MAIN LEGISLATIVE CHANGES IN HEALTHCARE SYSTEM IN BULGARIA DURING 1997-2012

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Summary. After the social and economic changes in Eastern Europe since 1990s, substantial changes were made in the health care systems in the countries. Most of them moved from centralized Semashko to decentralized health insurance systems of Bismark type. The latter also have an impact on the pharmaceutical systems and mostly on the way of financing, pricing and reimbursement of medicines. There is no historical overview of the basic changes in the health and pharmaceutical system in Bulgaria till now that stimulated out interest towards the topic. This paper presents a historical legislation analysis of the main health care and pharmaceuticals regulatory acts. The Healthy and Safe Conditions of Labour Act, Health Act, Health Insurance Act, Medicinal Products in Human Medicine Act were analysed, as well as the main regulations endorsed in the field. The analysis focused on the main changes that influenced the future of the health care and pharmaceutical system. The reforms in the sphere of health care are radical and substantial. They lead to regulation and protection of the rights in respect of the healthcare system, the rights of the patients, the rights of the citizens in relation to medical treatments, provided by the health institutions, as well as the rights of the health specialists when providing medical help and healthcare. These acts regulate the structure, activity, organization and management of the medical and pharmaceutical areas and their financing. The regulation of the pricing and reimbursement in Bulgaria was discussed. However, this paper was produced before the recent establishment of the National Council on Pricing and Reimbursement of Medicines which is expected to make the process more transparent, controlled and visible for the general public.

Key words: *health policy, health legislation, pharmaceutical legislation*

INTRODUCTION

After the social and economic changes in Eastern Europe since 1990s, substantial changes were made in the health care systems in the countries. Most of them moved from centralized Semashko to decentralized health insurance systems of Bismark type [1]. The latter also have an impact on the pharmaceutical systems and, mostly, on the way of financing, pricing and reimbursement of medicines [2].

There is no historical overview of the basic changes in the health and pharmaceutical system in Bulgaria till now that stimulated out interest towards the topic.

The goal of this work was to analyse in a historical manner the main legislation developments in the field of health care and pharmaceutical system reform with special emphasis on pricing and reimbursement of medicines.

METHODOLOGY

This paper presents a historical legislation analysis of the main health care and pharmaceuticals regulatory acts. The Healthy and Safe Conditions of Labour Act, Health Act, Health Insurance Act, Medicinal Products in Human Medicine Act were analysed, as well as the main regulations endorsed in the field. The analysis focused on the main changes that influenced the future of the health care and pharmaceutical system.

RESULTS

Overview of the main regulatory acts of health care system

With the health reform that has started in 1999 most of the good structural and functional decisions for the healthcare systems of a social type security have been implemented in Bulgaria. The model was defined as „public-private partnership“ in the sphere of healthcare.

The healthcare in the Republic of Bulgaria is financed by the state budget and by the health insurance systems, based on the principle of solidarity and universal access. The main forms of financing of the healthcare are the general tax treatment and social security, while private health insurance financing is also applied. The expenditures for drug products are an important part of the budget for healthcare. There is an increasing necessity of limitation of the increasing expenses for healthcare, including for drug products as well as of effective spending of the financial resources.

The reform in the healthcare started with the adoption by the National Assembly of five new acts, related to the healthcare system until 2000 (Healthy and Safe Conditions of Labour Act [3], 1997; Health Insurance Act [4], 1998; Professional Organizations of the Physicians and Dentists Act [5], 1998, Medical-Treatment Facili-

ties Act [6], 1999; Medicinal Products in Human Medicine Act [7], 2000 and 2007) and an act related mostly to public healthcare in 2004 (Health Act [8], 2004).

Another characteristic peculiarity of the changes in the system of healthcare is the regulation of the contractual rule in relation to the interrelations between the health institutions and the financing body (the National Health Insurance Fund – NHIF). All Bulgarian citizens are mandatory insured for a determined package of health services, paid by the NHIF. The health institutions provide healthcare on the basis of a contract concluded between them and the NHIF. The main obligations of the parties to the agreement, together with the prices, the methods of payment and procedures are determined in the National Framework Agreement, which is signed between NHIF and representatives of the professional organizations of the physicians and the dentists.

The third basic characteristic of the system is the right of the consumers to choose suppliers of health services which came into force in 2000 until present days. They are entitled to choose their personal physician and dentist for a primary medical service, health institution for specialized out-patient care, and from the 1st of January, 2004 for in-patient care as well.

The system of healthcare is managed by the Ministry of Health through 28 local units called regional health inspectorates. The minister of healthcare is a central single person organ of the executive power. The minister performs functions, more important of which are: conducts the state policy in the sphere of the healthcare and restructuring of the health sector; develops and controls the execution of the national health strategy; conducts drugs policy; issues, coordinates and offers to the Council of Ministers (CM) drafts of normative acts in the sphere of healthcare and controls their implementation; performs coordination between the ministry and other organs of the executive power, the NHIF and the professional organizations of the physicians, the physicians in dental medicine, medical nurses, midwifes, associated medical specialists and master pharmacists; creates by order consulting councils, commissions and expert work groups, which are assisted by the administrative echelons of the ministry; conducts the financial policy of the ministry, etc.

The NHIF is a relatively independent institution, created as a separate structure of the public system of healthcare and has its own organs of management. The main purpose of the NHIF is to ensure and guarantee free and equal access of the insured persons to medical help through a defined by type, scope and volume package of health activities, including drug products [9].

The National Health Insurance Fund is a legal entity with a scope of activity performing of the mandatory health insurance. Management bodies of the NHIF until 09.04.2010 were the Representatives Assembly, Managing Board (MB), Controlling Board (CB) and the director. After 09.04.2010 NHIF management bodies are the Supervisory Board (SB) and a manager [10].

The health institutions for out-patient and in-patient care have the legal status of limited liability companies or joint stock companies while the state health institutions are part-owners of the capital of the Ministry of Health or municipal.

The emergency medical help is financed by the republican budget through the Ministry of Health and is supervised directly by the Ministry. The created structure of the system for emergency medical healthcare ensures comparatively equal coverage of the structures of emergency medical care on the territory of the whole country.

Overview of the main regulatory acts of pharmaceutical system

The norms regarding the pharmaceutical system are set forth in the Drugs and Pharmacies chapter in the Human Medicine Act [11], voted by the National Assembly in 1995. Since its entry into force, over 30 regulations have been developed, which synchronized the Bulgarian legislation in the sphere of pharmaceutical products with the European directives and good practices. In parallel with the Drugs and Pharmacies in the Human Medicine Act, the sector is also regulated by the Narcotic Substances and Precursors Act [12], the Health Act [13], Medical-Treatment Facilities Act [14] and the Health Insurance Act [15], as well as by the secondary legislation for their implementation.

Pursuant to the Drugs and Pharmacies in the Human Medicine Act, the drugs policy of Bulgaria is supervised by the Ministry of Health together with the Bulgarian Agency for Drugs (Executive Drugs Agency – EDA). The Ministry of Health is responsible for the entire drug policy – planning, execution and control. The EDA issues licenses for retail and wholesale trade for pharmacies and provision of some medicines for treatment of specific illnesses, mandatory vaccinations and some health programs, such as tuberculosis, AIDS and others.

After Bulgaria became a part of the European Union in 2007, a totally new Drug Products chapter in the Human Medicine Act entered into force while the same was synchronized with the norms of the European Union. Till the end of 2012 this act was consecutively changed nearly 12 times to reflect the new European regulation requirements and Bulgarian conditions.

Regulating the pricing of medicines

Two of the main normative acts currently in force, which determine the norms of pricing in the country, are the Drugs and Pharmacies in the Human Medicine Act (2007) and Regulation for Prices and Reimbursement (2011).

• Until 1996 centralized price control was performed by the Price Committed at fixed prices in an entirely state market.

• **1996-2000 Regulations for the Prices of the Drug Products16: set forth the order and method for determining the prices, commercial margins, the size of the profit for the manufactured and sold in the country drug products**

• The prices of the drug products, made and sold in the country, are formed on the basis of the full costs for manufacturing and a maximum size of the profit over these costs.

• Margin for a whole seller – maximum margin of 10%.

• Margin for a retail-seller (pharmacy) – one time margin of 25% to the sale price.

• Until 2000 registration of the price of drug product is an inseparable part of the permission for use, issued by the Drugs Agency.

• During 2000 a new rule was implemented – forming of a limit price of all drug products – the lowest price of the prices in 42 countries in Europe, regressive scale of the margins in four price groups. During 2002 a 20% VAT over the drugs was implemented.

• **2000-2004 Regulations for the limit prices of the permitted for use drug products at their retail sale [17]: determined the rules and the normative limitations for forming and registration of the limit prices of the permitted for use drug products at their retail sale.**

• Forming of the limit price: price of manufacturer, announced by the relevant manufacturer in its leva equivalent, which shall not be higher than the lowest registered price in a country that is a member of the Council of Europe. Limit price. They were announced in the non-official section of "State Gazette" in a term of one month after the issue of the order by the Minister of Health for registration of a limit price for the drug product.

• margin for whole seller in an amount of 12, 10, 9 or 7 per cent according to the following criteria:

▪ 12 per cent – in the case of announced by the manufacturer price from 0.01 BGN to 1 BGN (price group A);

▪ 10 per cent – in the case of announced by the manufacturer price from 1.01 BGN to 7.00 BGN (price group B);

▪ 9 per cent – in the case of announced by the manufacturer price from 7.01 BGN to 30.00 BGN (price group C);

▪ 7 per cent, but no more than 15 BGN – in the case of announced by the manufacturer price over 30.01 BGN (price group D);

• margin for a retail seller in an amount of 33, 28, 25 or 20 per cent of the announced under item 1 price according to the criteria, determined in Art. 5.

▪ 33 per cent – in the case of announced by the manufacturer price from 0.01 BGN to 1.00 BGN (price group A);

▪ 28 per cent – in the case of announced by the manufacturer price from 1.01 BGN to 7.00 BGN (price group B);

▪ 25 per cent – in the case of announced by the manufacturer price from 7.01 BGN to 30.00 BGN (price group C);

▪ 20 per cent but no more than 30.00 BGN – in the case of announced by the manufacturer price over 30.01 BGN (price group D).

• During 2004 was determined the limit price of the drug products by physician's prescription. The price was to be the lowest price of 9 reference countries. Regressive scale of the margins in three price groups with a maximum margin of 38%.

• Since 2006, new rules were enacted:

• In the case of registration of the limit sale price for drug products without physician's prescription:

▪ 2006 annual confirmation of the price of manufacturer (Submission of a declaration/s for the presence and/or lack of change of the prices in the reference countries).

• **2004-2007 Regulations for the Rules for Forming and Registering of Prices of Drug Products in Retail Sale [18] – determined the rules for forming and confirming of limit prices of drug products**

• The limit prices of the drug products, issued by a physician's prescription, were announced by the Ministry of Health in a created for the purpose public register.

• margin for whole seller in an amount of 10, 9 or 7 per cent of the announced price:

▪ 10 per cent – in the case of price from 0.01 BGN to 7.00 BGN (price group A);

▪ 9 per cent – in the case of price from 7.01 BGN to 30.00 BGN (price group B);

▪ 7 per cent, but no more than 15 BGN – in the case of price over 30.00 BGN. (price group C);

• margin for retail seller in an amount of 28, 25 or 20 per cent of the announced:

▪ 28 per cent – in the case of price from 0.01 BGN to 7.00 BGN (price group A);

▪ 25 per cent – in the case of price from 7.01 BGN to 30.00 BGN (price group B);

▪ 20 per cent but no more than 30.00 BGN – in the case of price over 30.00 BGN (price group C).

• 2007 Regulation of the prices of drug products by physician's prescription and registration of the prices of drug products without physician's prescription:

• In the case of forming a price of drug products included in the Positive Drugs List and paid with public finances

• the lowest price for the same drug product, paid by the social health insurance funds of 8 countries (Romania, Estonia, Greece, Czech Republic, Lithuania, Hungary, Portugal and Spain).

• **2007-2011 Regulation for the Conditions, Rules and Order for Regulation and Registration of the Prices of the Drug Products19**

• margin for whole seller in an amount of 9,8 and 6 per cent of the announced price at the following criteria:

▪ At a price up to 10.00 BGN – 9 per cent;

▪ At a price from 10.01 up to 30.00 BGN – 8 per cent;

▪ At a price over 30.00 BGN – 6 per cent but no more than 15 BGN;

• margin for retail seller in an amount of 22, 20 or 18 per cent of the announced price at the following criteria:

- At a price up to 10.00 BGN – 22 per cent;
- At a price from 10.01 up to 30.00 BGN – 20 per cent;
- At a price over 30.00 BGN – 18 per cent but no more than 30 BGN.

• 2010 Amendment of the Regulation for the prices

• For the drug products paid with public finances is detailed the comparison of the price with the prices in the reference countries:

• the lowest price for the same drug product, paid by the social health insurance funds of 8 countries (Romania, Slovakia, Estonia, Greece, France, Lithuania, Portugal and Spain);

• the lowest price for the same drug product paid by the social health insurance funds of additional countries: Belgium, Czech Republic, Poland, Lithuania and Hungary;

• the lowest price of a drug product in the same drug and dosing form and in final package, closest to the announced.

• During 2011 the Regulation for Prices and Reimbursement united norms of the Regulation for the conditions and conditions of pricing of drug products in retail their sale, defining the method of pricing in Bulgaria. After 20.12.2011 when in force was the Regulation for Regulation and Registration of the Prices of the Drug Products, the conditions, rules and criteria for inclusion, changes and/or exclusion of drug products from the Positive Drugs List and conditions and order for work of the Commission of Prices and Reimbursement, the formed price was no longer a separate precondition for inclusion of the drug product in the Positive Drugs List, because it was specified in the application itself for inclusion and was confirmed by the Commission of Prices and Reimbursement.

• **2011: Regulation for Regulation and Registration of the Prices of the Drug Products, the Conditions, the Rules and Criteria for Inclusion, Changes and/or Exclusion of Drug Products from the Positive Drugs List and the Conditions and Order of Work of the Commission of Prices and Reimbursement [20]**

• margin for whole seller in an amount of 7,6 and 4 per cent of the announced price according to the following price ranges:

- Up to 10.00 BGN – 7 per cent;
- From 10.01 BGN to 30.00 BGN – 6 per cent;
- Over 30.00 BGN – 4 per cent but no more than 10 BGN;

• margin for retail seller in an amount of 20, 18 and 16 per cent of the announced price according to the following price ranges:

- Up to 10.00 BGN – 20 per cent;
- From 10.01 BGN to 30.00 BGN – 18 per cent;
- Over 30.00 BGN – 16 per cent but no more than 25 BGN.

By adopting the new regulation the terms in which the applications and the attached to them documents are reviewed were shortened from 90 to 60 days for

inclusion of the drug product in the Positive Drugs List and for confirmation of price under Art. 258, para. 1 of the Drug Products in the Human Medicine Act [21]. From 60 to 30 days was reduced the term for change or deletion of an already included in the Positive Drugs List drug product. In this way, the legal regulation was synchronized with the trends in the European legal order.

The performed changes in the legal framework endorse an easier procedure for inclusion of the medicinal products in the Positive Drug List as well as for confirmation of their prices which shall develop before one and the same body. The shortening of the normatively set forth terms for decision on the submitted applications are in line with the trends in the European legislation.

Regulating the reimbursement of medicines

One of the sources for reimbursement is the republican budget through the Ministry of Health covering 100% of the pharmaceutical costs, related to ensuring a treatment of the patients diagnosed with cancer, patients with AIDS, as well as expenses for national programs for public health and for vaccines for the immunization calendar.

The Health Insurance Act [22] adopted in 1998, as well as the creation of the National Health Insurance Fund (NHIF) are key elements of the system for reimbursement of the costs in medical and economic conditions. This is the legal basis for change of the Bulgarian health system, as well as for introduction of the mandatory, as well as the voluntary health insurance in the country.

During 2003 for the first time in Bulgaria was implemented the Positive Drugs List, updated in 2007:

- The drug products in international non-patent names (INN) in two parts:
- Part A, which includes the list of the drugs which satisfy the health needs of the population under the international non-patent names (INN);
- Part B, which includes the list of the commercial names of the drug products which under INN are included in part A and are ordered according to the evidences for their quality, effectiveness, safety and analysis of the pharmaceutical-economic specifications.

During the period 2003-2007 four updates of the list were promulgated.

NHIF, the Ministry of Health and the health institutions may include in their drug lists and reimburse only the included in the list drug products.

The level of the reimbursement and the amount of payment is determined by each institution in respect of the illnesses for which the drug products are ensured and within the limits of the relevant budgets (the Ministry of Health and health institutions through public procurements, NHIF through negotiation pursuant to the regulation).

During 2007 was introduced a new Positive-Reimbursement List. The Positive Drug List consists of four applications depending on the method of forming the

source of financing and is constantly updated. It is published on the Internet page of the Commission in the web-site of the Ministry of Health.

In line with the legislative changes and the newly adopted regulation the functions of the two commissions are united, created and having acted under the previous regulation - the Commission for Medicinal products Pricing and the Commission for the Positive Drug List. This leads to reduction of the terms for inclusion of the drug products in the Positive Drug List.

During 2011 with the amendment of the Health Insurance Act [23], in force as of 01.01.2011 is foreseen the legal opportunity that the NHIF negotiate with the marketing authorization holders or with their authorized representatives, for the drug products included in the Positive Drug List under Art. 262, para. 4, item 1 of the Drug Products in the Human Medicine Act [24], discounts of the amount at which is paid the relevant drug product on conditions and order determined with a specifically designated secondary piece of legislation – Regulation No. 10. Such are included only with the amendment in the regulation, in force as of 30.08.2011, by means of inclusion of a new Chapter Four “Conditions and Procedure for Negotiation of Discounts of the Amounts which the NHIF pays for Drug Products”.

For the period from 01.01.2011 until 30.08.2011, the effect of the norms of the Health Insurance Act, envisaging a legal opportunity for negotiation of discounts, which may lead to a reduction of the expenses of NHIF for drug products, was blocked due to lack of regulation in a secondary normative act of the conditions and procedure for this negotiation.

The amendments in the regulation of the Minister of Health from 30.08.2011 limit the scope of application of the negotiation by introducing additional criteria (the drug products to be with a level of payment 100 per cent, to be the only drug product under INN and not to participate in the determination of the reference amount with other drug products) which the drug products should meet and, in this way, they narrow the regulated with the act opportunity for negotiation of discounts for all drug products.

The envisaging of limitations in the scope of negotiation of discounts of the price of the drug products limits the application scope of the regulation of a normative act with a higher hierarchical level - namely the Health Insurance Act. The statutory text requires that the regulation settles “conditions, criteria and procedure” for negotiation of the discounts, without providing for limitations of the drug products which are included in the Positive Drug List. Under “conditions” the statute means the conditions of the negotiation and not such which will limit the objective scope of such contracting.

By amendment of June 29, 2012 of Regulation № 10 are abandoned the limitations in the scope of negotiation. Another important moment in the new version is that the negotiation of the discounts of the price of the drug products is now not a

legal opportunity for NHIF but its obligation. It is obliged to contract for discounts of the price of all drug products which it pays for and which are included in the Positive Drugs List under Art. 262, para. 5, item 1 of the Drug Products in the Human Medicine Act. The last departs from the statutory framework because at the moment of the secondary legislation amendments the Health Insurance Act does not set forth an obligation for negotiation but only a legal opportunity.

With the last amendments of the Health Insurance Act (State Gazette, issue 60 of August 7, 2012 - after the audited period) the statutory and secondary legislation framework are synchronized while in para. 10 of Art. 45 of the Health Insurance Act the words “may negotiate” are substituted with “negotiates”. As a result, commencing August 7, 2012, NHIF has the legal obligation to undertake a procedure for negotiation of discounts of the price of all drug products under Art. 262, para.5, item 1 of the Drug Products in the Human Medicine Act which it pays for and which are included in the Positive Drugs List.

Planned amendments in the Drug Products in Human Medicine Act

On July 12, 2012 the Council of Ministers introduced in the National Assembly a Bill of Amendment and Supplement of the Drug Products in the Human Medicine25 which sets forth new substantial amendments relating to the pricing (adopted on the second reading in the National Assembly on December 11, 2012).

According to the planned amendments, the Commission for Pricing and Reimbursement is substituted for a new body – National Council for Pricing and Reimbursement of Medicinal Products – a legal entity on budgetary allowance with a status of a state commission, a secondary unit disposing with budgetary credits to the minister of health. The operation of the council shall be assisted by administration whose structure and organization of work is determined by organizational rules, adopted by the Council of Ministers and financed by the state budget through the budget of the Ministry of Health.

The council shall regulate the prices of the drug products, included in the Positive Drugs List and paid for with public finances pursuant to the lowest reference prices of the member states, shall include, change or exclude drug products from the list, shall maintain and update the list. It is set forth that the council performs control over the sale of drug products with a confirmed limit and registered price.

Discussion and Conclusion

The reforms in the sphere of health care are radical and substantial. They lead to regulation and protection of the rights in respect of the healthcare system, the rights of the patients, the rights of the citizens in relation to medical treatments, provided by the health institutions, as well as the rights of the health specialists when providing medical help and healthcare. These acts regulate the structure, activity, organization and management of the medical and pharmaceutical areas and their financing.

The regulation of the pricing and reimbursement in Bulgaria was discussed. However, this paper was produced before the recent establishment of the National Council on Pricing and Reimbursement of Medicines which is expected to make the process more transparent, controlled and visible for the general public.

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