

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)

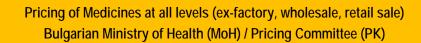
Task: Decision on marketing authorisation

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 pharmace-vigillance



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

Anex N1

Outpatient sector

Full or partial reimbursement by National Health Insurance Fund – up to 25%, 50%, 75%, 100% as per its' annual budget

Anex N2

Inpatient sector

Subject for possible 100% reimbursement in public hospitals by hospital budget

AnexN3

In and out patient

Subject for possible 100% reimbursement by MoH/ state budget

Anex N4

In and out patient

Subject for possible 100% reimbursement by MoH/ state budget

Open tender under Public Procurement Act in each hospital Open tender under Public Procurement Act (PPA) in MoH