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EVALUATION OF PROCUREMENT OF MEDICINES NOT INCLUDED IN VED LIST BY DISTRICT HOSPITALS OF THE KRASNOYARSK TERRITORY

K. G. Nozdrachev, PhD, Head of Department of Management and Economics of Pharmacy with a software course, V.F. Voyno-Yasenetsky Krasnoyarsk State Medical University, Krasnoyarsk, Russia, konoz@mail.ru

E.N. Bochanova, PhD, Assistant Professor of Department of Management and Economics of Pharmacy with a software course, V.F. Voyno-Yasenetsky Krasnoyarsk State Medical University, Krasnoyarsk, Russia, bochanova@list.ru

V.V. Bogdanov, Candidate of Pharmaceutical Sciences, Assistant Professor of Department of Management and Economics of Pharmacy with a software course, V.F. Voyno-Yasenetsky Krasnoyarsk State Medical University, Krasnoyarsk, Russia, bogdanovvv@krasgmu.ru

A.S. Shuvaeva, leading specialist of the Department of Organization of Pharmacological Support of the Ministry of Health of the Krasnoyarsk territory, Krasnoyarsk, annaxo@mail.ru

An analysis of the top-10 medicines purchased annually by regional hospitals in the Krasnoyarsk territory in addition to the list of VED showed that 8 out of 10 medicines are included in various standards of medical care and clinical recommendations approved by the Ministry of Health of the Russian Federation. The acquisition of medicines to ensure the implementation of standards of care is a priority in the medicine provision of medical organizations, despite the legal contradictions. In order to optimize the procurement of medicines by medical organizations, it is necessary to harmonize the standards of medical care, clinical recommendations and the list of VED.

Keywords: organization of provision of medicines, district hospitals, VED-list, cost optimization

On the territory of the Russian Federation, in accordance with Federal Law No. 61-FZ of 12.04.2010 "On circulation of medicines" and Government decree No. 865 of 29.10.2010 "On state regulation of prices for medicines included in the list of vital and essential drugs",

the state regulation covers prices for medicines included in the list of vital and essential drugs (VED), annually approved by the order of the government of the Russian Federation.

State regulation of prices for VED is carried out by registering the producers' maximum selling prices at the Federal level and setting the maximum wholesale and retail markups at the regional level. The registered producers' maximum selling prices are entered in the state register of prices. The register is published on the official website of the Ministry of Health of the Russian Federation on the Internet (<http://grls.rosminzdrav.ru>). Fixed prices for VED ensure the implementation of Federal law No. 61-FZ "On circulation of medicines", No. 323-FZ "On the basics of public health protection in the Russian Federation" and No. 178-FZ "On state social assistance".

Prices for other medicines are not subject to state regulation, prices for medicines that are not included in the VED – list are determined by pharmacy organizations independently, based on the costs associated with the purchase, storage, sale of medicines, etc.

The VED-list serves as the basis for providing medical care in a day or round-the-clock hospital. Prescription of medicines in the provision of medical care in stationary conditions can be carried out by the medical officer alone only in case of prescription of medicine, which is included in the VED-list. The medicines that are not included in the VED-list, if they are replaced due to individual intolerance, for life reasons, should be prescribed only by the decision of the Medical Commission, which is recorded in the patient's medical documentation and the log of the Medical Commission [1]. This method of prescription of the medicine is aimed at improving the availability of the medicine for medical organizations due to the lack of risk of excess prices for medicines included in the VED-list above the regulated level in the bidding process.

But the medicines that are not included in the VED-list can be included in the standards of medical care in the absence the duly approved documents regulating the development of a unified methodology of forming the list of medicines of standard [2]. There are quite a few such medicines: the VED – list for 2019 includes 735 medicines [3], which is significantly less than the total number of registered medicines in the Russian Federation – more than 32,000 [4].

Assessment of the cost structure of regional hospitals in the Krasnoyarsk territory has shown that the purchase of medicines that are not included in the VED-list accounts for about 16% of the funds [5]. The purpose of our study was to assess the feasibility of purchasing them.

The purpose of the study: to assess the feasibility of purchasing the medicines, not included into the VED-list.

MATERIALS AND METHODS

The analysis of consolidated applications for medicines for 40 regional hospitals (all health organizations – 1 level) of the Krasnoyarsk

territory, formed for the purpose of conducting joint bidding in 2015–2018, to identify medicines that are not included in the existing VED-lists purchased annually by these health organizations. The appropriateness of purchases was based on standards and clinical recommendations for the treatment of diseases published on the website of the Ministry of Health of the Russian Federation.

RESULTS AND DISCUSSION

Analysis of the range of medicines purchased annually in excess of the VED-list has shown that the largest share in both monetary and physical terms is accounted for by 10 medicines (see table).

In 2015, the largest share of costs was for Metamizole sodium (9.9%), in 2016, 2017, and 2018, the share of costs was 10.6%, 11.3%, and 9.1%, respectively. Despite the fact that the world health organization (WHO) does not recommend its use in medical practice either for fever control or for the purpose of analgesia, Metamizole sodium is widely distributed in Russia and the post-Soviet countries, both due to the traditional prejudice against opioid analgesics, and its low cost compared to other non-narcotic analgesics [6]. An essential argument for purchasing Metamizole is its inclusion into the list of medicines required for equipping the emergency medical teams [7].

Among other listed medicines that are not included in the VED-list, most medicines are included in various standards of medical care and/or clinical recommendations. According to the Federal law of 21.11.2011 №323-FZ "About basics of health protection of citizens of the Russian Federation", medical care is arranged and provided in accordance with the procedures of medical care, which are obligatory for execution in territory of the Russian Federation by all the health organizations on the basis of clinical guidelines and standards of medical care, except medical care provided within the frames of clinical testing [8].

**TOP-10 OF MEDICINES PURCHASED ANNUALLY BY REGIONAL HOSPITALS
IN THE KRASNOYARSK TERRITORY IN EXCESS OF THE VED-LIST**

Purchase date	2015		2016		2017		2018		2018 by 2015	
	mln. RUB	ths. pack.	mln. RUB	ths. pack.	mln. RUB	ths. pack.	mln. RUB	ths. pack.	growth. RUB	growth. RUB.
Purchased over the VED-list	22.2	124.5	24.9	143.9	21.5	117.5	22.0	93.3		
Medicine INN	% RUB	% pack.	% RUB	% pack.	% RUB	% pack.	% RUB	% pack.	growth. RUB	growth. RUB.
Metamizole sodium	9.9	18.4	10.6	15.1	11.3	18.7	9.1	22.4	-8.4	21.8
Articaine + Epinephrine	7.7	2.2	3.9	1.2	6.4	1.7	13.7	3.2	76.4	43.7
Nadroparin calcium	4.3	0.2	4.7	0.3	4.6	0.4	7.0	0.7	61.9	254.3
Deproteinized hemoderivative calves' blood (Actovegin)	4.1	1.0	4.0	0.9	3.1	0.7	1.1	0.2	-73.6	-81.6
Mifepristone	4.1	1.6	11.6	1.2	12.9	1.3	13.9	1.8	240.1	9.3
Papaverine	3.4	7.7	2.8	6.4	1.8	5.3	1.7	5.2	-49.4	-32.6
Nikethamide	3.2	1.5	2.5	1.3	1.8	1.2	1.4	1.4	-57.2	-7.2
Hydroxymethyl-khinoxalindi-oxide	2.8	1.0	2.1	0.8	2.0	0.8	2.1	1.1	-25.9	5.6
Ferrous sulfate + ascorbic acid	2.5	1.1	2.1	0.8	3.2	1.1	3.2	1.5	31.7	38.2
Enalaprilat	1.2	0.5	5.2	2.2	7.6	2.8	7.2	3.3	486.0	520.6

Articaine + Epinephrine (trade names – Ultracaine D–C, Ultracaine D–C Forte, Ubistesin, etc.) is a combined medicine, the effect of which is based on its components, and which has a local anesthetic effect. The medicine is indicated for infiltration and conduction anesthesia, including in dentistry [9]. Calcium nadroparin (trade name – Fraxiparin) is a direct-acting anticoagulant, indicated for treatment of deep vein thrombosis,

pulmonary embolism, acute coronary syndrome, prevention of thrombosis in patients with orthopedic, oncological and general surgical operations, as well as for hemodialysis and hemofiltration in patients with chronic renal failure [10,11]. Deproteinized hemoderivate of calves' blood (Actovegin) is registered in the Russian Federation for treatment of vascular and metabolic disorders of the brain, circulatory

disorders and their consequences (trophic ulcers), burns and wounds. Despite the fact that Actovegin is not used in a number of countries in America and Europe and its effectiveness is questionable [12], in the Russian Federation it is included in the standards of medical care for strokes, diabetic polyneuropathy, and treatment of meningococcal infection [13, 14]. Mifepristone (trade names – Genale, Miropristone, Ginestril, etc.) is a synthetic steroid antihistagenic agent that is used mainly for the medical termination of uterine pregnancy in the early stages and the preparation and induction of labor in full-term pregnancy [15]. Papaverine (trade names – Papaverine hydrochloride solution for 2% injection, Papaverine bufus) is a medicine of spasmolytic and hypotensive action, known in medical practice since 1848 [16], used for alleviation of spasms of smooth muscles of the abdominal cavity (cholecystitis, pylorospasm, spastic colitis, renal colic), peripheral vessels (endarteritis), as an adjuvant for premedication and as a part of complex therapy of pain syndromes in oncology [17]. The combination medication of “iron sulfate + ascorbic acid” (trade names – Sorbifer Durules, Ferroplex) is an effective medicine for treatment of iron-deficiency anemia (IDA), including in pregnant women. It not only quickly eliminates clinical symptoms, normalizes hemoglobin and is generally well tolerated by patients, but is also the most pharmacoeconomically beneficial. Sorbifer Durules has an additional advantage, as it is represented in the largest number of pharmacies among all iron preparations for oral administration [18, 19]. Enalaprilat (trade name- Enap P) is an active metabolite of enalapril, that is a widely known medicine included into the group of angiotensin-converting enzyme (ACE) inhibitors. This allows you to get a pronounced hypotensive effect with intravenous administration of the medicine in the treatment of arterial hypertension, hypertensive crisis not only in the hospital, but also at the

pre-hospital stage, where enalaprilat is also included into the list of medicines required for emergency medical teams supplies [7, 20]. The inclusion of sodium metamizole and enalaprilate into the mandatory range of medicines for units and kits of emergency medical teams requires not only the mandatory purchase of these medicines, but also regular replenishment of the stock. It is known that the content of the kits is regularly checked by various regulatory authorities (health insurance company, territorial compulsory medical insurance fund, Prosecutor’s office, etc.), and the availability of more effective and safe analgesics on the market (compared to metamizol) does not allow modifying the content of kits.

2 of 10 medicines, namely, niketamide (trade name – Cordiamine), hydroxymethylquinoxalindioxide (trade name – Dioxin) are not included into the VED – list and into the standards and clinical recommendations.

Niketamide is a respiratory stimulant, indicated for hypotonic conditions, as an additional medicine for collapse, shock, asphyxia, including in newborns [21]. Respiratory stimulants also include bemegrid (trade name – 0.5% Bemegrid solution for injection), methylamide ethylimidazoldicarbonate (trade name – 1.5% Etymizole solution in ampoules) and caffeine (trade name – Caffeine-sodium benzoate solution for injection). Among them, bemegrade, etimizol as well as nikethamide, are not included in the VED-list. Caffeine, on the contrary, is included into the VED-list and has the registered indications for use similar with niketamide, which makes its purchase for the needs of budget hospitals more rational.

Hydroxymethylquinoxalindioxide (trade name – Dioxydine) is the only antimicrobial medicine registered for intravenous infusions and external use (5 mg/ml solution) and for intracavity and external use (10 mg/ml solution), which allows it to be used not only systemically, but also for the treatment of wounds, cavities as

an antiseptic. The medicine is characterized by a narrow therapeutic margin, so it is necessary to strictly observe the recommended doses, not allowing them to be exceeded. Experimental studies have shown that Dioxydine has mutagenic, teratogenic, embryotoxic and damaging effects on the adrenal cortex. The Toxicological properties of Dioxydine in systemic use define the limitations to its use in the clinic. At the same time, such a well-known antiseptic as chlorhexidine, included in the VED- list in the form of a solution for local and external use, is not allowed for washing the cavities [22]. In addition to Dioxydine, the antiseptic of Miramistin, which does not have the ability to be absorbed through the skin and mucous membranes, is not included in the VED – list. In total, the VED- list includes 5 antiseptics: chlorhexidine, povidone-iodine, hydrogen peroxide, potassium permanganate, ethanol [23]. The absence of the medicine for registered intravital use in this list leads to the need to purchase the medicine in addition to the VED – list.

CONCLUSION

Analysis of the top 10 medicines purchased annually by regional hospitals in the Krasnoyarsk territory in addition to the list of VED showed that 8 of 10 medicines are included into various standards of medical care and clinical recommendations approved by the Ministry of Health of the Russian Federation.

The acquisition of medicines in order to ensure compliance with the standards of medical care is a priority in the provision of medicines to a health organization, despite the existing organizational and legal contradictions.

3. In order to optimize the procurement of medicines by health organizations, it is necessary to harmonize the standards of medical care, clinical recommendations and the VED -list.

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