





BELGIUM

Generic policies

- INN prescribing is in place (indicative) since October 2005.
- Generic substitution is not in place.

(draft law – April 2012):

Generic substitution (indicative) will be allowed for

- INN prescriptions
- prescriptions for antibiotics/antimycotics (acute diseases)
 because pharmacists will be obliged to dispense the "cheapest medicine"
 and for
 - prescriptions for medicines with a "reimbursement ceiling" (see Changes)
- Generic price link:
 - As from 2012, the price of a generic is no longer constantly connected to the price of the originator.
 - Only on initial inclusion on the (positive) reimbursement list, the price of the generic must be 31 % lower than the price of the originator (ex-factory level).
- No tendering-like practices are in place in the out-patient sector.
- Reference price system:
 - In place since June 2001
 - Reference groups at ATC 5 level (identical molecule)
 - · Off-patent medicines
 - Available generic (2 months prior to clustering)
 - Linear price cut (ex-factory level)

Latest developments (draft law – April 2012):

- Initial clustering: 31 % or 41 % (fully reimbursed medicines)
- After 2 years: 6 %
- After 4 years: 5,5 % or 7 % (fully reimbursed medicines)

Exceptions can be granted (intravenous forms – pharmaceutical forms with a proven substantial therapeutic added value) \rightarrow % is reduced by half

- Generics share:

23 % in volume (number of packages) and 13 % in value (NIHDI expenditure) in 2010 (scope: out-patient market - off-patent market)