

Methodical Approach to Carrying out a Multi-Aspect Examination of Pharmaceutical Products

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Abstract—The article presents the developed methodological approach to the technology of conducting a multi-aspect examination of the range of pharmaceutical products. This approach may be of interest for optimizing the prescription of pharmaceutical products by doctors in medical organizations during the pharmacotherapy of patients with various nosologies in the conditions of outpatient and inpatient treatment

Keywords—*pharmaceutical assistance, pharmaceutical products, comprehensive pharmaco-economic research, multidimensional assortment expertise*

I. INTRODUCTION

At present, there are developed traditional approaches to pharmaco-economic research. All of them provide for expert assessment of the assortment of pharmaceutical products by medical specialists [1-3]. Moreover, the main criterion for evaluating the examination is, as a rule, the optimality of the ratio “pharmacotherapeutic effectiveness - price”. During this assessment, the characteristics of drugs related to the so-called pharmaceutical (original / generic, the presence of a child's dosage form, the specifics of pharmacotherapy of a particular nosology, etc.) remain unaccounted for.

During the analysis of literary sources, it was found that doctors often experience difficulties in evaluating pharmaceutical products, in particular, various trade names with one international non-proprietary name, composition of pharmaceutical products, etc., since they do not have pharmaceutical training and cannot track the massive offers of the pharmaceutical product market [4-6]. This situation leads to possible incorrect estimates of pharmaceutical products during the examination of the assortment.

In this regard, the involvement of pharmaceutical specialists in the assortment examination at the preliminary stage with the further formation of information dossiers of data on pharmaceutical products for the subsequent provision of medical specialists during the medical examination procedure is relevant.

At present, joint diseases in children, united in the juvenile arthritis group, have a tendency to threaten growth and disability in the pediatric population, nosology pharmacotherapy is complex using a wide range of drugs,

which makes it expedient to test the above approach on this nosology [7-9].

II. EXPERIMENTAL

The methods used in our research are logical, systemic, structural, graphical, content analysis; economic and mathematical (groupings, ranking, cost); computer engineering.

III. RESULTS AND DISCUSSION

In order to provide an integrated approach to solving problems, a research concept has been developed that includes 2 blocks:

- 1) the development of a methodological approach to conducting multidimensional examination of pharmaceutical products from the standpoint of pharmaceutical characteristics;
- 2) testing the methodological approach on the example of examination of the assortment of pharmaceutical products for the treatment of children with juvenile arthritis (JA).

The technology for conducting a multidimensional examination of the assortment of pharmaceutical products (PhPs) includes four successive stages: pharmaceutical evaluation (examination) of pharmaceutical products from the standpoint of their characteristics with the involvement of highly competent pharmaceutical specialists, expert examination of the pharmaceutical products assortment by Medical Officers, analysis of compliance with consumer preferences, assessment of cost criteria (Fig. 1)

The purpose of the multi-aspect examination of the assortment of pharmaceutical products is a comprehensive examination of pharmaceutical products from the standpoint of pharmaceutical, consumer characteristics, economic and pharmacotherapeutic characteristics.

Conducting a multifaceted examination of the assortment of pharmaceutical products involves the consistent participation of highly competent experts - pharmaceutical and medical specialists.

So, at the first stage, highly competent pharmaceutical specialists implement pharmaceutical expertise of the assortment of pharmaceutical products.

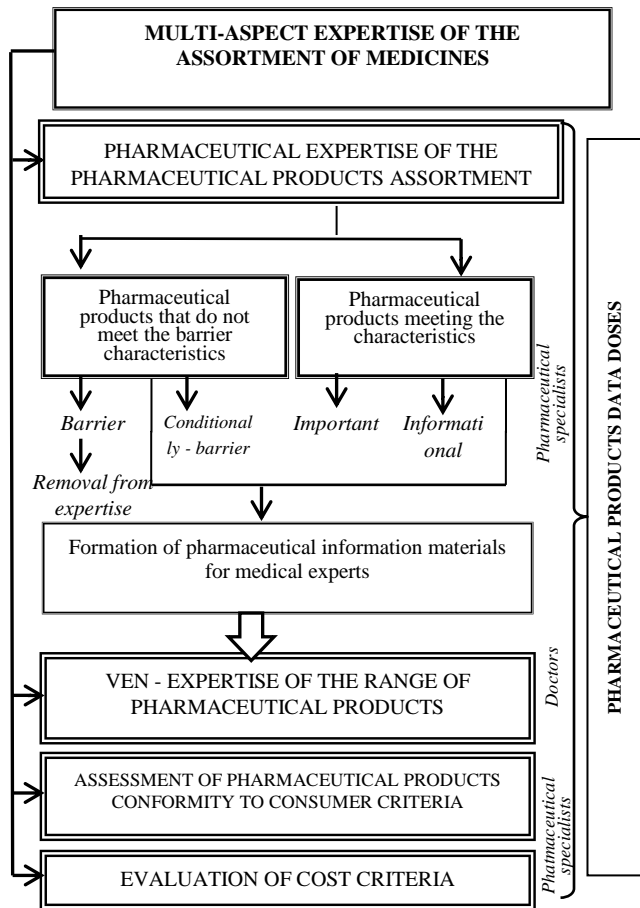


Fig. 1. Stages of multidimensional examination of the pharmaceutical products assortment.

The purpose of the pharmaceutical expertise is to prepare a pharmaceutical dossier for the assortment on the pharmaceutical characteristics of products. The received dossier is handed over to specialist doctors for a more accurate assessment of the assortment of pharmaceutical products at the stage of medical examination.

The technology of pharmaceutical expertise includes the sequential implementation of the following steps: determination of the criteria for pharmaceutical expertise of the assortment of pharmaceutical products for specific conditions of analysis; analysis of the list of characteristics of pharmaceutical products, the rationale for the choice of their use under specific research conditions; identification of the barrier (restrictive) characteristics of the pharmaceutical products; removal from the examination of pharmaceutical products that do not fully meet the criteria; formation of summary analytical information on the characteristics of the medicinal product for the training of medical specialists for the subsequent VEN examination.

In the course of the study, 19 basic characteristics of a pharmaceutical products were formed. 2 analytical characteristics of the pharmaceutical products (“safety” and “pharmacotherapeutic efficacy”) were identified, which are evaluated by the Medical Officer during the VEN examination. For various research tasks, the categories of characteristics of the pharmaceutical products and their

presence in the examination may vary depending on the nosology, age of the patient, etc.

During the examination, the experts analyze the presented list of pharmaceutical products in Pharmaceutical Chemistry, after which a list of pharmaceutical products that most fully satisfy all the characteristics is highlighted, after which analytical information materials with detailed information support are generated, which are transmitted for further medical examination.

At the next stage, highly qualified medical specialists carry out an examination of the assortment of pharmaceutical products in order to segment it according to the optimality of criteria: “pharmacotherapeutic effectiveness” - “price”, to justify the inclusion of pharmaceutical products in restrictive lists and to optimize the pharmacotherapeutic process.

Further, the assortment of pharmaceutical products is analyzed for compliance with consumer preferences of consumers, which implies an assessment of the compliance of the characteristics of pharmaceutical products with consumer criteria identified during a sociological study of consumers of services.

At the final stage, the cost criteria are assessed by comparatively evaluating the cost of the pharmaceutical products and the costs of the treatment.

The technology of multidimensional expertise of the assortment of pharmaceutical products was tested in the course of a comprehensive pharmaco-economic study of medical care for children with JA in the outpatient and inpatient settings of children's medical organizations in the Belgorod Region.

So, at the first stage, in the course of the content analysis of 900 case histories and 86 outpatient records, an informational array of pharmaceutical products was created - 80 and 72 pharmaceutical products for the treatment of JA, respectively, from the point of view of their characteristics. The structure of the assortment and consumption of drugs for the treatment of JA was determined, a detailed intragroup and segmentation analysis of the costs of the treatment was carried out.

For the pharmaceutical expertise, 19 characteristics of the pharmaceutical products were identified, while only 57% are reflected in the “Instructions for Use” (table I).

In the course of the analysis, in particular, it was found that more than 90% of all pharmaceutical products do not have a child dosage and only 30% of them have the possibility of dividing with minimizing the risk to the child's body. Only 6% of drugs have a children's dosage form.

It was revealed that 67% of outpatient pharmaceutical products are prescription products, however, in 8 out of 10 cases, they went to the pharmacy without a documented prescription. According to the results of expertise, about 20% of drugs with restrictions on prescription were removed from the assortment.

Further, analytical information materials have been generated with the pharmaceutical characteristics of the selected assortment presented in detail for the preparation of Medical Officers for the subsequent VEN examination, as

TABLE I. LIST OF CHARACTERISTICS OF DRUGS ANALYZED DURING PHARMACEUTICAL EXPERTISE AND CATEGORY DISTRIBUTION (FOR EXAMPLE, THE ASSORTMENT OF MEDICINES FOR THE TREATMENT OF JUVENILE ARTHRITIS IN OUTPATIENT AND INPATIENT CONDITIONS)

№	Feature Name	Category characteristics of the pharmaceutical products depending on the conditions of medical care		Information from the manual
		<i>Inpatient conditions</i>	<i>Outpatient conditions</i>	
1	Международное непатентованное наименование (МНН) препарата	Important	Informational	Yes
2	Trade name (TN) of the drug	Informational	Important	Yes
3	Age restrictions	Barrier	Barrier	Yes
4	Type of dosage form	Important	Important	Yes
5	Pharmaceutical product composition	Informational	Informational	Yes
6	Drug manufacturer: domestic / foreign	Important	Informational	Yes
7	Belonging to the Vital and Essential Drugs list	Important	Informational	No
8	Presence of a children's dosage of a Pharmaceutical product/ minimizing the risk of Pharmaceutical product division	Informational	Important	No
9	The presence of a children's dosage form of Pharmaceutical product	Informational	Important	Yes
10	Treatment duration	Important	Important	Yes
11	Features of Pharmaceutical product storage	Informational	Важная	Yes
12	Reference listed drug / generic	Informational	Informational	No
13	Pharmaceutical product going along with the main one	Informational	Informational	No
14	Peculiarities of the contact	Informational	Important	Yes (supplements the instructions)
15	Legal classification	Informational	Important	Yes
16	The amount of the pharmaceutical product per course of treatment	Important	Important	No
17	Multiplicity of reception (the presence of prolonged forms)	Important	Important	No
18	Safety of the pharmaceutical product	Barrier	Barrier	The doctor evaluates during the VEN examination
19	Pharmacotherapeutic efficacy	Barrier	Barrier	

well as for the segmentation of the pharmaceutical products assortment under study for the treatment of JA according to the degree of clinical significance, economic feasibility and compliance with consumer criteria.

IV. CONCLUSION

1. For the first time, a technology has been proposed for conducting a multidimensional expertise of the assortment of pharmaceutical products, which is implemented with the involvement of pharmaceutical and medical specialists, which includes: pharmaceutical products evaluation from the position of optimal characteristics expertise of the assortment by medical specialists; Consumer Expectation Analysis; assessment of cost criteria;

2) The methodological approach was tested on the example of optimizing drug care for children with JA in the outpatient and inpatient settings of children's medical organizations of the Belgorod Region;

3) Information portfolios on the pharmaceutical characteristics of the pharmaceutical products assortment have been developed to prepare Medical Officers for the subsequent VEN - assortment expertise.

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