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## THE STUDY OF EXTEMPORANEOUS COMPOUNDING OF HOMEOPATHIC MEDICINAL PRODUCTS

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*Key words: extemporaneous compounding; homeopathic medicinal products; allopathic medicinal products; pharmaceutical formulations*

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*The studies have shown that the manufactured homeopathic medicinal products (MP) existing at the current domestic pharmaceutical market are not appropriate for the individual approach of homeopathic treatment, so the need in their extemporaneous compounding is pressing. One of the ways to solve this problem is expansion of the chain of specialized homeopathic pharmacies and departments on the basis of the existing pharmacies of the general profile. To implement this method, the specificity of the production function of pharmacies (departments), which is based on extemporaneous compounding of homeopathic MP, has been investigated. It has been found that the proportion of extemporaneous compounding of homeopathic MP by means of intrapharmacy products among the total number of extemporaneous compounding of homeopathic MP in specialized pharmacies constitutes 89.79%, and in pharmacies of the general profile (homeopathic department) it is 14.04%. It is important to mention that the proportion of funds for implementation of homeopathic MP in the total cost of medicines sold by pharmacies according to prescriptions of extemporaneous compounding is higher than 50%. It is based on preparation and sale of solid, liquid and soft medicinal dosage forms of 77.16%, 14.37% and 8.74%, respectively; and it proves the expedience of creating such specialized pharmacies (departments).*

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The priority for use of homeopathic treatment is an individual approach to each patient, and it is possible by disposal of homeopathic medicinal products (MP) from pharmacies under prescriptions of homeopaths. The conclusions of the study of availability of homeopathic MP at the domestic pharmaceutical market were given in our previous studies. They indicate that offers of foreign manufacturers are prevailing. However, they do not satisfy completely the need in the individual approach to treatment [6, 11]. When choosing homeopathy as a method of treatment, extemporaneous compounding of homeopathic MP is important and necessary. These medicines are of high quality and available at their price [4, 9]. Therefore, within the current economic climate in the country, it is important to increase extemporaneous compounding of homeopathic MP under the terms of both specialized homeopathic pharmacies and departments on the basis of the existing pharmacies of the general profile, which have material support and are eligible to produce products according to the current license provisions. The practicability of homeopathic MP compounding within the pharmacy conditions has been also confirmed by the results of opinion surveys conducted by us among the population of some regions of Ukraine [6, 11].

The aim of our work was to determine the production process output and its characteristics. This is possible due to the study of extemporaneous compounding of homeopathic MP.

### Materials and Methods

Personal conclusions of the study of specialized homeopathic and allopathic pharmacies producing extemporaneous homeopathic MP in Odessa and Poltava re-

gions were used in the research. More than 650 stopwatch readings were conducted; more than 800 prescription formulations for the period of 2013-2014 were studied. 71.0% of them were formulations for homeopathic MP.

In our study the following research methods were used: historical, comparison, logical, analytical analysis, statistical, interviews, questionnaires, direct supervision, stopwatch study, work time study. The results were processed by computer programmes and presented graphically. Regulatory documents of the Ministry of Public Health of Ukraine concerning the production regulation and drug quality control in pharmacies were used in the studies [1, 2, 3, 4, 5, 7, 8, 10].

### Results and Discussion

Analysis of extemporaneous compounding of homeopathic MP has shown that it is divided into repetitive and individual formulations. Therefore, much attention is paid to production of the intrapharmacy products for repeated formulations in some pharmacies under research. This step makes it possible to reduce time for dispensing a drug by prescription and to reduce the cost of MP per each formulation. However, the possibilities for production of intrapharmacy products in specialized homeopathic pharmacies and pharmacies of the general profile, which prepare homeopathic MP prescribed by homeopaths, are not the same. Therefore, there is a need for the constant study of formulations to determine the repeated ones and for further recommendations to use them in preparing intrapharmacy products. It has been found that this work is organized better in specialized homeopathic pharmacies.

Table 1

## The structure of extemporaneous compounding of homeopathic MP

The sale of homeopathic MP of extemporaneous compounding	Specialized homeopathic pharmacies		Pharmacies of the general profile with the homeopathic department	
	Annual average number of prescriptions			
	Absolute index	%	Absolute index	%
Intrapharmacy products according to the repeated formulations	14352	89.79	1176	14.04
MP produced according to individual prescriptions	1632	10.21	7200	85.96
Total:	15984	100.0	8376	100.0

As shown in Table 1, the proportion of extemporaneous compounding of homeopathic MP due to intrapharmacy products among the total number of extemporaneous prescriptions for homeopathic MP in specialized pharmacies constitutes 89.79%, and in pharmacies of the general profile (homeopathic department) it is only 14.04%.

The abovementioned facts indicate that more attention should be paid to development of specialized homeopathic pharmacies while expanding the pharmacy chain to provide patients with homeopathic MP prepared extemporaneously. It is clear that this approach requires considerable time and money, so development of homeopathic departments in pharmacies of the general profile is also promising. To confirm this information we studied additionally some aspects of extemporaneous prescriptions of homeopathic departments. For this purpose, the analysis of extemporaneous prescriptions received by the homeopathic department of the pharmacy of the general profile within a month was conducted. It has been found that these prescriptions for homeopathic MP are received regularly, their daily number ranges from 1 to 55. Thus, the homeopathic department has a daily load of extemporaneous compounding of homeopathic MP (Fig. 1).

It is important to mention that under these conditions the proportion of funds for dispensing homeopathic MP in the total cost of medicines sold by a pharma-

cy by prescriptions of extemporaneous compounding is higher than 50% and it ranges from 29.0% to 85.0% within a month (Fig. 2). In other words, there is an economic efficiency for specialized homeopathic pharmacies (departments) when introducing extemporaneous compounding of homeopathic MP.

It is known that each medicinal dosage form of extemporaneous compounding has its own production technology; and it is also important for extemporaneous homeopathic MP [4]. Extemporaneous compounding of homeopathic MP is presented by solid, liquid and soft medicinal dosage forms. Therefore, the next step of our study was the comparison of the ratio of different medicinal dosage forms in specialized homeopathic pharmacies and departments in pharmacies of the general profile (Tab. 2).

Table 2 shows that the ratio of different medicinal dosage forms of homeopathic MP in specialized pharmacies and pharmacies of the general profile (homeopathic department) is almost the same. It has been determined that solid medicinal dosage forms prevail – 72.37% and 81.96%, respectively, on average – 74.16%. Rubbing (powders, trituration), granules (globs, diabetes pills) are among them. Globes are the most common.

As for the ratio of liquid medicinal dosage forms in extemporaneous compounding of homeopathic MP, they are 17.54% and 11.19%, respectively, on average – 14.37%. These medicinal dosage forms include formu-

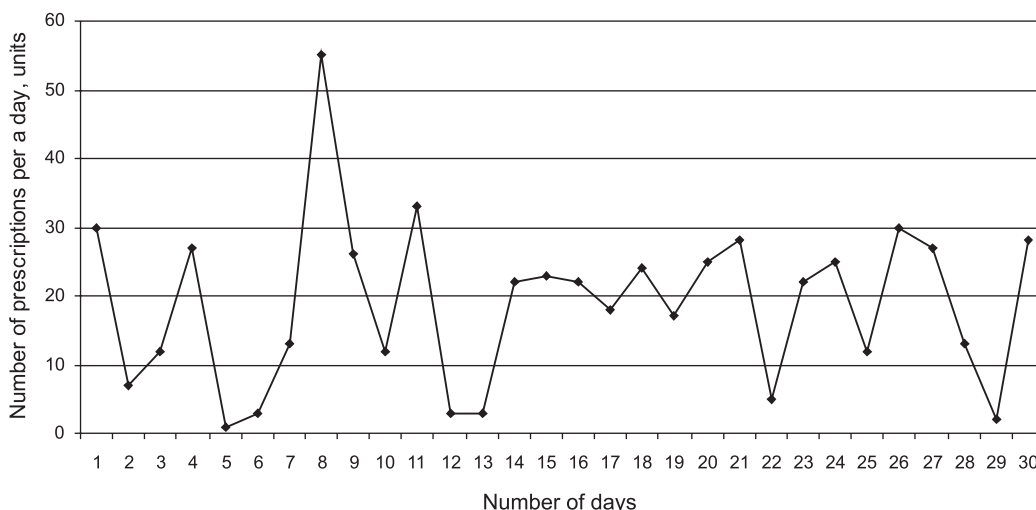


Fig. 1. The average number of prescriptions for extemporaneous compounding of homeopathic MP within a month in the homeopathic department of a pharmacy of the general profile.

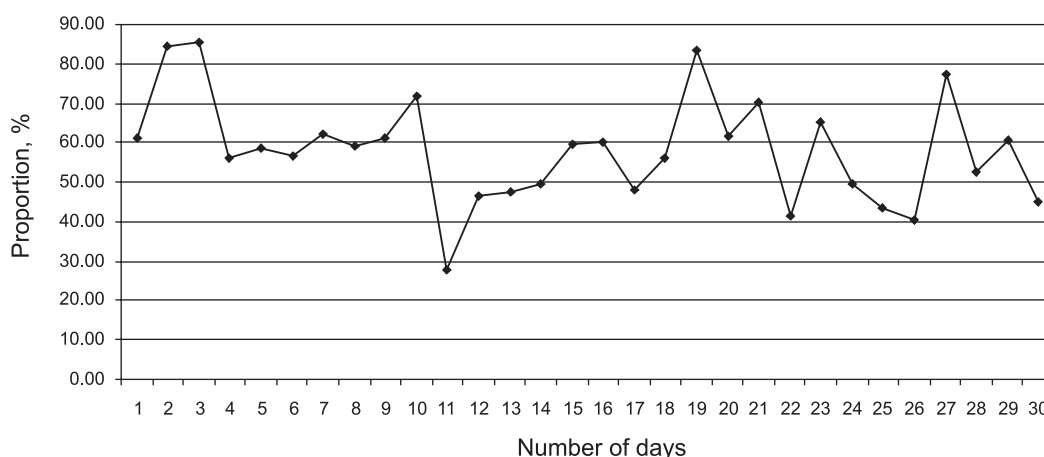


Fig. 2. Proportion of the cost of homeopathic MP of extemporaneous compounding in the total cost of extemporaneous MP sold by a pharmacy of the general profile.

Table 2

The ratio of medicinal dosage forms in extemporaneous compounding of homeopathic MP (%)

Medicinal dosage forms	Specialized homeopathic pharmacy	Pharmacy of the general profile with the homeopathic department	Average
Solid	72.37	81.96	77.16
Liquid	17.54	11.19	14.37
Soft	10.09	6.85	8.47
Total:	100.0	100.0	100.0

lations for internal (mixture, drops) and external (alcohols, oils, liniments) use.

Soft medicinal forms constitute 10.09% and 6.85% in total, on average – 8.47%. It has been determined that ointments (balms, suspension ointments, emulsion creams, combined ointments) and suppositories are among them.

It has been also found that by the complexity (the number of components), extemporaneous compounding of homeopathic MP consists of one-component or three-component formulations in 80% of cases. This is due to the fact that one-component medicines (monodrugs) are received by prescriptions of homeopaths in different dilutions (potencies), they create favourable conditions for individual approach in homeopathy.

#### CONCLUSIONS

1. Extemporaneous compounding of homeopathic MP in the pharmacy conditions is pressing at the current domestic pharmaceutical market. It requires the fur-

ther development by expanding the chain of specialized homeopathic pharmacies and homeopathic departments on the basis of the existing pharmacies of the general profile.

2. The study of extemporaneous compounding of homeopathic MP conducted has allowed to determine its characteristics under the conditions of specialized homeopathic pharmacies (departments). It is associated with the ratio between intrapharmacy products and individual prescriptions, their daily number, the availability of solid, liquid and soft medicinal dosage forms, domination of one-component formulations over three-component ones.

3. The economic efficiency of homeopathic MP of extemporaneous compounding at the pharmaceutical market both for patients (availability) and pharmacies has been proven; it has been confirmed by the proportion of their costs in the total cost of extemporaneous MP of the general profile and it is up to 85.0%.

#### REFERENCES

1. Грошовий Т.А., Марценюк В.П., Кучеренко Л.І. та ін. Математичне планування експерименту при проведенні наукових досліджень у фармації: Підруч. – Тернопіль: ТДМУ, 2008. – 368 с.
2. Закон України «Про лікарські засоби». [Електрон. ресурс]. – Режим доступу: <http://zakon4.rada.gov.ua/laws/show/про%20лікарські%20засоби>.
3. Наказ «Про затвердження Інструкції про порядок контролю якості лікарських засобів під час оптової та роздрібною торгівлі». [Електрон. ресурс]. – Режим доступу: <http://zakon3.rada.gov.ua/laws/show/z0107-02>.
4. Основы гомеопатической фармации: Учеб. для фармац. вузов / Под ред. А.И.Тихонова. – Х.: НФАУ; Золотые страницы, 2002. – 576 с.

5. Пархоменко В.М. Методи вибіркових обстежень: Навч. посіб. – К.: 2001. – 148 с.
6. Толочко В.М., Вакуленко Д.В. // Фармац. журн. – 2014. – №2. – С. 13-19.
7. Code of Federal Regulations Parts 210 and 211: Current good manufacturing practice in manufacturing, processing, packing or holding of drugs; general and current good manufacturing practice for finished pharmaceuticals. Rockville, MD, US Food and Drug Administration, 2006. [Електрон. ресурс]. – Режим доступу: <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm070342.pdf>
8. Hahnemann Laboratories, Inc. [Електрон. ресурс]. – Режим доступу: <http://www.hahnemannlabs.com/preparation.html>
9. <http://www.who.int/medicines/areas/traditional/Homeopathy.pdf>
10. Kayne S.B. Homeopathic Pharmacy: Theory and Practice. – Elsevier Churchill Livingstone, 2006. – P. 386.
11. Safety issues in the preparation of homeopathic medicines. [Електрон. ресурс]. – Режим доступу: <http://www.who.int/medicines/areas/traditional/Homeopathy.pdf>
12. Tolochko V.M., Vakulenko D.V. // Матер. за IX Междунар. научна практ. конф. «Научният потенциал на света – 2013». Т. 15 «Лекарство». София: «БелГРАД – БГ» ООД, 2013. – С. 12-13.

#### **ВИВЧЕННЯ ЕКСТЕМПОРАЛЬНОЇ РЕЦЕПТУРИ ГОМЕОПАТИЧНИХ ЛІКАРСЬКИХ ЗАСОБІВ**

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**Ключові слова:** екстемпоральна рецептура; гомеопатичні лікарські засоби; алопатичні лікарські засоби; лікарські форми

Визначено, що присутні на сучасному вітчизняному фармацевтичному ринку гомеопатичні ЛЗ промислового виробництва повністю не задовольняють індивідуальний підхід гомеопатичного методу лікування, тому потреба в збільшенні їх екстемпорального виробництва є актуальною. Одним із напрямків вирішення цієї проблеми є розширення мережі спеціалізованих гомеопатичних аптек та відділів на базі діючих аптек загального профілю. Для реалізації такого напрямку досліджена специфіка виробничої функції аптек (відділів), яка базується на екстемпоральній рецептурі гомеопатичних ЛЗ. З'ясовано, що питома вага екстемпоральної рецептури гомеопатичних ЛЗ за рахунок внутрішньоаптечних заготовок серед загальної кількості екстемпоральних рецептів на гомеопатичні ЛЗ у спеціалізованих аптеках сягає 89,79%, а в аптеках загального профілю (гомеопатичний відділ) складає 14,04%. Важливо зауважити, що питома вага коштів за реалізацію гомеопатичних ЛЗ в загальній вартості відпущених з аптеки ЛЗ за рецептами екстемпорального виготовлення складає понад 50% і базується на виготовленні й відпуску твердих, рідких і м'яких лікарських форм, відповідно, 77,16%, 14,37% і 8,74%, що обґрунтовує доцільність створення таких спеціалізованих аптек (відділів).

#### **ИЗУЧЕНИЕ ЭКСТЕМПОРАЛЬНОЙ РЕЦЕПТУРЫ ГОМЕОПАТИЧЕСКИХ ЛЕКАРСТВЕННЫХ СРЕДСТВ**

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**Ключевые слова:** экстемпоральная рецептура; гомеопатические лекарственные средства; аллопатические лекарственные средства; лекарственные формы

Исследования показали, что присутствующие на современном отечественном фармацевтическом рынке гомеопатические ЛС промышленного производства в достаточной мере не удовлетворяют индивидуальный подход гомеопатического метода лечения, поэтому потребность в увеличении их экстемпорального производства является актуальной. Одним из направлений решения этой потребности является расширение сети специализированных гомеопатических аптек и отделов на базе действующих аптек общего профиля. Для реализации такого направления исследована специфика производственной функции аптек (отделов), которая базируется на экстемпоральной рецептуре гомеопатических ЛС. Выяснено, что удельный вес экстемпоральной рецептуры гомеопатических ЛС за счет внутриаптечных заготовок среди общего количества экстемпоральных рецептов на гомеопатические ЛС в специализированных аптеках достигает 89,79%, а в аптеках общего профиля (гомеопатический отдел) составляет 14,04%. Важно обратить внимание на то, что удельный вес средств от реализации гомеопатических ЛС в общей стоимости отпущенных из аптеки ЛС по рецептам экстемпорального изготовления составляет более 50% и базируется на изготовлении и отпуске твердых, жидких и мягких лекарственных форм, соответственно, 77,16%, 14,37% и 8,74%, что обосновывает целесообразность создания таких специализированных аптек (отделов).