

National Health Policy and Rare Diseases

**Ministry of Health of Bulgaria
Department “National Health Policy”**

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ATTEMPTS FOR DEFINITION


● 4 IMPORTANT “I”:

- Institution
- Information
- Ideology
- Interests

● Political decisions are formed within the frames of the institution. A combination of rational information processing, different ideologies and personal interests are needed in order to influence policies.


ATTEMPTS FOR DEFINITION

Consensus among responsible partners about the priority problems and necessary approaches and strategies for their successful solutions



HEALTH POLICY

Health policy provides organized efforts to attract or direct the public awareness towards healthcare problems, prevention, treatment and rehabilitation by the the means of scientific knowledge and appropriate technologies



PUBLIC HEALTH IMPORTANCE OF RARE DISEASES

Law for medicines and pharmacies in human medicine

51. (New – DV, issue 120 / 2002 , corr., is. 2 / 2003)
“Rare diseases” are conditions, characterized by a prevalence less than 5 per 10 000 persons.

PUBLIC HEALTH IMPORTANCE OF RARE DISEASES

- (4) (New - DV, is. 120 / 2002, corr., is. 37 / 2005)
Criteria, conditions and order for designation of a medicinal product, intended for the treatment of rare diseases are described by a regulation of the Minister of health. The requirements for documentation, that should be presented for authorization of medicinal products for treatment of rare diseases are specified in the regulation under art. 18, par. 2.

PROBLEMS

- **Identification**
- **Diagnosis**
- **Treatment**
- **Rehabilitation**
- **Re-socialization**
- **Prophylaxis**

SPECIFIC AIMS OF THE DRUG POLICY

- **To assure safety, efficacy and quality of all drugs in the market**
- **To assure accessibility of the basic medicines to all in need**
- **To improve drug prescription and their distribution**
- **To create a system for implementation of a rational drug use among healthcare professionals and public**

MAIN GUIDES FOR **THE REALIZATION** **OF THE DRUG POLICY AIMS**

- **Adequate drug legislation, including all procedures regarding guaranteed assurance with quality, effective and safe medicinal products**
- **Effective regulatory procedures**
- **Effective price policy for drugs**
- **Effective procedures about the licensing regiments for trade with medicinal products**
- **Provision of expensive drugs from the budget and their optimal usage**
- **Adequate drug delivery and distribution**
- **Rational drug usage by regular optimization of the treatment schemes for expensive drugs, paid by the state budget.**
- **Consignment of independent drug information**

POSITIVE DRUG LIST

- **Art. 5. The positive drug list includes medicinal products, which are applied for effective prophylaxis and treatment of:**
 - 1. diseases, leading to high incidence and prevalence;**
 - 2. diseases with a high level of disease-related mortality;**
 - 3. diseases with a high level disease-related disability;**
 - 4. infectious and parasitic diseases, that are associated with a significant risk for the public health;**
 - 5. pediatric diseases;**
 - 6. pregnancy diseases;**
 - 7. rare diseases.**

TREATMENT, PROVIDED BY THE REIMBURSEMENT INSTITUTIONS

- Wilson disease
- Gaucher disease
- Cystic Fibrosis
- Hereditary metabolic diseases
- Echinococcosis
- Idiopathic thrombocytopenic purpura
- Cushing
- Disturbances in the metabolism of aminoacids
- Multiple sclerosis
- Myasthenia gravis
- Crohn disease
- Dermatomyositis

PARTNERSHIP

**Ministry
of Health**

**Medical
Universities**

**National
Centres**

**Patient
Organizations**

**Non-governmental
Organizations**

DECISION MAKING

- Opportunities
- Action

willingness

readiness

resources

partners

consensus

FINAL

