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Research article / Оригинальная статья

## Issues of National Drug Security in Formation of a Reserve of Antibacterial Agents Intended to Eliminate Medical and Sanitary Consequences of Emergencies

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### Abstract

**Introduction.** The article considers the issues of forming a reserve of antibacterial agents designed to eliminate medical and sanitary consequences of emergencies from the perspective of national drug security.

**Aim.** To determine the degree of import substitution of antibacterial agents included in the regional drug reserve.

**Materials and methods.** We carried out a content analysis of data from regulatory documents and research papers related to formation of drug reserves, a logical and structural analysis of the range of antibacterial agents included in the reserve of the Tomsk region, and an analysis of data from the National Drug Register. In the study, we used the Anatomical Therapeutic Chemical (ATC) Classification System of drugs.

**Results and discussion.** It was established that for 19 international nonproprietary names (INN) of antibacterial agents belonging to the group of antibacterials for systemic use (ATC code J01) and forming the reserve of the Tomsk region, 294 brand names (BN) were registered on the pharmaceutical market of the Russian Federation in 2021. The share of registered domestic BN was 49.3 %, and the degree of import dependence of domestic drug manufacturing on foreign-made active pharmaceutical ingredients (APIs) was 81.4 %. It was found that 6 Russian enterprises manufacture APIs that supply production of 10 antibacterial agents included in the drug reserve. A classification of medicines by strategic availability for replenishing the drug reserve was developed. A map on strategic availability of domestically manufactured antibacterial agents included in the reserve was drawn up.

**Conclusion.** We demonstrated high dependence of antibacterial reserve formation on import of this group of medicines and APIs to the Russian Federation. The classification of medicines which takes into account the possibility of replenishing the drug reserve in emergency conditions and if import of medicines stops can be recommended for use by the center for disaster medicine to optimize the nomenclature of drug reserves at various levels from the perspective of national drug security promotion.

**Keywords:** drug supply in emergencies, import substitution of drugs and active pharmaceutical ingredients, national drug security, reserve of medical supplies

**Conflict of interest.** The authors declare that they have no obvious and potential conflicts of interest related to the publication of this article.

**Contribution of the authors.** Larisa Yu. Chernikova, Elena V. Karakulova were engaged in drawing up the design of the study. Larisa Yu. Chernikova, Nikolay L. Denisov, Elvira G. Morozova conducted research, analysis of the obtained data. Vadim N. Dmitruk, Larisa Yu. Chernikova, Elena V. Karakulova participated in writing the text of the article. All the authors contributed to the discussion of the article.

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## Вопросы национальной лекарственной безопасности при формировании резерва антибактериальных средств, предназначенного для ликвидации медико-санитарных последствий чрезвычайных ситуаций

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## Резюме

**Введение.** В статье рассмотрены вопросы формирования резерва антибактериальных средств, предназначенного для ликвидации медико-санитарных последствий чрезвычайных ситуаций, с позиции национальной лекарственной безопасности.

**Цель.** Определить уровень импортозамещения антибактериальных средств, входящих в резерв регионального уровня.

**Материалы и методы.** Проведен контент-анализ данных нормативных документов и научных работ, связанных с формированием резервов лекарственных средств, логический и структурный анализ номенклатуры антибактериальных средств, входящих в резерв Томской области, анализ данных Государственного реестра лекарственных средств. В исследовании использовали анатомо-терапевтическо-химическую (АТХ) систему классификации лекарственных средств.

**Результаты и обсуждение.** Установлено, что для 19 международных непатентованных наименований (МНН) антибактериальных средств, относящихся к группе антибактериальных средств для системного применения (код АТХ J01) и образующих резерв Томской области, на фармацевтическом рынке РФ в 2021 году зарегистрировано 294 торговых наименования (ТН). Доля зарегистрированных отечественных ТН составила 49,3 %, а уровень импортозависимости производства отечественных препаратов от иностранных активных фармацевтических субстанций (АФС) – 81,4 %. Установлено, что 6 российских предприятий выпускают АФС, обеспечивающие производство 10 антибактериальных средств, включенных в резерв. Разработана классификация лекарственных средств по стратегической доступности для пополнения резерва лекарственных средств. Составлена карта стратегической доступности производства антибактериальных средств резерва на территории РФ.

**Заключение.** Показана высокая зависимость формирования резерва антибактериальных средств от импорта в Российскую Федерацию данной группы препаратов и АФС. Классификация лекарственных средств, учитывающая возможность пополнения резервов в условиях чрезвычайных ситуаций и при прекращении импорта лекарственных средств, может быть рекомендована для использования службой медицины катастроф для оптимизации номенклатуры резервов различного уровня с позиции обеспечения национальной лекарственной безопасности.

**Ключевые слова:** лекарственное обеспечение в чрезвычайных ситуациях, импортозамещение лекарственных препаратов и активных фармацевтических субстанций, национальная лекарственная безопасность, резервы медицинского имущества

**Конфликт интересов.** Авторы декларируют отсутствие явных и потенциальных конфликтов интересов, связанных с публикацией настоящей статьи.

**Вклад авторов.** Л. Ю. Черникова и Е. В. Каракулова занимались составлением дизайна исследования. Л. Ю. Черникова, Н. Л. Денисов и Э. Г. Морозова проводили исследования и анализ полученных данных. В. Н. Дмитрук, Л. Ю. Черникова и Е. В. Каракулова участвовали в написании текста статьи. Все авторы участвовали в обсуждении результатов.

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## INTRODUCTION

A reserve of medical supplies intended to eliminate medical and sanitary consequences of natural and man-made disasters (further referred to as "Reserve") is an indispensable component of state guarantees for medical care provision for the population affected in emergencies. Currently, a potential risk of emergencies in the Russian Federation against the background of unstable epidemiological situation in the world requires maintaining drug reserves in constant readiness at all levels of the Unified State System for the Prevention and Elimination of Emergencies (RSE). Medicines from the reserves of RSE territorial subsystems are in most demand [1–6].

Availability and efficiency of the drug reserve in the Tomsk region determine promptness of emergency delivery of medicines included in the reserve when the state of emergency is declared. For guaranteed and uninterrupted

drug supply in emergencies, the reserve should be formed from domestically produced medicines<sup>1</sup> [7–9], since independence of production of life-saving and essential medicines of imported APIs, as well as availability of medicines in the required volume and range characterize national drug security [10–12]. Otherwise, the formation of the reserve is impossible, since the access of foreign-made APIs to the pharmaceutical market of the Russian Federation for some reason or another can be terminated at any time [13–16].

The ABC analysis of the range of medicines in the reserve of the Tomsk region, intended to provide care and treatment for 500 victims, showed that antibacterial

<sup>1</sup> Order of the Ministry of Health of the Russian Federation No. 66 (13.02.2013) "On approving the strategy for drug supply of the population of the Russian Federation for the period up to 2025 and the plan for its implementation". Available at: <https://www.garant.ru>. Accessed: 10.11.2020. (In Russ.)

agents (ABA) constitute one of the main groups of medicines<sup>1</sup>, which determined the choice of this group as a model for the study.

**The aim** of present study was to determine the degree of import substitution of ABA included in the reserve of the Tomsk region.

## MATERIALS AND METHODS

In the study, we carried out a content analysis of data from scientific publications and regulatory documents [1] and a logical and structural analysis of the range of ABA reserve of the Tomsk region<sup>2,3</sup>. To classify ABA included in the reserve, we used the Anatomical Therapeutic Chemical (ATC) Classification System of drugs. For processing the data array, we used the MS Excel 2010 software.

## RESULTS AND DISCUSSION

At the first stage of the study, an analysis of the degree of import substitution of ABA included in the reserve of the Tomsk region was carried out. For this, the range of ABA included in the reserve, formed according to the order of the Healthcare Department of the Tomsk Region No. 150 of 05.03.2018<sup>4</sup>, was compared with data of the National Drug Register (NDR) as of 30.03.2021<sup>5</sup>. The analysis showed (table 1) that according to the NDR data, at the time of the study, 294 brand names (BN) were registered in the Russian Federation, which can form the nomenclature of 19 international nonproprietary names (INN) of ABA included in 8 subgroups of antibacterials for

systemic use (ATC code J01) and forming the reserve of the Tomsk region.

The share of brand names of domestically produced ABA was 49.3 % (145 BN), which indicates relatively high dependence of ABA reserve formation on import of this group of medicines to the Russian Federation. Quinolone antibacterials (ATC code J01M) had the largest number of BN, their share in the total number of BN was 31.0 % (91 BN). Analysis of the imported medicines / domestically produced medicines ratio in this group exhibited the prevalence of BN of foreign-made ABA, their share was 59.3 % (54 BN), which is associated with a wide range of imported medicines with the INN "Levofloxacin" (27 BN). The second largest group in the range of BN is presented by other beta-lactam antibacterials (ATC code J01D) with a share of 30.3 % (89 BN) and a degree of import substitution of 49.4 % (44 BN). In this group, only one foreign-made medicine is registered for the INN "Ceftaroline fosamil". This may threaten promptness of medical care provision in emergencies, since import of this medicine to the pharmaceutical market of the Russian Federation may be terminated.

In other ABA groups, approximately equal shares of medicines produced by domestic and foreign manufacturers were identified.

Therefore, in 2021, the degree of import substitution of ABA included in the reserve of the Tomsk region was 49.3 %, which is significantly lower than 90 % specified in the corresponding decree of the President of the Russian Federation<sup>6</sup>. The state of affairs is exacerbated by the fact that for manufacturing many domestically produced ABA, imported APIs are used. It is proved by the findings of the analysis on supply of Russian manufacturers of ABA included in the reserve with domestically produced APIs (table 2).

The obtained findings demonstrate that the majority of ABA produced in the Russian Federation is manufactured from foreign-made APIs; the degree of import dependence in this parameter is 81.4 %. It is worth noting that tetracyclines (ATC code J01A), sulfonamides and trimethoprim (ATC code J01E), and aminoglycoside antibacterials (ATC code J01G), having the largest number of registered BN of domestically produced ABA, are 100 % dependent on APIs manufactured abroad. Additionally, the degree of import dependence is high in the groups of other antibacterials (ATC code J01X) (94.4 %), other beta-lactam antibacterials (ATC code J01D) (81.8 %), quinolone antibacterials (ATC code J01M) (81.1 %), and beta-lactam antibacterials, penicillins (ATC code J01C) (81.2 %).

The analysis of data on registration of APIs used for domestic production of ABA showed that the largest importers were China and India; their combined share was 50 % (figure 1).

<sup>6</sup> Decree of the President of the Russian Federation No. 598 (07.05.2012) «On improving the state policy in the field of healthcare». Available at: <http://publication.pravo.gov.ru/Document/View/0001201205070022>. Accessed: 30.03.2021. (In Russ.)

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<sup>2</sup> On approving the range and volume of medicines and medical supplies included in the reserves of material resources of the Tomsk region for prevention and elimination of intermunicipal and regional emergencies". Available at: <https://www.tcmk-tomsk.ru/pages/normativnyie-dokumentyi/>. Accessed: 01.10.2020. (In Russ.)

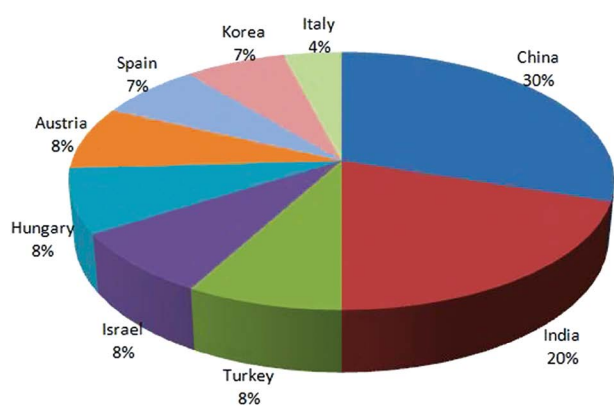
<sup>3</sup> Order of the Ministry of Health of the Russian Federation No. 598 (26.08.2013) "On approving the regulations on the reserves of medical resources of the Ministry of Health of the Russian Federation for elimination of medical and sanitary consequences of emergencies, its nomenclature and volume". Available at: <http://base.garant.ru/71700934/>. Accessed: 01.10.2020. (In Russ.)

<sup>4</sup> On approving the range and volume of medicines and medical supplies included in the reserves of material resources of the Tomsk region for prevention and elimination of intermunicipal and regional emergencies". Available at: <https://www.tcmk-tomsk.ru/pages/normativnyie-dokumentyi/>. Accessed: 01.10.2020. (In Russ.)

<sup>5</sup> National Drug Register of the Russian Federation. Available at: <http://www.grls.rosminzdrav.ru>. Accessed: 30.03.2021. (In Russ.)

**Table 1.** Characteristics of the range of antibacterials in the reserve of the Tomsk region in terms of production

ATC code	Group	INN	Registered by BN					
			Total		Domestically produced		Foreign-made	
			abs.	%	abs.	%	abs.	%
J01A	Tetracyclines	Doxycycline	7.0	2.4	5.0	71.4	2.0	28.6
J01C	Beta-lactam antibacterials, penicillins	Ampicillin	5.0	1.7	4.0	80.0	1.0	20.0
		Phenoxymethylpenicillin	1.0	0.3	1.0	100.0	0	0
		Oxacillin	1.0	0.3	1.0	100.0	0	0
		Amoxicillin + clavulanic acid	22.0	7.5	10.0	45.5	12.0	54.5
		TOTAL	29.0	9.9	16.0	55.2	11.0	44.8
J01D	Other beta-lactam antibacterials	Cefazolin	10.0	3.4	7.0	70.0	3.0	30.0
		Cefatoxime	20.0	6.8	12.0	60.0	8.0	40.0
		Ceftriaxone	34.0	11.6	11.0	32.4	23.0	67.6
		Imipenem + [cilastatin]	3.0	1.0	2.0	66.7	1.0	33.3
		Meropenem	21.0	7.1	12.0	57.1	9.0	42.9
		Ceftaroline fosamil	1.0	0.3	0	0	1.0	100.0
		TOTAL	89.0	30.3	44.0	49.4	45.0	50.6
J01E	Sulfonamides and trimethoprim	Co-trimoxazole (sulfamethoxazole and trimethoprim)	6.0	2.0	3.0	50.0	3.0	50.0
J01F	Macrolides, lincosamides, and streptogramins	Azithromycin	38.0	12.9	20.0	52.6	18.0	47.4
J01G	Aminoglycoside antibacterials	Gentamicin	4.0	1.4	2.0	50.0	2.0	50.0
J01M	Quinolone antibacterials	Ofloxacin	21.0	7.1	11.0	52.4	10.0	47.6
		Ciprofloxacin	28.0	9.5	11.0	39.3	17.0	60.76
		Levofloxacin	42.0	14.3	15.0	35.7	27.0	64.3
		TOTAL	91.0	31.0	37.0	40.7	54.0	59.3
J01X	Other antibacterials	Metronidazole	27.0	9.2	16.0	59.3	11.0	40.7
		Nitroxoline	3.0	1.0	2.0	66.7	1.0	33.3
		TOTAL	30.0	10.2	18.0	60.0	12.0	40.0
TOTAL			294.0	100.0	145.0	49.3	149.0	50.7



**Figure 1.** The structure of registered foreign-made APIs for manufacturing of domestically produced antibacterials

Therefore, real import substitution of ABA included in the reserve of the Tomsk region accounts for only 18.6 %. The analysis of data on distribution of manufacturing of domestically produced APIs demonstrated that Russian-made APIs that can be used for manufacturing ABA included in the reserve are produced by 6 companies (table 3).

The conducted analysis showed that the largest manufacturer of APIs in the Russian Federation is Sintez JSC, it produces 8 APIs from 3 ATC subgroups of antibacterials for systemic use (code J01). Two manufacturers – Irbit Chemical and Pharmaceutical Plant JSC and Active Component CJSC – synthesize one API not included in the range of substances produced by Sintez JSC. Other Russian manufacturers duplicate the range of APIs produced by Sintez JSC.

Therefore, 9 out of 19 INN of antibacterials included in the reserve are not supplied with domestically produced APIs: Doxycycline, Amoxicillin + clavulanic acid, Imipenem + [cilastatin], Ceftaroline fosamil, Co-trimoxazole (sulfamethoxazole and trimethoprim), Gentamicin, Ofloxacin, Ciprofloxacin, and Metronidazole.

Following the conducted analysis of the range of ABA included in the reserve of the Tomsk region from the perspective of national drug security, we elaborated a classification of INN of ABA included in the reserve based on the strategic availability of medicines for replenishing the reserve under conditions of emergency and if import of medicines stops. We identified the following groups of medicines:

**Table 2. Characteristics of the range of domestically produced antibacterials included in the reserve of the Tomsk region in terms of API origin**

ATC code	Group	INN	Registered by BN					
			Total		Domestically produced APIs		Foreign-made APIs	
			abs.	%	abs.	%	abs.	%
J01A	Tetracyclines	Doxycycline	5.0	3.4	0	0	5.0	100.0
J01C	Beta-lactam antibacterials, penicillins	Ampicillin	4.0	2.8	2.0	50.0	2.0	50.0
		Phenoxymethylpenicillin	1.0	0.7	0	0	1.0	100.0
		Oxacillin	1.0	0.7	1.0	100.0	0	0
		Amoxicillin + clavulanic acid	10.0	6.9	0	0	10.0	100.0
		TOTAL	16.0	11.1	3.0	18.8	13.0	81.2
J01D	Other beta-lactam antibacterials	Cefazolin	7.0	4.8	2.0	28.6	5.0	71.4
		Cefatoxime	12.0	8.3	2.0	16.7	10.0	83.3
		Ceftriaxone	11.0	7.6	1.0	9.1	10.0	90.9
		Imipenem + [cilastatin]	2.0	1.4	0	0	2.0	100.0
		Meropenem	12.0	8.3	3.0	25.0	9.0	75.0
		Ceftaroline fosamil	–	–	–	–	–	–
		TOTAL	44.0	30.3	8.0	18.2	36.0	81.8
J01E	Sulfonamides and trimethoprim	Co-trimoxazole (sulfamethoxazole and trimethoprim)	3.0	2.1	0	0	3.0	100.0
J01F	Macrolides, lincosamides, and streptogramins	Azithromycin	20.0	13.8	8.0	40.0	12.0	60.0
J01G	Aminoglycoside antibacterials	Gentamicin	2.0	1.4	0	0	2.0	100.0
J01M	Quinolone antibacterials	Ofloxacin	11.0	7.6	0	0	11.0	100.0
		Ciprofloxacin	11.0	7.6	0	0	11.0	100.0
		Levofloxacin	15.0	10.3	7.0	46.7	8.0	53.3
		TOTAL	37.0	25.5	7.0	18.9	30.0	81.1
J01X	Other antibacterials	Metronidazole	16.0	11.0	0	0	16.0	100.0
		Nitroxoline	2.0	1.4	1.0	50.0	1.0	50.0
		TOTAL	18.0	12.4	1.0	5.6	17.0	94.4
TOTAL			145.0	100.0	27.0	18.6	118.0	81.4

Group I "High availability" (domestically produced medicines and domestically produced APIs) encompasses 10 INN: Ampicillin, Phenoxymethylpenicillin, Oxacillin, Cefazolin, Cefatoxime, Ceftriaxone, Meropenem, Azithromycin, Levofloxacin, and Nitroxoline.

Group II "Medium availability" (domestically produced medicines and foreign-made APIs) includes 8 INN: Doxycycline, Amoxicillin + clavulanic acid, Imipenem + [cilastatin], Co-trimoxazole (sulfamethoxazole and trimethoprim), Gentamicin, Ofloxacin, Ciprofloxacin, and Metronidazole.

Group III "Low availability" (foreign-made medicines and APIs) includes 1 INN – Ceftaroline fosamil.

To assess the possibility of sustainable functioning of the reserve of the Tomsk region, we drew up a map of strategic availability of domestically manufactured ABA in the Russian Federation (figure 2).

According to the map, production of ABA classified as groups I and II by strategic availability is concentrated in Siberian and Ural Federal Districts. This fact may be taken into account when planning the inclusion of ABA

in the reserve of the Tomsk region, since close proximity of pharmaceutical manufacturers reduces shipping time, which is essential for replenishing the reserves.

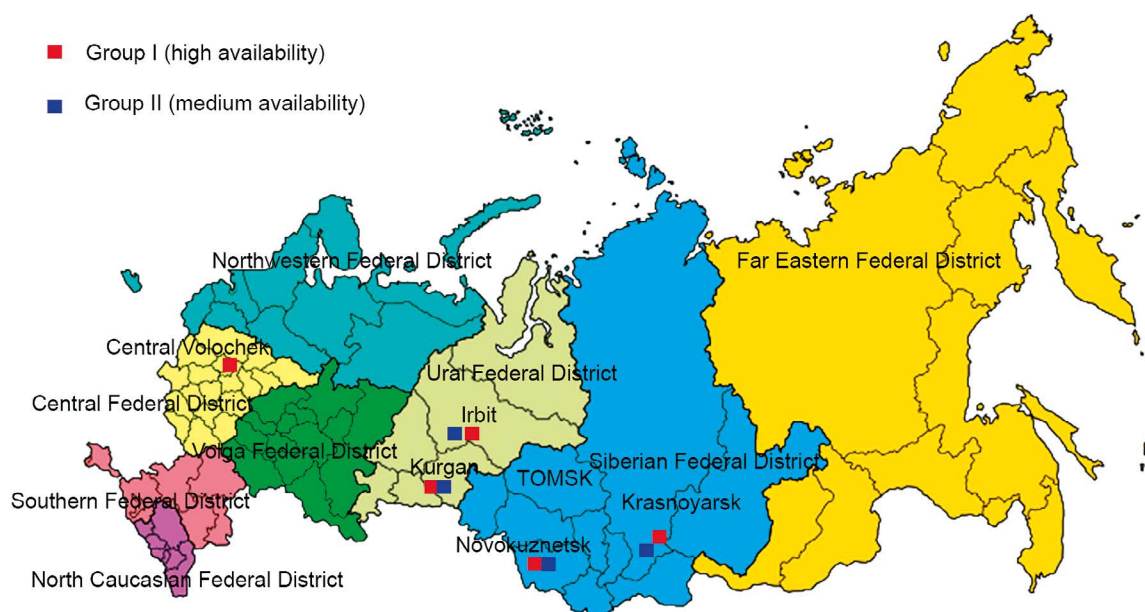
## CONCLUSION

Following the conducted study, we identified that for 19 INN of antibacterials included in 8 groups of antibacterials for systemic use (ATC code J01), 294 brand names were registered in the Russian pharmaceutical market in 2021. The share of domestically produced medicines was 49.3 % (145 BN). The degree of import substitution of ABA included in the reserve of the Tomsk region, with account of the sources of API production, was 18.6 %. Only 6 Russian manufacturers supply the production of ABA included in the reserve with APIs.

The classification of medicines by strategic availability developed using the reserve of the Tomsk region as an example can be recommended for use by the center for disaster medicine to optimize the range of medicines included in reserves at different levels from the perspective of national drug security promotion.

**Table 3.** Russian manufacturers of APIs for antibacterials included in the reserve of the Tomsk region.

ATC code	Group	INN	Manufacturers					
			Sintez JSC	DEKO Company LLC	Kraspharma SC	Irbital Chemical and Pharmaceutical Plant JSC	Active Component CJSC	Organica JSC
J01A	Tetracyclines	Doxycycline	–	–	–	–	–	–
J01C	Beta-lactam antibacterials, penicillins	Ampicillin	+	–	–	–	–	–
		Phenoxymethylpenicillin	+	–	–	–	–	–
		Oxacillin	+	–	+	–	–	+
		Amoxicillin + clavulanic acid	–	–	–	–	–	–
J01D	Other beta-lactam antibacterials	Cefazolin	+	+	–	–	–	–
		Cefatoxime	+	+	–	–	–	–
		Ceftriaxone	+	+	–	–	–	–
		Imipenem + [cilastatin]	–	–	–	–	–	–
		Meropenem	+	+	–	–	–	–
		Ceftaroline fosamil	–	–	–	–	–	–
J01E	Sulfonamides and trimethoprim	Co-trimoxazole (sulfamethoxazole and trimethoprim)	–	–	–	–	–	–
J01F	Macrolides, lincosamides, and streptogramins	Azithromycin	–	–	–	–	+	–
J 01G	Aminoglycoside antibacterials	Gentamicin	–	–	–	–	–	–
J01M	Quinolone antibacterials	Ofloxacin	–	–	–	–	–	–
		Ciprofloxacin	–	–	–	–	–	–
		Levofloxacin	+	–	–	–	+	–
J01X	Other antibacterials	Metronidazole	–	–	–	–	–	–
		Nitroxoline	–	–	–	+	–	–
TOTAL			8	4	1	1	2	1



**Figure 2.** A map of strategic availability of domestically produced antibacterials included in the reserve of the Tomsk region

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