The Toolkit for Effective Application of Drug Evaluation in RA and Ways of Its Improvement

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Դեղերի գնահատման արդյունավետ կիրառման գործիքակազմը ՀՀ-ում և նրա կատարելագործման ուղիները

Պապոյան Տաճատ Ա.
Ասպիրանտ, Վիճակագրության ամբիոն, ինֆորմատիկայի և վիճակագրության ֆակուլտետ Հայաստանի պետական տնտեսագիտական համալսարան (Երևան, ՀՀ)

Ամփոփագիր. Ուսումնասիրության առարկա է դարձել ՀՀ-ում դեղերի գնահատման արդյունավետ կիրառման գործիքակազմը և նրա կատարելագործման ուղիները:
ԽՍՀՄ-ի փլուզումից հետո ԱՊՀ երկրներում դեղագործական տնտեսության տարերային ձևավորումը համապատասխան օրենսդրական դաշտի և փորձի բացակայության պայմաններում, առաջ քաշեց բազմաթիվ հիմնախնդիրներ (տեղական և ներկրվող դեղերի որակի ապահովումը, դեղատների անհավասարաչափ բաշխումը, բնակչության դեղորայքային ապահովումը, անհսկելի ինքնաբուժումը և այլն), որոնք առ այսօր մանրակրկիտ ուսումնասիրության և գիտականորեն հիմնավորված լուծումների կարիք ունեն: Այս տեսանկյունից մեր կողմից ընտրված թեման արդիական է և կարևոր նշանակություն ունի: Անկախություն ձեռք բերելուց հետո Հայաստանի հանրապետությունում ձևավորվեց նոր տնտեսություն իր այնպիսի հատկանիշներով, որոնք բացակայում էին խորհրդային տարիներին (դեղատների սեփականաշնորհում, մրցակցություն, տեղական արտադրողների և մատակարարների թվի աճ, փոփոխություններ օրենսդրական դաշտում, շուկայական հարաբերություններ և այլն): Ժամանակը թելադրում էր ունենալ միջազգային պահանջներին և չափանիշներին բավարարող դեղագործական կազմակերպություններ, արտադրողներ և մատակարարներ:
Դեղը, առանց որի դժվար է պատկերացնել ժամանակակից բժշկական օգնությունը, առանձնահատուկ ապրանք է. Դեղի արտադրության, տեղափոխման, պահպանման և նույնիսկ ոչնչացման համար պահանջվում են հատուկ պայմաններ:
Հանգուցաբառեր և բառակապակցություններ՝ դեղ, գնահատում, կիրառում, արդյունավետություն, կատարելագործում, ուղի

Инструментарий для эффективного применения оценки лекарственных средств в РА и пути его совершенствования

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Аннотация. Предметом исследования стал инструментарий эффективного использования лекарственной оценки в РА и пути его совершенствования.
После распада СССР элементарное формирование фармацевтической экономики в странах СНГ, в условиях отсутствия соответствующей правовой базы и опыта, поставило множество вопросов (обеспечение качества отечественных и импортных лекарств, неравномерное распределение аптек, лекарственное обеспечение населения, непонятное самолечение и др.), которые до сих пор тщательно изучаются и нуждаются в научно обоснованных решениях. С этой точки зрения выбранная нами тема актуальна и важна в Республике Армения. Сформировалась новая экономика со своими особенностями, отсутствовавшими в советские годы (приватизация аптек, конкуренция, увеличение числа местных производителей и поставщиков, изменение правового поля, рыночных отношений и т.д.). Время диктовало наличие фармацевтических организаций, производители и поставщики, соответствующие международным требованиям и стандартам.
Препарат, без которого сложно представить современную медицинскую помощь – это особенный продукт. Для производства, транспортировки, хранения и даже уничтожения препарата необходимы особые условия.

Introduction. The beginning of 2014 was marked by the introduction of the long-awaited requirement for mandatory compliance with the rules of drug production and quality control, which is an important step in ensuring the high quality, safety and effectiveness of the drugs used. Good manufacturing practice is understood as part of a quality assurance system that aims to ensure the uniform production and control of medicinal products in accordance with quality standards appropriate for the intended use of these medicinal products.

The purpose of good manufacturing practice is to ensure a consistent manufacturing process and control, which makes it possible to obtain drug substances, finished products, intermediates, excipients and other materials used in the manufacture of drugs that meet certain standards. Standards are a derivative of any process that leads to the creation of such standards, that is, they are secondary. Standards are defined during the development of pharmaceutical products by conducting pharmaceutical, preclinical and clinical research, within which the optimal quality indicators of the pharmaceutical substance and finished product are selected, ensuring the maximum safety and effectiveness of the drug. Some standards are purely pharmaceutical, such as sterilization regulations, but validation of these standards is also based on testing methods in living systems, including humans. The purpose of good manufacturing practice is to develop and comply with rules that allow the production of medicines of a given quality, with their continuous improvement, taking into account scientific and technological progress.

Normative-legal base – the normative-legal base regulating the proper production process includes legal and scientific aspects.

Legal requirements – all aspects that in one way or another affect the production of medicines are regulated in detail at the highest legislative level.

This is appropriate because the lives and well-being of millions of people depend on the quality, safety and effectiveness of medicines.

Literature Review. The existence of an unambiguous and understandable legal formulation of the requirements for compliance with scientific principles and good manufacturing practice guidelines eliminates many questions that so often arise in the domestic sphere of drug circulation due to insufficient legal regulation of the actions of certain legal entities. At the same time, it is obvious that currently there is a positive trend in the regulation of this sector.

The manufacturer is obliged to cooperate exclusively with suppliers and contractors who work in accordance with the principles and rules of good manufacturing practice (such manufacturers and contractors must be included in a special register of the authorized body). An institute of qualified (individuals) is introduced, who bear legal (even criminal) responsibility for the quality of manufactured and imported goods and compliance with registration conditions. Since the experience and skills of such people play a decisive role in quality assurance, strict legal requirements are set for their qualification.

The fulfillment of duties by a qualified person is regulated not only by labor relations with the employer (producer), they are also subject to administrative regulation by the authorized body. In addition, the authorized body is endowed with sufficiently large rights (including the right to impose sanctions), which allows monitoring compliance by manufacturers with all legal requirements, which ensures reliable protection of public health.

The scientific basis of the principles and rules of good manufacturing practice is a set of guidelines, as well as their annexes, which regulate in detail all the technical and documentation requirements for the production of drugs intended for medical use. These guidelines, while containing scientific requirements, are legally binding. An important feature of the legislation regulating the scientific and technical spheres of economic activity, including the circulation of drugs, is the legal recognition of the need to update scientific and technical requirements in accordance with the current achievements of scientific and technological progress. Such a system allows us to respond in time to the challenges of our rapidly changing world [**5**, pp. 803-806].

No country in the world, for various reasons, can fully provide itself with all the medicines necessary to meet the health needs. In this regard, each country must cooperate with other subjects of international law to obtain the necessary starting materials, raw materials, intermediate products, auxiliary materials, pharmaceutical substances or finished products. One of the conditions for complying with the principles and rules of good manufacturing practice is the regular (at least every 3 years) inspections by the authorized body of the country. At the same time, it is obvious that no

organization is able to cope with such a number of objects that are subject to inspection.

In this regard, abroad, including in the EU, the practice of mutual recognition of the conformity of production by one country to another country's principles and guidelines of good manufacturing practices has been developed. Thus, the regulatory framework for pharmaceuticals in other countries is evaluated and the existing controls and enforcement measures ensure a level of public health protection.

The evaluation is expressed by a review of relevant documents and includes a review of the regulatory system of that country and, if necessary, pilot inspections at one or more sites of production of pharmaceutical substances in that country.

During the assessment, special attention is paid to:

- the production experience of the country,
- the regularity of inspections to verify compliance with good manufacturing practice,
- the effectiveness of enforcement measures in accordance with good manufacturing practices,
- providing information about the offending manufacturers of pharmaceutical substances [**4**, pp. 278-281].

Research Methodology. The selection of research methods is a rather complex process. When choosing research methods for the work we do, we make decisions based on expediency. The methods studied by us are the set of cognitive methods and methods used to reveal the nature and internal patterns of the system.

System analysis is a method of scientific cognition, which is a sequence of actions aimed at discovering structural connections between the variables or elements of the investigated system. It is based on metascientific, experimental, natural scientific, statistical, mathematical methods.

Applying this method, we were able to get more detailed information about the importance and role of the toolkit for effective use of drug evaluation in RA and ways to improve it. And it became clear to us that it is extremely important.

Deduction is one of the types of reasoning, in a broad sense, one of the methods of research. It has traditionally been defined, and is sometimes defined today, as reasoning by which a particular conclusion is made from general premises, and in that sense it is opposed to induction. But this definition needs to be adjusted, because some types of reasoning considered unconditionally deductive do not have such a feature. Therefore, deduction is currently more often understood as an analytical consideration, where the conclusion is obtained only as a disclosure-separation of the information not implicitly contained in the premises.

Due to this, the conclusion in deduction is always reliable (if the premises are reliable). Deduction, understood in this way, is fundamentally opposed to considerations that give only a probable conclusion (incomplete induction, analogy, etc., and full induction is considered as deduction). The theory of deduction is the main content of logic, sometimes it is even identified with formal logic in general. Based on the fact that deduction as a method of research does not give "something new", some logicians considered it an incomplete way of weighing, of no special importance for science, and according to them, only induction gives true knowledge.

Others, on the other hand, have favored deduction, finding that it gives a necessarily true conclusion and is "true in all possible worlds", while induction (incompletely) gives only a probabilistic or contingently true conclusion.

Thus, revealing the nature of human needs, their specific manifestations are considered from the point of view of individual social groups or individual individuals. It turns out that spiritual demands prevail for believers or intellectuals, unlike other social groups.

The method of induction is applicable to the cognition of any phenomenon. All results have a price. Through the mentioned method, it is found out what is common in terms of the price of all results, or how the price is formed. As a result, the essence of the concept of price is clarified.

Through this method, we were able to come to general conclusions in the study results and make recommendations to improve the situations through them.

The phenomenon studied through the method of synthesis is considered in the internal relationship or unity of its various components, already known properties, which makes it possible to recognize the essence of the phenomenon as a whole. From this point of view, the application of the synthesis method contains a complex combination of mutual influences.

Through the method of synthesis, the study of the mutual influence of individual components makes it possible to reveal the behavior of the phenomenon. If any of these components changes, it immediately affects the overall behavior. The general feature of the phenomenon, in turn, affects the behavior of individual components by the principle of inverse relationship.

Through the methods of analysis and synthesis, the regularities of any system are revealed. After that, various institutions of society are considered in mutual influence and unity, as a result of which it is possible to study their nature, which is presented in different characteristics.

Through the method of analysis, any phenomenon is a set of different components. For example, society as a whole consists of different social groups, political and state institutions, educational and scientific centers, different areas of production, etc.

During recognition, they are studied separately, the role and functions of each in public life are revealed. When studying the properties of any substance, it is divided into parts, and the properties of each of them are revealed. This way of knowing is called the method of analysis. In addition to the analysis, the synthesis method allows you to get an idea of the connections between the components of the object under study.

Through these methods, we were able to study different points of view, as well as international experience, and consolidate and synthesize common information, which we were able to effectively apply in our work.

Analysis. The modern global trends in drug supply optimization and regulation are aimed at the global harmonization of drug quality assurance requirements at all stages of drug circulation, which is significantly hindered by many problems, especially in newly independent countries. Along with the vital problems of the pharmaceutical sector, such as the imperfection of the legislative regulation of drug circulation, the low economic availability of drugs, the insufficient control of drug circulation, the presence of unregistered, falsified, low-quality drugs on the market, the quality assurance of drugs at all stages of drug circulation is also a serious problem in Armenia today. Proper fulfillment of requirements. Only one component of drug quality assurance in the pharmaceutical market, even in the most perfect state, cannot be sufficient for the constant assurance of drug safety, efficacy and quality, even in the event that all components are subject to regular monitoring and adherence to the rules of good manufacturing practice in pharmaceutical factories [**1**, pp. 25-31].

In the modern medical and pharmaceutical world, effective drug evaluation plays a key role in ensuring the safety and efficacy of treatment. A proper assessment allows doctors to make informed decisions and patients to receive the treatment that is truly right for them. Drug evaluation tools are constantly evolving, and it is important to understand their features as well as ways to improve them.

Currently, the pharmaceutical market includes about 70% generic drugs. Most of these drugs are essential. Some of them have a negative risk/benefit ratio. The variety of drugs, the complexity of their safe and effective use, as well as the differences in their relative cost significantly complicate the orientation of the health care system worker, and the need arises for the health care system to have drug use procedures that will promote rational, evidence-based, clinically relevant, safe, and cost-effective to effective drug therapy.

On the other hand, the absence of well-founded and defined Cus leads to the fact that the prescribing and administration of drugs is chaotic and often irrational, which further complicates the situation. In such circumstances, an important tool for achieving a balance between health care needs and budgetary costs is the formulary system, which allows meeting the minimum needs of the health care system.

The formulary system is an ongoing process that includes:

- the selection of the most effective, safe and cost-effective drugs from the drugs available on the pharmaceutical market,
- development and distribution of reliable and objective information about these drugs,
- consultation of the staff of the preventive medical institution and its quality improvement,
- following the correct use of drugs,
- Application of measures to prevent and correct medication errors.

Hospitals and health systems have used formularies since the 1940s. Later, formularies evolved from simple drug lists to complex systems that can ensure safe, effective, and cost-effective drug administration.

The following criteria are used to include drugs in the formulary list:

- existence of a justified demand for the drug,
- efficiency, safety, quality,
- comparative cost-effectiveness,
- financial availability,
- availability of financial resources.

Accordingly, the use of drugs included in the formulary list ensures effective, safe, affordable and appropriate drug treatment of a specific disease, because the formulary limits the number of drugs used in medical practice to only those drugs that comply with the principles of evidence-based medicine.

The form system provides an opportunity to solve the following problems:

- lack of funds for the purchase of medicines,
- continuous expansion of pharmaceutical alternatives,
- incorrect prescription and use of drugs,
- lack of objective and reliable information about drugs,
- high costs of drugs and excess stocks caused by unjustified purchases,
- availability of drugs of questionable quality on the pharmaceutical market.

Effective functioning of the formulary system as a whole is a true measure of implementation of the concept of effective drug use.

The formulary system is developed individually for preventive health facilities that have money to buy drugs.

Based on the formulary system, regional pharmaceutical formularies are drawn up, and based on them, the national pharmaceutical formulary (pharmacy) is drawn up [**2**, pp. 18-21].

Key Components of a Drug Evaluation Toolkit

Clinical trials

Clinical trials are the basis for evaluating the effectiveness and safety of drugs. They include several stages.

Phase I: Safety evaluation in a small group of healthy volunteers.

Phase II: Evaluation of efficacy and side effects in a cohort of patients.

Phase III: A large trial in a large group of patients to definitively assess efficacy and monitor side effects.

Phase IV: Post-marketing surveillance of medicines to detect rare side effects and long-term effects.

Regulatory documents and standards: The main organizations that regulate the use of medicines provide standards and guidelines that include requirements for the evidence base, safety, efficacy and quality of medicines.

Cost and economic efficiency assessment systems: Economic evaluation includes an analysis of the costs and benefits of drug use. This helps to make decisions about the appropriateness of introducing new drugs into the health system. Evaluation methods include cost-impact analysis, cost-benefit analysis, and cost-utility analysis.

Post-marketing surveillance data and pharmacovigilance: Pharmacovigilance involves collecting data on side effects and other problems that emerge after a drug enters the market. This helps to quickly identify and eliminate potential risks to patients.

Clinical guidelines and recommendations: Clinical guidelines provide physicians with information about best practices in the use of drugs for various diseases.

Ways to improve drug assessment tools

Enhancing data integration: Integrating data from different sources, such as clinical trials, pharmacologic controls, and observational studies, allows for a more complete picture of a drug. The development of electronic medical records and databases aid in data collection and analysis.

Development of new technologies: Modern technologies can significantly improve data analysis and prediction of side effects.

These technologies can help more accurately predict the effectiveness and safety of drugs and personalize treatment.

Improvement of economic evaluation methods: Cost-benefit evaluation methods should consider not only direct costs, but also indirect effects, such as improved quality of life for patients. Developing more accurate cost-effectiveness assessment models will help allocate resources more efficiently.

Increasing data transparency and accessibility: Availability of clinical trial and post-marketing surveillance data to the medical community facilitates more informed decision-making. Transparency of reporting and access to complete research results help build trust in medicines.

Improving regulatory processes: Regulatory bodies must adapt to the rapidly changing environment of the pharmaceutical industry. Flexibility in regulatory processes and the willingness to adapt more quickly to new data and technologies will help speed up the process of evaluating and introducing new drugs.

Effective drug evaluation requires the use of multifaceted tools and continuous refinement of approaches. Clinical trials, regulatory standards, economic evaluation, and post-marketing surveillance form the basis of drug evaluation, but innovation and improvement in these areas are needed to achieve the best results. Integrating new technologies, improving assessment methods and increasing transparency will help ensure safe and effective treatment [**3**, pp. 77-78].

Conclusions. Thus, health is one of the fundamental human rights, which is necessary for the realization of many other rights, in particular, development and living a decent life.

Realization of the right to health is the primary goal of state policy. Access to medicines is a critical element of the right to health. One of the main challenges of the government of each country is to provide the population with guaranteed quality and adequate quantity of medicines on a regular basis, as well as conducting a reasonable price policy. The problem of poor access to medicines is most acute in low- and middle-income countries, and the full enjoyment of the right to health remains an illusion for millions today, as there are many barriers to the availability and access to good quality and affordable medicines. In terms of human rights, access to medicines is fundamentally linked to the principles of equality and non-discrimination, transparency, participation and accountability.

Each country is responsible for developing national health legislation, policies and strengthening the relevant system. To this end, key issues related to access to medicines, such as price and quality control, dosage and efficacy, procurement practices and procedures, supply chains, etc., should be considered.

Observing the conformity of the proper production activities of the production of drugs and pharmaceuticals in the Republic of Armenia is a process of assessing the compliance of the GMP rules in the area of drug production in order to ensure the quality of the drugs circulating in the Republic of Armenia, which also includes the evaluation of the activities of the quality control laboratory.

The issue of implementing proper production activities throughout the circulation of drugs is very topical, because the solution to this problem provides the population with quality, effective and safe drugs on the one hand, and on the other hand, in the conditions of high competition, promotes the growth of the turnover of pharmaceutical organizations (manufacturers and suppliers). In many countries of the world, in order to ensure the quality of drugs, the rules of proper production activity have been introduced, which are important for the regulation of the circulation of drugs, particularly the activities of pharmaceutical companies, by the regulatory bodies of those countries.

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