





Albania

Flowchart of the pharmaceutical system in the in- and out-patient sector 2016

New pharmaceutical

AUTHORISATION CLASSIFICATION

PRICING at x-factory level

Ministry of Health (National Agency of Drugs and Medical Devices)

<u>Task:</u> Decision on authorization and categorization Criteria: Quality, safety, efficiency

Law No.105/2014, dated 31.07.2014 on Pharmaceuticals and Pharmaceutical Services

The Albanian Medicines and Medical Devices Agency is also in charge of pharmacovigilance.

Ministry of Health - Drugs Prices Commission

Task: Decision on all drugs prices

<u>Criteria:</u> The lowest price in 5 countries of reference. The price of generic should not exceed 80% of brand's.

OUT-PATIENTS

IN-PATIENTS

Distributors

PRICING at wholesale and harmacy level

Wholesalers: Maximum mark-up 11% of the CIF/ex factory price divided between Importers 8% and distributors 3%.

Pharmacies: Maximum mark up 25% of the wholesaler price.

Recently changed by Council of Ministers Decision Nr. 143 dt.18.02.2015

VAT: standart rate is 20%, for all medicines is 0%.

Rimbursed Drugs:

Diferent mark up scheme at wholesale and pharmacy level

(Average wholesale mark-up 7.2%, Average pharmacy mark-up 19.6%.)

Drugs Reimbursement List

Compulsory Healthy Insurance Fund the administering body, third party pay er.

Drugs Reimbursement List Commission – regulatory body, decision making authority

Criteria: price referencing, cost effectiveness

List composition: 322 active principles, 1070 trade names

Reimbursement percentage: 50-100%

Exemption from co payment: 14 people categories

Public Hospitals

Wholesalers: Maximum mark up 6-8% of the CIF/ex factory price

Ministry of Health

<u>Task:</u> Preparing the hospital pharmaceutical formulary on yearly basis <u>Criteria:</u> pharmacological, medical therapeutic.

Compulsory Health Insurance Fund

<u>Task</u>: Monitoring all pharmaceutical expenses

<u>Criteria:</u> Prescription guideline pharmaceutical formulary of MoH.

Regional Hospitals

<u>Task:</u> Tendering medicines <u>Criteria:</u> only active principles listed and aprooved by MoH

REIMBURSEMENT