Macedonian pharmaceutical bulletin, 68 (Suppl 1) 471 - 472 (2022)
Online ISSN 1857 - 8969
DOI:10.33320/maced.pharm.bull.2022.68.03.226
Short communication

Management of national pricing policy of medicines

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Introduction

Medicines contribute with at least 20% in overall national spending and even more than 40-50% in high income counties. The Price is an economic category. Principally, it is defined as monetary expression of the product value, with a specific, nationally-important and sensitive role in the overall health management system. Value, as well prices, can differ in different circumstances. There are multiple factors that have influence on the medicines prices: country, region, target group of patients, demand, market competition, purchasing power – GDP, pricing policy, reimbursement policy, etc. The relative importance of above factors differs in relation to the national health management policy, as well as to the objectives and developmental tendencies of the future national health priorities, in order to achieve the state of sustainability.

WHO promotes that equitable access to medicines and other medical technologies depends on affordable pricing and effective financing. Affordable prices are fundamentally related to the national living standard, on one hand, as well as to the national reimbursement health policy, on the other hand. Promoting fair prices and cost-effective interventions is central to the achievement of universal health coverage, within the social constraints of the national health management system.

There exists a universal need to promote equity in access to effective new products, by ensuring that medical advances are affordable and working with all stakeholders to sustainably respond to public health needs and possibilities in terms of finances, in the framework of desired and prospective differentiation in the participation in the overall public health management income according a measurable criterion.

The importance of price regulation and transparency was emphasized by the European Commission with adoption of the Council's Directive relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems *(Official gazette of EC,* Council Directive 89/105/EEC, *1989).*

The prior format of our paper is intended to focus on analytical review of the methodological and empirical evidence of the concepts, methods and potential implications of various concepts for calculating the elements of the national pricing policies of medicines, with particular emphasis on EU experience, as well as neighboring countries of Republic of North Macedonia.

Materials and methods

The analysis and comparisons were conducted based on regulatory materials, laws, methodologies, and other primary and secondary source of information that refer to price regulation, that is, policy for determining drug prices and reimbursements for drug prices by health insurance funds. One of the sources were the official websites of the health authorities in the reference countries and in the Republic of North Macedonia. For the research purposes of this analysis, a comparative method was used to analyze the regulatory materials and models of medicines price determination, nationally and regionally. In this context, comparative analyses, on a selected sample of representative categories of medicines would be conducted, in order to sustain and further re-orient the derived tendencies and future developmental orientations.

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Results and discussion

Fundamental medicines pricing model in Republic of North Macedonia relies on special Law on medicines and medical devices, as well as supporting Methodology, which are expected to be fundamentally in line with contemporary EU tendencies in this field, stipulated in the objectives in the EU pharmaceutical strategy (Making medicines more affordable (europa.eu)) as '*to* en*sure that patients have access to affordable medicines and that health systems remain financially sustainable'*, comprised of revising the pharmaceutical legislation, cooperation on pricing, reimbursement and payers for the period 2021-2024, improving transparency, and, issuing country-specific recommendation for accessibility, efficiency and sustainability.

Management of the national pricing policy of medicines is important mechanism for obtaining and maintaining a high-quality pricing model adequate to specific pharmaceutical market. National pharmaceutical pricing authority, Ministry of health of Republic of North Macedonia, sets the ceiling (maximal) prices for all medicines with registration status as prescription medicines, as well approves their wholesale and retail prices. National drugs pricing methodology (*Methodology for the method of forming the prices of medicines, Official Gazette of RM, 2011 – Official gazette of RNM, 2019*) is basically determined by the provisions of Law on medicines (*Law on medicines and medical devices, Official Gazette of RM, 2007- Official gazette of RNM, 2021).*

All the manufacturers of drugs are required to sell their product equal to or lower than the ceiling price. Pharmaceutical companies set up prices of new medicines basically according to the economic value (or justifiable price) of their largest markets.

The key areas for national medicines pricing policy considerations, from managerial perspective, are calculation elements and methods, as well as the price negotiation power of the national healthcare authorities and payers, with producers or distributors of medicines, from national, but also from international, particularly regional, aspect. According to the national methodology for determining drug prices, the reference countries for the Republic of North Macedonia are: Bulgaria, Serbia, Slovenia, Croatia and Greece. Thus, reference countries for the Health Insurance Fund are Bulgaria, Serbia, Slovenia and Croatia, for the drugs from the List of drugs that are covered by the Health Insurance Fund in accordance with the provisions of the Law on Health Insurance and the Rulebook of the reference prices of drugs (*Rulebook on the method and methodology for determining the reference prices of medicines, Official Gazette of RM, 2009 - Official Gazette of RNM, 2021).* Following the differences in the methodologies of determining maximal and approved prices of medicines, of the Ministry of Health, and the reference prices of the Health Insurance Fund, there are some price differences at wholesale and at retail price level. Each such price difference for prescription medicines is covered by the patients at their own expense. Among other differences in these two specific pricing methodologies, MoH's and HIF's, there is also a difference in data sources from the reference countries. However, differences also exist in the pricing processes and methods nationally, but also regionally between mentioned reference countries.

Conclusion

Despite the differences in the national methodologies and regulations, conclusion are oriented towards the fact that the principles of price determination as ceiling price and approved formed price for medicines by brand names with specific generic name (INN) of the drug with pharmaceutical dosage form and strength, and the ones from the HIF's side, set by generic names of drugs with specific pharmaceutical dosage form and strength, probably could be harmonized and synchronized using models and experiences from reference countries that are most convenient to our country needs and possibilities in terms of medicine, management, economy and finances. The application of relevant international methodologies for methodology harmonization, as well as for creating and benefitting from justifiable price of the medicines is highly dependent on changes in the national price determination model, as well as on the national readiness to protect the affordability of all health beneficiaries regardless the differences in their living standard on the basis of purchasing power – GDP.

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