

ROMANIA

Recent and planned developments in pharmaceutical policies 2016

Special topic: Out-of pocket payments

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CHANGES IN PRICING

- Annual price review: starting in November, applicable in April.
- Price cuts for off-patent drugs: once the patent expires, it will be done gradually over 3 years, starting from April 2017; at the end of this period, the off-patent drugs should be as low as the maximum threshold given to the generics;
- Better price conditions for essential generics (established by WHO) and for immunological medicines, as well as for blood and plasma derivatives: rather than the minimum, for this category of drugs, the list price can be equal to maximum average of the 3 lowest prices in the 12 countries Romania references to, or the the price of the off-patent drug within the same INN available on the market (whichever is the lowest); the co-payment will not be affected, since another condition for this principle to apply is for the drug to be on the free of charge reimbursement sublist;
- Other changes in pricing policies: the exchange rate (a more realistic one, established by the National Bank of Romania); a more clear and predictable legislation.

Romania reviewed its entire pricing methodology, which was adopted on October 31.

CHANGES IN REIMBURSEMENT

- The reimbursement list changes every time a drug receives an approved price by the Ministry of Health. This may influence the amount of the reimbursement, as well as the co-payment and it depends on the type of drug: innovative, off-patent, generic or biosimilar.
- The state reimburses at the level of the lowest price in the INN, on four reimbursement levels (20%, 50%, 90% or 100%). Clusters were introduced in 2010 – in the same INN, the level is set at the average of 25% lowest drug prices;
- Since Oct 2015, cost-volume and cost-volume-result contracts were introduced (e.g. for hepatitis C treatment), for which the price negotiated are confidential.

Note: the state regulates the price only for drugs for which a medical prescription is mandatory; the reimbursement is made only if these drugs are written on an electronic prescription.

OTHER CHANGES

- Encouraging generics use by making them more profitable for manufactures, wholesales and pharmacies (introducing the essential generic medicines list).
- Pro-vaccination campaign, launched on November 9 by the Ministry of Health, after a serious drawback in the vaccination rate and also after several deaths from measles.
- The Ministry of Health also launched on October 12 an online platform for announcing drug shortages by patients, doctors and other people interested. The ministry, with help from the National Medicines Agency and the National Health Insurance House, investigates each case and presents a solution in a given timeline. (www.medicamentelipsa.ro)
- A software application program for monitoring stocks at the manufacturers, the wholesales and the pharmacies is currently discussed and meant to be adopted soon enough. Also, the software application would be linked with the mandatory public service and shall give alarms when the stocks fall under a certain given level, which allows the authorities to take measures in investigating and also creating a list of vulnerable drugs.

OUT-OF POCKET PAYMENTS

Out-patient

Prescription-only medicines – Romania has an INN prescribing system. There are 4 percentage reimbursement rates:

- 90% - for medicines within sublist A (mainly brand names with many generics)
- 50% - for medicines within sublist B (mostly originator drugs and also some more expensive generics)
- 100%, sometimes 120%, to cover the expense of off-patent and also biosimilar drugs - for medicines within sublist C (mainly drugs for certain chronic diseases, with prescription monitoring and consumption control; treatment of diseases included in national programmes like oncology, HIV, diabetes, TBC; ambulatory treatment for children, students under 26 years, pregnant women)
- 20% - for medicines within sublist D (mainly "old" molecules)

The reimbursement level is set to the lowest price for the same INN drugs (or clustering when for the same INN there are many generics in the market). If the patient chooses the medicine that gives the reimbursement level, he/she has to cover the payment depending on the reimbursement sublist. If the patient chooses another medicine within the same INN, he has to cover the payment depending on the reimbursement sublist plus the price difference between the reimbursement level and the actual price of the chosen medicine.

Over-the-counter (OTC) medicines – they are fully paid out-of-pocket by the patient, no matter if they are prescribed or not.

In-patient

Patients do not have to pay for medicines they receive during their stay, as long as the required medicines are available. However, in many situations, patients have to buy their prescribed medicines from pharmacies, even if they are hospitalized.