PHARMACIA

Pharmacia 71: 1–8
DOI 10.3897/pharmacia.71.e131159

Research Article

A comparative analysis of pricing and reimbursement systems between Italy and Bulgaria

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Received 3 July 2024 ♦ **Accepted** 10 July 2024 ♦ **Published** 29 July 2024

Citation: Cannavale C, De Rosa A, Yordanov E, Parvova I, Hristov E, Petkova V (2024) A comparative analysis of pricing and reimbursement systems between Italy and Bulgaria. Pharmacia 71: 1–8. https://doi.org/10.3897/pharmacia.71.e131159

Abstract

Pricing and reimbursement in the European Union (EU) are unified by Directive 89/105/EEC/21.12.1988. The directive has a framework nature; it defines deadlines for decision-making, legal protection, publicity of information, tacit consent, etc. The specific mechanisms are subject to national measures, leading to differences in Member States. The aim of the study is a comparative analysis of the regulatory measures for pricing and reimbursement of medicinal products in Bulgaria and Italy. We looked at four main pricing and reimbursement measures: positive drug lists, reference pricing, health technology assessment, and innovative schemes. We used documentary analysis and synthesis, comparative, and statistical methods. The two countries' pricing and reimbursement systems are fundamentally different. Italy's system has long traditions and guarantees stability in the availability and affordability of medicinal products for the population. Since 2000, the regulations concerning the pricing and reimbursement system in Bulgaria have been amended more than 42 times, which characterizes the Bulgarian pricing and reimbursement policy as regulatoryly unstable.

Keywords

pricing, reimbursement, cost sharing, comparative analysis, Italy, Bulgaria

Introduction

Healthcare has one of the highest shares, both in terms of public expenditure and as a share of GDP, for EU countries. Due to the fact that the health status of the population has a dramatic impact on the competitiveness and development potential of the nation, the economically developed countries of the world prioritize the financing of the sector. Drug therapy costs are one of the essential factors when considering and evaluating the level of efficiency of a country's health care system. Bulgaria, along with Romania and Croatia, is one of the last three countries accepted as EU members. In 2006–2007, in the process of the accession of the Republic of Bulgaria to the

EU, the drafting of a completely new law on medicinal products in human medicine began, with the aim of fully synchronizing the Bulgarian legislation with the current EU Directives (Lex.bg 2007). The approaches to pricing and reimbursement in EU member states were unified by Directive 89/105/EEC of 21 December 1988. Directive 89/105/EEC is one of the oldest European directives still in force in the field of medicine regulation. The directive defines general principles such as decision-making deadlines, means of legal protection, the institution of tacit consent in administrative procedures, etc. In practice, the specific mechanisms for pricing and reimbursement are left to the national level, which is why there are significant differences between EU member states. This is because, for various political, social, economic, demographic, and other reasons, EU member states cannot agree on uniform rules and norms for price regulation of medicinal products valid for all European citizens.

In order to meet the requirement of synchronizing Bulgarian legislation with EU law, in 2007 a completely new chapter, "Prices of medicinal products," was written in the law on medicinal products in human medicine (Lex.bg 2007). In accordance with Directive 89/105/EEC, a two-stage model was adopted for the formation of prices for medicinal products and their inclusion in the payment system of the National Health Insurance Fund: the first stage—an independent process of formation and registration of prices—and the second stage—inclusion in the system for reimbursement. Each procedure was expected to last up to 90 days, or a total of up to 180 days in accordance with the Directive. For each medicinal product, an independent administrative act is issued with the possibility of appeal in court. The positive drug list is updated on an ongoing basis, not once a year, as before, etc.—all the main principles of the Directive have been introduced into the Bulgarian legislation, with two main goals: establishing compliance with European law and ensuring the availability and affordability of medicinal products for Bulgarian citizens.

The aim of the study is to conduct a comparative analysis of the regulatory measures for pricing and reimbursement of medicinal products applied by the governments of Bulgaria and Italy. We propose that a comparative analysis between the pricing and reimbursement systems of a so-called "old" EU member state with well-established principles and a stable legislative framework and a "new" member state like Bulgaria would contribute to the correct understanding of the Bulgarian pricing and reimbursement system and the evaluation of its positive and negative sides, as well as the determination of guidelines for its improvement. Another main reason for this choice of countries is the fact that both Italy and Bulgaria fall into the list of the first 5 main EU countries "exporters" of medicinal products to other member states under the mechanism of the so-called "parallel trade." Many analysts believe that parallel trade source countries either have very strict pricing policies aimed at low medicinal product prices and budget constraints, or they have an unstable pricing and reimbursement system.

Materials and methods

We applied the "documentary analysis" and "content analysis" methods. We analyzed the legislation of both countries in the field of pricing and reimbursement of medicinal products—laws, regulations, manuals, and practical guidelines. The analysis is aimed at four main focuses: 1. presence or absence of a positive drug list; 2. international comparative analysis of prices; 3. assessment of health technologies; 4. the implementation of various innovative pricing and budgeting schemes, such as responsibility sharing and cost sharing. For the purposes of the analyses, we used publicly available sources of information—the websites of the relevant ministries of health, the drug agencies of Italy (AIFA 2024) and Bulgaria (BDA 2024), the pricing and reimbursement authorities, etc.

Results

We compared the main health-demographic and economic indicators between Bulgaria and Italy using data from the European Commission (OECD 2023a, 2023b) current as of 2023 (Table 1). The population of Italy is 59,030,133 people, or 8.6 times more than that of Bulgaria—6,838,937 people. The Italian population is developing steadily, while there is a demographic collapse in Bulgaria—the population has decreased by more than 2,500,000 in the period from 1990 until now.

Table 1. Comparison of health, demographic, and economic indicators between Bulgaria and Italy.

Health, demographic, and economic indicators	Italy	Bulgaria	EU
Total population (millions of people)	59 030 133	6,838,937	446 735 291
Population age 65 and older	23.8%	21.7%	21.1%
Life expectancy	83 years	74.3 years	81.5 years
GDP per capita (EUR PPP*)	EUR 33,688	EUR 20,709	EUR 35,219
Healthcare spending per capita	EUR 2,792	EUR 1,708	EUR 4,028
Out-of-pocket health care spendingper capita	EUR 614.24(22%)	EUR 580.72(34%)	EUR 604.2(15%)
Spending on pharmaceuticals per capita	EUR 178.12(29%)	EUR 394.8(68%)	EUR 145(24%)
VAT applied to all medicinal products	10%	20%	8.7%

*Purchasing Power Parity (PPP) is defined as a currency conversion rate that equalizes the purchasing power of different currencies by eliminating differences in price levels between countries.

The average life expectancy in Italy is over 84 years. Life expectancy in Bulgaria before the COVID-19 pandemic was increasing, but after it, it decreased by 3.7 years, falling from 74 years to 71.4 years between 2019 and 2021, the lowest level in the EU and the lowest for Bulgaria in two decades. Although life expectancy is recovering and will reach 74.3 years in 2022, it is still the lowest in the EU. Diseases such as stroke, ischemic heart disease, and COVID-19 are the main causes of mortality in 2021. High excess mortality rates in 2020–2022 also suggest that direct mortality is due to COVID-19. The share of the elderly population in Bulgaria is 21.7%, but as an absolute number, the Bulgarian population demonstrates one of the highest aging trends in Europe. The gross domestic product per capita of Italy, recalculated using purchasing power, exceeds that of Bulgaria, respectively: 33,688 euros against 20,709 euros. According to this indicator, Bulgaria lags behind Italy by 1.62 times, although for the last 15 years the average GDP growth has been between 2.5 and 3.8% on an annual basis. Along with Romania, Bulgaria continues to be the poorest EU member state. Health care costs per capita in Italy are 63% more than in Bulgaria, of which the Italian citizen pays 22% while the Bulgarian citizen pays 34%. The statistics place Bulgaria in last place in the EU in terms of expenditures paid by citizens. The total amount of drug therapy costs from the total health costs is equal to 178.12 euros for Italy against 394.8 euros for Bulgaria. And by this indicator, Bulgaria is once again in last place in the EU. The level of value-added tax (VAT) applicable to medicinal products in Bulgaria is 20%, while in Italy, VAT on medicinal products is 10%.

The foundations of the Italian health system were laid in 1945. In 1978, the National Health System (SSN 2024) was established, fundamentally revised, and upgraded in the period 1992–1993. The National Health System of Italy is based on the principles and organization of the British National Health Service (NHS 2024), built on the Beveridge model, and includes three main principles. The first principle is universality—all citizens have the same right of access to services provided by SSN. Second principle: solidarity—every citizen contributes to the financing of the national health service based on personal contributions based on progressive taxation. Third principle: uniformity (sameness, equality)—the quality of services provided by the national health service to all citizens in all regions must be the same. All Italian citizens participate in financing the system as taxpayers, each person giving a little while healthy to receive as much as needed in return if they become ill. (Italian Government 2001b; Martini et al. 2007)

Public expenditure in Italy is based on health insurance, which covers 97% of the total budget for health insurance, while the remaining 3% is in the form of co-payments by patients. The system is managed by the Ministry of Health, has a decentralized structure, and is divided into 3 main levels: 1. The national level, where the Ministry of Health prepares a health insurance plan; 2. The regional level, which covers 21 regions that adapt to the national level; 3. The local level, which includes 195 health facilities (Fig. 1).

The main structural unit in the Italian health system is the Italian Medicines Agency (AIFA). AIFA is responsible

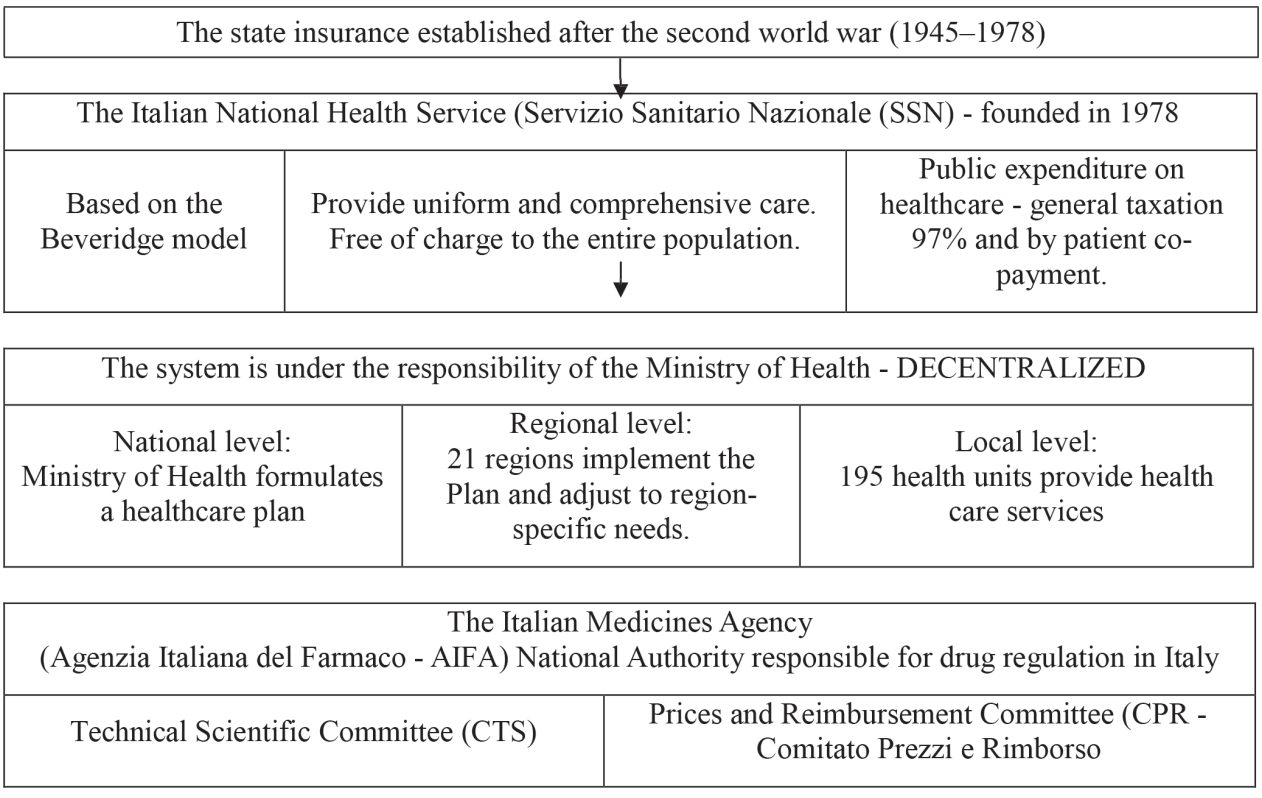

Figure 1. The Italian health system.

for drug regulation in Italy and is integrated into the pricing and reimbursement processes. In its activities, it is supported by four committees. 1. A technical and scientific committee that issues the marketing authorizations and classifies medicinal products for the reimbursement system. 2. The Committee performs its functions with the support of the National Medicines Board (NMB), which is responsible for drug monitoring in Italy. 3. The pricing and reimbursement system is ensured by a Pricing and Reimbursement Committee, which negotiates with the pharmaceutical companies the determination of the price of medicinal products and their reimbursement by the national health system using transparent methods and works together with 4. The Committee for Economic Planning, which is an interdisciplinary body between the Ministry of Health and the Ministry of Finance. Since 1978, Italy's health legislation has been changed a total of seven times, with the last change coming into effect in 2007. (Italian Government 2001a; Martini et al. 2007). The pricing and reimbursement process involves a series of steps and passes through various drug classification systems. Once a medicinal product is granted marketing authorization by the European Medicines Agency (EMA) or AIFA, decisions are made at the national level. Within a pre-specified period, the Marketing Authorization Holder (MAH) submits an application for reimbursement to the Italian National Pharmaceutical Formulary (its equivalent in Bulgaria is the Positive Drug List, respectively the National Council on Prices and Reimbursement of Medicinal Products). **Step 1**: Medicinal products are divided into three main groups. Group A includes essential medicinal products and those intended for chronic diseases, which are reimbursed at 100% by the National Health System. Group H includes medicinal products intended for use in hospital care. Group C includes medicinal products that are not subject to reimbursement. **Step 2**: Determining the degree of innovation of each medicinal product. Based on the degree of innovation, medicinal products are divided into three main groups: Medicinal products intended for the treatment of serious and severe diseases; Medicinal products intended to reduce or eliminate the risk of serious diseases; Medicinal products intended for the treatment of diseases with a milder profile, for example, allergic rhinitis. **Step 3**: The degree of innovation is determined in two directions: Availability of similar innovative medicinal products or expansion of therapeutic benefits compared to available medicinal products. As a result, medicinal products are classified into three new groups: 1. Medicinal products for/or: diseases for which no treatment is available; for patients with absolute contraindications when taking a medicinal product already available on the market; which present an additional therapeutic option. 2. Medicinal products that are intended for the treatment of patients resistant or unresponsive to first-line therapy (for example, patients with HIV). 3. Medicinal products for the treatment of diseases for which there is an available alternative. The products of the third group (for the treatment of diseases for which there is an alternative available) undergo so-called C-grouping and are subject to classification into three subgroups: First group C1: This group includes medicinal products that offer a better safety and efficacy profile or a better pharmacokinetic profile; Group C2: This group includes medicinal products that offer a pharmacological innovation as a new method of action but are not superior to the available therapies; Group C3: All technological innovations that do not provide additional therapeutic advantages over available therapies are classified in the third group. When determining the therapeutic benefit of a new medicinal product, AIFA evaluates primary and surrogate endpoints and, on this basis, classifies the medicinal products once again into three groups: The first group includes medicinal products with a large therapeutic benefit; the second group includes medicinal products with a partial therapeutic benefit; and the third group includes medicinal products with a minimal or temporary benefit. Each of these groups is further subdivided into those with 'Important', 'Moderate', or 'Minimal' therapeutic innovation. When a medicinal product does not possess any innovation compared to available medicinal products, AIFA may impose restrictions and include them in the group of medicinal products "marked by AIFA."

After finalizing the classification, AIFA proceeds to sign an agreement on the price of medicinal products with each MAH based on six criteria: 1. Cost-effectiveness of medicinal products that have no alternatives; 2. risk-benefit compared to alternative drug therapy; 3. average daily costs for therapy with the new medicinal products; 4. budget impact assessment; 5. determination of market share; 6. determination of price and consumption in certain EU countries. Medicinal products that fall into category C remain on the free market. (Italian Government 2001c; Martini et al. 2007; Official Journal of the Italian Republic 2007; PHIS/AIFA/GÖG 2009). In accordance with Directive 89/105/EEC of December 21, 1988, the deadline for making a decision on pricing and reimbursing should not be more than 180 days, but in practice, this deadline cannot always be met. Each pricing and reimbursement agreement is published in the Italian Official Gazette. Regions have the right to reduce the price of medicinal products and add a co-payment by the patient. In 1995, mandatory pharmaco-economic studies were introduced for innovative medicinal products.

The Bulgarian healthcare system, unlike the Italian one, is centralized. The model was created in 1998 and entered into force in 2000. The National Health Policy is implemented by the Council of Ministers, with practical guidance provided by the Minister of Health. The health care system in Bulgaria has a complex structure and includes many different state, municipal, and public bodies and institutions (Fig. 2). In contrast to Italy, where only one competent authority deals with pricing and reimbursement, in Bulgaria, six independent institutions are included in these processes: The National Council on Prices and Reimbursement (Lex.bg 2013); the Minister of Health, on whose behalf the regulation is issued; the National Health Insurance Fund (NHIF), which deals with the practical reimbursement of medicinal products; the Transparency Commission, to which decisions of pricing and reimbursement authorities can be appealed; and the judiciary, as all decisions are subject to judicial review (Fig. 3).

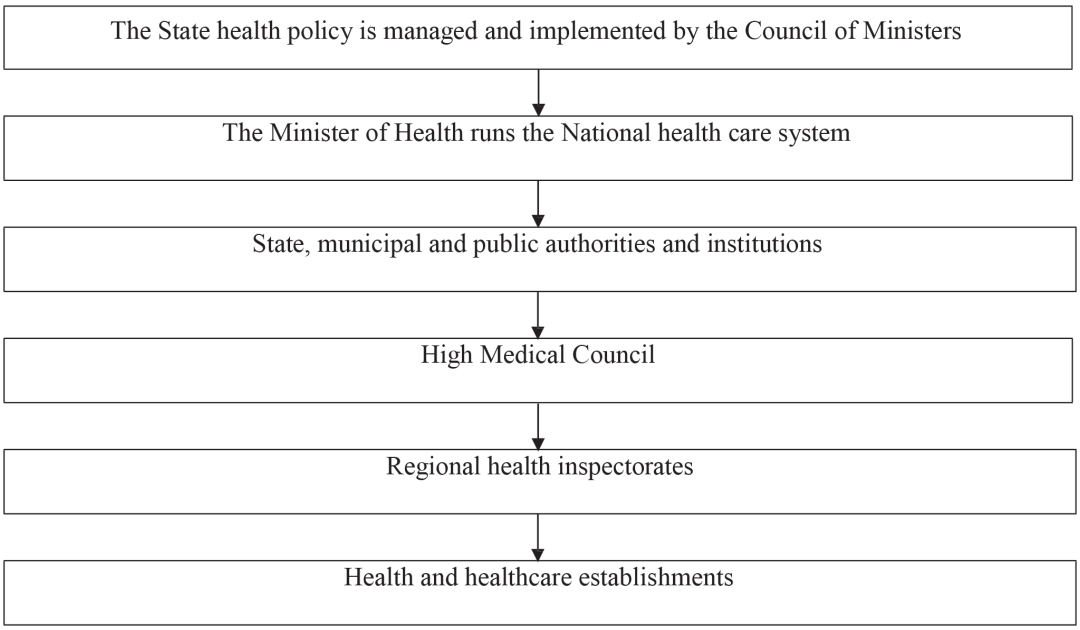

Figure 2. Structure of the Bulgarian Health System.

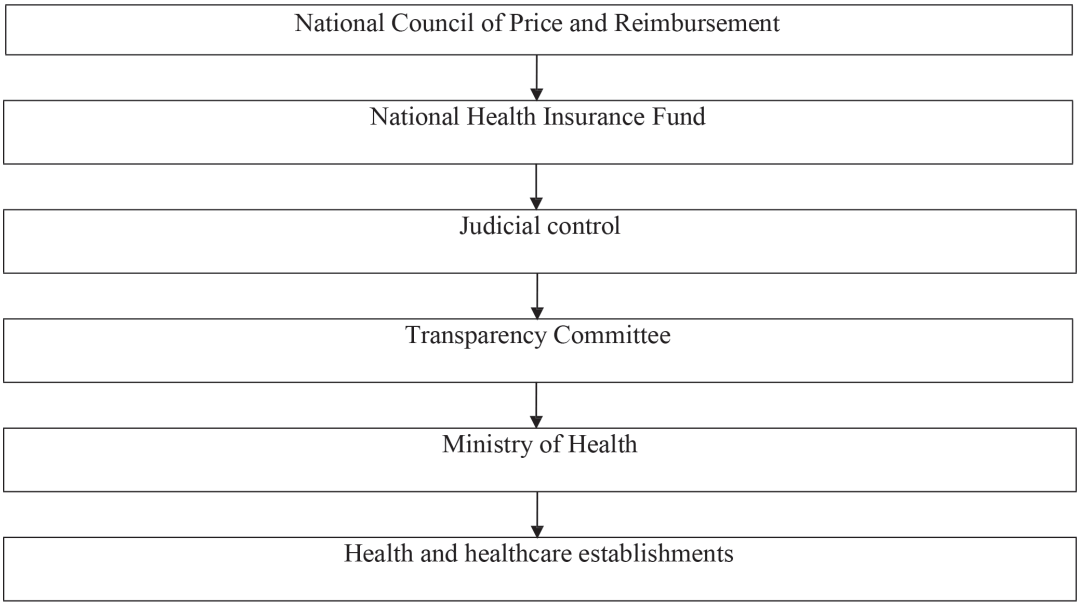

Figure 3. Pricing and reimbursement institutions in Bulgaria.

The main state authority for pricing and reimbursement in Bulgaria is the National Council on Prices and Reimbursement of Medicinal Products (NCPR). The Council has the status of a state commission and is appointed by the Council of Ministers on the proposal of the Minister of Health. NCPR determines the prices of medicinal products on the free market, registers the prices of medicinal products without a medical prescription, prepares the positive drug list (PDL), and determines the prices of medicinal products for reimbursement by the National Health Insurance Fund (Lex.bg 2013). If a product is included in the PDL and has a certain price, the NHIF must reimburse it. The Bulgarian positive drug list has four appendices: appendix 1: Medicinal products intended for the treatment of diseases, which are paid in accordance with the Law on Health Insurance; appendix 2: Medicinal products paid for from the budget of healthcare establishments; appendix 3: Medicinal products intended for the treatment of AIDS, infectious diseases, and diseases under national prevention programs outside the scope of the Health Insurance Act, paid in accordance with the Health Act, as well as vaccines for mandatory immunizations and re-immunizations, vaccines with special indications, and in extraordinary circumstances, specific serums, and immunoglobulins; and appendix 4: Ceiling prices of medicinal products. PDL includes medicinal products classified by pharmacological groups according to the code of the anatomo-therapeutic-chemical classification system, with the corresponding international non-proprietary names (INN), the trade names belonging to them, the corresponding defined daily dose/therapeutic course, the manufacturer's price, the marginal price of medicinal products in their retail sale, the

reference value for a defined daily dose/therapeutic course, the packaging value calculated on the basis of the reference value/therapeutic course for a defined daily dose, the level of payment by the NHIF, as well as diseases according to the international classification of diseases (ICD). Medicinal products in the PDL are selected according to evidence of efficacy, therapeutic effectiveness, safety, and analysis of pharmaco-economic indicators, and for medicinal products with a new international non-proprietary name, a health technology assessment is also carried out.

From 1999 to 2024, inclusive, the medicinal legislation of Bulgaria has been changed more than 42 times. As we indicated earlier, in Italy, the legislation has been changed seven times. In a series of tables, we present a comparative analysis of the pricing and reimbursement systems between Italy and Bulgaria and the most frequently used pricing and reimbursement techniques established in the practices of EU member states.

Bulgaria consistently uses international price referencing, while Italy has abandoned this price control measure and does not apply it. Bulgaria does not apply price measures based on the clinical performance of a medicinal product, while for the Italian price policy, this mechanism is essential. The price of medicinal products in Bulgaria is not determined and/or compared with the price of previous treatment for the relevant disease and applies pharmacoeconomic analyses, including health technology assessment, only for new active substances and new international non-proprietary names that are not present in the PDL (reference medicinal products: products with a complete dossier containing a new active substance for the EU). In contrast, both techniques used for price regulation are extremely important for the stability of the Italian health system (Table 2). In Table 3, we present a comparison of cost control measures. It is important to note that similar measures are not implemented in Bulgaria at the level of inclusion in the PDL by the NCPR. Cost control measures are implemented by the NHIF after inclusion in the system for effective reimbursement.

Table 2. Techniques used at the level of price regulation for the individual medicinal product.

Product price regulation	Bulgaria	Italy
Initial price decision based on clinical performance	No	YES
Initial price decision based on economic evaluation	YES - innovative MP only	YES
Initial price decision based on cost of existing treatments	No	YES
Initial price decision based on cost-plus calculations	No	No
Initial price decision based on international prices	YES	No
Controlled price updates	YES	YES
Other	–	–

In 2019, a controversial mechanism for discounting and rebates was introduced in Bulgaria called "Mechanism guaranteeing predictability and sustainability of the NHIF budget" as a compensatory measure applied to the availability of excess funds for health insurance payments for medicinal products, defined in the law on the budget of the NHIF for the relevant year. The so-called "Mechanism" is used directly for all medicinal products fully or partially paid by the NHIF and for all MAHs. The MAH of medicinal products fully reimburses the excess amounts set in the budget of the NHIF for fully or partially paid medicinal products. For the implementation of the "Mechanism," individual contracts are concluded annually between the NHIF and the MAHs. The methodology is too controversial, legal disputes are ongoing, and decisions have already been made in favor of the MAHs. Bulgaria does not apply the "Volume vs. Price" method or a system for freezing prices and reducing them. Italy implements all effective control of expenditure measures at the national level listed in Table 3 (Vogler et al. 2011; EC 2008).

Table 3. Control of expenditures.

Control of expenditure	Bulgaria	Italy
Use of discounts/rebates	YES *	YES
Payback	YES *	YES
Price-volume agreements	No	YES
Use of price freezes and cuts	No	YES
Other	–	–

* Introduced into Bulgarian legislation in 2019, further developed in 2020 and 2021, challenged in court.

Italy applies budgeting at the level of MAH and profit control, and it implements the so-called tax benefits, which can be related to investments in research and development or in production capacity. Bulgaria does not apply any price control measures at the level of MAHs (Table 4).

Table 4. Measures at the marketing authorization holder level.

Industry regulation	Bulgaria	Italy
Profit control/ company budget	No	YES
Tax benefits	No	YES
Others	–	–

Italy and Bulgaria have established systems for creating a positive drug list with clearly defined rules regarding which products are included (Andre et al. 2010). Both countries do not have an official negative list of drugs explicitly prohibited for reimbursement. Regarding Italy, it is a matter of interpretation whether there is no established negative drug list concerning the so-called AIFA-marked products list. In Italy, medicinal product pricing agreements are applied, while in Bulgaria, international referencing is used. Pharmacoeconomic evaluation and health technology assessment in Bulgaria are conducted only for innovative medicinal products, whereas in Italy, they are conducted for all medicinal products (Table 5) (Leopold 2012; Vogler 2021).

The only similarity in the mechanisms for control at the level of physicians between the two countries is the presence of clinical guidelines and prescribing guidelines.

Table 5. Reimbursement decision-making mechanisms.

Product reimbursement	Bulgaria	Italy
Reference price system	YES	No
Positive lists	YES	YES
Negative lists	No	No
Based on economic evaluation	YES	YES
Health technology assessment	For innovative MP only	
Other	–	–

Italy has a prescription quota, a monitoring system, an electronic prescription, and a pharmaceutical budget for prescribing. The electronic prescription and monitoring system is one of the best measures to control overprescription by doctors and illegal dispensing of medicinal products by pharmacists. Bulgaria still does not have an adequate system for monitoring the prescription; the electronic prescription is in the initial stage of introduction, and the process is very difficult, with strong denial by the medical organizations and opposition between the professional organizations of doctors and pharmacists, as well as by the various industrial organizations (Table 6).

Table 6. Mechanisms for control at the level of physicians.

Physicians	Bulgaria	Italy
Clinical practices/prescriptions Guidelines	YES	YES
Education and information	–	YES
Monitoring of prescribing patterns	–	YES
Electronic prescription	+/–	YES
Prescription quotas	No	YES
Pharmaceutical budgets	No	YES
Financial incentives	No	YES
Other	–	–

At the level of patients, both countries apply cost sharing on the part of the patient, but in Bulgaria, this share is larger. In Italy, the co-payment by the patient is fixed at the package level in the amount of 1–2 euros, which also includes the fee for providing pharmaceutical care. At the level of pharmacists, Bulgaria does not apply pricing and reimbursement techniques. Italy applies techniques of generic substitution, financial incentives to limit dispensing, and clawback in the case of undue cost increases, all of which are well established and contribute to the stability of the Italian healthcare system (Table 7) (Arts et al. 2006; Martini et al. 2007; PHIS/AIFA/GÖG 2009).

Table 7. Patient and pharmacist-level control mechanisms.

Patients	Bulgaria	Italy
Information education campaigns	No	YES
Cost sharing	YES	Co-payment only
Other	–	–
Pharmacists		
Generic substitution	No	YES
Financial incentives	No	YES
Claw-back	No	YES
Other	–	–

Discussion

In the objectives of this study, we expressed our understanding that a comparative analysis between the pricing and reimbursement systems of a so-called "old" EU Member State with well-established principles and a stable legislative framework and a "new" Member State like Bulgaria would contribute to a proper understanding of the Bulgarian pricing and reimbursement system and an assessment of its positive and negative aspects, as well as the identification of guidelines for its improvement. We found that the pricing and reimbursement systems of Italy and Bulgaria are completely different and differ in the basic principles implemented in them. From 2000 to 2024, the medicinal legislation of Bulgaria was amended more than 42 times. Along with the Medicinal Products in Human Medicine Act, the pharmaceutical sector is also regulated by the Health Act, the Health Insurance Act, the Healthcare Establishments Act, etc., which are also subject to a huge number of amendments and additions. The Bulgarian pricing and reimbursement system is in permanent regulatory instability and volatility. There are serious deficiencies in the provision of medicinal products on the market and in ensuring accessibility at the micro and macro level. The presence of an ever-changing regulatory environment is a serious challenge for pharmaceutical companies operating in the country, as they must constantly adapt to new regulations and policies. Italy has a fixed legislative framework based on well-established principles that ensures a stable regulatory environment and predictability for pharmaceutical companies, medical professionals, and the population, there is guaranteed availability and accessibility of medicinal products to the population. By strengthening the information infrastructure geared towards eHealth, Italy has been able in recent years to increase its focus on measuring the efficiency of healthcare and to move towards better monitoring of the performance of hospitals and pharmacies to ensure that the main population centers receive optimal healthcare. The National Medical Devices Committee and the Regional Health Services Agency are contributing to promoting the adoption of new cost-effective health technologies. In addition, some regions are establishing their own agencies to monitor the quality of pharmaceutical and medical care, conduct comparative effectiveness analyses, and provide scientific support to regional health services. Essential to the pricing and reimbursement processes is the establishment of structural and staff stability and sustainability in the representation and composition of the various bodies and committees responsible for decision-making in the pricing and reimbursement processes. In Italy, a sustainable process of staff selection and training ensures the stability of institutions. Unfortunately, in Bulgaria, the institutions are undergoing significant staffing and structural changes, which, in addition to regulatory instability, can lead to inconsistency and confusion in decision-making.

Conclusion

In general, our analysis reports that many of the principles outlined in Directive 89/105/EEC have been implemented in Bulgaria; European experience is also reflected, but there are still a number of areas in pricing and reimbursement activities that are subject to optimization. It is essential to ensure regulatory stability, predictability, planning, and mandatory substantive impact assessment of regulations rather than formal, close cooperation with stakeholders. The experience of the leading EU Member States should be studied methodically and implemented in Bulgarian practice.

Acknowledgments

This study was funded through targeted financing from the state budget by SU "St. Kliment Ohridski"—University Found of Scientific Research, Project N 3717/2022.

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