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Content analysis of the nomenclature of drug antibiotics of the cefalosporin range of the pharmaceutical market of the Republic of Uzbekistan

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Abstract

The article provides a review of literature data, a comparative analysis of standardized quality indicators of some drugs of the cephalosporin series and the results of content analysis of the nomenclature of cephalosporin series.The results of the study indicate a wide variety of assortment and reproducible drugs, high renewability of the nomenclature and market dependence on foreign manufacturers.

Keywords: Standardization, cephalosporin's, antibiotics, cephalosporin's, pharmacopoeialarticle, content analysis, registry, nomenclature, quality indicators.

INTRODUCTION

The article provides a review of literature data, a comparative analysis of standardized quality indicators of some cephalosporin drugs and the results of a content analysis of the nomenclature of cephalosporin drugs. The results of the study indicate a wide variety of assortment and reproducible drugs, high updatability of the nomenclature and market dependence on foreign manufacturers.

According to a new report published by Grand View Research, the global antibiotic market in 2018 was estimated at $ 45.31 billion, and is projected to grow by an average of 4.0% over the forecast period. Growth in cases of infectious diseases along with an imbalance in the supply and demand of antibiotics is the main factor stimulating the growth of this market.

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In a report by Allied Market Research, the global cephalosporin market was estimated at $ 27.764 million. According to their forecast, global demand for cephalosporin antibiotics will increase by an average of 14.7% by 2023 and reach 79 billion 920 million US dollars. During the forecast period, fifth-generation cephalosporins are expected to have the highest CAGR of 7.6%.

An increase in the number of people suffering from infectious diseases worldwide is a major driver of market growth. According to WHO estimates for 2016, about a million sexually transmitted infections (STIs) are acquired daily in the world, which is more than 340 million new cases of sexually transmitted diseases and protozoal infections per year. In addition, a 2016 research article states that urinary tract infections (UTIs) are one of the most common bacterial infections that affect nearly 150 million people a year worldwide. Thus, an increase in the prevalence of various bacterial diseases increases the base of cephalosporin consumers, which, in turn, should complement the growth of the cephalosporin market.

The priority direction of state policy in the field of healthcare is currently ensuring the rights of people to

protect their health and receive a guaranteed amount of quality medical and medicinal care.

Antibacterial agents are one of the most widely used groups of drugs for the treatment of infectious diseases, and they occupy second place in the world in terms of sales [1]. Among them, antibiotics account for a significant proportion.

The list of three vital groups (cephalosporins, penicillins and fluoroquinolones) of the highest priority antibiotics included cephalosporins, which are highly effective and relatively safe drugs. This is primarily due to the fact that their treatment is the most effective therapy for severe diseases caused, for example, salmonella infections, especially in children [3].

In many developed countries, cephalosporins in terms of sales are in first place among all groups of antibiotics, ahead of the group of macrolides and penicillins with a wide spectrum of action.

According to the WHO, the frequent use of antibacterial agents, including antibiotics, causes a number of undesirable reactions. In this regard, the correct choice of antibiotics can significantly reduce the cost of both the treatment of infectious diseases, the prevention of postoperative complications, and the elimination of the consequences of irrational use of antibacterial agents.

Aim of the studyis to analyze the market and availability of antibiotics in the Republic of Uzbekistan, to review the literature, to compare the standardized quality indicators of some drugs based on the cephalosporin series and to conduct a content analysis of the nomenclature of drugs.

MATERIAL AND RESEARCH METHODS

The research materials were data from the State Unitary Enterprise “State Center for Expertise and Standardization of Medicines, Medical Devices and Medical Equipment” on the registration of pharmaceutical products in the Republic of Uzbekistan (State Register of Medicines and Medical Devices No. 23, 2019 (as of March 1, 2019), regulatory framework of documents of the Pharmacopoeia Committee.

RESULTS

Our analysis of the structure of the pharmaceutical market of the Republic of Uzbekistan showed that the number of imported cephalosporins in 2016 amounted to more than 123 tons. According to the order of the Minister of Health of the Republic of Uzbekistan dated July 27, 2018 No. 3045 “On approval of the list of essential medicines”, 28 international non-panopled names of antibiotics are included, 8 medicines from the group of cephalosporins are on this list.

Table 1: Essential cephalosporin drugs

№	MHH	Dosageform
1.	Cefepim	Powder for solution for injection 0.5 g; 1 g; 2 g
2.	Cefazolin	Powder for solution for injection 0.5 g; 1 g
3.	Cefuroxime	Powder for solution for injection 0.75 g; 1.5 g
4.	Cefotaxime	Powder for solution for injection 0.5 g; 1 g
5.	Cefoperazone	Powder for solution for injection 0.5 g; 1 g
6.	Ceftriaxone	Powder for solution for injection 0.25 g; 0.5 g; 1.0 g; 2.0 g
7.	Ceftazidime	Powder for solution for injection 0.5 g; 1 g; 2 g
8.	Цефоперазон + Сульбактам	Powder for solution for injection 1 g; 2 g

The certification body for medical products on the basis of the State Unitary Enterprise “State Center for Expertise and Standardization of Medicines, Medical Devices and Medical Equipment” carried out certification work according to the 3-scheme, in which in 2017 the body received 19 applications from 3 local manufacturers for certification work on drugs cephalosporin series. As of December 1, 2018, 54 applications were received from 3 local manufacturers.

Table 2: Certification data for cephalosporin powder for injection

Nomination	2017 year	2018 year (to December 1st)	Total
	3-scheme	3-scheme	
Ceftriaxone (assodiumsalt)	342830	261320	604150
Cefotaxime	259280	347685	606965
Cefazolin (assodiumsalt)	1021684	585667	1 607351
Cefuroxime	-	147 474	147474
Total	1623 794 vials	1 342 146 vials	2965940 vials

Table 3: Distribution of cephalosporin preparations registered in the Republic according to the lists of vital WHO and essential medicines for the Republic of Uzbekistan

Nomination (generation)	WHO Essential Medicines	Essential medicines according to the list of the Republic of Uzbekistan
Cefazolin(I)	+	+
Cephalexin (I)	+	-
Cephalotin(I)	+	-
Cefaclor(II)	+	-
Cefamandol(II)	+	-
Cefepim (IV)	–	+
Cefoperazone (III)	–	+
Cefuroxime(II)	+	+
Cefixime(III)	+	-
Cefotaxime (III)	+	+
Cefpodoxime (III)	+	-
Ceftazidime (III)	+	+
Ceftibutene (III)	–	-
Ceftizoxime (III)	+	-
Ceftriaxone (III)	+	+

The content analysis took into account all drugs, substances containing the cephalosporin series, registered by various domestic and foreign manufacturers. The ratio of the shares of non-combined and combined drugs was distributed as follows: the total number of non-combined drugs containing the cephalosporin

series is 236 trade names, which corresponds to 83.09% of the total number of all analyzed items (284 units), and combined drugs are presented 48 names, which account for 38.60%.Domestic manufacturers registered 40 names of antibiotics.

As of March 1, 2019, only 15 cephalosporin substances were registered, 14 of them produced in China and 1 in India.

Table 4: Registered cephalosporin substances in the Republic of Uzbekistan

№	Internationalnomination	Thecountryofmanufacture	Amount
1.	Cefazolin	China	3
2.	Cefotaximesodium	China	4
3.	Cefodizimesodium	China	2
4.	Ceftriaxonesodium	China	3
5.	Cefuroxime	China	1
6.	Cefepimehydrochloride+L-arginine	China	1
7.	Ciprofloxacin	India	1
	Total		15

Table 5: The results of the assortment analysis, passed registration by year for Uzbekistan, CIS, foreign countries are presented.

Year	Uzbekistan	CIS	Foreign countries	Total
2014	9	10	22	**41**
2015	7	6	51	**64**
2016	6	10	39	**55**
2017	7	13	38	**58**
2018	10	6	57	**73**
2019	1	-	7	**8**
Total	**40**	**45**	**214**	**299**

As can be seen from the table, the highest registration was 2018, this is due to the registration of substances of active pharmaceutical ingredients.

CONCLUSIONS

1. The main directions of drug provision for the population of the Republic of Uzbekistan are characterized. A review of the literature data, a comparative analysis of standardized quality indicators of some drugs based on the cephalosporin series, the results of a content analysis of the nomenclature of drugs.
2. An analysis of the cephalosporin antibiotic market was carried out and it was established that 299 registered trade names of four generations of cephalosporins were admitted to the pharmaceutical market of the Republic of Uzbekistan.
3. The analysis of the data from the State Register of Medicinal Products and Medical Devices and Literature showed an increase in interest in antibiotic cefolosporins. The structure of each group of the studied nomenclature of drugs was studied by quality indicators, composition, release forms, origin and manufacturers.
4. The regulatory documents of medicines and substances registered in the Republic of Uzbekistan of the cephalosporin series have been studied. Pharmacopoeias of recent years, along with classical chemical methods, are increasingly using physical and chemical methods, primarily high performance liquid chromatography - to determine impurities and quantify. The prospects for the further development of methods for the analysis and standardization of cephalosporin derivatives are in the most complete use of spectral and chromatographic methods, their rational combination both with each other and with chemical methods, taking into account the resolution of each of them.

5. The results of the study indicate a wide variety of assortment and reproducible drugs, high updatability of the nomenclature and market dependence on foreign manufacturers.

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