

# Overview of the Essential Drugs Segment in the Russian Pharmaceutical Market Based on the Results of 2017

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#### Abstract:

The article shows the main trends in the segment with regulated pricing – the Essential Drugs List (EDL) segment of the Russian pharmaceutical market. The EDL segment of the Russian pharmaceutical market was assessed taking databases IQVIA (Retail audit, Budget audit, Reimbursement audit, in trade price rub, and only EDL products). According to the IQVIA data, in 2017 the Russian pharmaceutical market of EDL maintained its positive dynamics both by volume (+5%) and in the national currency (+9%). **Keywords**: drugs, EDL, marketing research.

### INTRODUCTION

In 2017 the Russian pharmaceutical market grew moderately (+9% by value) on the background of the continued economic recovery, the development of local production, strengthening of control, and regulation of public procurement.

One of the instruments for optimizing the choice of drugs to be used in the health care system is the Essential Drugs List (EDL). According to Federal Law of the Russian Federation No. 61-FZ "On drugs circulation" dated 12.04.2010 (as amended and supplemented, effective date 01.01.2017), the EDL is the list of drugs for medical use, which is annually approved by the Government of the Russian Federation and ensures priority health needs in the prevention and treatment of diseases, including the dominants in the Russian morbidity patterns (http://www.consultant.ru/document/cons\_doc\_law\_99350/) [1].

Russia has been performing works on compiling the EDL since 1992. Over the recent 25 years the List has been revised about 15 times.

The main legislative documents in the EDL circulation include the following:

- Federal Law of the Russian Federation No. 61-FZ "On drugs circulation" dated 12.04.2010 (as amended and 01.01.2017) effective supplemented, date (http://www.consultant.ru/document/cons\_doc\_law\_99350/) [1], - Federal Law of the Russian Federation No. 323-FZ "On fundamentals of protecting the health of citizens in the Federation" Russian 21.11.2011 dated (http://www.consultant.ru/document/cons\_doc\_LAW\_121895/) [2],

- Resolution of the Government of the Russian Federation No. 871 "On approving the rules for the formation of lists of drugs for medical use and the minimum range of drugs required to provide medical care" dated August 28, 2014 (http://www.consultant.ru/document/cons\_doc\_LAW\_167999/) [3].

The EDL is the most extended list of drugs in terms of the nomenclature. The 2017 EDL includes 648 international nonproprietary names (hereinafter referred to as INN) grouped according to the Anatomical Therapeutic Chemical Classification System.

The state regulates prices for the drugs included in the EDL. This includes state registration of the producers' maximum selling prices and setting of the maximum wholesale and retail markups to the actual selling prices.

It is necessary to note that under the modern conditions the state regulation of prices for drugs is one of the key measures to ensure the availability of drugs for patients in all developed countries of the world.

Further in the article the authors will consider the main trends in the segment with regulated pricing – the EDL segment of the Russian pharmaceutical market. The data for analysis were

provided by IQVIA (Total market – Retail audit, Budget audit, Reimbursement audit, and only EDL products in wholesalers/TRD price).

### MATERIALS AND METHODS

The methods of content analysis, system, logical, situational, and statistical analysis were used during the study.

#### **RESULTS AND DISCUSSION**

According to the results of 2017, the volume of the pharmaceutical market was RUB 1 trillion and 5.1 billion units, which was 7.2% higher by value and 1.4% higher by volume as compared to 2016.

The EDL segment is represented by 757 INN, which is slightly more than 3,000 trade names represented in the Russian market by almost 600 companies.

The Russian pharmaceutical market is steadily growing by value and is relatively stable by volume (Figure 1 and 2). In 2017 the EDL was 52% of the market in rubles and 51% in units.

The EDL segment structure was also stable by therapeutic groups (the rating was made by value, ATC): 9 of 10 most groups included the same categories as a year before. TOP 3 included mainly the drugs used in oncology (L01), antiviral (J05) and antibacterial (J01) drugs. The total share of top 10 was 25.5% of the market by value.

The rating of top 10 ATC groups by volume was also stable. The leaders (top 3) included Antibacterial (J01), blood substitutes and perfusion solutions (B05) and Nasal (R01) drugs.

Table 1 shows the rating of sales of the INN included in the EDL. The leader of the EDL rating is a vasoconstrictor INN – Xylometazoline (+9%), and such INN as Lenalidomide (+5%) and Pancreatin (+6%) remained on the  $2^{nd}$  and  $3^{rd}$  position of the rating, respectively. Such INN as Ibuprofen (+13%), Bisoprolol (+7%) and Sodium Chloride (+11%) topped the line. In general, in 2017 the sales of all INN in the EDL rating except for Rituximab increased as compared to the previous year. The sales of Rituximab had decreased by 5% during the year, and it moved from the 4<sup>th</sup> to the 6<sup>th</sup> position. This fact was due to the shift of the procurement cycle for preferential categories of citizens. The procurement was carried out in March 2018. That is why it was not specified in the database. Besides, in 2017 top 10 of INN included Ethylmethylhydroxypyridine succinate (+16%), Interferon beta-1a that showed the highest increase (+26%), coagulation factor VIII (+9%). They held the 8<sup>th</sup>, 9<sup>th</sup> and 10<sup>th</sup> positions, respectively.

The rating of sales by volume is represented by completely different INN. Cheap Sodium chloride (+11%), Xylometazoline (+4%) and Acetylsalicylic acid (-3%) had used to be and remained the leaders by sales in packages and held the  $1^{st}$ ,  $2^{nd}$  and  $3^{rd}$  positions, respectively. Ibuprofen (+11%) rose to the  $4^{th}$  position and shifted Ceftriaxone to the  $7^{th}$  position in the

rating. Enalapril (+1%), Pancreatin (+5%), Paracetamol (+5%), Omeprazole (+15%), and Hydrogen Peroxide (+18%) maintained their positions. The sales of most INN increased by volume as compared to 2016, except for Acetylsalicylic acid, Ceftriaxone and Paracetamol whose sales decreased by 3%.

According to the results of 2017, the share of drugs produced local manufacturer in the EDL segment was 33% by value. Accordingly, foreign drugs prevailed by the market value – 66%.

According to the results of the period under analysis, the rating of the leading Trade Name changed a little (Table 2). Like a year before, Revlimid, the antitumor drug, was at the top of the rating. Sovigripp, the Russian vaccine, demonstrated the highest increase of 153% in the rating, and rose from the  $66^{th}$  to the  $9^{th}$  position. The second drug in terms of the sales growth rate was

the anticoagulant Xarelto (+46%), which took the 4<sup>th</sup> position. The third drug was the Geptral hepatoprotector, the sales of which increased by 14%, which allowed it to climb one position and enter top 10. Sales of such antiviral drugs as Kagocel (-23%) and Ingavirin (-23%) decreased by almost a quarter. It caused their fall from the top of the rating to the 7<sup>th</sup> and the 8<sup>th</sup> positions, respectively. Kaletra (-11%), the drug for treating the HIV infection, also displayed the negative dynamics. However, it maintained the 6<sup>th</sup> position.

Sodium Chloride is at the top of the rating of trade name in terms of sales by value (Table 3). It increased by 11%. Almost half of the drugs underwent the negative dynamics: Acetylsalicylic acid (-13%), Ceftriaxone (-16%), Paracetamol (-8%), and Ascorbic acid (-16%).

Position in the rating		TNINI	Value,TRD bln. RUB	
2016	2017	INN	2016	2017
1	1	XYLOMETAZOLINE	10.79	11.73
2	2	LENALIDOMIDE	8.83	9.30
3	3	PANCREATIN	7.31	7.72
5	4	IBUPROFEN	6.72	7.63
6	5	BISOPROLOL	6.55	7.03
4	6	RITUXIMAB	7.27	6.89
8	7	SODIUM	5.79	6.44
12	8	ETHYLMETHYLHYDROXYPYRIDINE	5.19	6.03
17	9	INTERFERON BETA-1A	4.54	5.74
14	10	FACTOR VIII	4.86	5.31

Table 1 Top 10 INN by Value

Source: IQVIA databases Retail, Hospital, Reimbursement, Regional Reimbursement

Table 2 TOP 10 Trade name by Va	lue
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Position in the rating		Trade name	Corporation	Sales in TRE	), mln. RUB	Growth
2017	2016		_	2017	2016	2017/2016,%
1	1	Revlimid	Celgene	9,304	8,833	5%
2	3	Sodium chloride	Various producers	6,407	5,767	11%
3	5	Acellbia	Biocad	5,418	5,347	1%
4	8	Xarelto	Bayer	5,254	3,591	46%
5	7	Mexidol	Farmasoft	4,724	4,169	13%
6	6	Kaletra	Abbvie	4,668	5,230	-11%
7	2	Kagocel	Nearmedic plus	4,570	6,060	-25%
8	4	Ingavirin	Valenta	4,224	5,488	-23%
9	66	Sovigripp	Microgen	3,738	1,483	152%
10	11	Heptral	Abbott	3,613	3,175	14%

Source: IQVIA databases Retail, Hospital, Reimbursement, Regional Reimbursement

## Table 3 TOP 10 Trade Name by Volume

Position in the rating		Trade Name	Volume , mln units		growth
2017	2016		2017	2016	2017/2016.%
1	1	Sodium chloride	201	180	11%
2	4	Hydrogen peroxide	58	49	18%
3	2	Acetylsalicylic acid	55	63	-13%
4	3	Ceftriaxone	51	61	-16%
5	5	Paracetamol	39	42	-8%
6	6	Enalapril	38	38	1%
7	8	Chlorhexedin Bigluconate	34	32	7%
8	10	Rhinostop	33	29	15%
9	7	Ascorbic acid	31	37	-16%
10	13	Snup	25	24	4%

Source: IQVIA databases Retail, Hospital, Reimbursement, Regional Reimbursement

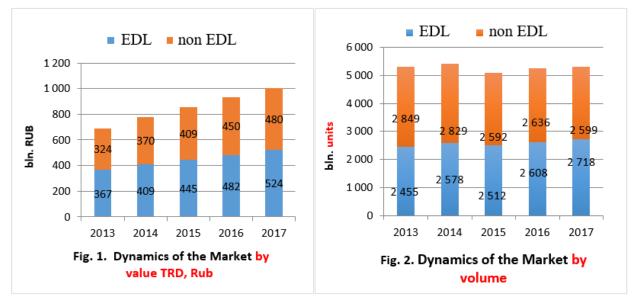


Figure 1 and 2. Dynamics of the Market by Value and by Volume Source: IQVIA databases Retail, Hospital, Reimbursement, Regional Reimbursement

#### CONCLUSION

In 2017, the Russian pharmaceutical market of EDL maintained its positive dynamics both by volume (+5%) and by value (+9%). The drugs included in the EDL entirely account for the purchases in the Reimbursement channel, and for about 80% of sales in the hospital channel. At the same time, in the structure of retail sales, they account for only about 37% by value.

Xylometazoline, Lenalidomide and Pancreatin are top 3 INN in the segment under analysis by value TRD, RUB). Leaders by volumeare Sodium Chloride, Xylometazoline and Acetylsalicylic Acid.

In 2017 as compared to 2016 the average price of a drug package from the EDL was RUB 188.8 in the total market (+6% as compared to 2016), RUB 129.9 (+3.2%) in retail, and RUB 235.0 (+1,7%) in the budget (state) segment. The highest price was observed in the extensive drug coverage channel – RUB 1,476 (+6.6%). At the same time, there was no inflation in the segment under analysis.

The Russian pharmaceutical market becomes more and more competitive. In 2017 the public sector made the main contribution to improving the medical procurement for the population. The share of reimbursement segment was considerably extended in the EDL sales structure. The economic efficiency of procurement that was mainly carried out centrally on the federal level was improved.

The new EDL adopted for 2018 included 60 new drugs, which creates the prerequisites to continue these processes. Thus, in the medium term, taking into account these trends, the market will maintain a certain balance of forces, although the share of the Russian companies will continue to grow. In particular, the introduction of additional preferences in the system of public procurement for full-cycle drugs produced in Russia (including substances) will facilitate this.

#### REFERENCES

- Federal Law of the Russian Federation No. 61-FZ dated 12.04.2010 "Ob obrashchenii lekarstvennykh sredstv" ["On drugs circulation"] (as amended and supplemented, effective date 01.01.2017).
- Federal Law No. 323-FZ dated 21.11.2011 "Ob osnovakh okhrany zdorov'ya grazhdan v Rossiyskoy Federatsii" ["On fundamentals of protecting the health of citizens in the Russian Federation"].
- 3. Resolution of the Government of the Russian Federation No. 871 dated 28.08.2014 "Ob utverzhdenii pravil formirovaniya perechney lekarstvennykh preparatov dlya meditsinskogo primeneniya i minimalnogo assortimenta lekarstvennykh preparatov, neobkhodimykh dlya okazaniya meditsinskoy pomoshchi" ["On approving the rules for the formation of lists of drugs for medical use and the minimum range of drugs required to provide medical care"].