

Рекомендована д. фармац. наук, проф. Б. Л. Парновським

UDK 615.2: 614.27] –053.2.007.62

EXPERT EVALUATION OF THE NECESSITY OF EXTEMPORANEOUS MEDICINE PRODUCTION FOR CHILDREN

©Yu. V. Kacheray

Lviv National Medical University by Danylo Halytsky

Summary: problematic aspects of extemporal medicines production in Ukraine were overviewed. A practical survey of pharmacists and pharmacy heads was held to evaluate the need of extemporal medicine production in pharmacies. The main reasons are established that affect the reduction in the number of pharmacy extemporaneous manufacturing and identified the essential factors was set.

Key words: extemporaneous medicines for children.

According to WHO requirements the preparations appointed in pediatric practice, can not contain substances that are lowering immunity toxic preservatives or colorants [1]. Only medications which are made in the pharmacy allow to exclude excipients such as preservatives, dyes, stabilizers, flavors, taste improvers et al., which can reveal undesirable properties especially in children. According to the Conception of Pharmaceutical Health Sector of Ukraine for 2011–2020, the rational medicine use is the creation conditions for the use of drugs when patients receive drugs according to their clinical needs in doses that meet their individual requirements [2], which is provided in the conditions of extemporal manufacturing, especially for children.

According to the license registry as for December 1, 2013 the production of medicines is carried by 426 pharmacies, representing about 3% of the total number of pharmacies in Ukraine. During 11 months in 2013 the number of pharmacies that are engaged in manufacturing medicines in pharmacies decreased by 2% [3]. Unfortunately the tendency towards a gradual reduction of pharmacy production is continuing. It is positive that the initiative State Drug Service of Ukraine in January 2015 will be held a National meeting (Kharkiv) for the medicine manufacturing in pharmacies. In this forum will be attended the heads of pharmacies, academics, industry experts, and so on. The purpose of this forum is to preserve the achievements of the medicine production in pharmacies and solve the issue of how to implement European practice in Ukraine [4].

Generalization of positive features and problematic aspects of modern extemporal medicine production in the European context of health care development and ensure to good pharmaceutical care were considered by O.Zalis'ka and B.Parnovskyy et al. [5].

The complex of activities to harmonize the pharmaceutical legislation in Ukraine with international standards, including the implementation of recommendations of Good Pharmacy Practice – GPP and EU requirements for mandatory production of extemporaneous medicines in pharmacies were described by K. Kosyachenko and A. Nemchenko and analysis of organizational and economic problems making extemporaneous preparations was held [6].

The issue of technological aspects of extemporal medicines are studied by prof. O.P.Hudzenko, L.L.Davtyan, T.H.Kalynyuk, A.S.Nemchenko, M.L.Syatynya, T.H.Yarnyh [7–13].

The aim of our study was held an expert evaluation by practical pharmacists expedient is preserving of pharmacy extemporaneous production of medicines.

The reseach methods. The study used methods of content analysis d expert evaluation. A survey practicing pharmacists, the heads of pharmacy which were on postgraduate training in Lviv during 2014.

Results and discussion. We conducted a survey of 149 pharmacists in specialties “General pharmacy” (30.0%) or “Organization and management of pharmacy” (70.0%) to study their opinions about what should be the modern ideal pharmacy.

Most of the surveyed people 78% were employees of private pharmacies, only 22% were from state. 77.8% of employees worked in cities, and 22.2% were in villages. Interestingly, 93.2% were confident that modern pharmacy must produce their own medicines, and only 13.3% of them worked in a pharmacies which have the manufacturing. Experts estimated the number of pharmacies of extemporal production was as follows: 41.3% were sure that is necessary 2–4 following pharmacies in the one area, 39.1% of them more than 5, and

19.6% believed that the need only 1 is enough in the one area.

We offered to pharmacists to express an opinion why it reduces the number of pharmacies of extemporaneous production. Our results are presented on Figure 1.

Pharmacists noted the main factors that don't contribute to the production of medicines, on the pharmaceutical market is rapidly increasing the number of medicines (32.0%) and unfortunately, doctors don't prescribe the recipes for extemporaneous medicines, especially for children (32.0%). Among other

unfavorable factors were noted the low income of extemporaneous medicine dispensing (13.7%), their short expiration date (9.1%), high cost for providing of special equipments in pharmacy and registration of license (9.1%) and the lack of proposals for appropriate substances and auxiliary materials for the medicine manufacturing (4.5%).

The second part of the questionnaire was included the questions to identify the most important factors that according to the expert assessment of pharmacists an extemporaneous production. The results are presented on Figure 2.

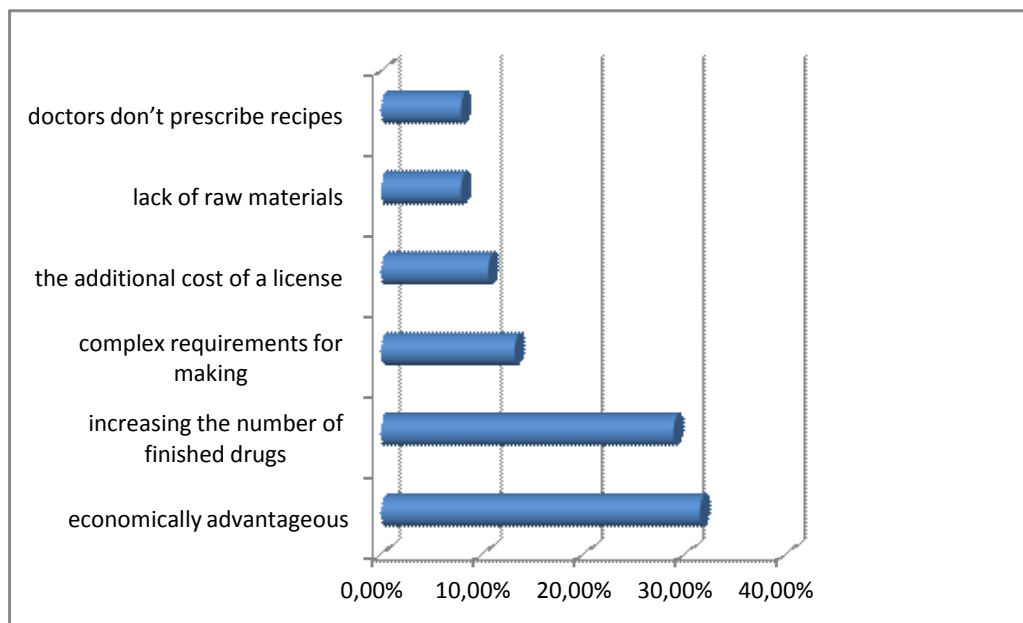


Figure 1. The factors which influence on reduction of the pharmacy number with extemporaneous production

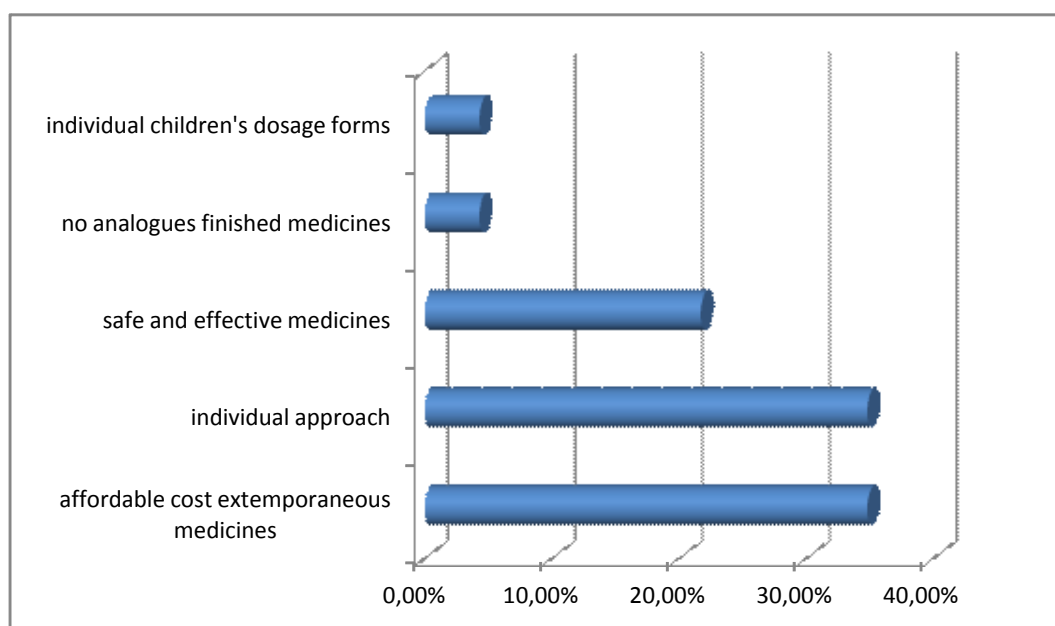


Figure 2. Factors that influence on the medicine extemporaneous production

We surveyed the heads of pharmacy that indicate which must be the ideal pharmacy in nowadays. 70.5% of experts considered that the pharmacy should make medicines, 18.1% of them indicated that a network pharmacy with a wide range of drugs and the possibility of individual approach to each patient. Only 11.4% indicated that the pharmacy must be modern, in the form of market. It should be noted that this opinion had the young professionals with experience less than 10 years.

Another problem is the issue of setting prices for «taxa laborum», that were indicated by pharmacists working in pharmacies with extemporaneous manufacturing. There is no unified approach to the methodology for determining «taxa laborum» in the pharmacies of various dosage forms, as well as payment labor costs of pharmacists engaged in production of medicines for individual prescription specifications.

For comparison, in many countries, the definition of «taxa laborum» in the manufacture of various dosage forms were approved at the state level. So in the Czech Republic despite constant changes in legislation (regulations pricing,

payment) rates are prices, in addition to the individual components prepared in the price of the drug is expressed as «taxa laborum» – the amount that reflects the work in the preparation of individual medicines [15]. In Slovakia, the relevant parameters (taxa laborum) for professional pharmacies are approved by the Ministry of Health [16]. In Poland, the same for all pharmacies the value «taxa laborum» is 2 euros [17]. In Ukraine, the current study is methodological approaches to the definition of «taxa laborum» taking into account the specific characteristics by each regional pharmacy.

Conclusions. 1. A survey of pharmacists and pharmacy heads, on issues of extemporal production of medicines were conducted. The main reasons are established that influence a reducing the number of pharmacy of extemporaneous manufacturing.

2. The analysis showed that in Ukraine there is a need on particular methodical materials concerning the formation of tariffs for «taxa laborum» depending on dosage forms based on the working costs by pharmacists.

Literature

1. [Electronic resource]. – Access: <http://www.who.int>
2. Order of the Ministry of Health of Ukraine I 13.09.2010 r. №769 [electronic resource]. – Access: <http://moz.gov.ua>
3. Extemporaneous production of medicines in Ukraine: Current State and Prospects // [electronic resource]. – Access: <http://www.diklz.gov.ua/control/chv/uk/publish/article/481041;jsessionid=0ADB8C5FA7E4C89D232E53A6B3AEF96>
4. [Electronic resource]. – Access: <http://www.diklz.gov.ua/control/main/uk/publish/article/650236;jsessionid=3FD19759C01BEBDBA038363AD7DE9628>
5. Extemporaneous production of drugs, traditions and problematic aspects / O. Zaliska, B. Parnovskyy, N. Buk, I. Hudzik // [electronic resource]. – Access: <http://www.apteka.ua/article/293675>
6. Kosyachenko K. L. Analysis of modern organizational and economic problems of manufacturing medicines in Pharmacies / K. L. Kosyachenko, A. S. Nemchenko // Management, Economics and Quality Assurance in Pharmacy. – 2011. – № 2. – P. 34–39.
7. The level of modern pediatrics extemporaneous drugs in the regional market / O. P. Hudzenko, O. D. Nemyatyh, I. H. Kozlova, K. V. Kulydyrkayeva // Ukrainian Journal of Clinical and Laboratory Medicine. – 2008. – Vol. 3. – № 3. – P. 9–14.
8. Vlasenko I. O. Production of medicines in pharmacies / I. O. Vlasenko, L. L. Davtyan, R. S. Korytnyuk // Pharmaceutical Courier. – 2012. – № 7–8. – P. 42–43.
9. Bilous S. Methodological approaches to the study of pharmaceutical medicine development of nanoscale ingredients / S. B. Bilous, T. H. Kalynyuk, I. S. Chekman // Clinical Pharmacy, Pharmacotherapy and Medical Standardization. – 2012. – № 1–2 (14–15). – P. 95–101.
10. Bilous S. B. Current Issues pharmaceutical development of soft medicines for external use / S. B. Bilous, T. G. Kalyniuk, N. I. Guz // Pharmaceutical Journal. – 2010. – № 2 – P. 17–27.
11. Nemchenko A. Analysis of the current state of manufacturing drugs in conditions of pharmacies in Ukraine / A. Nemchenko, A. Glushchenko, V. Sobolewsky // Pharmaceutical Journal. – 2006. – № 5. – P. 32–39.
12. Current the market pediatric facilities. Extemporalni medicines for children / M. Syatynya, V. Popovich, A. Gluschenko [et al.] // Zaporizkyy Medical Journal. – 2011. – Vol. 13. – № 5. – P. 130–133.
13. Yarnyh T. H. Development of technology extemporal emulsion chlorophyllipt / T. H. Yarnyh, A. Dankevych // Journal of Pharmacy. – 2011. – № 1. – P. 13–15.
14. [Electronic resource]. – Access: <http://www.pharmencyclopedia.com.ua/article/3160/oplata-praci>
15. [Electronic resource]. – Access: <https://cz.fagron.com/cs/target-group-cs/lekari/cena-iplp-taxa-laborum>
16. [Electronic resource]. – Access: <http://www.health.gov.sk>
17. [Electronic resource]. – Access: http://www.meduniv.lviv.ua/index.php?option=com_content&view=article&id=2381:n2805142&catid=1:latestnews&Itemid=50&lang=uk

ЕКСПЕРТНА ОЦІНКА НЕОБХІДНОСТІ ЕКСТЕМПОРАЛЬНОГО ВИГОТОВЛЕННЯ ЛІКІВ ДЛЯ ДІТЕЙ

Ю. В. Качерай

Львівський національний медичний університет імені Данила Галицького

Резюме: узагальнено проблемні аспекти екстемпорального виготовлення ліків в Україні. Проведено анкетування практичних провізорів та завідувачів аптек щодо оцінки необхідності екстемпорального виготовлення ліків в аптеках. Встановлено основні причини, які впливають на зменшення кількості аптек з екстемпоральним виготовленням та виявлено фактори.

Ключові слова: екстемпоральні ліки для дітей.

ЭКСПЕРТНАЯ ОЦЕНКА НЕОБХОДИМОСТИ ЭКСТЕМПОРАЛЬНОГО ИЗГОТОВЛЕНИЯ ЛЕКАРСТВ ДЛЯ ДЕТЕЙ

Ю. В. Качерай

Львовский национальный медицинский университет имени Данила Галицкого

Резюме: обобщенно проблемные аспекты экстемпорального изготовления лекарств в Украине. Проведено анкетирование практических провизоров и заведующих аптек по оценке необходимости экстемпорального изготовления лекарств в аптеках. Установлены основные причины, которые влияют на уменьшение количества аптек с экстемпоральным изготовлением и выявлены факторы.

Ключевые слова: экстемпоральные лекарства для детей.

Отримано 02.12.14