive to deliver more generics, in addition to a 30.35% margin, pharmacists share with wholesaler an extra 8% on the net retail price
- ⇒ Financial incentives for patients asking generics (reference price at national level and exemption from prescription fees at regional level)
- ⇒ Reference price on therapeutic class (e.g. PPIs) in several Regions

Regulatory strategies (not exhaustive):

- ⇒ Mandatory INN prescribing (August 2012) and generic substitution
- ⇒ Indicators of appropriate prescribing and consumption of several off-patent categories in the out-patient sector (Regional benchmark)
- ⇒ Notes on limitations (named “AIFA Notes”) for the appropriate use of prescribing pharmaceuticals proven to be effective in the treatment of specific diseases or those associated with frequent severe adverse events
- ⇒ Treatment Plans allow GPs to prescribe medicines for serious illness after diagnosis, initial prescription and monitoring by a specialist. Their aim is the management of the diffusion of medicines to targeted patients for:
 - products entering the market with uncertainty in the risk/benefit ratio
 - high-cost pharmaceuticals
 - second line treatments

Evaluations of some measures:

- ⇒ Decrease of antibiotics prescription and consumption rate of 6% in 3 years due to general public campaigns on rational use of antibiotics
- ⇒ Increase of the generic prescription rate of 6% in 5 years due to general public campaign and other measures