Hungary

High-cost medicines

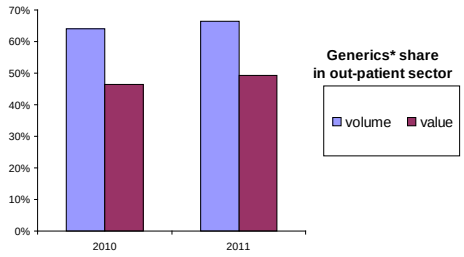
- No specific funding/reimbursement scheme for high cost medicines exists in Hungary but contracting a reimbursement volume agreement is a criteria of the inclusion of new innovative medicines

Generic policies

- Obligatory INN prescription for statins will be introduced in April 2012 (INN prescription is allowed)
- Generic substitution is indicative since 1995
- Stepped pricing system for generics: 40-20-10-5-5-5% lower price then the originator/previous generic
- Reference price system (since 1991 with recent changes on 1st October 2011)

  Active substance based reference groups
  - Usually the group is based on the group of interchangable products
  - recalculation of reference prices occurs quarterly with the exception of those groups where the recalculation occurred already 4 times, the reference price in those groups are set only 2 times per year
  - eligibility criteria for being a reference product: 1% DOT market share in 2 consecutive months out of the 6 previous months before setting the reference price
  - products that were at least 5% more expensive then the reference product at the time of setting the reference prices receive 15% less reimbursement
  - the products that were less then 5% more expensive or cheaper then the reference product are the so-called preferential products that can be dispensed in the frame of the reimbursement scheme for patients in socio-economically disadvantageous situation and pharmacists are financially incited to dispense these medicines

  Therapy based reference groups
  - the necessary market share criterion in the therapy based fixed groups was reduced from 50% to 40%
- If a more expensive product then the reference product is dispensed in the pharmacy then the co-payment of the reference product must be printed on the sales slip



* products are considered as generics if at the end of the year - within the given ATC and with the same route of administration - products of more than two marketing authorisation holders were reimbursed

Changes in the pharmaceutical system – end 2011/2012

- A new reimbursement scheme for biological products will be introduced :

  On 1st of February the list of biological product groups where the new scheme will be implemented (where biosimilars are available) was published on OEP's website. Companies can lower their prices until 20th of March. The cheapest products in the groups will be the so-called preferential products, more expensive ones will be either delisted or patients have to pay significantly higher co-payment (depending on the difference in prices). Companies will have the opportunity to lower their prices after the first round until 10th of April but the status of preferential and non-preferential products will remain unchanged for one year (from July to next July) and non-preferential products cannot achieve the low co-payment level of preferential products. Doctors have to prescribe preferential products within the group at least in 40% in the first year and 70% in the second year.

  If a new biosimilar gets reimbursement during the year then doctors have to prescribe it at least in 10% until next July.
- Several products were moved from the out-patient to the hospital sector with the 1st of February

Evaluations and studies on pharmaceutical policies

No relevant studies are available yet.