

BULGARIA

International Healthcare and Health Insurance Institute BG

Flow chart – pharmaceutical system in Bulgaria in the in- and out-patient sector

New pharmaceutical

Marketing Authorisation and Classification
European Medicines Agency/ Bulgarian Drug Agency (BDA)

Task: Decision on marketing authorisation
Criteria: Quality, safety, efficacy, (Bulgarian Law on Pharmaceutical Products or **Regulation EC 726/ 2004**)

Task: Decision on prescription and dispensing requirements
Criteria: Bulgarian Law on Pharmaceutical Products and Regulation N3 for the criteria for classification of the pharmaceutical products and the documentation for changes in the classification (SG 28/14.03.2008)
According to the Law on Pharmaceutical Products and Regulation N2/2008 BDA is responsible for the pharmaco-vigilance

Pricing of Medicines at all levels (ex-factory, wholesale, retail sale)
Bulgarian Ministry of Health (MoH) / Pricing Committee (PK)

Task: Registration of ceiling price of all pharmaceuticals, which have marketing authorisation
Criteria: International price comparison

Drugs without reimbursement enter the market

Reimbursement of Medicines - Positive Drug Committee - interdisciplinary
Task: Decision on reimbursement and level of reimbursement
Criteria: pharmacological, medical therapeutical and pharmaco-economical criteria

<p style="text-align: center;">Anex N1 Outpatient sector</p> <p>Full or partial reimbursement by National Health Insurance Fund – up to 25%, 50%, 75%, 100% as per its' annual budget</p>	<p style="text-align: center;">Anex N2 Inpatient sector</p> <p>Subject for possible 100% reimbursement in public hospitals by hospital budget</p>	<p style="text-align: center;">AnexN3 In and out patient</p> <p>Subject for possible 100% reimbursement by MoH/ state budget</p>	<p style="text-align: center;">Anex N4 In and out patient</p> <p>Subject for possible 100% reimbursement by MoH/ state budget</p>
<p>Open tender under Public Procurement Act in each hospital</p>	<p>Open tender under Public Procurement Act (PPA) in MoH</p>		