

REPUBLIC OF MOLDOVA

Recent and planned developments in pharmaceutical policies 2015

Pre-launch activities: horizon scanning and forecasting

<p>D E V E L O P M E N T S</p>	<p>Registration of manufacturer prices</p> <p>General Information: Moldova's pharmaceutical market is constituted, mainly of imported medicines. At the moment there are about 6300 registered medicines, including 82% are imported (50% of medicines are from Europe, 17% from the ex-Soviet territory and 15% from other countries); medicines of local producers constitute about 18% of the total amount.</p> <p>Legislation regarding Registration producer price - Government Decision no. 525 of 22.06.2010 (beginning of the price registration)</p> <ul style="list-style-type: none"> • Prices are declared annually by the producer /manufacturer; • The price accepted for registration must comply to the following requirements: <ol style="list-style-type: none"> 1. To be the average price of the lowest three prices of the reference countries: Romania, Greece, Bulgaria, Serbia, Croatia, Czech Republic, Slovakia, Lithuania and Hungary; 2. Generic medicine price should not exceed 75% of the original medicine; 3. The price of the medicine which can not be found in the reference countries must be equal to the average of International Non-proprietary Name price (INN) recorded in the Register. <p>Other factors which influence prices:</p> <ul style="list-style-type: none"> - The average exchange to the previous month compared to the period when the dossier is evaluated; - National currency fluctuation - if during one month the national currency is devalued by more than 5%, the price recorded in MDL shall be adjusted according to the average exchange rate. <p>Legislation regarding the determination of the final price – Government Decision no. 603 of 02.07.1997</p> <ul style="list-style-type: none"> • Pharmaceutical warehouses can apply a commercial surplus up to 15%; • Drugstores – up to 25%. 	<p style="text-align: center;">Reimbursement</p> <p>General Information:</p> <ul style="list-style-type: none"> - Methodology of reimbursement of medicines was implemented for the first time in 2005 by the Government Decision no.1372, regarding the method of reimbursement of medicines in compulsory insurance healthcare conditions. - Since 2013 all medicines without GMP Certificate have been excluded from the List of reimbursement of medicines. - At the moment, the List of reimbursement of medicines includes 554 medicines (INN – 88), of which 285 medicines (INN – 59) are 100% compensated; 22 medicines (INN – 6) are 70% compensated; 247 medicines (INN – 23) are 50% compensated. - The list contains drugs from different pharmacotherapeutics groups: cardiovascular agents, digestives, endocrine therapy, drugs used in diabetes, drugs used in asthma therapy, antiepileptics, dermatologicals (epidermolysis bullosa), treatment and prophylaxis agents used in children (0-5 years), prophylaxis of iron deficiency anemia and folic acid deficiency during pregnancy. <p>The methodology for calculating the amount of any particular medicines included in the compensated medicines list</p> <ol style="list-style-type: none"> 1. The Ministry of Health and Health Insurance Company proposes the List of medicines which are going to be compensated for, according to the amount planned for repayment. 2. Products proposed to be included in the List have to be registered in Moldova. 3. The List is sent to a representative number of pharmacies (about 25%) to collect data on current retail prices. <p>Retail prices have to be indicated for all trade names and for all types of packaging which are in the market at the moment of collection .</p> <ol style="list-style-type: none"> 4. Completed Lists are evaluated and minimum, maximum and average value is calculated for every trade name, taking into account dose, division and company producers. 5. Depending of the average retail prices the median price is calculated, regardless of formulation, division or producer. 6. The rate of compensation is established by the Ministry of Health - it can be: 50%, 70% or 100%.
	<p>The Republic of Moldova intends to make the following changes:</p> <p>1. Manufacturer's Registration price</p> <p>Price of medicines listed in the National Price Register can apply a commercial surplus added to the</p>	

manufacturer price using the following scheme:

From (MDL)	From (MDL)	Commercial surplus, pharmaceutical warehouse, (%)	Commercial surplus, pharmacy (%)	Commercial surplus, total, (%)
0,00	50,00	15	25	40
50,01	100,00	13,75	22,5	36,25
100,01	200,00	12,5	20	32,5
200,01	400,00	11,25	17,5	28,75
More than 400,01		10	15	25

2. Reimbursement system

- For more intensive control on prescribing and dispensing of the compensated medicines have been elaborated two draft of orders:
 1. "Regarding the payment of compensated medicines from mandatory health insurance funds".
 2. "On approval of Instruction on recording and payment of medicines partially/fully compensated from mandatory health insurance funds" .
- Strategy of **e-prescription** is in the process of development. It is expected to be elaborated until December 2015.
- The **e-prescriptions** will be launched by December 2018.

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Pre-launch pharmaceutical policies: Horizon Scanning and Forecasts
Horizon Scanning and Forecasts are not applied in Moldova