



## Analysis of the Modern Pharmaceutical Market of Anxiolytic Drugs in Ukraine

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### ABSTRACT

The results of the marketing analysis of domestic selection of anxiolytic drugs registered in Ukraine are presented. There were analyzed the preparations for the following characteristics: the country - manufacturer, the firm - manufacturer, the active substance. It is established that the Ukrainian market is formed mainly by imported products. There were identified subgroups that were promising for further comprehensive market study for the purpose of expediency of local anxiolytic drugs.

**Keywords:** Medicines, anxiolytics, selection, diseases of the nervous system, marketing study.

### INTRODUCTION

The tempo of modern life, the rapid development of information technology in various fields of activity, unfavorable social situation have a strong impact on the human nervous system, and his mental health. At present, one of the leading medical and social problems is neurotic disorders.

Neurosis, neurotic disorders are diagnosed more often. According to WHO mental and neurotic disorders are common in all regions of the world, they affect every community and every age group in countries with different income levels. These disorders account for 14% of the global burden of the disease. About 75% of people suffering from these disorders live in low-income countries and do not have access to treatment they need. Neurotic disorders inevitably lead to lowering down of labor activity and work efficiency, promote worsening of quality of life<sup>1</sup>.

The nervous system always reacts to various stresses in man, that's why its dysfunction is the cause of many diseases. Provision of qualitative treatment and rehabilitation of mentally ill has become increasingly important lately and is targeted by government establishments, the media, public organizations and others. In modern medicine, the most common group of drugs used for treatment of neurosis, neurotic disorders are anxiolytics (tranquilizers). The main clinical effects of this group of drugs is to eliminate worry, anxiety and fear; reduce internal stress, aggression, insomnia and other manifestations of neurotic, neurosis-like, psychopathic and psychopathic-like states, autonomic dysfunction, emphasizing the importance of rational pharmacotherapy in these disorders of the human body<sup>2,3</sup>.

In conditions of limited health care financing, it is necessary to use highly efficient, safe and affordable treatment regimens of the nervous disorders with the use

of anxiolytic drugs. In this regard topical study of the domestic pharmaceutical market of anxiolytic drugs becomes exceptionally important. The study aimed at assessment of this group of drugs is also conditioned by relatively high volumes of industrial production of this pharmacotherapeutic group of drugs in the world, which in turn allows us to determine the need to expand the market for domestic pharmaceutical enterprises.

### MATERIALS AND METHODS

During the study there were used methods of information search, comparison and systematic analysis. The objects of the study were: the State Register of Medicinal Products of Ukraine by December 2016, reference book "Compendium 2016" and information retrieval system "Drugs" of LLC "Morion".<sup>4-6</sup>

### ATC classification system

According to the uniform anatomical therapeutic and chemical classification by the system ATC (Anatomical Therapeutic Chemical) there was analyzed a group of drugs belonging to the group N "Drugs to treat diseases of the nervous system" subgroup N05 – Psycholeptic drugs, N05B – anxiolytics<sup>5</sup>.

### RESULTS AND DISCUSSION

#### Epidemiological aspects

The first phase of the study analyzed the epidemiological aspects of nervous disorders in Ukraine and abroad. According to the WHO prognosis some part of life to be lived by people in disability because of mental disorders will be 20% (in 2000 - 12.3%) in 2020 in the European Region<sup>7</sup>. This dynamics is characteristic of Ukraine where a contingent of disability due to mental disorders increased by 32% in 1990 compared to 2003 and amounted to 53.1 cases per 10 thousand of population<sup>8</sup>. In the scientific and educational literature researchers



generally indicate that a priority task of medical science is to preserve the mental health of the nation in all countries.<sup>8</sup> Thus, in 1992 the UN General Assembly adopted resolution №46/119 “Protection of persons with mental illnesses and improvement of mental health care”, according to which medication should fully meet the needs of the patient<sup>9</sup>.

### Morbidity

Accounting system of morbidity that has developed in Ukraine today is mainly based on the study of population references to outpatient institutions. Morbidity indices characterize the level of the primary disease - the number of newly recorded cases (all first discovered cases for the year per 1,000 population of the area) and the second figure - the total morbidity (prevalence) - the number of cases registered over time, the rate for 100 thousand populations<sup>10</sup>.

### Dynamics of morbidity

According to the Guide of Medical Statistics Center of MOH of Ukraine, it is found that the incidence of patients with mental and behavioral disorders is increasing every year, and remains at a high level. For example, in 2015 compared to 2014, the number of newly reported cases of morbidity among patients of working age increased (from 331.7 to 334.0 per 100 thousand of population respectively) in Ukraine<sup>10</sup>, which also confirms the relevance of this study.

### Objects of the study

In order to highlight objects of the study, it was determined that one of the most typical clinical manifestations of neurosis and psycho-emotional disorders within psychosomatic diseases were anxiety disorders. According to the ICD-10 anxious and anxious-phobic states can be classified as psychosomatic neurosis in clinical practice and as separate nosological forms (generalized anxiety disorder, social phobia, panic attacks, etc.). Separately there were marked anxiety and depressive disorders, which were the most common (65%) non-psychotic forms of depression genesis. It is anxiolytics that are the main drug group for the treatment of anxiety - depressive disorders<sup>11,12</sup>.

### The purpose of the study

Therefore, the purpose of this study was to analyze the structure of the domestic market of anxiolytics for the treatment of neurotic disorders and establish the trend of its development.

### Analysis of the registered anxiolytic drugs

According to the State Expert Qualification of Ministry of Health of Ukraine 13 trade names of anxiolytic drugs are recorded in Ukraine by December 2016, without considering the forms of production (Table. 1), of which drugs for INN “Diazepam” are related 3, “Phenazepam” and “Buspirone” - have 2 trade names, others are presented by 1 trade name<sup>4</sup>.

**Table 1:** Analysis of the registered anxiolytic drugs as to INN (by December 2016).

ATC Code	INN	Number of trade names	Relative share, %
N05B A01	Diazepam	3	23,0
N05B A02	Chlordiazepoxide	1	7,7
N05B A04	Oxazepam	1	7,7
N05B A24	Gidazepam	1	7,7
N05B A25	Phenazepam	2	15,4
N05B B01	Hydroxyzine	1	7,7
N05B E01	Buspirone	2	15,4
N05B X03	Etifoxine	1	7,7
N05B X04	Fabomotizole	1	7,7
<b>Total</b>		<b>13</b>	<b>100</b>

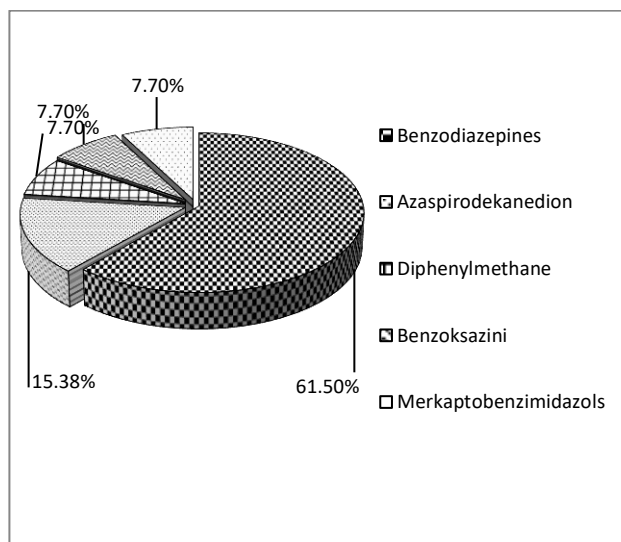
The first place among ATC groups of anxiolytics by the number of registered trade names (TN) takes derivatives of benzodiazepines (N05BA) - 61.5% (Diazepam, Chlordiazepoxide, Oxazepam, Gidazepam, Phenazepam), the second one – derivatives of azaspirodekanedion (N05BE01) (Buspirone) as well as derivatives of groups of diphenylmethane (Hydroxyzine), benzoksazini (Etifoxine), merkaptobenzimidazoli (Fabomotizole) are presented by 1 TN in December 2016 (Fig. 1).

Analysis of the anxiolytic pharmaceutical market has shown that among these 13 drugs 5 were domestic

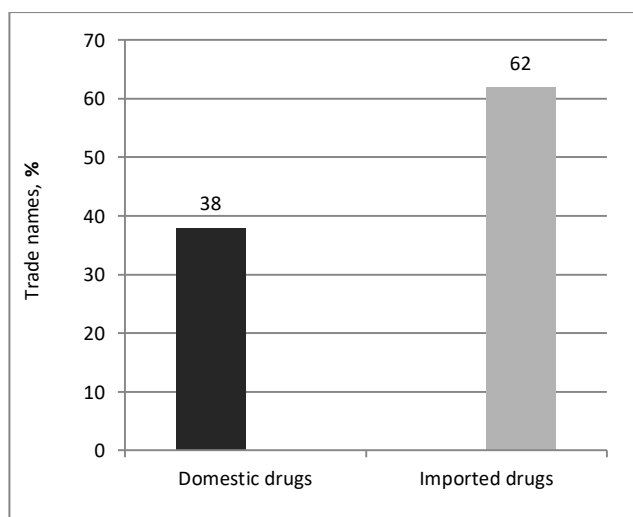
medicinal products (38.5%), other 8 were imported (61.5%) (Fig. 2).

Domestic preparations are produced by 2 enterprises InterChem SLC and “Zdorovye Narody”, LTD. Today the leading manufacturer is InterChem SLC, which produces three drugs that is more than 23% of the market segment, the second place is taken by “Zdorovye Narody”, LTD (15.4%).





**Figure 1:** Distribution of anxiolytic drugs of ATC group N05B by chemical class of compounds



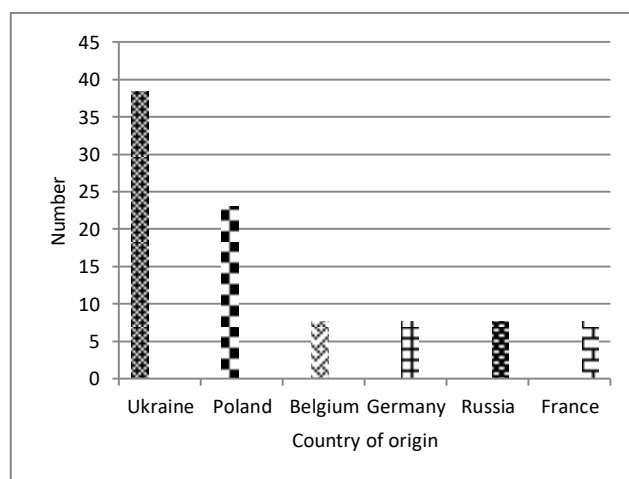
**Figure 2:** Comparative histogram of the domestic market of anxiolytic agents.

Foreign anxiolytic drugs on the pharmaceutical market of Ukraine are represented by 6 countries, including Poland occupying a leading place. The share of supply of these drugs from Poland by Warsaw pharmaceutical plant "Polfa" JSC is 23.1% of the total selection (Fig. 3).

In Ukraine there are also medicines from Hungary (Egis), Belgium (UCB Pharma), Germany (Sandoz), France (Biocodex), Russia (Pharmstandard - Leksredstva), which supply one drug (7,7%).

**Comparative analysis of regulatory lists of the anxiolytic drugs**

Comparative analysis of the selection of studied drugs showed that 9 drugs by INN were most used (Tabl. 2).



**Figure 3:** Comparative histogram of the market of anxiolytic drugs, depending on the country of origin.

**Table 2:** Comparative analysis of regulatory lists of the investigated anxiolytic drugs according to INN

S.No	INN	National list of essential medicines (2016)	The State Formulary of Drugs of Ukraine (2016)	The list of drugs of domestic and foreign production, which can purchase health care institutions of Ukraine for the budget (2016)	The Treatment Protocol «Reaction to severe stress and adjustment disorders Post-traumatic stress disorder» (2015)
1	Diazepam	+	+	+	+
2	Chlordiazepoxide		+	+	+
3	Oxazepam		+	+	+
4	Gidazepam		+	+	+
5	Phenazepam		+	+	+
6	Hydroxyzine		+	+	
7	Buspirone		+	+	+
8	Etifoxine			+	
9	Fabomotizole		+	+	

Only diazepam was included to the National List of Essential medicines (2016). The State Formulary of Drugs of Ukraine (2016) contains 8 of 9 INN drugs<sup>13</sup>.

In general, the “Unified clinical protocols of primary, secondary (specialized) and tertiary (highly specialized) medical aid, response to severe stress and adaptation disorders. Post-traumatic stress disorder”<sup>14</sup> states that benzodiazepines and buspirone can be used.

## CONCLUSIONS

1. The work analyzes the selection of anxiolytics. It is established that the leading position in the domestic market is occupied by imported anxiolytic drugs (over 61%). Poland is among the leading importing countries.

2. The most common anxiolytics in the total range of group N05BA are benzodiazepines, which share is 61, 5%.

3. Comparative analysis of the investigated anxiolytic drugs showed a small number of names of drugs, which required further study to create a reasonable formulary lists for health care institutions to provide efficient, affordable and sustainable use of drugs in limited funding.

4. The results of the market study of the pharmaceutical market has shown the need to create domestic anxiolytic drugs based on innovative substances that protect the vital interests of citizens, society and the state and will ensure drug safety in Ukraine.

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