PPRI
Pharmaceutical Pricing and Reimbursement Information

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

RUSSIA

Recent and planned developments in pharmaceutical policies 2015

Pre-launch activities: horizon scanning and forecasting

DEVELOPMENTS

Changes in pricing

New pricing rules for generics and biosimilars included into Essential Drug List (EDL) (approved by the government and actual from October 01, 2015).

1. *Price for "generic" should not exceed 80% of the "referral" drug price.*
2. *Price for "biosimular" should not exceed 90% of the "referral" drug price.*

"Referral drug" is the same INN registered first in country.

EDL is the first step for marketed drug before inclusion into reimbursement programs. Federal Ministry of Health is responsible the dossier expertise of drugs submitted for EDL inclusion. EDL drugs can be included into reimbursement programs and lists after another specialized expertise.

Changes in reimbursement

New rules for tendering (approved by the government and actual from December 10, 2015) require excluding from the tender those medications manufactured in other than EurAsEC in case there are 2 or more participants from these countries.These rules are applicable for state-budgeted medical institutions (nor applicable for private ones) and for reimbursement of expenses (for EDL included drugs) for patients according to the following programs:

Federal programs:

- *National Project "Health" (HIV, hepatitis, vaccination)*
- *Tuberculosis*
- *Oncology*
- *Diabetes*
- *Pediatry*
- *Orphan diseases*

Regional Programs (depending on regional priorities)
Hospital purchasing (using hospitals' funds)
Mandatory Health Insurance Fund
"Additional Medical Provision" Program (mainly for disabled)
Hospital purchasing

Other changes: *No changes.*

SPECIAL TOPIC

Policies for biosimilars:

Reimbursement process for biosimilars is the same as for other drugs.

- *The price stetting is the same as for other medications (market authorization – EDL – reimbursement programs)*
- *There is a price linkage between original biologic and biosimilar in term of the upper margin cap (10% less or more than the original drug)*
- *Biosimilars are the subject of INN-based tenders as well as any other medications. The winner should be less expensive than others.*

The reimbursement process is the same as for other medications (market authorization – EDL – reimbursement lists/programs – tendering). Biosimilars are included into reference pricing system as well.
There is no demand-side measures related to biosimilars but anyway payers have an opportunity to pay less during INN-based tendering. Biosimilar substitution is allowed but exact situation depends on disease, current and proposed treatment and GPs opinion.
Market access advantages promised to locally manufactured drugs (including biosimilars) would likely enhance the uptake of biosimilar medicines.

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