MoH

PPRI Pharmaceutical Pricing and Reimbursement Information

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

SPAIN

Recent and planned developments in pharmaceutical policies 2016

Special topic: Pricing and reimbursement policies for biosimilars

DEVELOPMENTS

CHANGES IN PRICING AND REIMBURSEMENT

DIFFERENT KINDS OF AGREEMENTS HAVE BEEN IDENTIFIED IN OUR DATABASE:

RISK SHARING, CAPS FOR EXPENDITURE, PHARMACOCLINIC PROTOCOLS, PATIENT REGISTRIES, SUBGROUPS OF PATIENTS, MAXIMUM COST/PATIENT, PRICE/VOLUME

OTHER CHANGES

Please indicate recent and planned changes related to (please indicate the status of implementation and dates):

- *e.g. changes in generic policies (i.e. introduction, change from indicative to mandatory generic substitution and INN prescribing)*
- *e.g. volume control, prescription monitoring, prescription budgets, measures to improve prescribing performance*
- *e.g. measures to improve medicines management at the interface of out-patient and in-patient sectors*
- *e.g. educational and information activities*
- *e.g. IT projects*

These changes depend on the Autonomous Communities

SPECIAL TOPIC

POLICIES FOR BIOSIMILARS

Please describe in brief the pricing procedure for biosimilars and possible outcomes (e.g. the extent of price difference and savings between originator and biosimilars) in your country:

- *How is the procedure of price setting on biosimilars in your country?*
  A Pharmacoeconomic assessment is performed in the Directorate General for Pharmacy when the pricing application from the Company is submitted, the Interministerial Pricing Committee (IPC) makes a decision
- *Is there a price linkage between the original biological and the biosimilar?*
  30% below the original is a general rule (criteria of IPC) although it is not mandatory and it is adjusted on a case/case basis
- *Do you tender for biosimilars?*
  A central procurement has been authorised for epoetins in 2014 and 2015

Please describe in brief the reimbursement procedure for biosimilars in your country:

- *How is the procedure of reimbursement setting on biosimilars in your country?*
  Reimbursement setting, as for other medicines, is predefined by therapeutical subgroup, additional conditions might be set through the pricing and reimbursement procedure
- *Are biosimilars included in the reference price system?*
  Yes, they are included for pricing purposes

Demand-side measures related to biosimilars in your country:

- *Are doctors adviced switch from original biologicals to biosimilars, and/or between biosimilars? Do you know whether, or not, switches occur (out-patient/in-patient sector)?*
  Switch depend on the prescriber and hospitals
- *Is biosimilar substitution in community pharmacies (out-patient sector) allowed? If allowed, is it mandatory, or not? Is allowed only for naïve patients or for all patients?*
  Biosimilar substitution is not allowed in Spain (Ministerial Order 2874/2007)

Further measures and discussions in your country:

- *Which are further measures to enhance uptake of biosimilar medicines?*
- *Which measures are planned or discussed?*