

# **The National Medicines Policy 2018-22 in Poland. From Creation to Implementation**

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## **Introduction**

Medicines policy play a major role in protecting, maintaining and restoring people's health. The regular provision of appropriate medicines of assured quality, in adequate quantities and at reasonable prices, is therefore a concern for all national governments (Kanji et al., 1992; Wirtz et al., 2017).

Drug policy is an integral part of state health policy, assuring access to safe and effective medicines while reducing patient participation in treatment costs. Pharmaceutical policy is a subdivision of health policy that deals with the development, provision and use of medications within a health care system. It embraces drugs (both brand name and generic), biologics (products derived from living sources, as opposed to chemical compositions), vaccines and natural health products.

Medicine Policy includes:

- └ Funding of Research in the Life Sciences
- └ Patent Law
- └ Licensing
- └ Pricing
- └ Reimbursement
- └ Formulary management
- └ Eligibility
- └ Prescribing
- └ Pharmacy services

## **Materials and methods (or other sections)**

“The State Medicines Policy 2018-22” is a document of a strategic nature that defines the priorities of the Government of the Republic of Poland in the field of drug management in the indicated period ([www.gov.pl](http://www.gov.pl)). The document was created on the basis of the guidelines of the World Health Organization (WHO, 2016), it sets medium- and long-term goals for participants and decision-makers of the pharmaceutical market and identifies the main tools to achieve them.

The project was implemented through a systematic process of consultation with all interested parties, and its adoption was made through a consensus balancing the often contradictory goals and aspirations of communities widely associated with pharmacotherapy.

## **Results and discussion**

How to assess the degree of its implementation?

In the short-term perspective, the Policy, by indicating specific solutions, highlights the ways of correcting the system's operations under the applicable legal status.

In the medium and long-term perspective, the document defines the necessary changes in the legislative environment.

The establishment of the Medical Research Agency and the reduction of bureaucratic burdens in planning and implementing clinical trials in Poland can undoubtedly be considered as effective implementation of the provisions of the document. The changes in the law have led to better control and wider cooperation of the services established

for this purpose in the scope of limiting parallel exports of drugs.

It should be emphasized that the level of patient copayment for drugs in outpatient treatment has decreased. The main challenges that have not yet been realized include the amendment to the Reimbursement Act. On the other hand, we are pleased with the adoption of the act on the profession of pharmacist, an act that has been awaited by the environment for many years, allowing for the redefinition of the pharmacist's tasks. It also contributed to fight against COVID-19 pandemic as pharmacist role in assisting patients and vaccinating them was crucial in this period.

The solutions under the Act on the Medical Fund are interesting and promising.

As regards purely operational tasks, it seems appropriate to continuously update the content of drug programs and the reimbursement list, transfer selected drugs from drug programs to the chemotherapy catalog / pharmacy list, and define the criteria, perhaps based on MCDA for orphan medicinal products (<https://www.termedia>) leading to a selection of medicinal products available under the National Program for Rare Diseases (<https://www.gov.pl/>).

Drug policy as an integral part of health policy should be flexible, keep pace with systemic changes in health care and changing health needs of the society.

### Conclusions:

An access to innovative and generic therapies plays an important role in the treatment of severe, chronic, both common and rare diseases.

Drug reimbursement should be created in the context of epidemiology and demographic changes, and include both direct and indirect costs.

A medicines policy is based on a complex process of development, implementation and monitoring with adjustments, if necessary.

Throughout the entire process, careful planning, taking into account political and economic dynamics and the involvement of all stakeholders is needed.

### Acknowledgements

I would like to thank all persons who have contributed to the development of the Policy: Jakub Adamski, Artur Falek, Anna Lech, Iga Lipska, Iwona Skrzekowska-Baran, Rafal Zysk.

I would also like to acknowledge Anna Rozalska.

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