Methods of financing and decision making for pharmaceuticals in Bulgaria

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²ISPOR Bulgaria Chapter

In Bulgaria, a series of reforms was launched in 1991, including price liberalization, liberalization of foreign trade, abolition of central planning and market liberalization.

Compared to some other countries, the reform was slow, economic policies were inconsistent, and privatization was unsubstantial and delayed.
The health insurance system

- The current health insurance system is decentralised and pluralistic compulsory health insurance system, with employee contributions and contractual relationships between the National Health Insurance Fund (NHIF) as a purchaser and healthcare providers.

- The NHIF provides most of the funding through its 28 regional bodies (the regional health insurance funds), it finances the entire healthcare network for outpatient care, and since July 2000, it also finances contracted hospitals.

- NHIF was founded on 15th March 1999 as an independent public institution separated from the structure of the social healthcare system and has its own bodies of management.

- The NHIF budget is separated from the state budget. The National Assembly votes on it on an annual basis.

- The NHIF Budget Act determines the amount of health insurance contribution.
**National Framework Contract & private health insurance**

- Health care is provided in accordance with the **National Framework Contract**.

- **Clinical Pathways** were introduced in 2001 as part of the National Framework Contract with the aim of improving the continuity and coordination of care across different disciplines and sectors by aiding the management of resources.

- **Private insurers** provide an alternative means of funding healthcare as well as those drugs and treatments that are restricted in the state health insurance package.

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**NHIF contract partners**

- GP practices 4030, doctors 4700;
- Specialists practices 3050; doctors 11400;
- Dental practices 5432; dentists 5775;
- Laboratories – 650;
- Hospitals – 330;
- Pharmacies – 2040.

Positive drug list

- Definition: shall include MPs dispensed on medical prescription which cover the health needs of the population and are reimbursed by the budget of the NHIF, the state budget out of the scope of compulsory health insurance or by the budgets of the hospitals.

- Annexes:
  - MPs for insured citizens;
  - MPs for inpatients
  - MPs for rare diseases, HIV and infectious diseases, diseases out of scope of compulsory health insurance, vaccines etc.
  - Ceiling prices of MPs included in the PDL.

PDL – criteria

- evidence for efficacy
- therapeutic effectiveness
- safety
- pharmacoeconomic indicators.

MPs not included in the PDL can be purchased through funds of the national budget outside the scope of the compulsory health insurance if necessary for the prevention or treatment of epidemic outbreaks, epidemics or pandemics, and in cases of suspected or proven dissemination of chemical or biological agents or nuclear radiation.
The reform of the healthcare system is one of the declared priorities of the Bulgarian government.

The main focus is on optimisation of the number of hospital beds in the different regions, implementation of eHealth, price control over medicinal products and eventual introduction of DRGs.
The aim of the presentation

- The presentation is analyzing the impact of the regulatory changes on the medicines prices and National health insurance fund (NHIF) budget.
The access to medicines paid with public funds in Bulgaria is ensured through NHIF, hospitals budgets, and Ministry of health (MoH).

The NHIF reimbursed medicines for ambulatory patients’ therapy, hospitals paid medicines for inpatients later reimbursed by the NHIF as part of the hospital services tariff, and MoH supplied and financed the list of life saving and very expensive medicines.

Pharmacoeconomic evidences

- Cost of the therapy with the medicine under consideration.
- Comparison of the cost of therapy with available alternatives.
- Cost-consequence ratio.
- Economic evaluation of the additional benefits.
- Budget impact analysis.
Reimbursement assessment of the PhEcon dossier

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<thead>
<tr>
<th>Indicator</th>
<th>Weight</th>
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<tbody>
<tr>
<td>Pharmacoeconomic evidences</td>
<td>40 points</td>
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<tr>
<td>- The cost of therapy with the medicinal product</td>
<td>If the cost of therapy is lower than with alternatives – 15 points</td>
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<td>- Cost comparison with alternatives</td>
<td>If cost the therapy is higher with the medicine but it decreases the total COI therapy – 15 points</td>
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<tr>
<td>- Cost consequence ration</td>
<td>Lower with current therapy – 15 points</td>
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<tr>
<td>- Economic assessments of additional benefits</td>
<td>Cost of additional benefits exceed the cost of therapy – 15 points</td>
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<tr>
<td>- Budget impact analysis</td>
<td>Medicinal product will decrease the budget for the diseases – 10 points</td>
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Pharmacoeconomic methods applied in Bulgaria

- CEA
- CUA
- CMA
- CBA
Impact of generic competition on market share and prices of cardiovascular medicines on the Bulgarian pharmaceutical market

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In the beginning of 2011 with the amendments in the Health Law and Health Insurance Law all medicines supplied and paid by the MoH was transferred to NHIF.

This change let to fluctuations in medicines prices and increased the financial burden over NHIF as well as over the pharmacies.
• For some medicines the prices paid by the NHIF rose more than 300%, while for medicines paid hospital budget a decrease of prices was observed.

• To cope with financial impact new regulation was proposed that was hardly criticized.

• The Bulgarian government has approved an increase in the number of reference countries used in the establishment of the maximum prices of reimbursed medicines on the Positive Drug List to 12 from 8 with the adoption of the amendments to the Ordinance on Regulation and Registration of Medicine Prices.

• Italy, Finland, Denmark and Slovenia have, as a result, been added to the reference countries. The price proposed by the manufacturer cannot now exceed the equivalent of the lowest producer price of a drug on the reference markets of Denmark, Estonia, Finland, France, Greece, Italy, Lithuania, Portugal, Romania, Slovakia, Slovenia and Spain.
Furthermore, a drug can now be placed on the Positive Drug List if it is reimbursed by national health insurance funds in at least five of 17 countries.

These are Romania, France, Estonia, Greece, Slovakia, Lithuania, Portugal, Spain, Belgium, the Czech Republic, Poland, Latvia, Hungary, Italy, Finland, Denmark and Slovenia.

In the past, drugs reimbursed in three of eight countries (Romania, the Czech Republic, Estonia, Greece, Hungary, Lithuania, Portugal and Spain) could be reimbursed in Bulgaria.

In conclusion, all stakeholders agree that the regulatory changes in the field of financing of pharmaceuticals should be accompanied with unambiguous administrative procedure assessing in advance the negative and positive impact on the whole market.
The regulations changes slowly towards the concretization and obligations for pharmacoeconomic analyses.

Scientific researches moves simultaneously with the international ones and towards the creation of the scientific skills.

The research teams improve their capabilities.

Need of capacity building for governmental institutions.

Need of national pharmacoeconomic guideline.

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