



BULGARIA

International Healthcare and Health Insurance Institute

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Pharmaceutical system in Bulgaria in the in- and out-patient sector – August 2011

Marketing Authorisation and Classification –New pharmaceutical 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: 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 and Reimbursement of Medicines for out- and inpatient sectors

- Ø Regulation of prices of the POM in the Positive Drug list (PDL) according the lowest referent member state countries' price;
- Ø Regulation of the prices of generic medicines out of the PDL;
- Ø Registration of maximum retail sale price of POM medicines, out of PDL and OTC medicines

Pricing, based on external price referencing

Decision on reimbursement and level of reimbursement, based on pharmacological, medical therapeutical and pharmaco-economical criteria

Price is regulated on ex-factory level with regressive mark –ups for wholesalers and retailers.

Standard VAT – 20% for all medicines

Transparency Committee under Council of Ministers as appeal structure

Pricing & Reimbursement Committee (PRC) –under Ministry of Health (MoH)

- Ø Approves, changes, exclude the price of the medicines **in the PDL**; Approves, changes, exclude the price of the POM **out of PDL and OTC** medicines; Approves, changes, exclude the price of the **generic POM** out of PDL ; Approves/Registers price of **medicines from Parallel Import**;
- Ø Approves or changes the pharmaco-therapeutic formularies and treatment algorithms;
- Ø Includes, changes or exclude POM in the PDL;
- Ø Maintains and updates the PDL;

Pricing of POM out PDL & OTC – 30 days

Pricing & Reimbursement of medicines in the Positive Drug List – 60 days

Positive Drug List – 3 Annexes:

Anex N1

Outpatient sector

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

Possibility for additional negotiation of the reimbursed price in the PDL

Anex N2

Inpatient sector

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

Open tender under Public Procurement Act (PPA)

AnexN3

In and out patient

Subject for possible 100% reimbursement by MoH/ state budget for infectious diseases, AIDS, vaccines, force major & others

Open tender under PPA