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PPRI Pharmaceutical Pricing and Reimbursement Information

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

ESTONIA

Recent and planned developments in pharmaceutical policies 2016

Special topic: Pricing and reimbursement policies for biosimilars

DEVELOPMENTS

CHANGES IN PRICING

No changes in the overall pricing conditions.

We are introducing the risk and cost division strategy of reimbursed pharmaceuticals, to enforce the MAH to use the payback scheme (to EHIF) of exceeded part of agreed volume part of pharmaceutical

CHANGES IN REIMBURSEMENT

No changes in the overall reimbursement conditions.

Applied additional possibility for MoSA, SAM and EHIF to initiate the reimbursement of new pharmaceutical in the situation, where there is clear need for the medication and no one of MAH-s applies.

OTHER CHANGES

Recent and planned changes related to:

- *Planned importation rights for hospital pharmacies (regarding the unauthorized pharmaceuticals): possibility to buy directly from wholesale companies outside from Estonia.*

SPECIAL TOPIC

POLICIES FOR BIOSIMILARS

Pricing measures

- *First biosimilar in the group has to be priced at 15% below of original biological*
- *If the new biosimilar is being reimbursed or reference price in the group of biosimilars changes, the transition period (3...6 months) for the price change is being applied*

Reimbursement issues

- *The biosimilars belong into the positive list, the reimbursement conditions are similar to corresponding original biologicals ie like generics*
- *The biosimilars are reimbursed by simplified procedure ie like generics*
- *The biosimilars are included into the reference price system ie like generics*

Demand-side measures

- *If the biosimilar product has been prescribed by INN, the pharmacy has to offer the most advantageous product in the group (the possibility to prescribe by trade name exists as well)*

Further measures and discussions:

- *None*

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SUPPLEMENT

Definitions

Biosimilar: A biological medicine that is developed to be similar to an existing biological medicine (the "reference medicine"). Biosimilar medicines can only be marketed following the patent expiry of the reference medicine.

Switch: Decision by the treating physician to exchange one medicine for another medicine with the same therapeutic intent in patients who are undergoing treatment.

Substitution: Practice of dispensing one medicine instead of another equivalent and interchangeable medicine at the pharmacy level without consulting the prescriber.

Source: European Commission, "What you need to know about biosimilar medicinal products". A Consensus Information Document. 2013 http://ec.europa.eu/DocsRoom/documents/8242/attachments/1/translations/en/renditions/native

This document can also be consulted for further definitions related to biosimilar medicines.

For further terms on pharmaceutical policies, please consult the glossary of the WHO Collaborating Centre of Pharmaceutical Pricing and Reimbursement Policies: http://whocc.goeg.at/Glossary/Search

PPRI Network Queries

PPRI Policy Monitoring network query: PPRI network members are invited to use information that was provided in the PPRI Policy Monitoring network query launched by the PPRI Secretariat on 24 February 2016.

PPRI network query on generics and biosimilar policies: PPRI network members are invited to use information that was provided in the network query on generics and biosimilar policies launched by the PPRI Secretariat on 7 January 2016.

Break-out Poster Session

- Please prepare the poster in line with the template above. As supportive information, please consult the draft poster about Austria.
- Please send the country poster by 22 April 2016 to ppri@goeg.at to allow us to include it in the meeting's documentation (online) at the PPRI Intranet. After the meeting, the poster will be made available at http://whocc.goeg.at/Publications/CountryPosters.
- Bring your printed poster with you! You are recommended to print a poster in A0 or A1 size but you can also just print an A2 or A3 sheet. Furthermore, it is suggested to bring some copies of A4 sheets to share them with the participants.
- There will be four groups. The discussions in each group will be guided by facilitators.
- Every country is kindly invited to present. Even if you have not prepared a poster, a country representative will be kindly asked to inform about his/her country. The PPRI Secretariat will prepare which country will be attributed to which group.
- Country representatives have approx. five minutes to briefly present the two topics. They are kindly asked to be available for further questions.
- If there are more than one representative from one country, they are kindly advised to split, and non-presenting country representatives should join other groups. It might be helpful if they also bring one of the A4 copies about their poster with them.
- If you cannot attend the PPRI network meeting, we highly appreciate if you could prepare and share your poster.