LITHUANIA

Recent and planned developments in pharmaceutical policies 2019

Special topic: patient-based reimbursement decisions

CHANGES IN PRICING

July 1st, 2018 modified price for generic and biosimilar medicines: First generic enters market it should reduce the price by 30 %.
First biosimilar enters market it should reduce the price by 20 %.
The Price List is updated every 4 months.
July 1st, 2018 change of reference countries in EPR: the price is calculated by the average of the 3 lowest prices in EU countries, if medicines group consists of one producer.

WHOLESALERS MARK UP SCHEME Manufacturer price in EUR / Maximum wholesalers mark up of manufacturers price in EUR	PHARMACY MARK UP SCHEME Pharmacy purchasing price in EUR / Maximum pharmacy mark up of pharmacy purchasing price in EUR
• up to 49,99 EUR /0,51 EUR • 50 EUR to 263,29 EUR/ 2,45 EUR	• up to 47,46 EUR /1,00 EUR • 47,46 EUR to 144,8 EUR/ 5,10 EUR

CHANGES IN REIMBURSEMENT

Reimbursement List review – ongoing.
April 1st, 2019: all medicinal products are reimbursed by 100%, except some from B list (50%).
Fixed patient co-payment if medicinal product is reimbursed at 100 % level:
• if medicinal products retail price is up to 20 Eur: patient co-payment is 20 % of reimbursed (base) price;
• if medicinal products retail price is more than 20 Eur: patient co-payment is 4,7 Eur.
Pharmacies are allowed to provide discounts equally for co-payment and base price.

OTHER CHANGES

Changes in Pharmacy law: new Composition of Reimbursement Committee (RC), changes regarding implementation of new HTA system.
Changes in the Compulsory Health Insurance (CHI) law: The RC decisions are not necessarily re-evaluated by the CHI board.
Remote selling of pharmaceuticals allowed from 1st November 2019.
OTC drugs are allowed to be sold in retail. For the time being only 16/44 are available on the market. The medicines have to be: single active substance; indicated for adults and children older than 12 years; if used *per os*, it must not contain alcohol; cannot be under “Safety feature” requirements.
Since 1st March 2019, every active-substance *naive* patient will be given the drug with the lowest co-payment.
Active-substance *naive* patient is defined as: one that has never used the active substance before; or one that has used the active substance over 6 months ago.
Surge in usage of e. prescription.
1st April 2019 changes in pricing for medicines that classed as "narrow therapeutic index" medicines. All medicines that included in Price list should comply with the maximum possible co-payment requirements, except medicines classed as "narrow therapeutic index" medicines (antiepileptics and immunosuppressants).

SPECIAL TOPIC: patient-based reimbursement decisions

There is a separate process for reimbursing medicines on name patient basis. It is for rare diseases and rare conditions.
The responsible physicians have to apply using standard form to the Rare Diseases Committee. However, the drug must be authorized, and being part of an early access scheme does not grant permission to use this way of reimbursement.
The Application from hospital is evaluated by the State Medicines Agency (the clinical part). The decision is done by the Rare Diseases Reimbursement Committee. It is composed of physicians, delegates from MoH, NHIF.

Decisions are made for every single patient, but if the number of patients is increasing and/or the price is very big, we sign agreements with the producer on more patients, which might not even be there yet. The time limit is set in case of urgent diseases cases.

The procedure of evaluation and decision making is the same for in- and out- patient sector.
The clinical efficacy is assessed, the drug undergoes price negotiation, price fixing is sometimes employed, co-payment mechanisms with the manufacturer is also discussed.
The are no co-payments for drugs, reimbursed via this procedure.