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NATIONAL DRUG POLICY

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Abstract:

The national drug policy is a professional and political document that defines the goals and priority tasks of the pharmaceutical sector, as well as the ways to achieve them. This document should form a framework for the development and operation of the pharmaceutical industry. The balance between all participants interested in the formation of this document, is the basis for the simultaneous harmonization of different interests and equal sharing of responsibilities. The necessity of developing a national drug policy arises from a number of determinants, which are reflected in the fact that: the drug saves lives, people can not predict the disease, drugs are complex chemical compounds and biologically active substances. People can not choose the right treatment without diagnosis and medical therapy, drugs are expensive, financial resources are always insufficient. The history of the National Medicines Policy (WHO) is relatively long: 1985. Conference of Experts on the Rational Use of Medicines in Nairobi (Kenya), 1987. Establishment of an Expert Working Group to Develop a Guide to National Medicines Policies, 1988 .publishing of a guide to BNPs, 1992. monitoring indicators of the national drug policy, 1995. the report of the committee of experts on the national drug policy was published. 2000. national drug policy monitoring indicators. 2002. published new guidelines for national drug policy. The national drug policy represents: Commitment to the goal and guidelines for action, should be a written document that contains the medium and long-term goals, priorities and strategies and key approaches to achieve them, provides a framework within which to coordinate the activities of The pharmaceutical sector, taking into account the public and private sector as well as all key actors in the pharmaceutical sector, should be developed systematically through the process of negotiation and harmonization of all interests. In a broader sense, national drug policy should promote equity and sustainability of the pharmaceutical sector, the main objectives of national drug policy are to ensure that drugs are effective, high quality, safe and relatively inexpensive, be not only present in the market, but also accessible to the population, in order to meet the needs of the entire population (essential medicines) and to ensure that medicines are used rationally. An integral part of the national drug policy process is the development of an action plan and work program for the development of the list of essential medicines. The essence of the concept of

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essential medicines is that the use of a limited number of carefully selected medicines, based on agreed therapeutic guidelines, leads to a better supply and lower costs, essential are those medicines that meet most of the needs for the health care of the majority of the population and therefore should always be available in the necessary dosage forms and at affordable prices. The essential drug list is a basic tool for drug management. The first WHO EDL (Essential Drug List) was published in 1977, and the last 15 were published in March 2007. The current WHO EDL (15th revision) contains 27 different therapeutic categories within which 388 drugs are distributed. (INN), with certain pharmaceutical qualities and forms. The drugs (INN) on the list are mainly representatives of the therapeutic-pharmacological groups, which gives the possibility that other drugs belonging to the same group, which are also effective, be included in the list as an alternative. The list of models is divided into main list and additional list. Drugs are listed INN, without being associated with specific brand names or manufacturers. The main list represents the minimum number of drugs that are needed for the health care system. It contains the most effective, safest and most economical drugs for priority diseases.
Keywords: *Development and purpose of national drug policies, history of national drug policies, compilation of the list of essential drugs.*

1. Introduction:

The right to health and health care is a fundamental human right, which presupposes that all available resources of society must be used to provide accessible, efficient and quality health care that meets the needs of all citizens. WHO. Globalization, TRIPS and access to pharmaceuticals. WHO Policy Perspectives on Medicines No.3. Geneva: World Health Organization; 2001. WHO/EDM/2001.2. The basic human freedoms have been analyzed and elaborated by the author Jasarevic and Maloku (2021) in the book Criminology (etiology and phenomenology of criminality), while in the penal-procedural aspect they have been elaborated in the book Criminal Procedure I and II. by the authors Jasarevic and Maloku (2021). Health is an economic potential and part of human capital, as well as a means to increase productivity and reduce public costs of treatment. The policy in the field of drugs, harmonized with the policy of the World Health Organization, is one of the goals in reforming the health system. Twenty years ago, the World Health Organization introduced the concept of a national drug policy as a recommendation. According to the latest WHO publication ("WHO Drug Strategy 2004-2007", Geneva 2004), 44% of countries had a national drug policy document in 1999, and the target is as early as 2007. 59% of countries have one. Many developed European countries do not have a national drug policy as a written document, but have legislation that provides all its element. (Rawlins, M. and A. Culyer.

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(2004)). The national drug policy contains instructions on how to achieve the goal of providing a framework for coordinating the activities of all participants in the field of drugs. It tells about real and applicable legislation, quality assurance system, testing and quality control, rational use, pharmaceutical inspection, determination of essential drugs, university and postgraduate education, monitoring and evaluation, drug information, domestic industry development. The authors Shabani and Maloku in their books Sociology (2019) and Tema te patologia sociae (2019) research and elaborate on the misuse and addiction of narcotic substances in individuals. Crime is a phenomenon that can be detected, prevented and fought with various preventive and repressive measures. (Maloku, 2016:120), therefore, the national drug policy contains instructions to prevent this negative phenomenon.

2. Methodology

In this paper, appropriate methods were used to achieve the goal. (Karović, et al., 2020: 107). The basis for the development of the indicator was the Delphi study conducted at the Harvard School of Public Health. The Delphi Group consisted of 54 internationally recognized experts from 12 countries, who reached a consensus on seven priorities for improving pharmaceutical business in the public and private sectors of developing countries. (Agency for Medicines and Medicines BiH http://www.almbih.gov.ba, Agency for Medicines and Medical Devices of BH, by 15th January 2020:) These are the following priorities: Establishing appropriate legislation, the selection of essential drugs and drug registration procedures, the importance of allocating resources for drugs from the health budget and developing relevant public sector financing policies, improving procurement procedures in the public sector, improving drug distribution and logistics in the public sector, establishing drug pricing policies in both the public and private sectors, the role of information and continuous educational programs for improving the use of medicines. Court of Justice of the European Union. (2018) , Judgment of the Court (Grand Chamber) in Case C-121/17), available at: accessed on 03/06/2021.

These seven components provide the basis for the selection of indicators for monitoring the national drug strategy. The indicators were tested in 1996 in 12 countries with a systematic survey approach. Purpose of this paper is to know the quantity of this problem (Maloku, 2015:29), at the national and international level.

3. Results and Discussion

Table no.1: The link between the main components and the three main objectives of GNPs,

GNP components	Purpose		
	Availability	Quality	Rational use
System of essential	+	(+)	+
The cost	+		
Funding	+		
Supply system	+		(+)

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Regulation and quality system		+	+
Rational use			+
Survey	+	+	+
Development of human resources	+	+	+
Monitoring and evaluation	+	+	+

In Denmark, only insulin preparations enter the category of drugs on the positive list, while all other drugs of therapeutic importance are classified in groups for which the participation is 25% and 50% of the reference price and limit determined by the Ministry of Health. In Germany, there is a negative list of drugs, which includes over-the-counter drugs, combined preparations containing more than three active ingredients and the like. (European Commission. (1989). Thyra DE JONGH, Lennart VELTEN and Lonneke SCHRIJVER PE 662.910 – June 2021). 25% and 50% are paid for important drugs. In Finland, a co-payment has been established for all categories of patients and for all drugs of therapeutic importance. However, its amount is much higher for drugs used in the treatment of chronic diseases. (Austin. Z, Gregory PAM. (2007). Fjortoft N. Self-assessment in pharmacy education. *Am J Pharm Educ.* 2006;70(3) Article 64. [PMC free article] [PubMed] [Google Scholar]) Health insurance in Finland reimburses only the difference between the mandatory co-payment and the cost of the drug to the extent of 100% for drugs for treatment: diabetes, multiple sclerosis, Parkinson's disease, epilepsy, cancer, then 75% for nine chronic diseases (hypertension, Crohn's, angina pectoris, heart failure, etc.) and 50% in less severe and acute conditions. In Great Britain there is a so-called blacklist of drugs (benzodiazepines, contraceptives, antirheumatic ointments, antidiarrheals, antianemia drugs) for most prescription drugs, determined every year. (Broz, T., (2014) Source / Izvornik: Fiscus : razborito i odgovorno upravljanje financijama javnog sektora, 2018, 3, 1 – 18). The following are exempt from paying the participation fee: unemployed persons, social cases, all children up to 16 years old, students up to 19 years old, pregnant women, mothers with small children up to 1 year old, all persons over 60 years old and patients suffering from some serious diseases. (European Commission. (2012) european free trade association) chronic disease. In Italy, the criteria for a positive list are based on pharmacotherapeutic principles and on the price/efficiency and benefit/risk ratio. Essential drugs (antineoplastics, antiepileptics, antidiabetics, anti-parkinsons, etc.) are included in category A and are free. Within this category is subgroup X, which includes all drugs for hospital use. (Ivčić, Snježana. (2018). Croat Med J. 2021 Dec; 62(6): 553–560.doi: 10.3325/cmj.2021.62.553). Medicines of greater therapeutic importance belong to class B and are reimbursed at 50% of their price. Other drugs fall into category C and are paid for in full. In Spain there is a negative list of about 700 different OTC drugs, cold and cough drugs, antacids, laxatives, antidiabetics, etc. In Switzerland there is a positive list and the condition for inclusion is pharmacoeconomic data. Stone RH, Rafie S, Ernest D, Scutt B. (2020). Emergency Contraception Access and

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Counseling in Urban Pharmacies: A Comparison between States with and without Pharmacist Prescribing. Pharmacy. 2020;8(2):105. 222. All drugs are classified into 5 groups according to the strength of action and reimbursement rate:
A and B are prescription drugs
C drugs without a prescription only in pharmacies
D drugs that are distributed outside the pharmacy
C other drugs.
Reimbursement is the product of pharmacoeconomic indicators (benefit / risk, price / efficiency, efficiency compared to similar drugs, household drugs, etc.) In Poland, drugs from the positive list are prescribed in 4 groups: drugs without participation, free drugs for certain categories, hospital drugs and drugs with 30% and 50% participation. (Robinson, R., (1993)). The process of creating a PNB is complex, comprehensive and extremely demanding and takes place in 8 steps: organize the process, identify the main problems, make a detailed analysis of the situation, set goals and guidelines, make a draft of the text of the document, it is shared with everyone and the draft is revised, formally verified, officially launching the grass policy. The implementation of the PNBs is realized through the preparation of the title of the plan (3-5 years), the approval of the annual action plans, the determination of the time limits, the determination of the responsibilities of the institutions and the provision of finances. (Russell, L., (1999)). A grass policy can only be successfully implemented if the government is committed and willing to take the initiative.

4. Conclusion

The essence of the concept of essential medicines is that the use of a limited number of carefully selected medicines, based on agreed therapeutic guidelines, leads to a better supply of medicines, more rational prescribing and lower costs. Essential drugs are those drugs that meet most of the health care needs of the majority of the population and therefore should always be available in the necessary dosage forms and at affordable prices. The development of drug policies in different countries has increased the demands for deeper knowledge in this area. (World Health Organization. (2001). Globalization, TRIPS and access to pharmaceuticals. World Health Organization. https://apps.who.int/iris/handle/10665/66723). Thus, there is a need to identify, recognize drug consumption trends and set priorities in the interest of regulatory bodies, as well as to build health education and information programs. (World Health Organization: How to develop and implement a national drug policy. 2001, WHO: Geneva, 2). Data on drug use are also very important to assess the effectiveness of measures taken to improve the situation. There has been an increasing need to provide information on the use of drugs not only through the commercial channels of pharmaceutical companies, but through special studies. This is also a consequence of the development of national insurance and health care systems. This paper contributes to existing scientific literature (Maloku, Jasarevic, Maloku, 2021:52). The main findings of this paper should

contribute to and initiate not only scientific workers, but also experts from practice, to launch a series of research projects in the future with the aim of obtaining relevant (scientific). (Maloku, Kastrati, Gabela & Maloku, 2022: 139).

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