

ITALY

Recent changes in pharmaceutical policy measures and developments in pharmaceutical expenditure

Major changes in pharmaceutical policy in 2012-2013

The Law n.189 - 8.11.2012 (*also Known as Balduzzi Decree*) introduces important changes in the pharmaceutical setting:

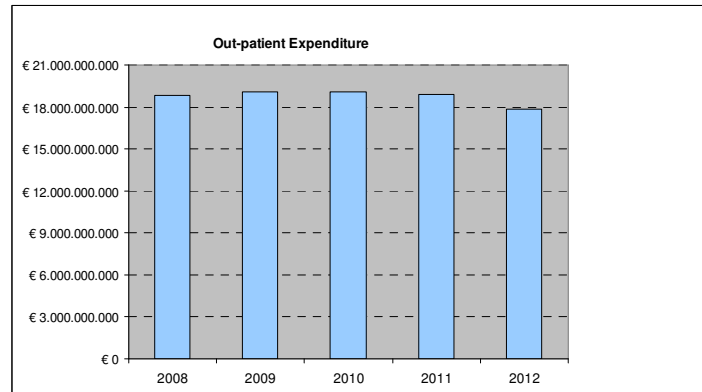
- Revision of the National Pharmaceutical Formulary (placing in the non-prescription group those drugs considered therapeutically exceeded. (ongoing, expected to be concluded).
- Pharmaceutical companies can apply for reimbursement before Italian marketing authorization if the application relates:
 - orphan drugs;
 - medicines of exceptional therapeutic and social importance, adopted after the proposal of the Technical-Scientific AIFA Commission;
 - medicines used exclusively in hospital setting or in similar facilities.
- Improvement of innovative medicines access across Italian Regions.
- Changes in the modality of drugs prescription: in order to encourage the prescription of generic drugs the physicians must indicate in the prescription just the name of the active ingredient. If necessary, the physician can also choose to prescribe by brand name providing a short motivation in the prescription.

Law n. 135 – 7.08.2012:

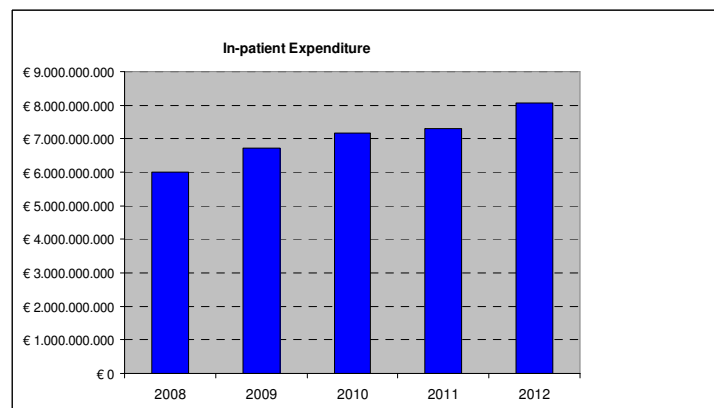
- National Ceiling of Out-patient medicines is set at the 13,1% the National Health Fund for Y2012 and at 11,35% for Y2013.
- Increasing of the National Ceiling for hospital medicines set at the 3,5% of the National Health Fund for the Y2013 (2,4% for the Y2012).
- Changes concerning modalities to refund in case of exceeding hospital expenditure ceiling (50% pay-back in charge of Pharmaceutical Company and 50% pay-back in charge of the Region in which the ceiling exceeds).

Development of pharmaceutical expenditure in the last 5 available years

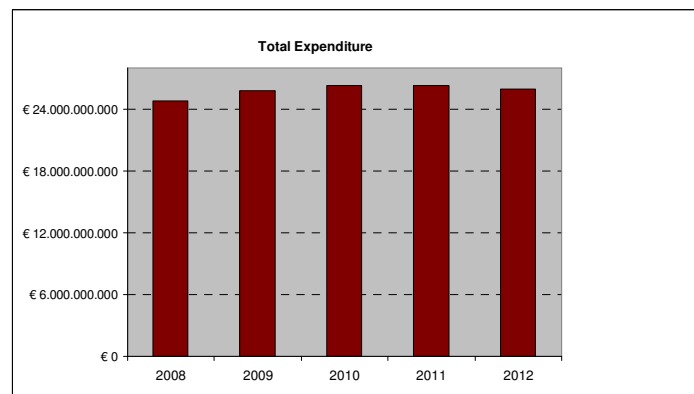
Out-patient sector



In-patient sector



Total market (out-patient + in-patient)



Source: OECD HEALTH DATA 2013 Electronic questionnaire