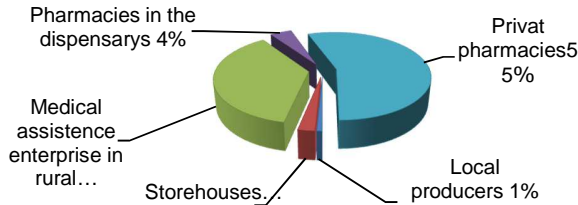




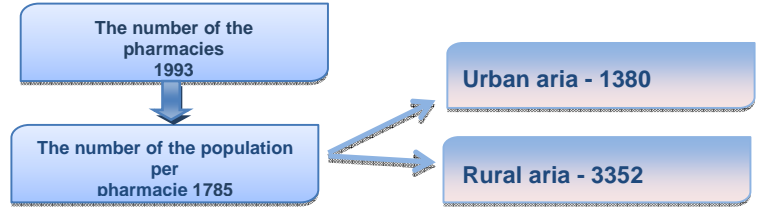
## Pharmaceutical system in the Republic of Moldova

The Republic of Moldova is a landlocked country in Eastern Europe, bordered by Romania to the west and Ukraine to the north, east, and south. It declared independence in 1991 as part of the dissolution of the Soviet Union. Moldova is a member state of the United Nations, the Council of Europe, the World Trade Organization (WTO), the Organization for Security and Cooperation in Europe (OSCE), the GUAM Organization for Democracy and Economic Development, the Commonwealth of Independent States (CIS) and aspires to join the European Union. Its population is 3 557 634.

### Types of the pharmaceutical enterprises

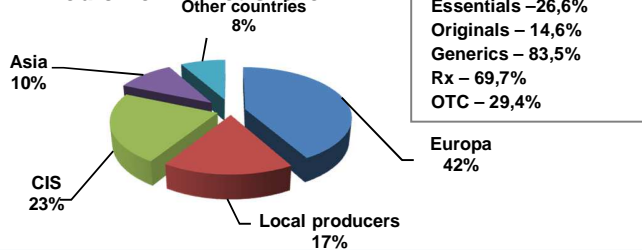


### Distribution of pharmacies



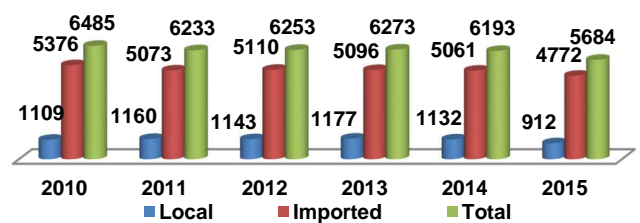
- The most of the pharmaceutical enterprises are located in the urban area.
- Rural area is assured by the pharmaceutical services through medical assistant sections.
- The suppliers (45) import the medicines from 57 countries. They provide the hospital sector (state procurements) and private pharmacies.
- The local producers cover 17% of the pharmaceutical market. 26% from their portfolios are essential medicines. The most representative groups are D, J, A, C, N and R. Moldavian producers export their medicines in 11 countries.

### Medicine market share



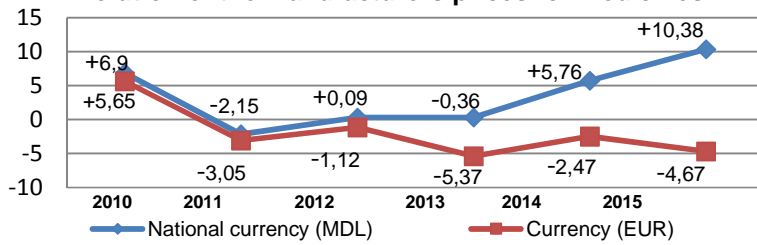
Essentials – 26,6%  
 Originals – 14,6%  
 Generics – 83,5%  
 Rx – 69,7%  
 OTC – 29,4%

### Authorization of medicines



- For the registration of the medicine the applicant shall submit the dossier in CTD format. The procedure for issuing the certificate of the registration of the drug lasts 210 days.
- The medicines quality is checked by the Laboratory for Quality Control, which is certified according to ISO 9001: 2008. It performs subsequent control, selective to products manufactured according to GMP standards and series-by-series for non-GMP drugs.

### Evolution of the manufacturers prices for medicines



### Differentiated value added tax

Purchase price (MDL)	Final margin	Wholesale margin	Pharmacy margin
0 - 30,00	< 40 %	< 15 %	< 25 %
30,01 - 60,00	< 37 %	< 12 %	< 25 %
60,00 - 120,00	< 26 %	< 10 %	< 16 %
120,01 - 240,00	< 21 %	< 8 %	< 13 %
>240,00	< 16 %	< 5 %	< 11 %

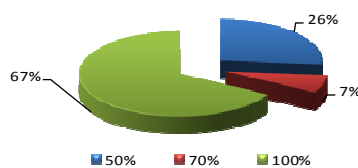
**Annotation:** The average exchange rate in August - 1 EUR = 21.1864 MDL, but on 25 September - 22.6684 MDL

- The medicines prices are regulated by the Government. Prices for all types of medicines (Rx and OTC) are declared annually by the producer/manufacturer. The price accepted for registration must comply the following requirements:
  - is the average price of the lowest three prices of the reference countries: Romania, Greece, , Serbia, Croatia, Czech Republic, Slovakia, Lithuania and Hungary;
  - generic medicine price does not exceed 75% of the original medicine;
  - medicine price that can not be found in the reference countries must be equal to the average of International Non-proprietary Name (INN) recorded in the Register.

**Annotation:** Although the prices measured in a foreign currency fell, they raised in the national currency due to the MDL depreciation.

- For drugs from warehouses and pharmacies are established differentiated value added tax. This law was implemented since the 1st of October.

### The rate of compensation



### Pharmacotherapeutic groups included in the Reimbursement program

Pharmacotherapeutic group	INN	Pharmacotherapeutic group	INN
Cardiovascular agents	19	Drugs used in diabetes	7
Digestives	5	Epidermolysis bullosa	5
Endocrine therapy	3	Autoimmune disease	3
Drugs used in asthma therapy	4	Ophthalmic diseases	4
Treatment and prophylaxis agents used in children (0-5 years)	12	Prophylaxis of iron deficiency anemia and folic acid deficiency during pregnancy	2
Cystic fibrosis	2	Mistena gavis	1
Antiepileptics	6	Multiple sclerosis	1
Parkinson's disease	2		
Nervous system	11	<b>Total</b>	<b>87</b>

- The methodology of reimbursement of medicines was implemented for the first time in 2005.
- 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 87 INN (584 medicines). The list contains drugs from 16 pharmacotherapeutics groups.
- The procedure for inclusion in the list of the reimbursement medicines recently has been changed. The submission of dossiers by producers.
- The approval decision belongs to the Council (Minister of Health, Medicines and Medical Devices Agency, National Health Insurance Company, etc.), which sets the rate of the compensation (10-100%).