



ISSN (E): 2277- 7695

ISSN (P): 2349-8242

NAAS Rating: 5.03

TPI 2018; 7(4): 762-766

© 2018 TPI

www.thepharmajournal.com

Received: 06-02-2018

Accepted: 08-03-2018

Tolochko VM

Management and Economics of
Pharmacy Department, National
University of Pharmacy,
Kharkiv, Ukraine

Adonkina VIu

Management and Economics of
Pharmacy Department, National
University of Pharmacy,
Kharkiv, Ukraine

Semchenko KV

Pharmaceutical Technology of
Medicines Department, National
University of Pharmacy,
Kharkiv, Ukraine

Vakulenko DV

Management and Economics of
Pharmacy Department, National
University of Pharmacy,
Kharkiv, Ukraine

Homeopathic medicines in Ukraine: Research of legislative support, range and economic availability

Tolochko VM, Adonkina VIu, Semchenko KV and Vakulenko DV

Abstract

In recent years, in Ukraine, there has been an increase in attention to non-traditional methods of treatment, in particular to homeopathy, which stands out from all known medical systems by its special understanding of the disease and the way of its treatment. Homeopathy offers different approaches to stimulating and normalizing the body's protective forces, affecting the internal processes of self-regulation. For treatment, constitutional drugs that have an effective effect on the innate predisposition to the disease are used, taking into account the individual characteristics of each patient, which is possible only through the use of homeopathic medicines (HoM), including extemporal manufacturing in the conditions of homeopathic pharmacies. Therefore, in order to identify and expand the possible positions of HoM, it is expedient to study the legislative support, the range and economic availability of ready-made HoM in the pharmaceutical market of Ukraine.

In the course of the analysis, it was found that the range consists of HoM of 11 anatomical groups, which are represented in the vast majority with solid medicinal forms of foreign production, the share of which reaches 86%. The results of the analysis of the socioeconomic availability of ready-made HoM showed that virtually all of them are highly accessible to the Ukrainian patient. Only one medicine that has a solvency adequacy ratio of more than 15% and is used to treat a tuberculin constitution is not readily available to the average resident of Ukraine.

Keywords: homeopathic medicine (HoM), solvency adequacy ratio, economic availability, pharmaceutical market, trade name (TN)

1. Introduction

Today, there is a growing focus on non-traditional methods of treatment, in particular homeopathy, which is one of the promising directions of the development of medicine of the 21st century. It has a long history, and is gaining further recognition both in the professional medical environment and among the population of the most countries of the world. According to the WHO, in Australia, Europe and North America, complementary and alternative medicine, one of which is homeopathy, is increasingly used in addition to allopathic medicine. In its practice, HoM are used by about 50% of physicians in India, 40% in the UK, 32% in France, 25% in Germany and 22% in Austria.^[1, 3, 8] Homeopathy is an independent, original look at health and disease, has its own methodology and technology of health correction, which is confirmed by therapeutic methods, long-term clinical observations and toxicological practices. It is relevant an individual approach to the treatment of the disease, taking into account the nature of the disease, as with the use of ready-made HoM and HoM of extemporal preparation in the conditions of specialized pharmacies^[7].

Traditions of homeopathy in Ukraine have more than a century and a half (the first homeopathic pharmacy was opened 167 years ago in Kiev,) and it has now become further developed. So, the list of medicines (M) authorized for use in Ukraine, includes HoM, which are allocated to a separate pharmacotherapeutic group in the "State Register of Medicinal Products"^[4, 7]. In accordance with the Law of Ukraine "On Medicinal Products" (1996), HoM have the legislative status of the medicines and are subject to licensing by the relevant state authorities. Since 1981, within the European Community, a unified registration system for drugs has begun, in which certain changes took place in 1995. Legislative act related to the HoM, was introduced by the European Union in 1992, and the European Pharmacopoeia Commission (EPHC) in 1996. In accordance with the requirements of the European Community (EU Directive 75/318, 92/73 EU, 92/74 EU and Directive 2001/83 of the European Parliament and of the Council of November, 6, 2001 "On the Community code relating to medicinal products for human use"), HoM must meet the same requirements as

Correspondence

Tolochko VM

Management and Economics of
Pharmacy Department, National
University of Pharmacy,
Kharkiv, Ukraine

licensed pharmacotherapeutic agents, however, in relation to the first, there is no requirement to prove effectiveness [2].

Today, in many countries of the world, including Ukraine, sufficient experience of using HoM was accumulated in the treatment of allergic and ENT diseases, skin diseases, cardiovascular system, lung diseases, diseases of the locomotorium apparatus, diseases of the gastrointestinal tract, diseases of the kidneys, prostatitis, adenoma of the prostate, gynecological diseases, thyroid diseases and endocrinopathies, neuroses, depressions, as well as with various diseases of childhood, etc. [4]. But among the representatives of allopathic medicine there are opponents of homeopathy. For example, some European scientists, after the American, Australian and Russian ones, officially separated homeopathy from medicine. However, in Ukraine, homeopathy remains an integral part of health care. In a number of cases, the treatment with HoM is a method of choosing a patient. This is due to the fact that in recent years the problem of side effects is becoming more acute in the use of allopathic medicines [4]. Homeopathy doctors also argue that ready-made HoM should be selected individually, taking into account the nature and characteristics of each patient individually. It is also advisable to rely on HoM for extemporal preparation.

At the same time, there are certain problems with extemporal HoM preparation in Ukraine. To eliminate them, it is necessary to carry out a number of organizational and economic actions [6, 9, 10].

Therefore, attention to the range of ready-made HoM does not decrease. In this regard, we conducted a study on legislative support, the range and economic availability of ready-made HoM in the pharmaceutical market of Ukraine by the beginning of 2018, including for providing recommendations on possible scientific and practical directions of expansion of the HoM nomenclature of extemporal preparation in pharmaceutical conditions.

2. Materials and methods of research

The range of HoM and their socio-economic accessibility were analyzed according to the State Register of Medicinal

Products (<http://www.drlz.com.ua/>). The price was determined by monitoring the HoM offers in pharmacies of different cities of Ukraine. For the analysis of the socio-economic accessibility of HoM, the solvency adequacy ratio (C_{a.s.}) was calculated, which shows the wage share that is spent on the purchase of one package of M and is calculated by the formula: $C_{a.s.} = P/W_{a.w.} \times 100\%$, where C_{a.s.} – solvency adequacy ratio; P – the average weighted price of one package of M for a year; W_{a.w.} – average wage per year. The value of the average wage in Ukraine for the years studied was found on the site: www.ukrstat.gov.ua. All trade names (TN) of HoM were divided into three categories: high availability, value of the solvency adequacy ratio (C_{a.s.}) of which was less than 5%, moderately available (C_{a.s.} more than 5% and less than 15%) and little available (C_{a.s.} more than 15%) [5].

3. Results and its discussion

The current arsenal of ready-made HoM in the pharmaceutical market of Ukraine includes 175 trade names (TN), and, taking into account all dosage forms and doses, - 185 proposals. In the State Register of Medicinal Products, there are registered HoM of 31 manufacturing enterprises, including 7 domestic: "Liktravy" JSC, "National Homeopathic Union" JSC, Biolik PAO, National Homeopathic Union PrAT, Arnika Ltd, Homeopathic Pharmacy Ltd, LLC "Factory of plant medicinal products" Natural medicines " and 24 foreign ones: Bionorica SE, Kehlbeck GmbH & Co. KG, "Biologische Heilmittel Heel GmbH", Deutsche Homoeopathie-Union DHU-Arzneimittel GmbH & Co. KG., Doktor Willmar Schwabe GmbH & Co.KG, Dr. Theiss Naturwaren GmbH, "Deutsche-Homoeopathic Union" (DHU), Dr. Friedrichs GmbH and Co. KG, Hevert Arzneimittel, Cefak KG, «Steigerwald Arzneimittelwerk GmbH» (Germany); Guna (Italy); Leros s.r.o, "Dr. Muller Pharma" (Czech Republic); Richard Bittner AG (Austria); "Jadran" Galenski Laboratorij d. d. (Croatia); Apoteka Ink, Юніфарм, "Unipharm, Inc." (USA); Herbamed AG (Switzerland); Laboratoires Boiron (France); Natur produkt pharma (Poland); "Materia Medica Holding", LLC "Taleon-A" (Russia) (Fig. 1).

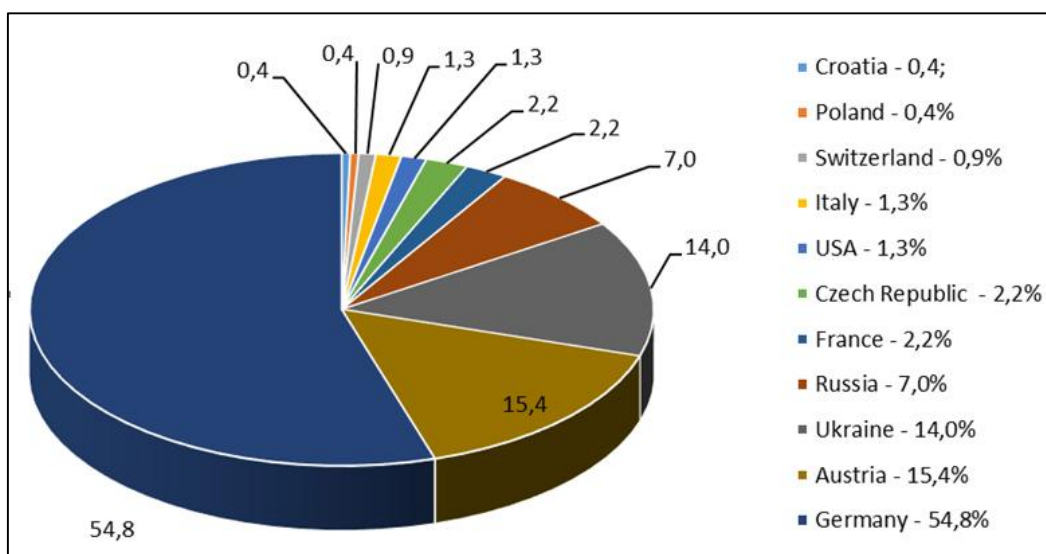


Fig 1: HoM producing countries in the pharmaceutical market of Ukraine

At the beginning of 2018, the main part (86.0%) of the range of ready-made HoM presented on the pharmaceutical market was of foreign origin and only 14% of them were of domestic

production. That is, on the domestic market preparations of foreign production predominate. The direct leaders among manufacturers-suppliers of ready-made HoM to the

pharmaceutical market of Ukraine are well-known firms – "Biologische Heilmittel Heel GmbH" (Germany), Richard Bittner AG (Austria), Deutsche Homoeopathie-Union DHU-

Arzneimittel GmbH & Co. KG. (Germany), etc. Top 10 countries of ready-made HoM are shown in Fig. 2.

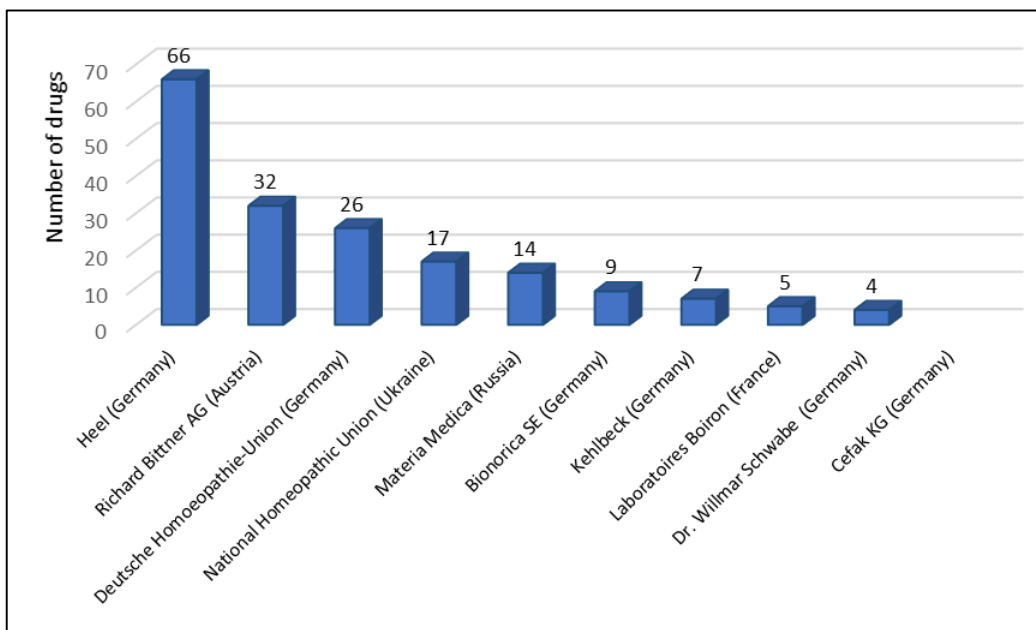


Fig 2: Top 10 countries-producers of ready-made HoM, which medicines are presented in the domestic pharmaceutical market

Ready-made HoM are presented on the pharmaceutical market by the following dosage forms: oral drops, tablets, injection solutions, granules, syrups, species, rectal suppositories, nasal spray, ointments (gels), eye drops, effervescent tablets, etc. (Fig. 3). From Fig. 3 it is evident that liquid and solid forms account the largest share of medicines in the whole range of HOM – each for 48,2%, for semi-solid – 2,7%, for sprays – 0,9%. The largest depth of the range is

characteristic of foreign products, which prevail in the market (86,0%). Ready-made HoM of domestic manufacturers are represented, mainly, by solid forms (granules) and oral drops. Perhaps this is why there is a need to fill the existing niche, which was formed due to the absence of other dosage forms of domestic manufacturers in the market. This may be relevant for further research on the development and production of missing HoM dosage forms.

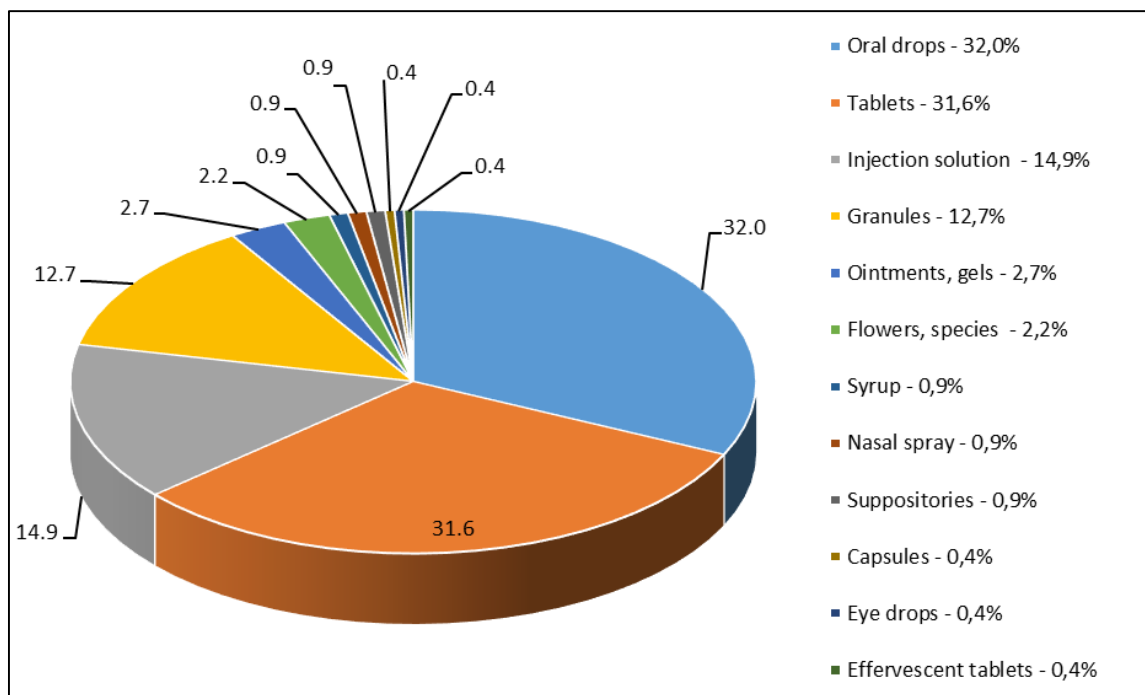


Fig 3: Distribution of ready-made HoM in the domestic pharmaceutical market by dosage forms

As the analysis of ready-made HoM by the ATC-classification showed, they are presented in the pharmaceutical

market of Ukraine with 11 anatomical groups of the first level (Fig. 4).

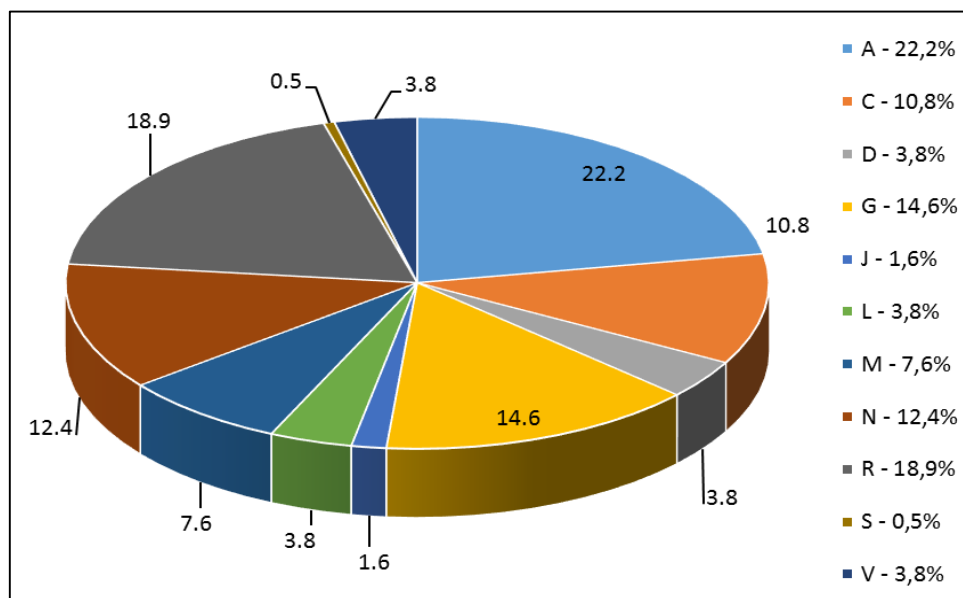


Fig 4: Distribution of ready-made HoM in the domestic pharmaceutical market by anatomical groups

Among them, the largest share is group A – «Alimentary tract and metabolism» – 41 TN (22,2%), namely, its subgroups:

- A03AX – «Other drugs for functional gastrointestinal disorders» (Spascupreel, Gastrokind, Enterokind, Fortacel D5);
- A05BA – «Liver therapy» (Galstena, Ves-Norma, Hepeel, Chole-Gran);
- A16AX – «Various alimentary tract and metabolism products» (Guna-Bowel, Glyoxal compositum, Natrium sulfuricum salt of Dr. Schuessler № 10, Natrium phosphoricum salt of Dr. Schuessler № 9, Natrium chloratum salt of Dr. Schuessler № 8, Restructa pro injectione S, Gastro-Gran, Momordica compositum, Ubichinin compositum etc.).

Group R – «Respiratory system» – 35 TN (18,9%), such subgroups:

- R02A – «Throat preparations» (Tonsilotren, Berberis comp iov-maliuk);
- R05X – «Other cold preparations» (Imupret, Tonsipret, Hevert Pulmo, Viburcol, Umckalor, Aflu Theiss, Antigrippin for childrens, Broncho-Gran, Influcid, Aflubin, Vocara, Oscillococcinum);
- R07AX – «Other respiratory system products» (Gaimorin, Lymphomyosot).

Group G – «Genito-urinary system and sex hormones» – 27 TN (14,6%), such subgroups:

- G02CX – «Other gynecologicals» (Climaxan, Klimakto-Gran, Masto-Gran, Klimakt-Heel, Gynacoheel, Klimaktoplan, Evica);
- G03XA – «Antigonadotropins and similar agents» (Mastodynon, Metro-Adnex-Injeel, Remens, Uro-Gran);
- G04BX – «Other urologicals» (Cefagil, Gentos, Impasa, Enuran);
- G04CX – «Other drugs used in benign prostatic hypertrophy» (Afala, Prostaton, Homvio-Prostan).

Group N – «Nervous system» – 23 TN (12,4%), such subgroups:

- N05CM – «Other hypnotics and sedatives» (Nervoheel, Homvio-Nervin, Dormikind, Son-Norma, Notta, Uspokoi);
- N06DX – «Other anti-dementia drugs» (Memoria);
- N07XX – «Other nervous system drugs» (Cerebrum

compositum H, Sclero-Gran, Tenoten, Tenoten children).
Group C – «Cardiovascular system» – 20 TN (10,8%), such subgroups:

- C01EX – «Other cardiac combination products» (Angio-Injeel, Cralonin, Cardio-Gran, Aurocard, Aesculus compositum, Pumpan, Tonginal, Homviocorin etc.).

It was found that in the pharmaceutical market of 14 first-level anatomical groups, ready-made HoM are represented by only 11 groups. There are no medicines of such groups: B – «Blood and blood forming organs», H – «Systemic hormonal preparations, excluding sex hormones and insulins», P – «Antiparasitic products, insecticides and repellents». Allopathic medicines included in these groups can cause serious adverse reactions to the human body, therefore, it may be expedient in the future to develop and manufacture ready-made or extemporaneous HoM of these groups.

The results of assessing the socioeconomic availability of ready-made HoM, performed on the basis of the solvency adequacy ratio (Ca.s.), are given on Fig. 5.

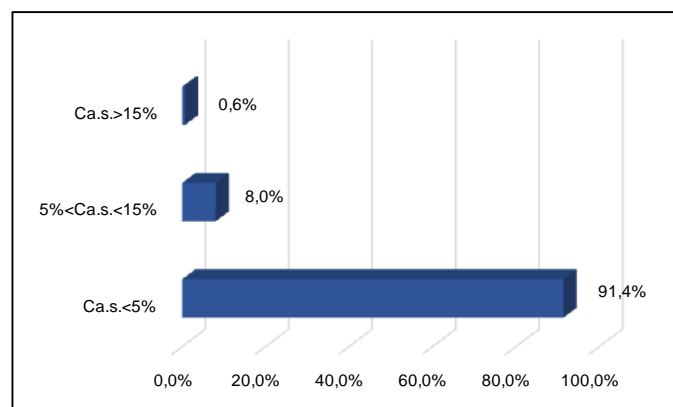


Fig 5: Distribution of ready-made HoM in the domestic pharmaceutical market in terms of solvency adequacy ratio (Ca.s.)

In the course of the analysis, it was found that the most (91.4%) of ready-made HoM, which are registered in Ukraine, have the solvency adequacy ratio (Ca.s. < 5), which confirms their high availability for the average resident of Ukraine.

The group of moderately available included 14 ready-made

HoM (8.0%) from various pharmacotherapeutic groups:

- «Liver therapy» (Hepeel etc.);
- «Various alimentary tract and metabolism products» (Thyreoida compositum etc.);
- «Other cardiac combination products» (Cralonin);
- «Other gynecologicals» (Climakto-Gran);
- «Other urologicals» (Cefagil);
- «Other drugs for disorders of the musculo-skeletal system» (Discus compositum, Zeel T);
- «Other nervous system drugs» (Cerebrum compositum H);
- «All other therapeutic products» (Placenta compositum).

One medicine was allocated among all the others – Nigersan D5 (Kehlbeck, Germany), which belongs to the subgroup L03AX – «Other immunostimulants» and is used for isopathic treatment of a tuberculin constitution and its secondary diseases, which has a solvency adequacy ratio (Ca.s. >15), which characterizes it as a little available medicine for the average resident of Ukraine.

Thus, according to the results of the socio-economic accessibility analysis, it was found that the overwhelming majority of ready-made HoM presented in the pharmaceutical market are available to patients who prefer non-traditional treatments.

4. Conclusion

Ready-made HoM are present in a large number in the pharmaceutical market of Ukraine, and are actively used. Legislative support which regulates the circulation and use of the HoM is also created and is in operation.

1. Thus, the modern arsenal of ready-made HoM includes 185 medicines, taking into account all the proposals. In the pharmaceutical market, they are represented by medicines of both foreign and domestic origin, the share of which is 86% and 14%, respectively.
2. By the dosage forms, ready-made HoM are distributed evenly. The biggest medicines share falls on liquid (48,2%) and solid (48,2%) dosage forms, which make up more than a half of the entire range. Domestic medicines are represented mainly by granules and oral drops. The absence of other forms of ready-made HoM in this segment of the market indicates a niche that can be filled by starting the production of those dosage forms that are not available on the market, which will increase both the physical and economic availability of ready-made HoM of domestic production.
3. According to the ATC classification, ready-made HoM belong to 11 anatomical groups of 14 existing ones. There are no medicines of the following groups: «Blood and blood forming organs», «Systemic hormonal preparations, excluding sex hormones and insulins», «Antiparasitic products, insecticides and repellents». Among all groups, the largest share is Group A - «Alimentary tract and metabolism» - 22,2%. It includes medicines that have different mechanisms of action on the body and cover a variety of diseases that are associated with metabolism and digestive tract.
4. According to the results of the socioeconomic accessibility assessment, it was found that a large share of ready-made HoM (91.4%) are highly available, (8.0%) of medicines are moderately available and only one medicine for the treatment of tuberculin constitution and its secondary diseases (0,6%) is not readily available to the average resident of Ukraine.

References

1. Biloshits'ka IV, Vishnevs'ka LI. Gomeopatichni likars'ki zasobi na rinku Ukraini. Farmatsevt Praktik. 2015; 1:8- Electronic resource: http://nbuv.gov.ua/UJRN/farmpr_2015_1_5. Earch date 30th Marth, 2018.
2. Direktiva 2001/83/ES Evropeiskogo Parlamentu i Radi vid 6 listopada 2001 r. pro printsipi Spivtovaristva (ES) vidnosno likars'kih zasobiv, pokazanih dlya zastosuvannya lyud'mi. Official Journal of the European Communities. 2001; L311:67-119.
3. Demchenko VO, Tkachenko NO, Maiboroda OO. Doslidzhennya vitchiznyanogo farmatsevtichnogo rinku gomeopatichni likars'kih zasobiv. Aktual'ni pitannya farmatsevtichnoi i medichnoi nauki ta praktiki. 2010; 4:20-22.
4. Popovich VP, Gluschenko OM, Kostyuk IA. Suchasni stan farmatsevtichnogo rinku gomeopatichni likars'kih zasobiv Ukraini. Farmatsevtichnii chasopis. 2014; 1:114-118.
5. Tolochko VM, Mischenko OYa, Adonkina VIu. Beta-adrenoblokatori: doslidzhennya asortimentu, sotsial'no-ekonomichnoi dostupnosti ta obsyagiv spozhivannya v Ukraini. ScienceRise. 2015; 4(17):20-26.
6. Tolochko VM, Vakulenko DV, Litovchenko RG. Doslidzhennya napryamkiv pokraschennya zabezpechennya naseleennya gomeopatichnimi likars'kimi zasobami. In: Materiali IV mizhnarodnoi nauk.-prak. konf. Aktual'ni problemi rozvitku galuzevoi ekonomiki ta logistiki; 2015 kvitnya 2-3; Harkiv. Harkiv: NFaU; 2015, 276-277.
7. Tolochko VM, Vakulenko DV. Issledovanie prisutstviya gomeopaticheskih preparatov na farmatsevticheskom rinke Ukraini. Sovremennii nauchnii vestnik. 2013; 34(173):96-104.
8. Shulga LI. Rastitel'nie lekarstvennie sredstva v stomatologii: vzglyad spetsialistov meditsini i farmatsii. Nauchnie vedomosti Belgorodskogo gosudarstvennogo universiteta. Seriya Meditsina. Farmatsiya. 2013; 11(154):97-103.
9. Tolochko VM, Vakulenko DV. Study of problematic aspects of homeopathic medicinal products compounding in the pharmacies. Retsept. 2016; 19(3):309-316.
10. Tolochko VM, Vakulenko DV, Shyshkina IV. The study of extemporaneous compounding of homeopathic medicinal products. Visnik farmatsii. 2015; 1:60-63.