

## Fair access to ARV drugs

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### 1. A brief description of the current situation

#### 1.1 Country profile

Becoming a new European Union member in the beginning of 2007, Bulgaria has faced the requirement for harmonization of European Union regulations including drug policy and drug prices. In addition to the reform of the Bulgarian healthcare system, this harmonization has turned into a real challenge for the country. A major problem of the national healthcare policy is the insufficiency of budgetary healthcare resources. The latter have reached on the average 4.2 per cent of the Gross Domestic Product (GDP) for the last six years, as compared to 3.6 per cent of GDP in Romania an average of 5.3 per cent in Central and Eastern European countries, and 8.5 per cent in the old EU Member States.<sup>1</sup>

Obviously, in order to achieve the common values and principles of the EU healthcare systems, harmonization of prices should be accompanied by price differentiation in specific cases. The importance of price harmonization and price differentiation is clearly outlined in case of diseases requiring innovative expensive drugs and large treatment expenditures. Therefore, these comments will focus on the presently existing and possible future policies in the area of antiretroviral drugs for HIV infection.

#### 1.2 Overview of drug policy

Drug policy in Bulgaria is determined by the Ministry of Health, which has 3 working bodies: Pharmacopoeia Committee, Higher Council of Pharmacy and Bulgarian Drug Agency. In addition, to the Council of Ministers function the Committee for Positive Drug List, the Medicinal Product Pricing Committee, and the Transparency Committee. Drug policy including price formation is regulated by the *'Law on the medicinal products in human medicine (In force from 13.04.2007)'*<sup>2</sup> and the corresponding by-laws.

Until 2000 Bulgaria has applied a price formation system based on the „cost-plus pricing” formula. At present 3 types of prices are used for price control of drug products: a) Reference prices for drug products from the Positive Drug List; b) Ceiling prices for drug products dispensed with medical prescription and not on the Positive List; c) Maximal Sell Prices for drug products dispensed without prescription. The current law specifies the mechanisms of price regulation and the working out of a single Positive List. In addition, it defines the Positive List Inclusion Criteria and implements Council Directive 89/105 in terms of transparency. The Positive Drug List includes drug products reimbursed by the National Health Insurance Fund (NHIF), the state budget, and the budget of the healthcare establishments, and intended for treatment of rare

<sup>1</sup> Rossen Kazakov. Pricing and reimbursement policies in new EU accession countries. *Journal of Generic Medicines* (2007) 4, 249-258. doi:10.1057/palgrave.jgm.4950068;

<sup>2</sup> 'Law on the medicinal products in human medicine' [http://www.bda.bg/regulations/zakoni/zlphm\\_en.pdf](http://www.bda.bg/regulations/zakoni/zlphm_en.pdf)

diseases and AIDS, as well as for prevention and treatment of infectious diseases. Ceiling-prices are based on the lowest registered prices in 8 cross-reference countries.

Price decisions are independent from reimbursement decisions. NHIF makes decisions on reimbursement. The reimbursement rate is determined according to three drug categories. The ministry of Health, NHIF and medical treatment facilities procure drugs through public tenders according to the *'Law for the public procurement'*<sup>3</sup> and the related by-laws.

### 1.3 Fair access to ARV drugs

The introduction of antiretroviral therapy (ART) has been a keystone in the fight against AIDS. This treatment has changed the course of the disease and contributed to the improved life quality and life expectancy of the patients. ART gives the ethical basis for increasing the scope of testing in order to improve the rate of diagnosis and to offer timely treatment and care. Last but not least, ART decreases the transmission risk. These are the grounds of UNAIDS policy for Universal Access to prevention, treatment and care as one Millennium Development Goals (MDG). Affordable ARV Treatment has been also the focus of the *'Political Declaration on HIV/AIDS'*<sup>4</sup> by the UN General Assembly on 2 June 2006 as well of the Ministerial Conference: Partnership and Responsibility – Together Against HIV/AIDS, Bremen, 2007. *'Bremen's Declaration'*<sup>5</sup> clearly claimed for cooperation to ensure access to affordable medication. This declaration was the basis for the political initiative of Germany and Bulgaria on price differentiation for HIV/AIDS drugs.

Bulgaria is still a low HIV prevalence country. But it is situated on the cross-road of the HIV epidemics in Eastern and Western Europe. Although the number registered cases in 2007 have been only 821, the estimated number is 4,200 cases, which will increase to 11,400 until 2014. ARV treatment in Bulgaria is free for all persons fulfilling the criteria of the *European AIDS Clinical Society*<sup>6</sup>. Two hundred and fifty patients are presently on ARV treatment in Bulgaria. This small number allows the complete coverage of ARV treatment by the state budget. However, according to the estimations and moderate prognoses, the number of patients in need of ART in the next 5-7 years will increase 10 times to reach 2,600 in 2014.

Providing treatment for the quickly increasing number of patients will become a real challenge for healthcare budget. The prices of ARV drugs in Bulgaria are comparable to those in the other EU countries, because the reference prices are based on the prices in 8 EU countries. However, on the GDP/per capita<sup>7</sup> basis, the cost of AR treatment in Bulgaria (8,116 euro per patient per year)<sup>8</sup> is about 5 times higher as compared to Germany, 6.5 times as compared to France and 7.3 times as compared to Belgium.

<sup>3</sup> 'Law of the public procurement' [http://www.bcnl.org/doc\\_en.php?DID=316](http://www.bcnl.org/doc_en.php?DID=316)

<sup>4</sup> Political Declaration on HIV/AIDS' from the UN General Assembly on 2 June 2006, Millennium Development Goal on HIV/AIDS

[http://data.unaids.org/pub/Report/2006/20060615\\_HLM\\_PoliticalDeclaration\\_ARES60262\\_en.pdf](http://data.unaids.org/pub/Report/2006/20060615_HLM_PoliticalDeclaration_ARES60262_en.pdf)

<sup>5</sup> 'Bremen's Declaration on Responsibility and partnership- Together Against HIV/AIDS', from 13.03.07

[http://www.eu2007.de/en/News/download\\_docs/Maerz/0312-BSGV/070Bremen.pdf](http://www.eu2007.de/en/News/download_docs/Maerz/0312-BSGV/070Bremen.pdf)

<sup>6</sup> Guidelines for the Clinical Management and Treatment of HIV – infected Adults in Europe, European AIDS Clinical Society [http://www.eacs.eu/guide/1\\_Treatment\\_of\\_HIV\\_Infected\\_Adults.pdf](http://www.eacs.eu/guide/1_Treatment_of_HIV_Infected_Adults.pdf)

<sup>7</sup> Eurostat yearbook 2008.

<sup>8</sup> T. Varleva, H. Taskov, "Post Bremen – affordable ARV initiative: progress in Bulgaria" 10th Meeting of the "HIV/AIDS Think Tank" 9 - 10 April 2008 Brussels, Centre Albert Borchette, [http://ec.europa.eu/health/ph\\_threats/com/aids/docs/ev\\_20080409\\_rd04\\_en.pdf](http://ec.europa.eu/health/ph_threats/com/aids/docs/ev_20080409_rd04_en.pdf)

The present price formation model in Bulgaria does not allow differentiation of prices of ARV drugs. Pharmaceutical companies would not negotiate price reduction because of their commitment to the EU reference prices and the apprehension for parallel trade. The tender system could not influence the prices either, because of products exclusivity leading to the fact that certain products are only procured by a single company.

Obviously, other ways and means are needed to achieve access to innovative and high-priced pharmaceutical products and affordable treatment of HIV patients in countries with relatively low GDP per capita like Bulgaria.

## 2. ARV drugs price policy under debate

In June 2007 Bulgaria together with Germany and the European Commission initiated a pilot project for negotiations with pharmaceutical companies on price differentiations for life-saving drugs against HIV/AIDS. The main goal of these discussions was to explore different approaches for achieving an affordable price of ARV treatment. Discussions were concentrated in two main directions a) Rebate negotiation, and b) price for disease treatment/management.

Rebate negotiation was accepted by certain companies as a means to reduce treatment cost. An important condition for further negotiations was to prepare an estimation of volume of the drug needs for the following 3-5 years, outlining the gap between estimated costs and national budget for ARV drugs. Based on data about drug volumes companies could decide what part of ARV treatment could be covered by natural rebate.

In line with the concept about the integrity of HIV/AIDS interventions, participation of drugs manufacturers in promotion of prevention; expansion of testing/early diagnosis and capacity building of HCW was discussed as a holistic approach for contribution to the overall cost of management of HIV disease. But it should be kept in mind that only pharmaceutical industry can play major role for achievement of full costs of treatment. For additional interventions there are many other sources for support.

Irrespective of the discussed approaches, the development of a National Strategy, and National Program with detailed budget and a reliable M&E system was defined as important prerequisites for further negotiations. In the next few months the Bulgarian Government will adopt a comprehensive National Strategy and Action Plan for HIV/AIDS with detailed budget until 2015. It will clearly identify the priority targets and unmet programmatic and financial needs. The existing National M&E system will be updated with new indicators and set of interrelated models<sup>9</sup> for measuring the effectiveness and cost-effectiveness of interventions, including the costs of treatment and treatment outcome. This will constitute a good basis for a concrete discussion on

<sup>9</sup> Models for HIV estimation and projection (EPP, Spectrum and Workbook); [http://www.unaids.org/en/KnowledgeCentre/HIVData/Epidemiology/epi\\_software2007.asp](http://www.unaids.org/en/KnowledgeCentre/HIVData/Epidemiology/epi_software2007.asp)  
National AIDS Spending Assessment (NASA); <http://www.unaids.org/en/KnowledgeCentre/HIVData/Tracking/Nasa.asp>  
Resource needs model (RNM); <http://www.unaids.org/en/PolicyAndPractice/ResourcesAndFunding/default.asp>  
Goals model, <http://www.constellagroup.com/international-development/resources/software.php>  
The Allocation By Cost-Effectiveness (ABC) Model; <http://www.heart-intl.net/HEART/Math/excelpro/Index.htm>

the participation of pharmaceutical industry in achievement of MDG for universal access to prevention, care and treatment.

### 3. Conclusions

Undoubtedly the successful fight against life-threatening diseases like HIV/AIDS depends on the access to innovative and high-priced pharmaceutical products. The present price formation models do not allow a real income-dependant price differentiation. Obviously additional ways and means are needed to achieve the common values and principles of health systems in the EU: access to good quality care; equity and solidarity. One way is the development of lasting partnerships between all stakeholders. Bulgaria has made a step in this direction by starting a discussion with the pharmaceutical industry and inviting its representatives as regular members of the National AIDS Coordination Committee of HIV/TB.

### 4. Topic for Discussion

- Natural rebate and/or price for disease treatment/management as an instrument to achieve fair ARV drug prices differentiation.