MOLDOVA

Recent and planned developments in pharmaceutical policies 2018

Special topic: national incentives and derogatory procedures for orphan medicines

CHANGES IN PRICING

Please indicate recent and planned changes related to:

- price changes –
- price reviews - every year, depending on reference countries
- distribution remuneration (= margin) changes (wholesale, pharmacy) – no changes
- discounts / rebates (out-patient, in-patient), managed-entry agreements, clawback/paybacks
- change in VAT on medicines– no changes
- other changes in pricing policies (e.g. change of reference countries in EPR) – there are some adjustments for the Government Decision regarding manufacturer prices, like equalling regulation for local and foreign producers and comparing even to one prices from reference countries (compare to at least 3 before that)

Please indicate whether the changes have already been

CHANGES IN REIMBURSEMENT

No changes till now

Please indicate recent and planned changes related to:

- changes/modifications of reimbursement lists
- changes/modifications of reimbursement rates
- changes/modifications of co-payment
- changes/modifications in the reference price system (methodology)
- reimbursement reviews
- changes in the assessment/appraisal of products to be included in the reimbursement system
- other changes/modifications of the reimbursement system

Please indicate whether the changes have already been implemented or not; and if yes, when: e.g.: 01/05/2018: change in reimbursement rate, by reducing the rate from 90% to 85%.

OTHERS CHANGES

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

- 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 – promotion companies for generic uses
- e.g. IT projects

SPECIAL TOPIC: National Incentives and Derogatory Procedures for Orphan Medicines

Legislative requirements for the placing on the pharmaceutical market of an orphan medicinal product

According to the definition, an orphan medicine is the medicine used to diagnose, prevent and treat a rare disease: no more than 5 cases per 10000 population at the time of application.
In order to stimulate the placing on the market of orphan preparations, the following derogations from the general requirements for the authorization of medicinal products are provided for:
1. Orphan medicinal products shall be authorized on the basis of incomplete documentation (non clinical and incomplete clinical studies) when the applicant can demonstrate that:
1) the level of scientific data does not allow for more complete information to be provided;
2) the presentation of complete data is in contradiction with the general principles of medical ethics.
In these cases, the applicant shall justify in non-clinical and clinical summaries the reasons why it is not possible to provide complete information and must provide a justification of the risk-benefit balance for the respective orphan medicinal product.
Also, during the authorization, the holder of the Registration Certificate may be required to conduct post-authorization safety and efficacy clinical trials, indicating the deadline for submission of the results in the Registration Certificate.
The continued validity of the Registration Certificate will be determined by the annual reassessment of the presented data (based on the reassessment of the risk-benefit ratio).
2. Primary and secondary packaging is accepted to be presented in the international language (s) and is exempted from the requirements of the Regulation on the Authorization of Medicines for Labeling.
3. The authorization fee is reduced by approximately 50%: 654 Euro for the orphan medicine versus 1383 Euro - the original medicine and 1234 Euro - the generic medicine.