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CIS GMP news

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Pharmasyntez 符合GMP所有标准

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Import of APIs, Drugs and BAA from China to Russia in 2018

从中国向俄罗斯原药、药品和生物添加剂进口

Information Provided by The State Institute of Drugs and Good Practices of The Ministry of Industry and Trade of The Russian Federation

MINPROMTORG RUSSIA

GXP SID&GP

BAA* 生物添加剂

0,7 mln packages

6,2 mln USD

Drugs 药品

0,7 mln packages

7,7 mln USD

API 原药

8 mln kg

0,3 bln USD

* Biologically Active Additives / Dietary supplements

GMP news

Pharmaceutical Industry Magazine

CIS GMP News

18+

Specialized publication dedicated to Good Manufacturing Practice, modernization of pharmaceutical production, and modern pharmaceutical manufacturing technologies

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OOO Media Pharm News
Golovinskoe sh., 5 korp. 1, 125212, Moscow, Russia

Editorial Board
Executive Director
Irina Litovkina, i.litovkina@gmpnews.net

Editor-in-Chief
Vyacheslav Fedorenko, v.fedorenko@gmpnews.net

Translator and Editor
Tatiana Vasileva, t.vasileva@gmpnews.net
Timur Kashapov, t.kashapov@gmpnews.net

External Translator and Editor
Translation Bureau – Perevod-kit, info@perevod-kit.ru

Graphic Design
Alena Prokopeva, a.prokopeva@gmpnews.net

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合作伙伴
OOO Media Pharm News（制药新闻媒体有限责任公司）
俄罗斯莫斯科市格拉温思科耶大街5号1座，邮编125212

编委会
执行董事
伊丽娜·利托夫金娜， i.litovkina@gmpnews.net

总主编
维亚切斯拉夫·费多林科， v.fedorenko@gmpnews.net

编译
塔季扬娜·瓦西里耶娃， t.vasileva@gmpnews.net
季穆尔·卡沙波夫， t.kashapov@gmpnews.net

外部编译
中文翻译翻译公司， info@perevod-kit.ru

平面设计
阿廖娜·普罗科列娃， a.prokopeva@gmpnews.net

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Dear readers, colleagues, partners!

One of the most important tasks of the CIS GMP news magazine is to tell about the Russian pharmaceutical industry and market, as well as markets of EAEU and CIS countries, not only in Russian, but also in all most spoken languages in the world. We have already released English-Arabic and English-Spanish editions, this autumn we plan to publish the English-German edition, and this time our team is pleased to present you the English-Chinese issue published on the eve of global pharmaceutical exhibitions, such as AchemAsia and CPhI China.

Speaking about the implementation of GMP standards, we mean a transition to a new level of quality assurance, safety and efficacy of medicines. We are striving to tell how the pharmaceutical market is developing, how production sites are being modernized, and how modern drug production technologies are being used and improved.

The market we are writing about becomes very attractive for investments. The manufacturing capabilities of most of the countries, the level of technological development, the practical application of artificial intelligence technologies make it possible today to talk about the established trend of localization of pharmaceutical production. At the same time, contract manufacturing and technology transfer sectors are growing. All this make the expansion of the medicines and medical products' markets possible.

Entering the Chinese market, we hope and believe that we will find companies interested in cooperation both with our project and with the companies we present, write about and promote. The GMPnews.net website, the CIS GMP news magazine and our partners are ready for long-term and mutually beneficial cooperation.

As the chief editor, I would like to thank the authors, experts, specialists, press services' representatives, translators, as well as the entire editorial board and all those who prepared and submitted unique materials. I express my deep gratitude to all the employees who helped to create and release a very complex English-Chinese summer edition.

Many thanks to all our partners! We highly appreciate established partnerships we build through the years and mutual understanding promotion. And we also welcome everyone for cooperation!

Vyacheslav Fedorenko
Editor-in-chief

尊敬的读者、同行及合作伙伴们！

《CIS GMP news》杂志最重要的任务之一是介绍俄罗斯、欧亚经济联盟和独联体国家制药行业和医药市场，不仅包括俄语，还囊括了世界上大部分主要语言。我们已经出版了英语-阿拉伯语、英语-西班牙语期刊，今年秋天我们还计划出版英语-德语版本，此次我们的编辑团队很荣幸能为您呈现英文-中文版本的期刊，并在AchemAsia和CPhI China等全球大展前发行。

谈到制药行业标准的良好实践，我们主要是要保障药品的质量、安全性和有效性向新的层次提升。我们尝试说明药品市场是如何发展、新药是如何开发、生产现场如何进行现代化，以及现代化生产技术如何被使用和改进。

我们所撰写的关于市场的信息，对投资非常有吸引力。大多数国家的生产能力、技术发展水平、人工智能技术的实际应用使得今天又可能进行讨论制药生产本土化的趋势。与此同时，合同制造和技术转让领域的活动正在增加。上述这些使得我们能够扩大药品和医疗产品的市场。

进入中国市场，我们非常希望并坚信我们会找到对我们的信息项目感兴趣的合作伙伴，以及我们代表进行推广的企业。GMPnews.net门户网站和《CIS GMP news》杂志已经时刻准备好与我们的合作伙伴进行长期互利的合作。

在此也对您表示感谢！作为总编辑，我想对作者、专家、学者、公司新闻服务代表、翻译、顾问，以及整个编委会和所有为期刊筹备工作和提交独特材料的人员表达谢意。同时我也向所有对夏季中文-英文版期刊中所遇到的难题提供帮助和解决方案的同事致以崇高的敬意。

非常感谢我们的所有合作伙伴！我们高度重视既定的伙伴关系并相互理解。在此也欢迎各方同仁与我们进行合作洽谈！

维亚切斯拉夫·费多林科
总主编

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Media partners: GMP IV ALL-RUSSIA GMP CONFERENCE, CPhI, ACHEMASIA

Regulation of Medicines

Turnover at the EAEU Level

25 March 2019

REVERA

Valentin Anikin
Associate of the Pharmaceuticals and healthcare specialization of REVERA

Dmitry Arkhipenko
Managing partner of REVERA

At the moment, the single EAEU market of medicines is legislated and is rapidly growing.

The 'single market' of medicines implies that all medicines conforming to the standards of good pharmaceutical practices (laboratory, production, clinical, pharmacovigilance practices, etc.) and duly registered pursuant to the unified rules of registration and expert evaluation will be freely traded within the EAEU.

The single EAEU market of medicines is regulated by the Agreement on uniform principles and rules of medicines turnover within EAEU of 23.12.2014.

All issues unified and harmonised at the EAEU level are key issues intended for the creation and proper operation of the single market of medicines.

HARMONISATION OF PHARMACOPEIAS

Standardisation of requirements to medicines is a prerequisite for the proper functioning of the single market. To this end, the EAEU Pharmacopeia is created – a uniform code of requirements to medicines applying to all EAEU member states.

Activities aiming at creating a uniform EAEU Pharmacopeia have been implemented since 2016. Harmonised uniform pharmacopeia articles (monographs) will be included into volume 1 of the EAEU Pharmacopeia and will set requirements to the quality control methods pertaining to medicines and equipment used in quality testing, packing materials, chemical agents, drug formulations, pharmaceutical substances, standard samples and additive agents used in the production of medicines intended for the EAEU market.

As of today, an outline of section 1 of volume 1 of the EAEU pharmacopeia has been published. Harmonised specific pharmacopeia articles (monographs) about pharmaceutical substances and medicinal raw material of natural origin (both vegetable and animal) will be included in the following volumes.

At present, the EAEU Pharmacopeia Committee has approved a number of draft pharmacopeia articles, such as "Equipment", "Physical and physico-chemical methods", "Tests for limit impurity content" and "Methods of quantitative measurement". Other pharmacopeia articles are at present under discussion. The list of approved pharmacopeia articles and the list of those under discussion are available at the Eurasian Economic Commission website[1].

It is worth noting that the EAEU pharmacopeia requirements will be mandatory for all medicines circulating in the EAEU. It is anticipated that the EAEU pharmacopeia will be updated at least once each 5 years.

PRECLINICAL AND CLINICAL STUDIES

Within the single market, preclinical and clinical studies (tests) of medicines in EAEU member states are conducted

[1] *http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/LS1/Pages/pharmacopoeia_PO.aspx*

ISSUES REGULATED AT THE SUPRANATIONAL LEVEL	ISSUES REGULATED AT THE NATIONAL LEVEL OF EAEU MEMBER STATES
development preclinical and/or clinical studies quality control registration manufacturing distribution of medicines	granting permits on preclinical and /or clinical studies of medicines price formation retail trade state purchases of medicines and other procedures related to cost recovery in the sphere of pharmaceuticals trade advertising

欧亚经济联盟药品流通规范

2019年3月25日

瓦连京•阿尼金
REVERA公司药剂学与医疗保健领域专业律师

德米特里•阿尔希片科
REVERA公司管理合伙伴伴

目前欧亚经济联盟正着手统一药品市场标准规定，以推动其积极发展。

统一药品市场意味着符合良好药品规范（实验室规范，生产质量管理规范，临床规范，药物警戒规范等）并按照统一注册与鉴定规范标准的药品将会在欧亚经济联盟框架内自由流动。

欧亚经济联盟统一药品市场受2014年12月23日欧亚经济联盟药品流通统一原则和规则的约束。

在超国家层面统一与协调处理药品问题是关键，它们旨在统一药品市场的建设与运作。

药典协调

药品要求标准化是统一市场运作的先决条件，因此目前正在创建欧亚经济联盟药典，对所有成员国药品进行统一要求。

自2016年以来，持续创建欧亚经济联盟统一药典。

欧亚经济联盟药典上卷包括确定对药品质量的控制方法、包装材料、试剂、剂型、原料药、标准试样、在欧亚经济联盟内流通的药品助剂生产要求等的协调一般性统一文章（专著）。

目前欧亚经济联盟药典上卷第一部的内容设计已发布。关于原料药、天然药材（植物源与动物源性药品）的协调一般性个人文章（专著）将作为下一卷。

欧亚经济联盟药典委员会赞成如下一系列药典文章，例如"设备"、"物理与物化方法"、"药品杂质检测"与"定量测定方法"。目前其它的药典文章正在讨论中。

在欧亚经济联盟委员会网站上公布了已赞成与正在讨论中的药典文章项目[1]。

欧亚经济联盟药典要求对于欧亚经济联盟框架内流通药品的标准是强制性的。欧亚经济联盟药典计划至少每5年更新一次。

[1] *http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/LS1/Pages/pharmacopoeia_PO.aspx*

在超国家层面药品监管问题	在欧亚经济联盟的成员国国家层面药品监管问题
开发 临床前研究与临床研究 质量控制 注册 生产 药品分布	药品临床前与临床研究授权 定价 零售 政府采购与涉及到药品流通领域成本回收问题及其它程序 广告

pursuant to the unified rules of Good Laboratory Practice (GLP)[2], Good Clinical Practice (GCP)[3] and the current requirements to studies (tests) of medicines. Also, the EAEU rules for studying biological medicines[4] and the EAEU rules for studying the bioequivalence of medicines[5].

REGISTRATION AND EXPERT APPRAISAL OF MEDICINES

For the purpose of free circulation of medicines within the EAEU, the Rules for registration and expert appraisal of medicines have been prepared and put into effect as from 06.05.2017[6]. The unified rules stipulate two procedures for the registration of medicines:

- mutual recognition procedure
- decentralised procedure

Under the mutual recognition procedure, medicines will first be registered in an EAEU country (a 'reference state') and obtain a registration certificate there. Thereupon, such medicines will be registered in other EAEU member states (so called 'recognition states'), under an abridged procedure, and will be granted a registration certificate in each recognition state.

The decentralised procedure differs in that the registration dossier will be simultaneously evaluated both in the reference state, and in the recognition states. This allows reducing the overall pendency time.

Within the mutual recognition procedure, EAEU member states have undertaken to mutually recognise the results of pre-clinical, clinical and other studies of medicines, results of production inspections, trials inspections, and pharmacovigilance inspections for the compliance with good pharmaceutical practices, and the requirements approved by the Eurasian Economic Commission[7].

For the purposes of registration and expert evaluation of medicines under the Eurasian Economic Commission Rules, the unified Nomenclature of pharmaceutical forms approved by EEC Board Decision No. 172 dated 22.12.2015 shall be used.

All medicines duly registered according to the unified rules and marketed within the EAEU must have marking in accordance with the uniform Requirements to medicines and veterinary drugs marking as approved by EEC Board Decision No. 76 dated 03.11.2016. Such medicines shall be accompanied with a core data sheet conforming to the uniform requirements as approved by EEC Board Decision No. 88 dated 03.11.2016.

In order to harmonise the pharmaceutical markets of EAEU member countries, a transition period has been established that will ensure a smooth transition from the national regulation to the unified regulation.

MANUFACTURING OF MEDICINES

The EAEU Good Manufacturing Practice (GMP) Rules were approved by EEC Council Decision No. 77 dated 03.11.2016. These rules are mandatory for all manufacturers within the EAEU territory and are applied for the issuance of production licenses and manufacturer inspections.

The status of manufacturer's Qualified Person has been established in order to secure proper compliance whith these rules. A Qualified Person is appointed by a manufacturer and certified in accordance with the procedure and requirements set out in EEC Council Decision No. 73 dated 03.11.2016. Duly certified Qualified Persons will be put on the relevant register available at the EAEU web-portal[8].

WHOLESALE TRADE, TRANSPORTATION AND STORAGE OF MEDICINES

Good Distribution Practice (GDP) Rules approved by EEC Council Decision No. 80 dated 10.11.2017 are used within the EAEU framework. These rules set out uniform requirements to the procedures of purchasing, storing, importing, exporting, trading (except retail sales to end consumers) without limitations of sales volumes, and transportation of medicines marketed within the EAEU.

EAEU member states still may regulate specific stages of medicines distribution at the national level, as long as such regulation complies with the EAEU GDP.

For instance, this applies to particular stages of distribution of narcotic/psychotropic drugs and their precursors, highly toxic medicinal agents and ionizing radiation emitting agents.

HARMONISATION OF PHARMACEUTICAL INSPECTION PROCEDURES

The EEC Council has established the harmonised requirements for pharmaceutical quality system inspections. The results of such inspections will be recognised in all EAEU member states. Such inspections will reveal whether the production schemes conform to the requirements of the EAEU Good

[2] *Approved by EEC Council Decision No. 81 dated 03.11.2016.*

[3] *Approved by EEC Council Decision No. 79 dated 03.11.2016.*

[4] *Approved by EEC Council Decision No. 89 dated 03.11.2016.*

[5] *Approved by EEC Council Decision No. 85 dated 03.11.2016.*

[6] *Approved by EEC Council Decision No. 78 dated 03.11.2016.*

[7] *Cl. 7 art. 7 Agreement on uniform principles and rules of medicines turnover within EAEU.*

[8] *https://portal.eaeunion.org/sites/odata/_layouts/15/Registry/PMM02/TableView.aspx?ItemId=371&ListId=0e3ead06-5475-466a-a340-6f69c01b5687*

PERIOD	PROCEDURE
till 31.12.2020	Applicants are entitled to choose the type of rules (national or unified) to be used for the registration of medicines. However, medicines registered in accordance with the national legislation of a member country will only be allowed in the market of such member country.
till 31.12.2025	All medicines registered under the national rules before 31.12.2020 must be reregistered pursuant to the single market rules.
as from 01.01.2026	Turnover of pharmaceuticals not duly registered or not conforming to the EAEU requirements will be ceased.

时期	规则
到2020年12月31日为止	申请人可以选择根据统一规则进行登记，以便注册和检验医用医药产品，或者根据成员国的法律进行注册。
到2025年12月31日为止	根据欧亚经济联盟成员国法律注册药品必须符合欧亚经济联盟统一要求。
从2026年1月1日起	根据成员国法律，颁发的药品注册证书失效，因此未通过注册程序或符合欧亚经济联盟要求的药品流通也将失效。

临床前与临床研究

欧亚经济联盟成员国统一市场框架内流通药品的临床前与临床研究要求按照良好药品实验研究规范（Good Laboratory Practice – GLP[2]）、良好药品临床试验规范（Good Clinical Practice – GCP[3]）与药品研究统一进行，另外还批准了欧亚经济联盟生物制品研究规范[4]与药品生物等效性研究规范[5]。

药品注册与检验

为了在欧亚经济联盟区域内药品市场自由流通的目的，而制定医疗药品注册与检验的规范标准，该标准自2017年5月6日生效[6]。统一规范药品注册方法的两种程序：

- 互认程序：
- 分散程序。

在互认程序框架内，首先药品在欧亚经济联盟成员国的一个国家（所谓参考国家）获得注册证书，之后，药品在其他欧亚经济联盟成员国国家（所谓承认国家），通过简易程序，获得注册证书。

分散程序的差别在于两个国家同时评估注册档案，这缩短了药物在几个国家注册的期限。

关于互认程序，目前这种程序已实现。欧亚经济联盟成员国相互承认药品临床前（非临床）、临床研究以及其它研究（测试）的结果，生产检验结果，药物警戒系统是否符合良好制药规范以及欧亚经济联盟委员会规定的要求[7]。

根据欧亚经济委员会的规定进行药品注册与检验时，应按照2015年12月12日欧亚经济联盟委员会第172号决议批准的统一药品命名标准进行。根据相同规则注册并在欧亚经济联盟框架内销售的药品必须按照欧亚经济委员会理事会第76号决议批准的医用药品和兽用药品的统一标签要求进行标识。这种药品应附有符合2016年12月3日欧亚经济联盟理事会第88号决议批准统一要求的使用说明。

为了协调欧亚经济联盟成员国的药品市场规定，通过建立过渡期，以确保通过单一法规顺利取代国家法规。

药品生产

2016年11月3日欧亚经济联盟理事会第77号决议批准了“良好生产规范”的标准要求。对于在欧亚经济联盟境内的所有制造商的要求都是强制性的，并且在颁发注册证书以及在检查制造商时都要考虑在内。

为确保遵守这些规范，明确制造商授权代表的状态。此授权代表由药品制造商委任，并根据2016年11月3日欧亚经济联盟理事会第73号决议批准的程序与要求进行认证。经认证的授权代表包含在欧亚经济联盟信息门户网站上的相关注册簿中[8]。

[2] 2016年11月3日欧亚经济联盟理事会第81号决议批准。

[3] 2016年11月3日欧亚经济联盟理事会第79号决议批准。

[4] 2016年11月3日欧亚经济联盟理事会第89号决议批准。

[5] 2016年11月3日欧亚经济联盟理事会第85号决议批准。

[6] 2016年11月3日欧亚经济联盟理事会第78号决议批准。

[7] 欧亚经济联盟内药品流通统一原则和规范”第7条第7款。

[8] *https://portal.eaeunion.org/sites/odata/_layouts/15/Registry/PMM02/TableView.aspx?ItemId=371&ListId=0e3ead06-5475-466a-a340-6f69c01b5687*

Manufacturing Practice.

General requirements to pharmaceutical inspections are set out in art. 10 of the Agreement on uniform principles and rules of medicines turnover within EAEU and the Rules of pharmaceutical inspections as approved by EEC Council Decision No. 83 dated 03.11.2016.

Pharmaceutical inspections are carried out by pharmaceutical inspectorates of EAEU member states. The inspectorates are guided by the General requirements to pharmaceutical inspectorates quality system as approved by EEC Council Decision No. 82 dated 03.11.2016. The register of EAEU pharmaceutical inspectors is available at portal.eaeunion.org[9].

Timeframes of routine pharmaceutical inspections, decision making procedures and lists of entities that have passed inspection checks and have been granted respective certificates will be established by respective pharmaceutical inspectorates.

SETTING GENERAL PHARMACOVIGILANCE REQUIREMENTS

The requirements to the pharmacovigilance system have been determined by EAEU Good Pharmacovigilance Practice (GVP) as approved by EEC Council Decision No. 87 dated 03.11.2016.

All entities must elaborate and implement their own pharmacovigilance systems to secure proper safety of medicines. All pharmacovigilance specialists within each entity shall be responsible for the proper functioning of the pharmacovigilance quality system.

Authorised government bodies will conduct inspections of pharmacovigilance systems. Such inspections may be abrupt, therefore entities must always make sure they are ready for them. ■

The full review at the following links

In Russian: ***https://app.luminpdf.com/viewer/oepeJP6kQifW6JZF3/share?sk=81227684-383c-435a-af46-7b717f75a67d***

In English: ***https://app.luminpdf.com/viewer/Le9t6qicffuKHfWSv/share?sk=bf610b1c-40c5-4a4b-a31e-e39fe09556da***

[9] *https://portal.eaeunion.org/sites/odata/_layouts/15/Registry/PMM09/TableView.aspx*

药品的运销、运输与储存

经2017年11月10日欧亚经济联盟理事会第80号决议批准的在欧亚经济联盟框架内良好运销的规范已生效。该规范对于欧亚经济联盟区域内的药品运销规定进行了统一要求，包括采购、储存、进口、出口、销售（向公众销售除外）过程，不限制在欧亚经济联盟区域内的药品运输。

在欧亚经济联盟成员国的国家立法层面，与欧亚经济联盟GDP不相矛盾的前提下，自行有权规范药物分配的各个阶段。

例如，这适用于麻醉药，精神药品或其前体药物，高毒性（剧毒）化合药物，作为电离辐射源的药物。

统一药品检查程序

欧亚经济联盟理事会已确定进行一次药品质量体系检查的统一要求，其结果将在所有欧亚经济联盟成员国中得到承认。在此检查过程中，要确定药品生产是否符合欧亚经济联盟良好生产规范的要求。

药品检查统一要求要符合欧亚经济联盟内药品流通统一原则和规范协定第10条，该条款是欧亚经济联盟委会理事会在2016年11月3日通过的第83号关于药品检验规范的决议。

药品检查由欧亚经济联盟成员国国家的药品检查员执行。执行检查时，检查员要遵照2016年11月3日欧亚经济联盟理事会第82号决议批准的药品检查员质量系统统一要求。欧亚经济联盟检查员目录表也可在portal.eaeunion.org上获得[9]。

计划药品检查日期，作出决策程序以及成功通过检查并获得相关证书的主体清单，由相关药品检验规定。

药监部门的总体要求

药物警戒系统要求由欧亚经济联盟的良好药物警规范确定，该规范经2016年11月3日欧洲经济第87号理事会决议批准。

组织必须制定并实施自己的药物警戒系统，以控制药物安全。药物质量体系的运作由药物警戒的结果决议，负责该组织药品警戒系统的所有专家。

授权的国家机构对组织中的药品警戒系统进行检查。这种检查可能是突然的，因此组织必须始终为它们做好准备。■

链接为完整的综述如下：

俄文: https://app.luminpdf.com/viewer/oepeJP6kQifW6JZF3/share?sk=81227684-383c-435a-af46-7b717f75a67d

英文: https://app.luminpdf.com/viewer/Le9t6qicffuKHfWSv/share?sk=bf610b1c-40c5-4a4b-a31e-e39fe09556da

[9] *https://portal.eaeunion.org/sites/odata/_layouts/15/Registry/PMM09/TableView.aspx*

The GMP Inspectorate in Russia:

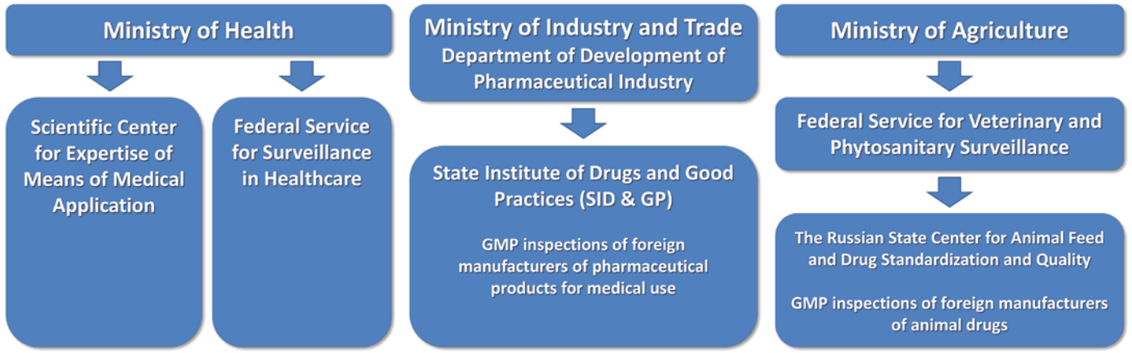
FSI SID & GP is the authority for conducting GMP inspections of foreign medicine manufacturers

5 March 2019

The GMP inspectorate in Russia within the system for regulation of medicines is a quite young structure. Even though the demands on organising production and controlling the quality of finished medicines were formulated back in 1974 and the first ever rules for organising production and quality control of medicines in modern Russia appeared in 1991, the GMP inspectorate was only set up in 2013. At this time, the Ministry for Industry and Trade of the Russian Federation (Minpromtorg) was empowered to approve rules for good production practice and issue conclusions on conformity of manufacturers of medicines for medical application with these rules' requirements. Since then, the Rules for Good Manufacturing Practice (approved by order of the Ministry for Industry and Trade of the Russian Federation No. 916 dated 14.06.2013) have been in effect in Russia. In essence, these are a translation of the GMP EU rules that were effective when the order was drawn up. In 2014, as the expert organisation involved in licensing control over pharma enterprises located in the Russian Federation, FSI State Institute of Drugs and Good Practices (FSI SID & GP) began operating as part of the Minpromtorg commission. Since 2015, FSI SID & GP has been authorised to inspect manufacturers of medicines for medical use produced outside the Russian Federation for conformity with the GMP rules. The purpose of the inspections is to issue conclusions on conformity by medicine manufacturers with the requirements of the rules for good manufacturing practice. SID & GP is thus empowered to conduct inspections of foreign sites operated by medicine manufacturers and the Minpromtorg Department for development of the pharmaceutical and medical industry checks on compliance with the GMP by domestic producers.

As the GMP inspectorate, SID & GP is a structure that appeared only a few years ago but has already earned an excellent reputation among foreign inspectorates and manufacturers.

Apart from ensuring the quality of medicines, the inspectors also promote the GMP rules and make all market players aware of the need to observe



Regulation System of Medicines in Russia

俄罗斯GMP监察机构：

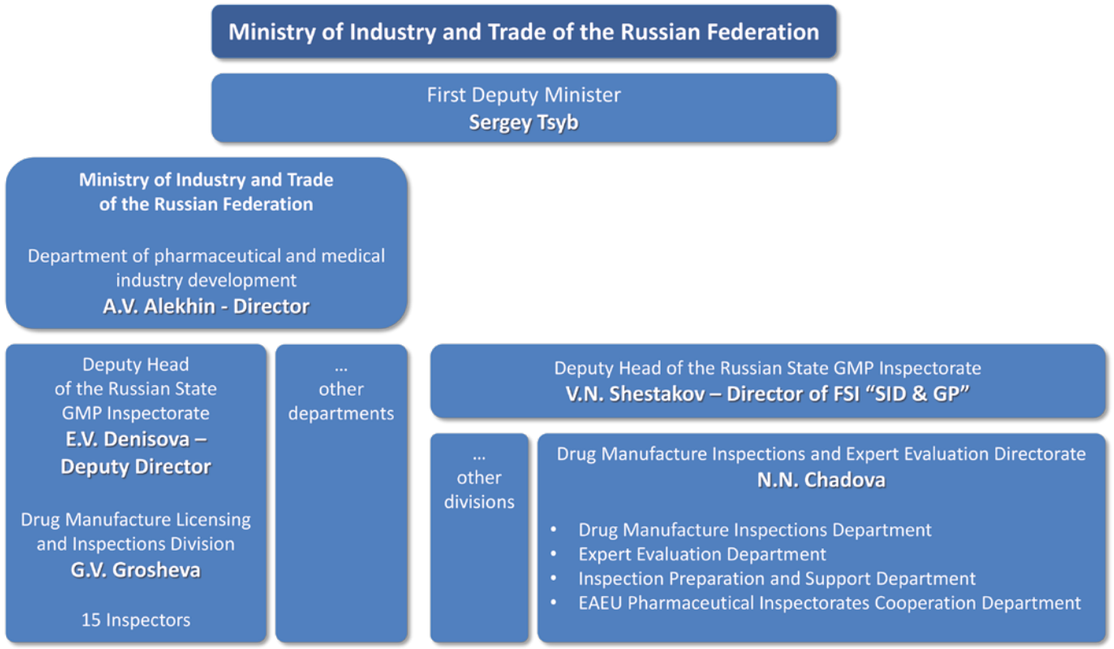
联邦预算机构“国家药物和GP研究院”是授权对国外制药厂进行GMP监察的机构

俄罗斯联邦药品监管系统

俄罗斯药品监管体系中的GMP监察机构是一个很年轻的国家机构。虽然在1974年就已制定成品药生产企业质量控制要求，1991年颁布俄罗斯现代史上首部制药企业质量控制规定，但GMP监察机构成立于2013年。其时由俄罗斯联邦工贸部批准生产质量管理规范及签发医用药品生产企业符合该规范要求的结论。此后俄罗斯境内开始执行药品生产质量管理规范（俄罗斯联邦工贸部2013年6月14日第№916号令批准），这部规范实质是第№916号令制定时欧盟现行的GMP标准的译本。2014年，联邦预算机构“国家药物和GP研究院”作为隶属于俄罗斯工贸部委员会成员的鉴定组织，开始对俄罗斯境内的制药企业进行许可监察。自2015年以来，联邦预算机构“国家药物和GP研究院”授权对俄罗斯联邦境外的医用药品生产企业进行符合GMP标准的检查，为企业签发生产质量管理规范符合性结论。国家药物和GP研究院授权对境外制药企业进行检查，俄罗斯工贸部下属制药和医疗行业发展司则检查本地制造商是否符合GMP要求。

国家药物和GP研究院作为GMP监察机构虽然仅成立几年，但已向国外监察机构和制药企业展现出自身的业务能力。研究院除确保药品质量外，还承担了普及GMP标准的责任，向所有市场参与者贯彻只有遵循这些标准才能生产出高质量药品的意识。GMP标准将“质量”概念提升到全新高度，使其成为评估生产企业工作的最重要标准之一，也是衡量企业竞争力的准绳。

虽然成立不仅，但仅2016年国家药物和GP研究院已对俄罗斯联邦境外的国外药品生产企业的工厂进行了1499次检查。对中国制药企业进行了27次现场检查，并据此签发了14个GMP标准符合性结论。药品监察机构提出的批评意见包括：



GMP Pharmaceutical Inspectorate Structure

these standards in order to manufacture high-quality medicines. It is the GMP rules that raise the "quality" concept to a fundamentally new level and make it one of the crucial criteria for assessing a manufacturer's operation, including from the point of view of competitiveness.

Despite the fact it was created only recently, SID & GP since 2016 has already managed to conduct 1499 inspections of foreign sites where medicines are manufactured outside the Russian Federation. 27 of these were carried out at pharma company sites in China. As a result of these inspections, 14 GMP standards compliance certificates were issued.

Among the critical comments identified by the Russian Inspectorate are the following:

- the procedure for issuing a production permit is ambiguous and not systematic. For example, the same form and the same rules of its execution are used by the authorized person for permission to mark the commercial series of the substance and for permission to issue the commercial series of the substance with the mark. In a series release permit, the authorized person does not record the number of the specification to which the series corresponds. The authorized person does not take into account the correctness of the consumer marking on the packaging of the substance during the issuance of the permit for the series. When a series of substances are shipped from the warehouse, the storekeeper does not make a record confirming the checking of the series status;
- the method of determining impurities in the substance does not comply with the ND RF:
  - the procedure for the analysis of the parameter "Microbiological purity" does not include verification of the correct calculation of the number of colonies by the second microbiologist
  - to control the parameter "Authenticity by IR spectrometry" substance is not set quantitative criteria for compliance between the spectra of the test sample and the standard sample
  - specification of package labelling substance contains conflicting information: "For the production of sterile and non-sterile dosage forms»;
- do not provide a justification for exclusion of continuous monitoring for particulates in the working area of purity class A for critical operations (filling aluminium containers). Monitoring of the concentration of aerosol particles takes place at the beginning and the end of a filling process. There is no justification for the lack of monitoring of aerosol particles concentration in the equipped state for the isolated zones with the unidirectional air flow of class A.

It should be noted that FSI SID & GP not only conducts GMP inspections of foreign pharma manufacturers; it also works to establish mutual relations with foreign colleagues, and international organisations for the purpose of harmonising the legislations and unifying requirements in the sphere of Good Manufacturing Practices. In particular, work is under way and working meetings are held with EDQM and EMA, the regional office of the ISPE for countries of the EAEU and the CIS, the status of a WHO Educational Centre has been obtained for GMP and GDP inspectors, as well as that of a preliminary PIC/S applicant.

INTERNATIONAL COOPERATION

2018 was marked by broader international co-operation and development

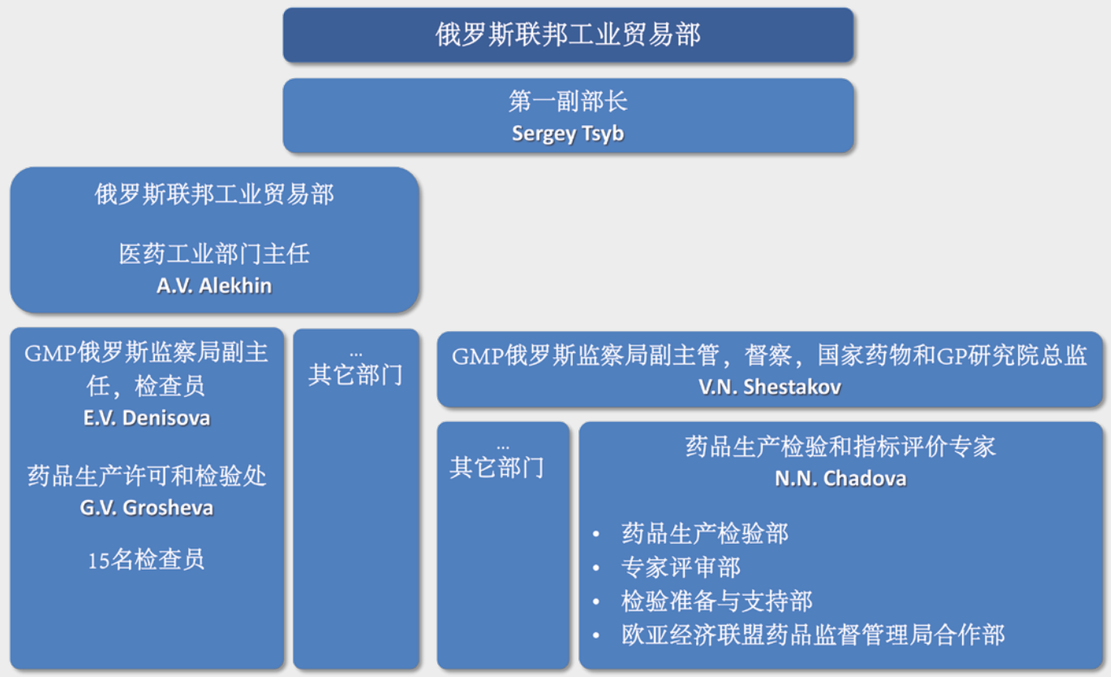
- 颁发生产许可证的程序不系统，不清晰。例如，授权人使用相同的格式和规定办理药品商业系列标志和已有标志药品商用系列的标志许可。授权人未在批量生产许可证中记录系列相对应的规格编号。在办理批量生产许可证期间，授权人并未考虑药品包装上使用消费标志的正确性。从仓库发出药品时仓库管理员未记录药品系列状态检查的情况；
- 确定药品杂质的方法与俄罗斯联邦规范文件不符：
  - 分析参数“微生物纯度”的过程中未检查第二位微生物学家统计的菌落数的准确性；
  - 为控制药品“红外光谱法真实性”参数，检查样品与标准样品光谱间未建立对应的定量标准；
  - 药品包装标识有相互矛盾的信息：“用于生产无菌和有菌药剂”；
- 未提出关键工序（填充铝容器）A类清洁工作区未连续监测颗粒的理由。在填充开始和结束时监测气溶胶颗粒的浓度。未提出A类单向气流释放区在填充状态时未监测气溶胶颗粒浓度的理由。

值得一提的是，国家药物和GP研究院在对外国制药企业进行GMP检查的同时，还与外国同行和国际组织建立了合作关系，协调统一药品生产质量管理规范领域的法规和要求。与EDQM和EMA，EAEU和独联体国家的ISPE区域办事处举行工作会议，并取得世界卫生组织GMP和GDP监察教育中心地位及PIC/S初步申请人的资格。

国际合作

2018年着力扩大国际合作，推动与外国同行的合作，签署了多个合作协议。例如，基于与COFEPRIS（墨西哥）和CDSCO（印度）代表b2b会议结果，确立了合作重点。

与MHRA（Medicines and Healthcare products Regulatory Agency）举行工作会议，确定合作方向，并于2019年1月29日签署合作备忘录，共同举办培训活动，抵制不合格药品，长期共享信息。在俄罗斯-意大利药品和医药分组第一次会议上探讨了监管机构合作的前景，“国家药物和GMP（生产质量管理

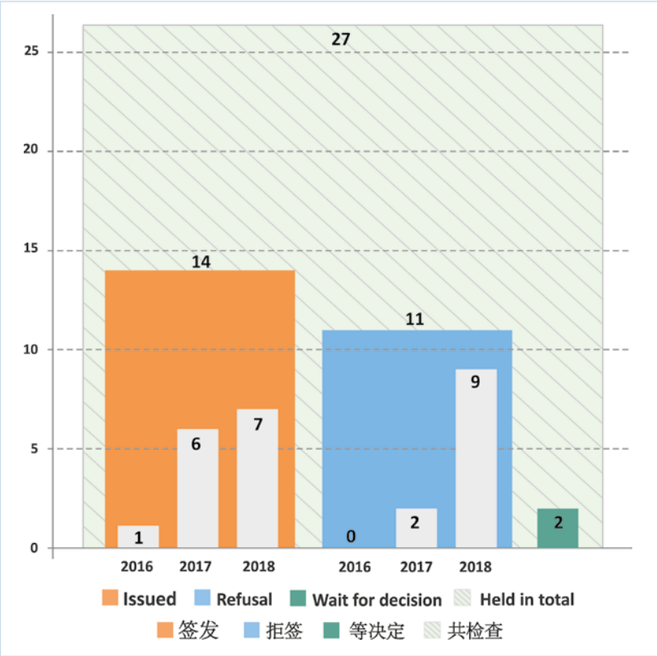


GMP药品监督机构

supported by PHARMASYNTEZ

GMP INSPECTIONS HELD BY RUSSIAN INSPECTORATE IN CHINA

俄罗斯监察机构在中国进行的GMP检查



Data of the Department of Economics and analysis of pharmaceutical and medical industry of FSI SID & GP

联邦预算机构“国家药物和GP研究院”制药和医疗行业经济与分析部数据

of mutual relations with foreign colleagues, sometimes resulting in co-operation agreements being signed. For instance, B2B meetings with representatives of COFEPRIS (Mexico) and CDSCO (India) determined the collaboration targets.

Working meetings were held with MHRA (Medicines and Healthcare products Regulatory Agency), where lines of cooperation were determined, resulting in the signing on 29 January 2019 of a memorandum of cooperation. This provides training events to be held and assistance provided in combating substandard medicines, as well as regular exchange of information. The prospects for collaboration between regulators were discussed at the first meeting of the Russian-Italian subgroup of pharmaceuticals and medicine as part of the discussion between representatives of the FDA, MHRA and SID & GP on Appendix 1 to the European GMP rules. Moreover, this meeting was followed by launch of educational projects for the Russian inspectorate by Fedegari, the leading Italian manufacturer of equipment for the pharma industry.

The first visit to Japanese colleagues was made by representatives of the Russian inspectorate: as part of the professional collaboration on GMP compliance inspections, meetings were organised with the PMDA (Pharmaceuticals and

俄罗斯联邦境内出售中国药品和膳食补充剂。截止2018年底合计达到140万包，比2017年减少6.4%。按价值计市场占比下降2.9%，约9亿卢布。显而易见，受国家进口替代和扶持国内生产企业计划的影响，中国药品和膳食补充剂在俄罗斯医药市场呈逐渐减少趋势（2017年中国药品和膳食补充剂市场销量以包装计较2016年减少20%，为150万包，以卢布计减少9.1%，约为9亿卢布）。如果仅看中国药品的市场，2018年为70万包，5亿卢布，较上一年分别减少了（以包装计）29.3%和（以卢布计）13.9%。2017年药品市场量达到90万包，6亿卢布。比2016年分别减少（以包装计）16.6%和（以卢布计）6.4%。整体来讲，中国药品在俄罗斯药品市场销售总额中的份额（以包装计和以卢布计）都有所下降，以包装计为0.01%（2016年-2017年为0.02%），以卢布计为0.04%（2016年-2017年为0.05%）。中国主要向俄罗斯医药市场出口仿制药。2016-2018年俄罗斯共售出29种INN（国际非专利药品名称）（30种商品名）中国药品。2种INN（国际非专利药品名称）为原研药，2018年其销售数量为2.1万包，4830万卢布，较去年同期相比分别增长16.6%（以包装计），增加了1倍（以卢布计）。

2018年中国生产的仿制药（16种INN（国际非专利药品名称））的销量比2017年减少13.4%，为40万包。同期以价值计增长了2.1%为2亿卢布。2018年进口药品数量达800万公斤，比2017年减少12.4%。同期以价值计总量增长11.5%，达3亿美元。2017年进口总量为910万公斤，2亿美元，分别比2016年增长3.8%（以包装计）和16.2%（以价值计）。

2016年中国向俄罗斯出口药品占俄罗斯进口总量：以包装计为70%，以价值计为30%。2018年中国向俄罗斯出口药品占俄罗斯进口总量：以包装计为60%，以价值计为20%。

进口药品主要INN（国际非专利药品名称）为：赖诺普利，脱氧胆酸，强力霉素。

调查期间共进口453种INN（国际非专利药品名称）。

The Chinese market is represented on the territory of the Russian Federation by medicines and dietary supplements. According to the results of 2018, it amounted to 1.4 million packages, which is 6.4% less than the volumes in 2017. In value terms, the market fell by 2.9% to RUB 0.9 billion. It is obvious that within the framework of the implementation of state programs on import substitution and support of domestic manufacturers, the presence of Chinese medicines and dietary Supplements in the Russian pharmaceutical market is gradually decreasing. (In 2017, the volume of the market of medicines and dietary supplements from China decreased compared to 2016 by 20% in packages and amounted to 1.5 million units. and by 9.1% in rubles, amounting to 0.9 billion rubles).

If we consider only the market of medicines from China, in 2018 it amounted to 0.7 million units by 0.5 billion rubles, which is less than the volume of the previous year by 29.3% and 13.9%, respectively. In 2017, the volume of the market of medicines amounted to 0.9 million units 0.6 billion RUB, compared to 2016 is less than 16.6%, 6.4% respectively. In general, the share of Chinese medicines in total sales of medicines in the Russian market decreased both in physical and in value terms and amounted to 0.01% (0.02% – 2016-2017) in packages and 0.04% (0.05% – 2016-2017) in rubles.

Generics are mainly supplied to the Russian pharmaceutical market from China. Thus, in 2016 -2018, 29 INNs (30 tons) of Chinese medicines were sold in Russia. 2 INNs of them are original drugs, the volume of which at the end of 2018 was 21 thousand packs by 48.3 million rubles, which is more by 16.6% and 2 times, respectively, when compared with the same period last year. Sales of generic Chinese production (16 INNs) in 2018 declined by 2017, by 13.4% million packs and amounted to 0.4 million packs. At the same time, in value terms, there was an increase of 2.1% – 0.2 billion rubles.

The volume of imported pharmaceutical substances in 2018 amounted to 8.0 million kg, which is 12.4% less than in 2017. But in value terms, the volume increased by 11.5% and amounted to 0.3 billion USD. In 2017, the volume amounted to 9.1 million kg by 0.2 billion USD, which is more than in 2016 by 3.8% and 16.2%, respectively.

The share of imports of Chinese pharmaceutical substances in total imports of substances to Russia in 2016 was 70% in packages and 30% in value terms, in 2018 – 60% in packages and 20% in value terms.

Leaders in imports of INNs are lisinopril, Deoxycholic acid, Doxycycline.

453 INNs in total were imported in the period under review.

规范）研究院”参会代表与FDA，MHRA共同讨论了GMP欧洲标准附件1的修订问题。此次会后，意大利制药行业领头的设备制造商Fedegari公司开始着手俄罗斯监察机构的教育项目。

为落实行业间GMP符合性检查的合作，俄罗斯监察机构代表首次访问日本，与PMDA（日本药品医疗器械局）及制药公司代表—日本药品制造商协会成员进行会谈。

还与多个生产质量管理规范监察部门或专业机构签署了合作协议，包括保加利亚监察机构（Bulgarian Drug Agency – 保加利亚卫生部药品管理局）。

联邦预算机构“国家药物和GP研究院”院长弗拉迪斯拉夫·谢斯塔科夫称：“与外国同行建立有效的沟通渠道是协调GMP标准和要求，统一监察方法的方法之一。监管机构对产品的生产要求对于那些不仅在一个国家销售产品的制造商来说非常重要，当然，各国的检查机制和条件不同，不可能完全复制另一个国家的系统，因此交流经验，讨论现有区域的发展和合作是非常必要可行的工作方式。”

去年我们就EAEU和欧盟区域医药市场的问题和发展趋势举行了会议，并展开积极的工作。2018年4月，联邦预算机构“国家药物和GP研究院”院长弗拉迪斯拉夫·谢斯塔科夫在布鲁塞尔参加了欧亚经济委员会工作组、欧亚交流中心、欧洲药品质量管理局(EDQM)、欧洲制药工业协会联合会（EFPIA）和国际药品生产者协会（AIPM）举办的联席会议。会议主题是欧盟和欧亚经济联盟区域医药市场的趋势，先进经验及存在的问题。

“国家药物和GP研究院”继续与EDQM展开合作，并于2019年初在斯特拉斯堡EDQM总部举行了会议，会上除强调遵守国际GMP和GLP标准外，两个监管机构还详细讨论了俄罗斯药品生产商取得合格证书（CEP）的问题。

开始与FIMEA（芬兰社会保障和卫生部下属的

Medical Devices Agency of Japan) and representatives of pharma companies belonging to the Japan Pharmaceuticals Manufacturers Association (JPMA).

The countries with inspectors or relevant agencies handling matters of Good Manufacturing Practices include Bulgaria (Bulgarian Drug Agency of the Ministry of Health of the Republic of Bulgaria).

"Establishment of efficient communications channels with foreign colleagues is a way to harmonise the GMP requirements and standards and unify approaches for conducting inspections. This is important for medicine manufacturers with an active interest in the regulators' opinions regarding the requirements applied to manufacture of output distributed beyond a single country", according to FSI SID & GP's Director **Vladislav Shestakov**. *"The mechanisms and conditions for checks do, of course, differ. The system which is used in another country cannot simply be copied; exchange of experience, discussion of existing zones of development and collaboration are needed."*

Last year saw active work and meetings on problems and trends in the development of the regional pharma markets of the EAEU and the EU. In particular, in April 2018, Vladislav Shestakov, Director of FSI SID & GP, took part in a joint meeting of the working group of the Eurasian Economic Union Commission (EAEC), the Eurasian Communications Centre, the European Directorate for Quality of Medicines (EDQM), the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Association of International Pharmaceutical Manufacturers (AIPM) in Brussels. At the meeting were discussed the trends, the latest methods and the problems of the regional pharma markets of the European Union and the Eurasian Economic Union.

SID & GP has continued developing co-operation with EDQM and, in early 2019, held more detailed meetings at the EDQM headquarters in Strasbourg. The regulators discussed not only observance of the international GMP and GLP standards, but also the question of Russian manufacturers of pharmaceutical substances obtaining Certificates of Suitability to the monographs of the European Pharmacopoeia (CEP).

With representatives of FIMEA (the Finnish Medicines Agency under the Ministry of Social Security and Health of Finland), work has begun on the possibility of signing a memorandum of co-operation between Finnish and Russian GMP inspectorates.

There has also been collaboration on quality standards, security of regulatory data and best practices in conducting inspections of pharmaceutical manufacturers for compliance with the GMP with regulatory agencies of individual EU countries: FAMHP (Federal Agency for Medicines and Health Products) and AEMPS (Spanish Agency of Medicines and Medical Devices).

The experience of Chinese colleagues from the NMPA (National Medical Products Administration of China) in collaborating with international organisations and associations, such as the WHO, PIC/S, ICH and EMA has also been taken on board. At a meeting in Moscow, Deputy Director General of the Administration for Quality Control of Products and Medicines of Yunnan Province Xing Yawei noted that the given meeting was the first step in establishing professional contacts between representatives of China's NMPA and of the Russian GMP inspectorate.

Experience is being exchanged with colleagues from South-East Asia and SID & GP personnel visited Singapore to discuss proposals for co-operation on joint inspections in order to improve the quality of medicines manufactured in this region and circulating on the Russian market.

The strengthening of mutual trust between the inspectorates of different countries remains relevant to the SID & GP in 2019. Today, cooperation agreements have also been signed with such regulators of the Latin American region as the Center for State Control of Drugs, Equipment and Medical Devices, the National Regulatory Authority of Cuba (CECMED) and the Institute of Public Health of the Republic of Chile, ISP CHILE). In March, an agreement was signed on inspecting pharmaceutical companies for compliance with GMP regulations and helping to fight low-quality, counterfeit drugs with the Spanish Agency for Drugs and Medical Products (AEMPS).

The Russian inspectorate's openness to dialogue and interest in establishing relations of trust with foreign partners responsible for regulating medicine manufacturing, including with respect to compliance by manufacturing sites with the GMP standards, has engendered mutual interest: representatives of FSI SID & GP regularly encourage exchange of experience and tell of the work of the inspectorate in Russia at conferences and roundtables on relevant topics. At the XIII Summit in Spanish Pharmaceutical Inspections, Institute personnel were the only foreign guests. On the ISPE conference in Singapore were discussed topics like joining the PIC/S and mutual recognition of GMP inspections. At the International Conference of Drug Regulatory Authorities (ICDRA) in Dublin, work was performed to strengthen professional collaboration between the Russian GMP inspectorate and the WHO, EMA (European Medicines Agency), PAHO (Pan American Health Organisation), ICMRA (International Coalition of Medicines Regulatory Authorities), regulators from the European Union, Africa, Asia and America. In Riyadh, at the annual conference of the SFDA (Saudi Food and Drug Authority), Vladislav Shestakov was the honoured speaker at the opening of the conference and later, as part of the event, representatives of FSI SID & GP familiarised themselves with their colleagues' experience of the procedure for joining the PIC/S.

At the end of 2018, experts from State Institute of Drugs and Good Practices under Minpromtorg of Russia took part in the Second International Week in Regulatory Science and Good Regulatory Practices in Mexico, organised by the Ministry of Health of Mexico and the Federal Commission for the Protection against Sanitary Risk (COFEPRIS) with the participation of the Centre of Excellence in regulatory science and effective regulatory practices (CoE) and in cooperation with the National College of Biological Pharmaceutical Chemists of Mexico AC (CNQFBM). Here the SID & GP experts acquainted participants on the Latin American market with the specifics of how Russian and EAEU inspectors work and with the consequences of transferring to a unified medicine market within the EAEU.

Let us note that, in turn, SID & GP also invites colleagues to events held with the Institute's support: the GxP summit and the GMP conference. In 2018, the latter was attended by colleagues from Spain, Japan, Cuba, Kazakhstan, the USA, Croatia, Bulgaria, Mexico and the UK. ■

To find out more information about FSI SID & GP please visit: *https://gilsinp.ru*

Vladislav Shestakov
the director of FSI SID & GP

弗拉迪斯拉夫•谢斯塔科夫称
国家药物和GP研究院总监

芬兰药品管理局）代表讨论芬兰和俄罗斯GMP监察机构之间签署合作备忘录的工作。

与欧盟各成员国监察机构，如FAMHP（比利时药品与保健食品联邦局）和AEMPS（西班牙药品监督局）就制药企业进行GMP符合性监察时，质量标准、保护监管数据及维护最佳作业规范等问题的合作。

与NMPA（国家药品监督管理局）中国同行分享与世界卫生组织，PIC/S，ICH，EMA等国际组织和协会的工作经验。云南省食品药品监督管理局副局长邢亚伟在莫斯科会议时指出，此次会面是中国NMPA代表与俄罗斯GMP代表建立业务联系的第一步。

“国家药物和GP研究院”的工作人员访问新加坡，与东南亚同行交流经验，双方讨论了联合监察领域的合作建议，以提高该地区生产药品的质量，这些药品将在俄罗斯市场销售。

加强与不同国家监察机构之间的相互信任仍然是“国家药物和GP研究院”2019年的首要任务。目前已与古巴国家监管局（CECMED）药品、设备及医疗器械国家管理中心、智利共和国公共卫生研究院（Institute of Public Health of the Republic of Chile, ISP CHILE）等拉丁美洲地区监察机构签署了合作协议。3月份，与西班牙药品监督局（AEMPS）签署协议，旨在检查制药企业与GMP标准的符合性，携手打击低劣质假冒药品。

俄罗斯监察机构对对话合作持开放态度，对技术平台符合GMP标准、及与国外药品生产监管机构建立信任的合作伙伴关系有着浓厚兴趣，这是大家共同的利益：“国家药物和GP研究院”的代表们经常被邀请参加各类会议和专题圆桌会议，分享并讨论俄罗斯监察机构的工作情况。在西班牙举行的第十三届药品监察峰会上，研究院的工作人员是唯一的外国嘉宾。新加坡ISPE会议上讨论了加入PIC/S及与GMP监察结果相互承认的问题。在都柏林举行的药物流通领域监管机构国际会议（ICDRA）上讨论了加强俄罗斯GMP监察机构与世界卫生组织、EMA（欧洲医疗管理处）、PAHO（泛美卫生组织）、ICMRA（药品监管国际联盟）、欧盟、非洲、亚洲和美洲监察机构的互动和合作。在利雅得SFDA（沙特阿拉伯食品药品管理总局）年会上，弗拉迪斯拉夫·谢斯塔科夫作为会议开幕的名誉发言人，联邦预算机构“国家药物和GP研究院”的代表们在活动中学习了同行们加入PIC/S的经验。

2018年底，俄罗斯工贸部下属“国家药物和GP研究院”的专家参加了由墨西哥卫生部、墨西哥联邦抗癌保健委员会（COFEPRIS）组织的在墨西哥举办的第二届国际监管科学和生产质量管理实践周，监管科学和生产质量管理领域先进经验中心（CoE）与墨西哥国家化学家、药剂师和生物学家学院A.C.（CNQFBM）联合出席会议。会上“国家药物和GP研究院”的专家向拉丁美洲的同行们介绍了俄罗斯和EAEU监察机构的工作特点，以及向EAEU药物流通单一市场过渡的成果。

联邦预算机构“国家药物和GP研究院”也多次邀请同行们参加研究院举办的多项活动：GxP峰会，GMP会议。2018年西班牙、日本、古巴、哈萨克斯坦、美国、克罗地亚、保加利亚、墨西哥及英国的同行们都曾到访研究院。■

为了解更消息请进国家药物和GP研究院网站：
https://gilsinp.ru

Pharmaceutical Market of Russia

and Prospects for Cooperation

8 April 2019

MINPROMTORG RUSSIA

Roman Kutuzov
Corporate Communications Center S-GROUP

Anastasia Khalzova
Corporate Communications Center S-GROUP

In the past ten years, thanks to the growth in consumer demand and active government support, the Russian pharmaceutical market has developed rapidly: its annual volume in 2018 exceeded 19 billion dollars. In fact, during this time, the modern pharmaceutical industry was created in the country thanks to the efforts of local players and foreign investors. Gradually, the Russian pharmaceutical business has moved from imports to technology transfer and import substitution, and now it is developing innovative competencies, trying to create complex biosimilars and its own original products that are in demand not only in Russia but throughout the world. Russian companies are ready to cooperate with entrepreneurs from different countries, including the Asian region, to which they have always paid special attention.

In 2019, the Russian pharmaceutical industry marks the anniversary – 10 years ago, the Russian government launched the program "Development of the pharmaceutical and medical industry for the period up to 2020".

Its implementation was successful – according to the data of the Ministry of Industry and Trade of the Russian Federation the share of Russian drugs in 2018 on the local market approached 30%. In the segment of public procurement of drugs, these figures were even higher: from 2012 to 2018, the total amount of public procurement funding increased from $3.2 billion to $6.4 billion, while the share of domestic drugs increased from 22% to 33% in monetary terms.

The main landmark of the industry in terms of import substitution is the vital and essential drugs list. Over the past four years, it has expanded by 156 international non-proprietary titles, now it includes 734 titles, including vaccines, i.e. more than 7 thousand trade names. At the same time, more than 80% of titles are domestic drugs, of which 90% are full-cycle products.

Cooperation of Russia with the Asian countries can be analyzed based on the example of the largest Russian partner, China. Deliveries of ready-made

俄罗斯医药市场介绍和合作前景

2019年4月8日

罗曼•库图佐夫
S-GROUP企业传播中心

阿纳斯塔西娅•哈里佐娃
S-GROUP企业传播中心

过去十年消费需求增长，加之政府的积极扶持，俄罗斯医药市场得以快速发展，2018年年产量超过190亿美元。在此期间，当地企业和外国投资者共同努力在国内建设现代化制药工业，因此俄罗斯制药业从进口型正逐步转向技术转让和进口替代型，目前大力发展创新能力，尝试生产在俄罗斯乃至全世界都有需求的复杂生物仿制药品和自主研发药品。俄罗斯公司愿与不同国家的企业合作，尤为关注亚洲地区的企业。

2019年，俄罗斯制药业《2020年前国家制药和医疗产业发展规划》已实施10周年。

该规划已成功实施，根据2018年俄罗斯联邦工贸部的数据，俄罗斯本土药品的市场份额已接近30%。该比例在国家药品采购领域更高：自2012年到2018年，国家采购资金总额从32亿美元增加至64亿美元，本土药品份额从22%增加到33%。

行业进口替代的主要方向是生命必需和基本药物清单。过去四年中该清单增加了156个国际非专利药品名称（INN），目前已涵盖包括疫苗的734个国际非专利药品药品名称，或超过7000个商品名称。其中超过80%是本国药品，本国药品中的90%具备完整的生产周期。

俄罗斯与亚洲地区国家最大的合作伙伴—中国的合作是典型事例。中国出口到俄罗斯的成品药数量很少：根据分析机构RNC Pharma的数据，2018年共出口730万包，价值为2400万美元。

俄罗斯和中国在药品领域的主要合作是供应药物。RNC Pharma的统计数据显示，2018年中国公司向俄罗斯共出口7500吨，价值为2.82亿美元的药物，以货币计药物占市场份额不足20%，以实物计占市场达60%以上。从2016年到2018年，俄罗斯共从中国进口453种国际非专利药品名称的药物。

这种进口结构客观反映出俄罗斯医药市场的现况，即市场上本国药物份额仍然很少，在不久的将来这种情况会发生重大的变化。

国家对制药业的扶持措施

俄罗斯工贸部制药和医疗产业发展部主任阿列克西·阿廖欣称："俄罗斯市场正在逐步深化生产本土化以实现进口替代。俄罗斯制药公司从进口药品的包装开始，已逐步掌握成品活性药物的生产，目前制药公司在向自身合成药物和生产创新生物技术药品转型。政府会一直支持企业的转型。"

国家非常重视制药业，将大力扶持建立拥有完整生产线的制药公司。

俄罗斯联邦工贸部与俄罗斯政府其它部门共同为本国生产企业以及在俄罗斯联邦取得本地化地位的外国公司制定了一系列金融和非金融鼓励措施，现已落实执行。

工业发展基金以优惠的低利率贷款扶持创建新产业项目。

投资者可签订特别投资合同（SPIC）－根据投资者与俄罗斯联邦之间的协议，为获得稳定的税收和监管条款以及税收和其他优惠，投资者承诺在规定时间内掌握工业产品的生产。

medicines from China to Russia are small: in 2018, according to the analytical agency RNC Pharma, 7.3 million packages worth $24 million were shipped.

The basis of cooperation of Russia and China in the pharmaceutical industry are the supplies of pharmaceutical substances. According to RNC Pharma data, in 2018 Chinese companies exported 7.5 thousand tons of substances to Russia worth $282 million, what makes just under 20% of the market of substances in monetary terms and more than 60% of the market in physical terms. In total, from 2016 to 2018, 453 INNs of pharmaceutical substances were imported from China to Russia.

This import structure reliably reflects the situation on the Russian pharmaceutical market, where there is still little production of its own pharmaceutical substances, but in the near future the situation may change significantly.

GOVERNMENT SUPPORT FOR THE PHARMACEUTICAL INDUSTRY

"Import substitution on the Russian market followed the path of gradually deepening the production localization. Starting with the packaging of imported drugs, Russian pharmaceutical companies gradually mastered the production of finished pharmaceutical forms from active pharmaceutical substances, and now they are switching to their own synthesis of pharmaceutical substances and the production of innovative biotech drugs. The state has always supported and will support this process," says **Aleksey Alekhin**, head of the Department for the Development of the Pharmaceutical and Medical Industry at the Ministry of Industry and Trade of Russia.

Today, the state pays great attention to the production of pharmaceutical substances and is ready to support companies which create full-cycle drugs.

The Ministry of Industry and Trade of the Russian Federation, together with other Russian departments, has developed and implemented a set of measures for financial and non-financial incentives for domestic producers, as well as foreign companies that have received localized status in the Russian Federation.

The Industry Development Fund supports projects to create new industries with credit facilities at a low privileged rate.

The investor also has the opportunity to conclude a Special Investment Contract – an agreement between the investor and the Russian Federation, according to which the investor undertakes to master the production of industrial products within the stipulated time, and in return receives stability of tax and regulatory conditions and certain tax and other benefits.

In addition to import substitution, the main focus of the state program "Pharma 2030" will be the development of innovative industries and exports of pharmaceutical products

Another support mechanism is the "Third Extra" rule, which is used in public procurement of drugs. According to this rule, if two or more domestic manufacturers submit their bids, foreign products are automatically removed from the competition. In order for the products to receive the "Russian" status and the opportunity to participate in public procurement on equal terms with domestic market participants, a foreign pharmaceutical company must establish production in the Russian Federation with a sufficient degree of localization.

Many international pharmaceutical companies have taken this path in order to gain access to the Russian market – almost all representatives of Big Pharma have already created localized production in the Russian Federation.

FROM IMPORT SUBSTITUTION TO AN INNOVATIVE DEVELOPMENT MODEL

Now the Ministry of Industry and Trade of the Russian Federation is developing a new version of the state program to support the pharmaceutical industry for the period up to 2030 – Pharma 2030.

In addition to import substitution, the main focus of the state program "Pharma 2030" will be the development of innovative industries and exports of pharmaceutical products.

In 2019, a state venture fund with a capital of about $70 million will be created to support pharmaceutical innovations.

The Ministry of Industry and Trade of the Russian Federation also supports the Startup-Rally competition of innovation projects in the field of medicine and pharmaceuticals (*www.startuprally.ru*).

The competition has been held since 2017, thanks to which a database of promising scientific developments has been formed. The Startup-Rally 2019 final will be held in September at the BioTechMed forum in the Russian city of Gelendzhik. *For all questions, you can contact the initiator: project office "Prodvizhenie", iv.tsvetkov@sgr.com.ru, phone number: +7 (495)-1205333.*

"The Russian Federation has accumulated scientific and technological potential for the full-cycle production of not only generics but also complex biosimilars, as well as innovative biotech drugs that can be in demand around the world," said Alexei Alekhin.

Russian pharmaceutical companies produce monoclonal antibodies, insulin, hormones, blood clotting factors and much more. In 2019, a bioanalogue of the most expensive orphan drug in the world, eculizumab, was registered in Russia. It is important that it will cost at least 25% cheaper than the original drug.

As the successful example of Russian-Chinese cooperation to create high-tech industries can be considered an agreement signed in 2018 between the Russian company Biocad and the Chinese Shanghai Pharmaceuticals Holding to establish two joint ventures. These enterprises will produce for the Chinese market at least six products developed by Biocad based on monoclonal antibodies used in the treatment of cancer and severe autoimmune diseases. Analysts are confident that the joint Russian-Chinese production of monoclonal antibodies is very promising for both sides. ■

另一种扶持机制是国家药品采购时的“第三方即为多余”的规则。根据该规则，如果两个或更多本国生产商提交投标申请时，外国产品将自动退出招标。因此为使产品获得“俄罗斯”地位，公司得到与俄罗斯本土公司平等参与国家采购的机会，外国制药公司应在俄罗斯联邦境内建立生产线，并具有足够的本土化程度。

为进入俄罗斯市场，许多国际制药公司选择了这个方式，几乎所有大型制药公司都已在俄罗斯联邦境内完成了本土化生产。

从进口替代到创新发展模式

目前俄罗斯联邦工贸部正在制定新版的2030年前制药行业国家扶持规划—《2030制药业》。

除进口替代外，国家规划《2030制药业》的主要重点是发展创新产业及医药品出口。

为支持制药行业创新，2019年将成立一个约7000万美元的国有风险基金。

俄罗斯联邦工贸部支持举办医疗和药品领域的创新项目-初创公司拉力赛（网站www.startuprally.ru）。

该竞赛自2017年开始举办，由此形成了一个重要的科研成果数据库。2019年9月初创公司拉力赛的决赛将在俄罗斯格连吉克市的《BioTechMed论坛》举办。所有问题均可咨询竞赛组织方“推广部”办公室。电子邮件：iv.tsvetkov@sgr.com.ru。电话：+7（495）-1205333

阿列克西·阿廖欣还指出：“俄罗斯联邦已积蓄的科学和技术潜力不仅可以生产普通药品，还可以生产全世界者需要的复杂生物仿制药和创新生物技术药品。”

俄罗斯制药公司目前生产单克隆抗体，胰岛素，激素，血液凝固因子等药品。2019年，世界上最贵的孤儿药“依库珠单抗”的类似药物已在俄罗斯注册，类似药物比原药至少便宜25%。

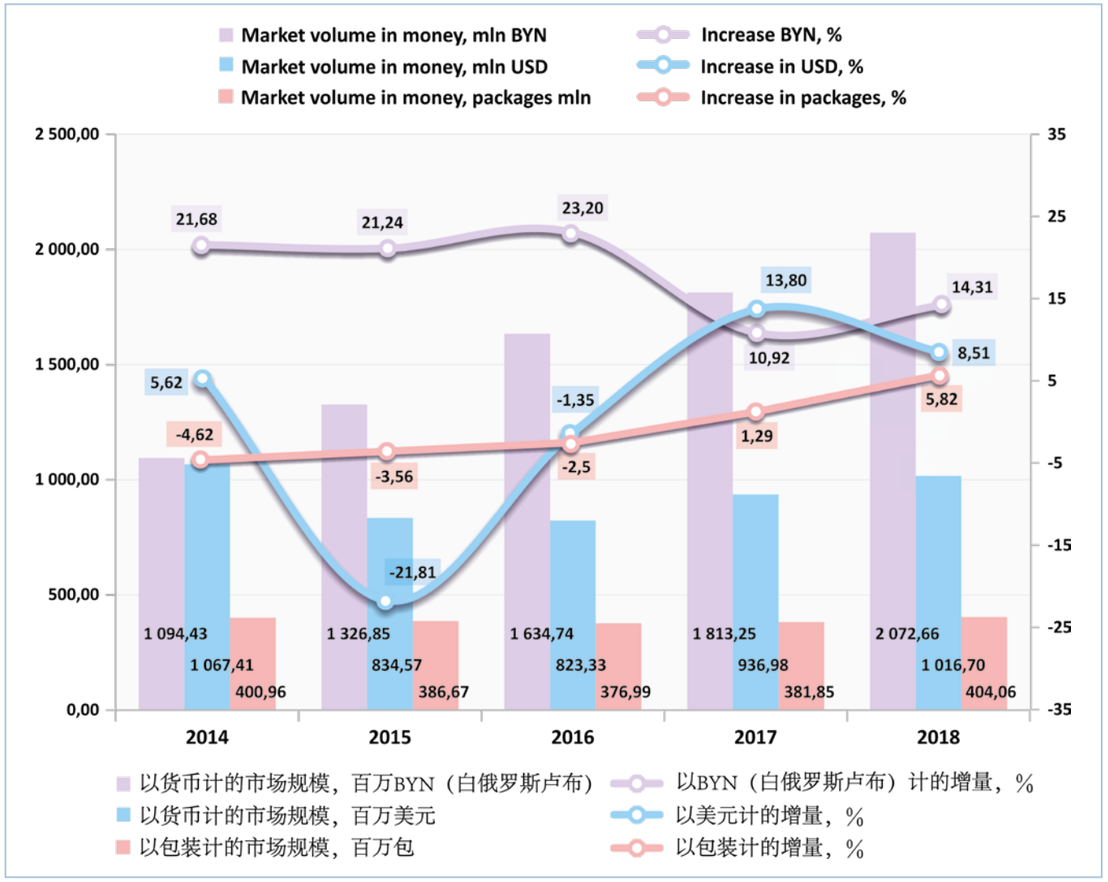
2018年俄罗斯Biocad公司与中国上海医药控股有限公司签署的两家合资企业协议是俄中合作建立高科技产业的成功典范。这些企业将为中国市场生产至少六种由Biocad公司研制的基于单克隆抗体的药品，用于治疗癌症和严重的自身免疫类疾病。分析人士相信，俄中联合生产单克隆抗体对双方的发展都具有广阔远景。■

Pharmaceutical Market of the Republic of Belarus in 2018

8 April 2019
Source: *www.intellix.by*

Tatyana Volynets
Analyst of Intelliks-M Company

In 2018, the pharmaceutical market grew by 5.82% in physical terms. In the Belarusian ruble market increase was 14.31%, in dollar terms the market grew less intensively, which is associated with a devaluation of the national currency. However, it should be noted that the gains in both



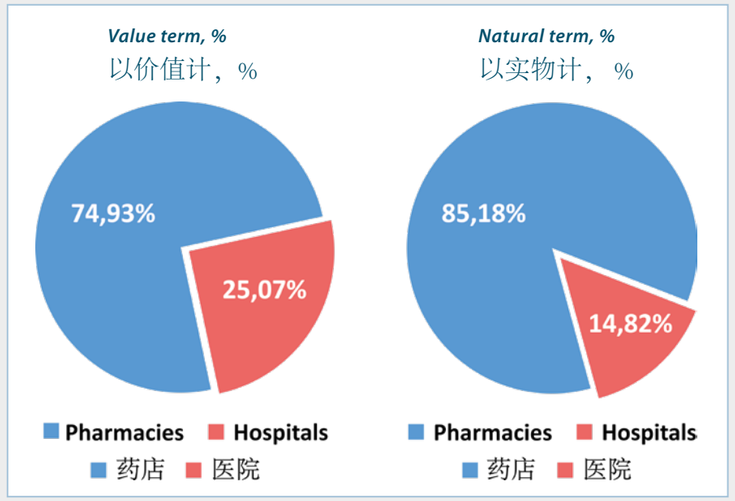
The volume of the pharmaceutical market of the Republic of Belarus 2014-2018
2014-2018年白俄罗斯共和国药品市场总量

2018年白俄罗斯共和国医药市场总结

Intellix

2019年4月8日
资料来源：*www.intellix.by*

塔季扬娜•沃伦涅茨
Intelliks-M公司分析师



Shares of pharmacy and hospital segments in 2018
2018年药店和医院的份额

2018年白俄罗斯医药市场增长量以实物量计为5.82%，以白俄罗斯卢布计为14.31%，以美元计市场增长量较少，这与白俄罗斯本国货币疲软有关。但应该指出的是，两种货币的增长量都比以包装计的增长量多。

2018年医药市场保持稳定，所有主要指标均未出现明显波动。

药店保持领先地位。持续下滑四年后零售市场的份额也有所增加。2011年零售市场的占比最大为81.23%。

2017年多个大型公司进行了资产交换和买卖交易。这直接影响到这些公司在2018年的排名。GSK收购Novartis除流感疫苗外的疫苗业务。Novartis收购GSK肿瘤类药品和其研发业务。这属于资产交换交易。此外，GSK还收购了Novartis Consumer Healthcare。资料来源：www.gsk.com。

Acino公司收购了Takeda公司的部分资产。资料来源：www.acino.swiss。其结果导致Takeda公司跌出TOP-10，NatiVita公司进入TOP榜，位列第10位。

值得注意的是，自2014年以来，白俄罗斯本国公司每年在TOP-10的数量都会增加一名。目前TOP-10中有6家是本土公司。

以货币计解剖治疗化学组前10位占据整个市场的三分之一以上。经过2017年显著增长后，2018年系统应用抗病毒药物跌出前10位。由抗凝剂占据了第10位。

曲妥珠单抗一直保持领先地位。流感预防疫苗五年来第一次进入前10名。

2014年国家药店数量显著增加，过去三年商业药店数量开始极速增长。目前根据自身份额比例，药店数量如同2013年已达到平衡。 ■

currencies are more significant than in packages. The pharmaceutical market in 2018 was stable, not showing significant fluctuations in all major indicators.

Average per capita consumption of pharmaceutical drugs in Belarusian ruble is growing annually in proportion to the rate. The cost of medicines in dollar equivalent remains almost unchanged.

The leading role is retained by the pharmacy segment. The retail market increased its share after a four-year decline. The maximum share of the retail market was in 2011 – 81.23%.

In 2017, there were several transactions for the exchange and purchase and sale of assets in large companies. It influenced the ratings of corporations in 2018. GSK acquired the Novartis vaccine business, excluding influenza vaccines. Novartis purchased the oncology package and development from GSK. It was an asset swap deal. In addition, GSK acquired Novartis Consumer Healthcare. Source: www.gsk.com

Acino has acquired part of Takeda's assets. Source: www.acino.swiss. As a result, Takeda left TOP-10, it allowed the company NatiVita to take the 10th position in the TOP.

It is noteworthy that since 2014 the number of domestic corporations has increased by one annually. Currently, six out of ten companies are domestic.

TOP-10 ATC-groups form more than a third of the entire market in monetary terms. After a significant increase in 2017, antiviral drugs for systemic use in 2018 left the top 10. Their place was taken by anticoagulants.

Trastuzumab has maintained its leading position. For the first time in five years, a vaccine for the prevention of influenza has hit the TOP-10.

Top 10 corporations occupy more than 40% of the total retail market, subject to the presence of more than 300 companies in this market of Belarus. 70% of sales in the top ten are domestic producers.

State networks showed a significant increase in the number of pharmacies in 2014, commercial networks began to actively grow over the last three years. Currently, the number of outlets in its proportion has come to equilibrium, as in 2013.

CORPORATION 集团公司	WHOLESALES IN USD, MLN 以美元计的销售额，批发价格，百万	NUMBER OF PACKAGES, MLN 包装数量，百万	INCREASE IN WHOLESALES IN USD, % 以美元计的增量，%	INCREASE IN WHOLESALES IN PACKAGES, % 以包装计的增量，%
BELMEDPREPARATY	95.53	56.41	-2.69	2.83
BORISOV PMP	67.49	85.30	7.18	2.64
LEKFARM	49.33	19.67	-0.87	9.88
PHARMLAND	30.59	20.28	8.10	14.17
SANOFI-AVENTIS	27.34	3.82	-3.78	-9.38
SANDOZ	26.67	5.84	32.15	24.60
BAYER HEALTHCARE	26.49	2.94	23.67	3.27
PHARMTECHNOLOGY	25.94	20.23	6.47	-1.91
NOVARTIS	23.35	2.38	4.16	11.56
NATIVITA	23.34	0.03	68.96	74.03
Others 其它	620.63	187.15	9.43	7.75

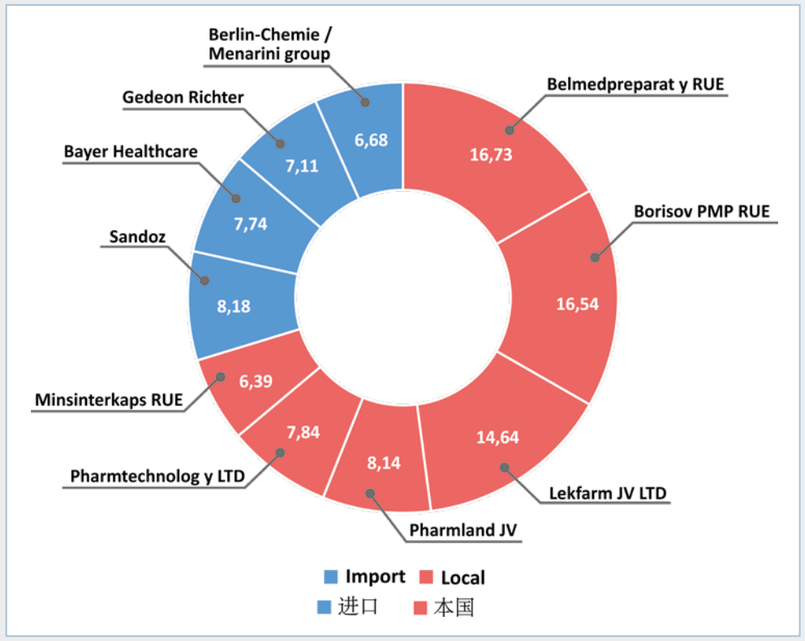
Top-10 companies in the pharmaceutical market of the Republic of Belarus 2018

2018年白俄罗斯共和国医药市场十大制造企业

ATC-2	WHOLESALES IN USD, MLN 以美元计的销售额，批发价格，百万	NUMBER OF PACKAGES, MLN 包装数量，百万	INCREASE IN WHOLESALES IN USD, % 以美元计的增量，%	INCREASE IN WHOLESALES IN PACKAGES, % 以包装计的增量，%
ANTIBACTERIALS FOR SYSTEMIC USE	70.31	19.00	4.72	-2.54
ANTINEOPLASTIC AGENTS	63.02	2.00	14.57	3.24
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	48.62	17.07	8.97	6.82
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	40.55	16.82	12.10	8.97
DRUGS USED IN DIABETES	33.07	7.87	4.64	7.36
ANALGESICS	30.65	35.73	3.42	1.78
NASAL PREPARATIONS	26.45	15.70	13.93	5.60
OPHTHALMOLOGICALS	25.13	9.82	1.46	4.61
ANTITHROMBOTIC AGENTS	23.90	6.41	16.03	6.06
CARDIAC THERAPY	23.43	20.83	8.63	9.44
Others 其它	631.56	252.81	8.40	6.57

Top-10 Anatomical-therapeutic groups on the pharmaceutical market of the Republic of Belarus 2018

2018年白俄罗斯共和国医药市场排名前10的解剖治疗化学组

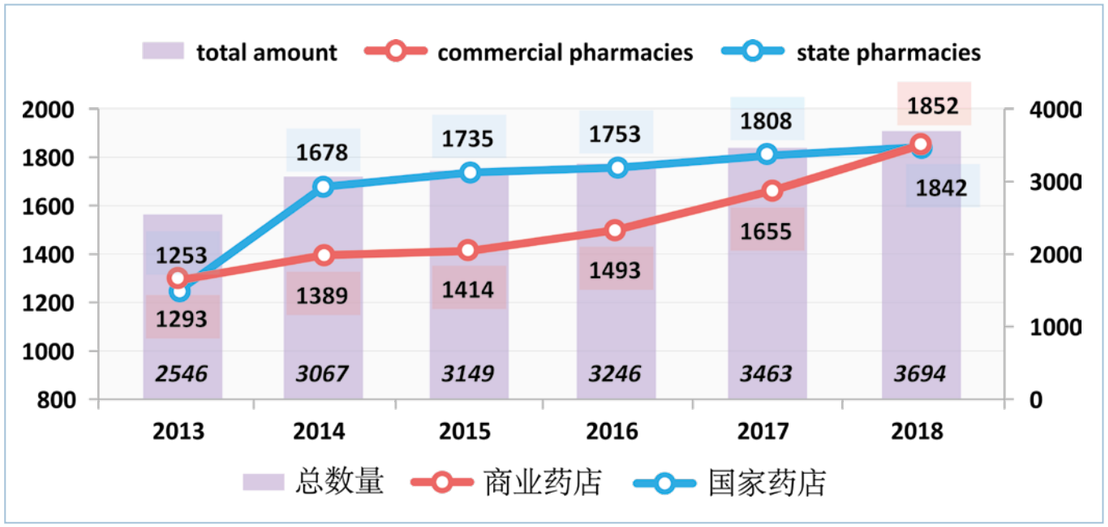


Top 10 Retail Pharmaceuticals Corporations

医药市场十大零售企业

INN 国际非专利药品名称	WHOLESALES IN USD, MLN 以美元计的销售额，批发价格，百万	NUMBER OF PACKAGES, MLN 包装数量，百万	INCREASE IN WHOLESALES IN USD, % 以美元计的增量，%	INCREASE IN WHOLESALES IN PACKAGES, % 以包装计的增量，%
TRASTUZUMAB	11.23	0.01	11.25	15.53
COAGULATION FACTOR VIII	10.87	0.09	14.97	25.95
AMOXICILLIN+CLAVULANIC ACID	10.51	2.26	11.91	18.26
TACROLIMUS	9.84	0.09	-0.33	16.76
SODIUM CHLORIDE	9.26	18.78	2.50	6.17
INSULIN-ISOPHAN	8.32	0.93	-4.90	1.23
AMOXICILLIN	8.32	2.98	-0.37	-8.37
VACCINE FOR THE PREVENTION OF INFLUENZA (INACTIVATED)	8.06	1.04	45.41	-8.86
LISINOPRIL	7.44	4.22	-0.19	-0.31
GLICLAZIDE	7.40	1.43	6.68	7.87
Others 其它	925.43	372.23	-7.93	-5.64

Top-10 INN on the pharmaceutical market of the Republic of Belarus 2018
2018年白俄罗斯共和国医药市场前10个国际非专利药品名称



Dynamics of the number of stores in the Republic of Belarus 2013-2018
2013-2018年白俄罗斯共和国药店数量变化

BIOTECHMED
SEPTEMBER 2019

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The Pharmaceutical Industry of Kazakhstan

at the End of 2018 and the Beginning of 2019

27 February 2019

Source: *http://www.energyprom.kz*

After many years of positive dynamics, Kazakhstan's drug manufacturers completed 2018 in a noticeable minus. Production of drugs fell by 14%, to 27.4 thousand tons. Production of other pharmaceuticals remained almost unchanged (plus marginal 0.3%) and amounted to 259.2 tons.

However, for the first month of 2019, the production of drugs increased immediately by 4.4 times, in comparison with January 2018, to 5.5 thousand tons, and the production of other pharmaceuticals – from 14.2 tons to almost 322 tons.

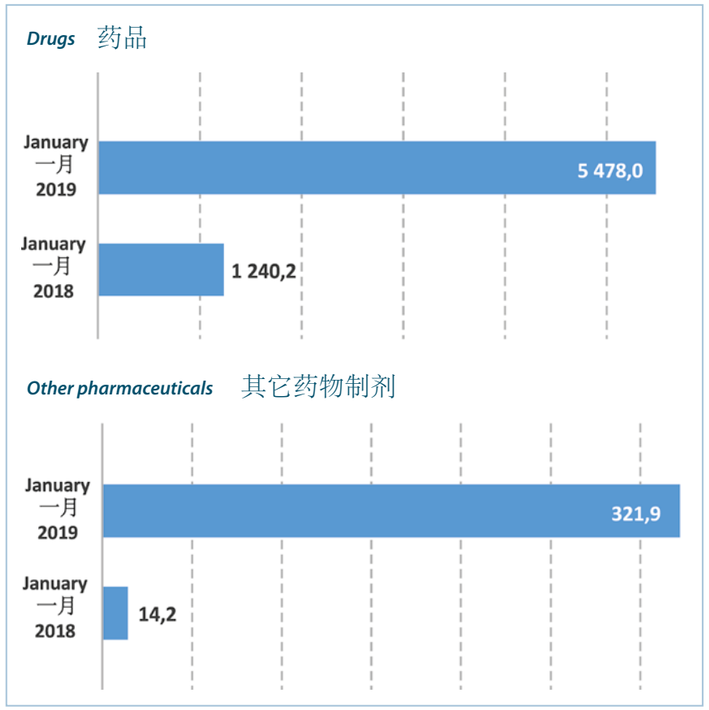
34.8% of the output in January was in Shymkent, 31% – in Almaty region and 22.7% – in Almaty. Together, the main southern metropolis of Kazakhstan and Almaty agglomeration provided 88.4% of output in the industry.

It bears reminding that in key pharmaceutical areas works large enterprises such as LLP "Zerde-Fito", JSC "Khimfarm" (trademark Santo Member of Polpharma Group) in Shymkent; LLP "Abdi Ibrahim Global Pharm" LLP, "Kelun-KazPharm", LLP "Dolce" in Almaty region, JSC "Nobel Almaty Pharmaceutical Factory", LLP "Aurora", LLP "Cheminnova Alimor Kazpharm", LLP "Rapid-Alimor Industries Pharm", LLP "Dosfarm" in Almaty, and others.

Point out, that Kazakh pharmacists are very far from ensuring the demand for medicines. Thus, at the end of the

Production of basic pharmaceutical products (tons). January

主要药物制剂的产量（吨）。一月



Source: Committee on statistics of the Ministry of National Economy of the Republic of Kazakhstan

资料来源：哈萨克斯坦共和国国民经济部统计委员会

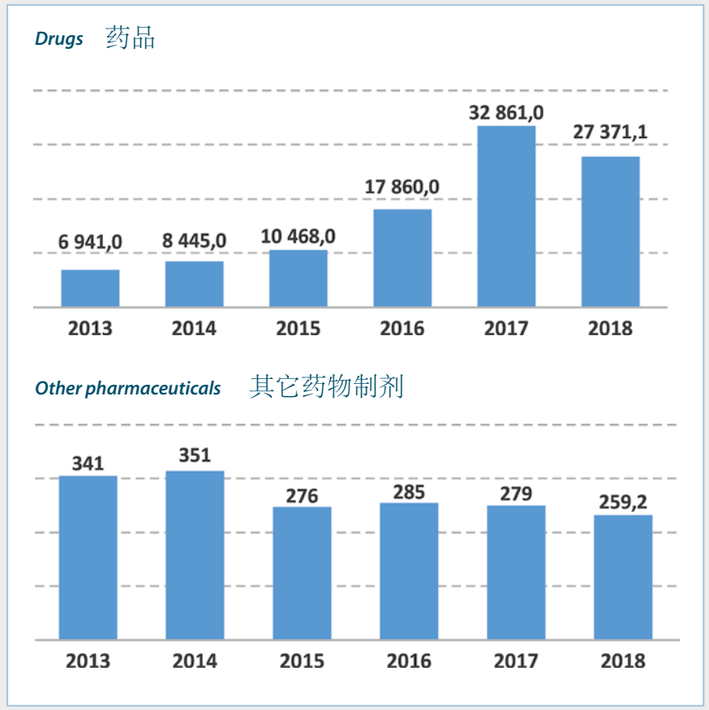
哈萨克斯坦制药业 2018年至2019年年初总结

2019年2月27日

资料来源：*http//www.energyprom.kz*

Production of basic pharmaceutical products (tons). Annual data

主要药物制剂的产量（吨）。成品数据



Source: Committee on statistics of the Ministry of National Economy of the Republic of Kazakhstan

资料来源：哈萨克斯坦共和国国民经济部统计委员会

多年正向增长后，2018年哈萨克斯坦制药厂的产量明显减少。药品产量下降14%，为2.74万吨。其它药物制剂的产量基本不变（小幅上涨0.3%），达到259.2吨。

2019年1月份的药品产量较2018年1月激增3.4倍，达到5500吨，其他药物制剂的产量从14.2吨增加至近322吨。

1月份药品产量地区比例为：奇姆肯特市34.8%，阿拉木图州31%，阿拉木图市22.7%。哈萨克斯坦南部主要特大城市和阿拉木图地区的产量占据了该行业总产量的88.4%。

主要制药区域内大型制药公司分布如下：Zerde-Fito LLP，Himfarm JSC（商标为Santo Member of Polpharma Group）在奇姆肯特市；Abdi Ibrahim Global Farm LLP，Kelun-KazPharm LLP，Dolce LLP在阿拉木图州，Nobel Almaty Pharmaceutical Factory JSC, Avrora

Balance of resources and use
原料和使用量对照表

	2018/12 TONS 吨	2017/12 TONS 吨	GROWTH PER YEAR, % 年增长量，%	2018/12, %	2017/12, %
Provitamins, vitamins and their derivatives 维生素原，维生素及其衍生物					
Resources 原料	162,4	154,9	4,8	**Share of resources** 原料份额	
Production 产量	1,5	0,6	150,0	0,9	0,4
Import 进口量	160,9	154,3	4,3	99,1	99,6
Use 使用量	162,4	154,9	4,8	**The share of the use** 使用量份额	
Export 出口量	0,4	1,7	-76,5	0,2	1,1
The sales in the domestic market 国内市场销售量	162,0	153,2	5,7	99,8	98,9
Antibiotics 抗生素					
Resources 原料	63,2	63,1	0,2	**Share of resources** 原料份额	
Production 产量	11,3	11,7	-2,8	17,9	18,5
Import 进口量	51,9	51,4	0,9	82,1	81,5
Use 使用量	63,2	63,1	0,2	**The share of the use** 使用量份额	
Export 出口量	0,0	0,0	-50,0	0,003	0,01
The sales in the domestic market 国内市场销售量	63,2	63,1	0,2	100,0	100,0
Other medicines and pharmaceuticals 其它药品和药物制剂					
Resources 原料	53 764,1	60 183,6	-10,7	**Share of resources** 原料份额	
Production 产量	27 630,3	32 099,6	-13,9	51,4	53,3
Import 进口量	26 133,8	28 084,0	-6,9	48,6	46,7
Use 使用量	53 764,1	60 183,6	-10,7	**The share of the use** 使用量份额	
Export 出口量	6 683,5	6 580,8	1,6	12,4	10,9
The sales in the domestic market 国内市场销售量	47 080,6	53 602,7	-12,2	87,6	89,1

Source: Committee on statistics of the Ministry of National Economy of the Republic of Kazakhstan
资料来源：哈萨克斯坦共和国国民经济部统计委员会

EnergyProm

last year, the market of vitamin products is blocked by local production by negligible 0.9%, vital antibiotics – only by 17.9%, other drugs – only by half (51.4%).

Any significant export is observed only in the sector of medicines in addition to antibiotics and vitamins, amounts to only 6.7 thousand tons and for the year almost has not changed (only +1,6%).

Despite the weak performance of the industry both in the domestic needs of the Republic of Kazakhstan and in the export direction, pharmaceutical companies report on the development of foreign markets. For example, according to Santo (JSC "Khimpharm"), the company provides the domestic market and exports to the markets of 8 countries – Russia, Ukraine, Kyrgyzstan, Mongolia, Uzbekistan, Turkmenistan, and Tajikistan.

According to Abdi Ibrahim Global Pharm, the company's exports are directed to Azerbaijan, Uzbekistan, Tajikistan, and Kyrgyzstan. The company also plans to expand its geography to countries such as Russia, Belarus, Turkmenistan, Moldova and Armenia. This pharmaceutical company was established in October 2012 through the integration of two major pharmaceutical companies – Abdi Ibrahim (Turkey) and Lancaster Group (Kazakhstan).

Almaty "Nobel" reports on the supply of medicines to Russia, Kyrgyzstan, Uzbekistan, Mongolia, and Belarus. According to the company, the share of exported products in production is gradually increasing.

The Committee of pharmacy of the Ministry of Health of the Republic of Kazakhstan is carrying out preparatory work for the price registration procedure. At the end of 2018, the law of the Republic of Kazakhstan "On amendments and additions to some legislative acts of the Republic of Kazakhstan on the circulation of medicines and medical products" was signed. The Ministry of Health for the first time was granted with a competence to regulate prices for all medicines.

There has been developed a portal where manufacturers should carry out price registration procedures (about 8 thousand names of medicines are registered in Kazakhstan). Subsequently, on the basis of these data, limit prices for wholesale and retail sales will be formed. Expert organizations are already forming limit prices with regard to the approved margins. ■

LLP, Cheminnova Alimor Kazpharm LLP, Rapid-Alimor Pharm Industries LLP, Dosfarm LLP在阿拉木图市等。

值得注意的是，哈萨克斯坦境内药剂师数量远远不能满足药品需求。去年维生素制剂市场的产量仅占本地总量的0.9%（完全可忽略不计），必需抗生素产量占比为17.9%，其他药品占51.4%。

出口方面，除抗生素和维生素外的药品出口仅为6700吨，且一年中无实际变化（仅为+1.6%）。

虽然该行业在哈萨克斯坦共和国国内满足消费需求及出口的指标较低，但制药公司仍公布了其在国外市场的发展状况。例如，根据Santo（Chimpharm JSC）的数据，该公司除满足国内市场需求外，产品还出口到以下8个国家:俄罗斯、乌克兰、吉尔吉斯斯坦、蒙古、乌兹别克斯坦、土库曼斯坦和塔吉克斯坦。

根据“Abdi Ibrahim Global Farm”提供的数据，该公司产品出口至阿塞拜疆、乌兹别克斯坦、塔吉克斯坦和吉尔吉斯斯坦。目前还计划向俄罗斯、白俄罗斯、土库曼斯坦、摩尔多瓦和亚美尼亚等国家出口，以扩大出口地理范畴。该制药公司成立于2012年10月，由两家大型制药公司——Abdi Ibrahim（土耳其）和Lancaster Group（哈萨克斯坦）合并而成。

阿拉木图的Nobel公司宣布将向俄罗斯、吉尔吉斯斯坦、乌兹别克斯坦、蒙古和白俄罗斯出口药品。该公司称，其产品出口份额占总产量的比例正在逐步增加。

哈萨克斯坦共和国卫生部药剂委员会正在进行价格登记程序的筹备工作。2018年底已颁布哈萨克斯坦共和国法《对哈萨克斯坦共和国药品和医疗器械流通法的修正和增补》。卫生部首次被赋权监管所有药品的价格。

门户网站已研发完成，药品生产商必须完成价格登记程序（哈萨克斯坦境内已注册约8,000种药品名称）。后续将基于这些数据确定批发和零售价格。根据批准的加价专家组织已确定边际价格。■

2018 Results:
Medicine Retail Segment

20 February 2019

According to the Monthly Retail Audit of the pharma market in Russia, conducted by the DSM Group, in 2018, 5.3 mln packs of medicines worth RUB 991.9 bln (in retail prices) were sold through pharmacies. This is a 4.6% increase in value terms and a 3.9% increase in physical terms over 2017.

Let us note that, despite the drop in growth rate in value terms over the last three years, the market dynamics in packages have been positive. This is partly a result of the inflation on medicine prices, which was 6.1% in 2018. The main price rise was experienced by medicines not subject to price regulation: 7.4%. Prices of medicines on the Essential Medicines List rose on average by 3.7%.

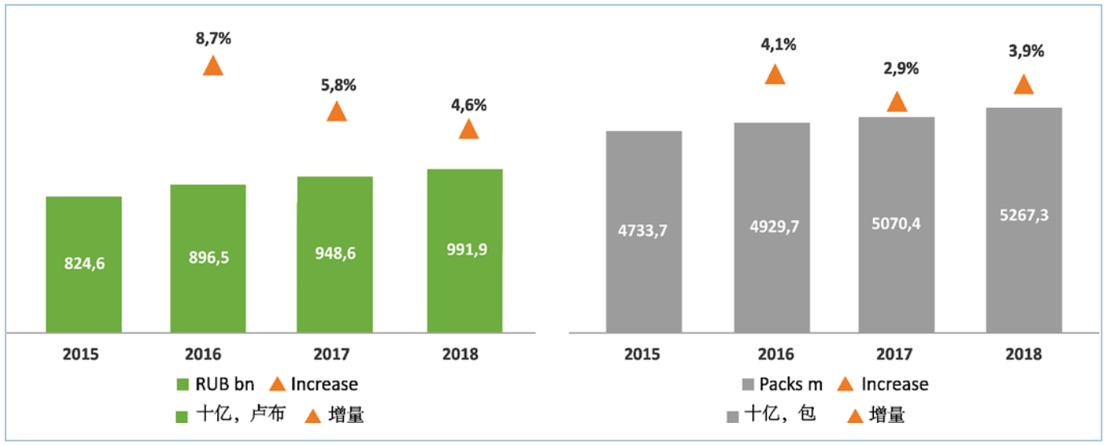
The second and probably more important reason for the low growth rates of sales in pharmacies in ruble terms was the uneven nature of seasonal diseases from year to year. In 2018, a higher demand for anti-cold and anti-viral medicines was observed only in March, whereas a high infection level is traditionally observed in February-March and September-October. In these terms, 2018 was an exception from the rule. The factors affecting such dynamics include the high level of public vaccination and the unusually warm autumn.

This resulted in a number of changes to the trends in the pharmacy market: a higher proportion of prescription medicines and a shift in consumption towards more expensive medicines.

PRICES AND PRICE STRUCTURE

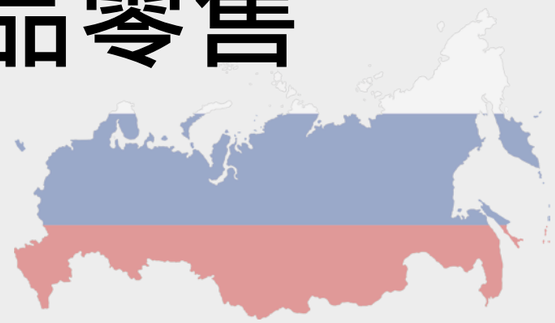
The price factor plays an important role in the growth of the pharma market. The given dynamics and structure of price segments testify that the structure of the commercial market for medicines in value terms shifted in 2018 towards expensive medicines year on year.

The greatest increase was seen in the "over RUB 500" segment: 8.9%, thus resulting in the share of expensive medicines growing by 1.6% in rouble terms.



Dynamics of medicine sales in pharmacies
药店药物销量动态

2018年药品零售领域总结

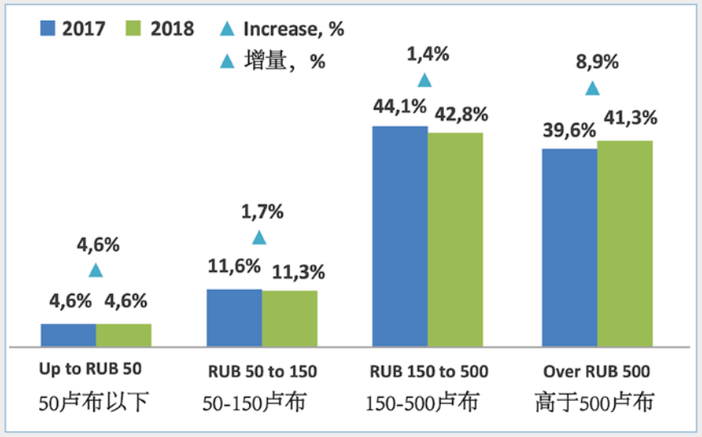


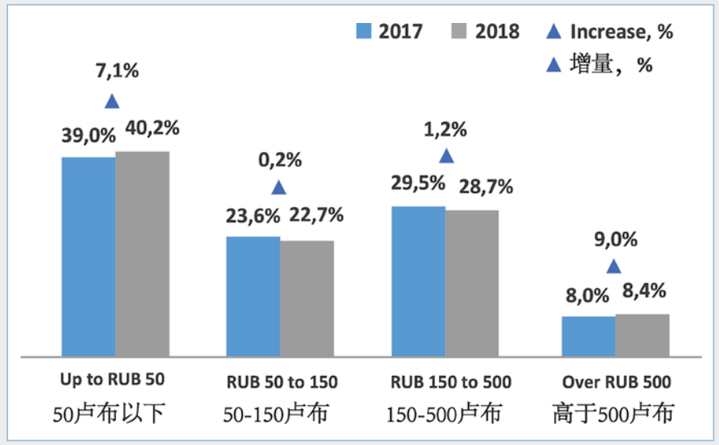
2019年2月20日

根据DSM集团股份公司对2018年俄罗斯药品零售市场每月数据的审计结果，药店共销售53亿件药品，价格约9919亿卢布（零售价格）。与2017年相比，药品销售以价值计增长4.6%，以实物计增长3.9%。

值得注意的是尽管过去三年市场态势以价值计的增长放缓，但以实物计的指标是增长的，其主要原因是药品的低通货膨胀率。2018年通货膨胀率为6.1%。

Dynamics and structure of price segments, RUB.
价格体系的动态和结构，以价值计



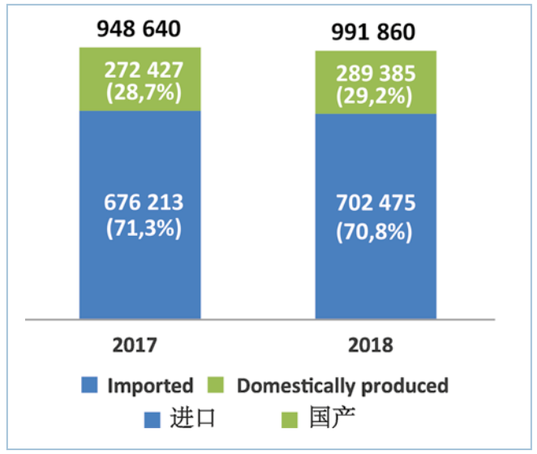


Dynamics and structure of price segments, packs.
价格体系的动态和结构，以实物计

未受价格监管影响药品的主要涨幅为7.4%。日常必备基本药物清单上的药物价格平均增加了3.7%。

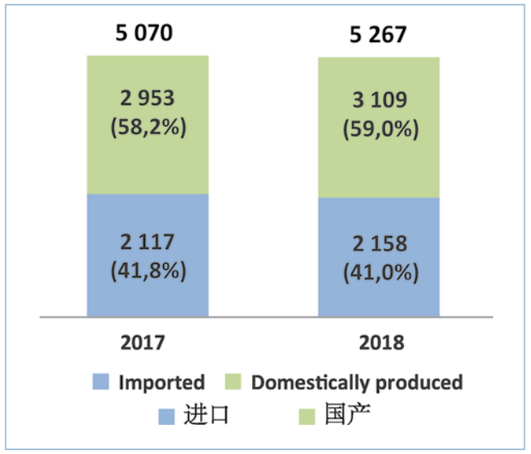
导致药店销量以价值计低增长率的第二个原因更为重要，即每年季节性疾病发病的不均衡。2018年仅3月份咳嗽和抗病毒药物的销量增长，而以往每年2月至3月及9月至10月期间均为高发病期。2018年该指标未出现在总排行中。影响这种态势的因素还包括居民的高接种率以及异常温暖的秋季。

Ratio of imported to domestically produced medicines, m RUB



进口药物和国产药物的占比，百万卢布

Ratio of imported to domestically produced medicines, m packs



进口药物和国产药物的占比，百万包

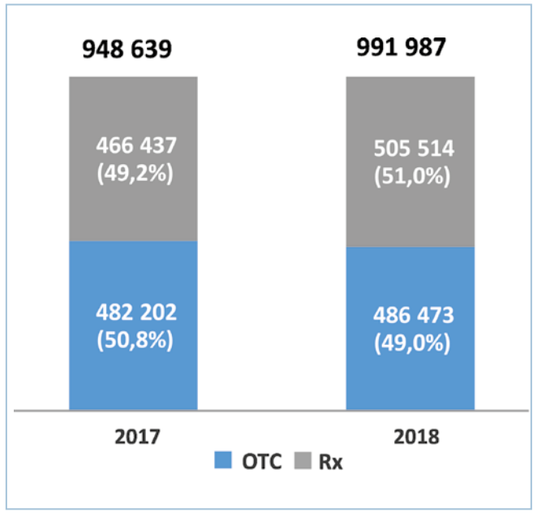
Among consumers, the "up to RUB 50" remains the segment most in demand: in terms of packs, the given medicines account for 40.2%. In addition, the volume of "low" price category medicines increased by 7.1% in physical terms and 4.6% in value terms. Thus the growth of the packs market is provided by the "cheapest" and the "most expensive" medicines.

RATIO OF SALES OF IMPORTED AND DOMESTIC MEDICINES

Overall, in 2018, the share of Russian medicines amounted to 29.2% in value and 59.0% in physical terms. In addition, the volume of sales of domestically made medicines increased more markedly than sales of imported medicines: +6.2% in rouble terms and +5.3% in packs. As a result, the share of Russian medicines in the structure of pharmacy sales is continuing to rise, in both value and physical terms.

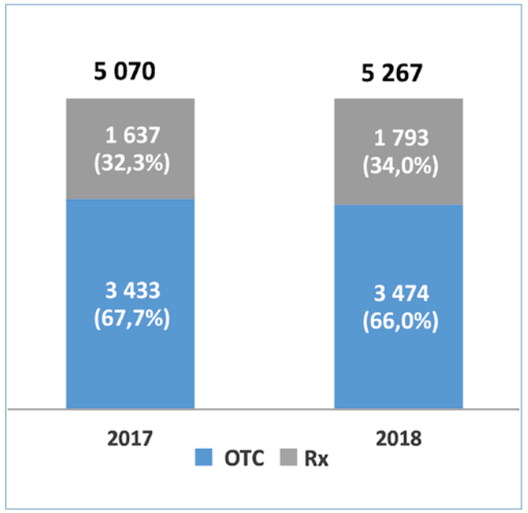
The weighted average price of one pack of domestic medicines in retail prices in 2018 was RUB 91 (+1.7% compared to 2017), which is roughly less than a

Ratio of OTC and Rx medicines, RUB m



OTC和Rx药物的占比，百万卢布

Ratio of OTC and Rx medicines, m packs



OTC和Rx药物的占比，百万包

药店领域销售药品的趋势为：处方药占比增加，消费转向高价药物。

价格和价格结构

价格因素对医药市场增长起着重要作用。以下价格动态和结构图表表明，2018年商业领域以价值计的药品结构较去年同期相比转向高价药品。

“高于500卢布”的药物增幅最大，增长了8.9%。这种增长使高价药物以价值计的份额增加了1.6%。消费者需求最多仍是“50卢布以下”的药物，其以实物计占比为40.2%。“低价”药物的销量以实物计增长7.1%，以价值计增长4.6%。因此，“最便宜”和“最贵”的药物是市场销量以实物计增长的主要因素。

进口药和国产品的销售比例

2018年总体来看，俄罗斯国产药物以价值计占29.2%，以实物计占59.0%。国产药销售额比进口药销售额的增长更为明显：以价值计为+6.2%，以实物计为+5.3%。国产药在药房销售中的份额持续增加，以价值计和以实物计的占比都在增加。

2018年国产药零售的加权平均价格为91卢布（较2017年增加1.7%），比进口药品包装价值的成本低了近2.6倍（药店进口药零售价格的成本约为325卢布）。进口药价格上涨幅度更大－增幅为2.8%。

处方药和非处方药的销售比例

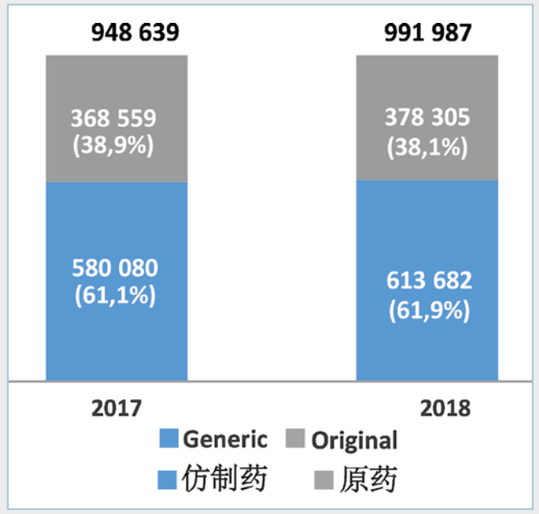
2018年非处方药以价值计占49.0%，以实物计占66.0%。处方药的销售增长率超过非处方药：以价值计为+8.4%，以实物计为+9.5%。以两种当量计处方药市场份额增加了1.8%。

处方药包装平均成本为282卢布，药店销售的非处方药每包平均成本为140卢布。两类药物价格较去年同期均有下降（分别下降1.1%和0.3%）。

原药和仿制药的销售比例

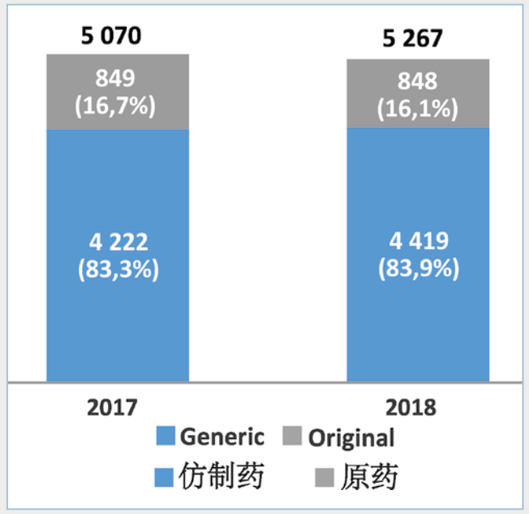
俄罗斯医药市场近年来的主要趋势是消费者转为购买仿制药。仿制药在销售量中占主要份额，且每年的市场份额都在增长。仿制药销售额以实物计增长了4.7%，2018年仿制药占据了83.9%的市场份额，份额增长了0.6%。仿制药份额以价值计从61.1%增加到61.9%。

Ratio of original to generic medicines, RUB m



原药和仿制药的占比，百万卢布

Ratio of original to generic medicines, m packs



原药和仿制药的占比，百万包

supported by PHARMASYNTEZ

RATING	CHANGE	ATC, LEVEL 1	VALUE VOLUME, RUB BN 2018	INCREASE IN VALUE VOLUME	SHARE
1	-	A Alimentary tract and metabolism	186.8	2.8%	18.8%
2	-	C Cardiovascular system	140.0	8.9%	14.1%
3	-	R Respiratory system	123.6	4.2%	12.5%
4	-	N Nervous system	112.2	3.0%	11.3%
5	-	M Musculo-skeletal system	81.6	5.8%	8.2%
6	-	G Genito-urinary system and sex hormones	80.0	3.9%	8.1%
7	-	J Antiinfectives for systemic use	73.2	2.1%	7.4%
8	-	D Dermatologicals	62.0	1.5%	6.2%
9	-	B Blood and blood forming organs	47.9	14.7%	4.8%
10	1	S Sensory organs	28.0	7.3%	2.8%
11	-1	L Antineoplastic and immunomodulating agents	27.0	0.1%	2.7%
12	-	ATC group not indicated	14.2	0.5%	1.4%
13	-	V Various	7.4	0.8%	0.7%
14	-	H Systemic hormonal preparations, excluding sex hormones and insulins	5.6	6.8%	0.6%
15	-	P Antiparasitic products, insecticides and repellents	2.4	2.6%	0.2%

third of the price of a pack of imported medicines (the cost of a pack of foreign medicines in retail prices in pharmacies was in the order of RUB 325). At the same time, the price of imported medicines rose more substantially: by 2.8%.

RATIO OF SALES OF PRESCRIBED AND OVER-THE-COUNTER MEDICINES

In 2018, over-the-counter medicines accounted for 49.0% of the market in value and 66.0% in physical terms. Sales of Rx-medicines increased faster than the sales volume of OTC ones: +8.4% in money and +9.5% in packs, so the share of prescription medicines on the market rose by 1.8% in both terms.

The average cost of a pack of prescription medicine was RUB 282, whereas over-the-counter medicines cost RUB 140 per pack in pharmacies. The prices of both categories of medicine dropped year on year (by 1.1% and 0.3%, respectively).

RATIO OF SALES OF ORIGINAL AND GENERIC MEDICINES

The main trend in the Russian pharma market for several years has been consumers switching to generic medicines. Generics predominate in sales volumes and their market share is growing by the year. In physical terms, generic medicine sales increased by 4.7%, bringing their market share in 2018 up to 83.9%, this being an increase of 0.6%. In money terms, the share of generics rose from 61.1% to 61.9%.

Consumers are switching over to generics mainly because of the increase in demand for unbranded medicines. For instance, sales of medicines in packs under INN grew by 5.6%, whereas branded generics by only 2.8%. The average cost of a pack of an original medicine was RUB 446 (+2.7% compared to 2017), whereas generics were sold at an average price of RUB 139 (+1.1%).

RATIO OF PHARMACY SALES BY ATC GROUP, LEVEL 1, IN RUSSIA

2018 saw virtually no change over 2017 in the structure of the pharmacy market by ATC group, level 1. A minimal increase over the 12 months was demonstrated by ATC group [L] "Antineoplastic and immunomodulating agents" (+0.1%), resulting in it dropping by one line. Such dynamics are largely a result of the low increase in "seasonal medicines" – immunoregulators; the end year results were lower by 0.5% in money terms.

Let us note, that other groups including medicines for treating cold and viral diseases also demonstrated

消费者转向仿制药与对非品牌药物的需求增加有关。以实物计的INN药物销售量增加了5.6%，而品牌仿制药仅增加了2.8%。原药包装平均成本为446卢布（比2017年增加2.7%），仿制药平均售价为139卢布（+1.1%）。

俄罗斯药店ATC组I级药品的销售比例

ATC组I级药品药店销售结构较2017年相比几乎无变化。ATC组[L]“抗肿瘤药和免疫调节剂”（+0.1%）12个月内增幅最小。因此此类药下移一行。这种变化主要是由于“季节性药物”－免疫调节剂的低增长率造成的；今年此类药物以价值计的销售量下降了0.5%。

值得注意的是其他包括治疗感冒和病毒性疾病的药物组，也出现低于市场的增长。这符合2018年的季节性规律：发病率低于往年，峰值集中在3月，秋季销售也未回暖。

ＡＴＣ排名以[A]组“治疗消化道和新陈代谢疾病的药物”为首，其份额为18.8%，显著高于ATC其它组。本组ATC排名第一位的是ESSENTIAL治疗肝胆疾病的药物，其次是“LINEX”益生菌，最后是保肝药Geptral。

以价值计排名第二的是ATC[Ｃ]组“治疗心血管

排名	变化	ＡＴＣ 1级	总金额 十亿卢布 2018年	金额增幅	份额
1	-	A 治疗肠道和新陈代谢病症的药物	186.8	2.8%	18.8%
2	-	C 治疗心血管系统疾病的药物	140.0	8.9%	14.1%
3	-	R 治疗呼吸系统疾病的药物	123.6	4.2%	12.5%
4	-	N 治疗神经系统疾病的药物	112.2	3.0%	11.3%
5	-	M 治疗肌肉骨骼系统疾病的药物	81.6	5.8%	8.2%
6	-	G 治疗泌尿生殖器官和性激素疾病的药物	80.0	3.9%	8.1%
7	-	J 全身用抗微生物药物	73.2	2.1%	7.4%
8	-	D 治疗皮肤病的药物	62.0	1.5%	6.2%
9	-	B 影响造血和血液的药物	47.9	14.7%	4.8%
10	1	S 治疗感觉器官疾病的药物	28.0	7.3%	2.8%
11	-1	L 抗肿瘤和免疫调节的药物	27.0	0.1%	2.7%
12	-	ATC组未指定药物	14.2	0.5%	1.4%
13	-	V 其它药物	7.4	0.8%	0.7%
14	-	H 全身用的激素药物（不包括性激素）	5.6	6.8%	0.6%
15	-	P 抗寄生虫病药，杀虫剂和驱虫剂	2.4	2.6%	0.2%

below-market growth. This corresponds to the seasonality in 2018: the infection peak came only in March and it was lower than in previous years, while there was no sales peak at all in the autumn.

The ATC rating is topped by the group [A] "Alimentary tract and metabolism", with a share of 18.8%, which is considerably greater than those of other ATC groups. The leaders in the given ATC are the medicine for treating diseases of the liver and bile ducts: Essentsiale, and the eubiotic Linex, followed in third place by the hepatoprotective Geptral.

In second place in value terms is ATC group [C] "Cardiovascular system" (14.1%), the leading brands in this group being Detralex, Concor and Lozap.

THE TOP-20 BRANDS IN VALUE SALES TERMS ON THE RUSSIAN COMMERCIAL MARKET

In aggregate, the TOP-20 brands account for 11.1% of the market. In the rating of leading brands in value sales on the commercial market, a number of substantial changes may be observed. First place in the top-3 remains the analgesic Nurofen, with a 0.8% market share. The direct anticoagulant Xarelto has risen to second place (+11 places), showing the maximum increase among the TOP-20 brands (+50,9%). The venotonic and venoprotective medicine Detralex was shifted down to the third place.

In physical terms, the leaders remain the "traditional" cheap medicines Bactericidal Plaster, Citramon and Acetylsalicylic Acid. Only four medicines among the TOP-20 in pack terms demonstrated negative dynamics: Citramon (-6.6%), Activated Charcoal (-6.0%), Valerian (-5.8%) and Validol (-3.8%). The most rapid growth was shown by Taufon

RATING 排名	CHANGE 变化	BRAND 品牌	VALUE VOLUME, RUB BN 2018 总金额十亿卢布 2018年	INCREASE IN VALUE VOLUME 金额增幅	SHARE 份额
1	-	NUROFEN	7.5	4.9%	0.8%
2	11	XARELTO	7.2	50.9%	0.7%
3	-1	DETRALEX	6.8	8.4%	0.7%
4	-1	KAGOCEL	6.7	7.6%	0.7%
5	-1	CONCOR	6.3	3.6%	0.6%
6	-1	CARDIOMAGNIL	6.2	3.5%	0.6%
7	-	INGAVIRIN	6.1	7.7%	0.6%
8	-	ACTOVEGIN	6.0	5.7%	0.6%
9	-	MIRAMISTIN	5.9	4.8%	0.6%
10	1	MEXIDOL	5.8	13.3%	0.6%
11	1	PENTALGIN	5.4	6.4%	0.5%
12	-2	TERAFLU	5.2	0.6%	0.5%
13	-7	ESSENTSIALE	4.8	-17.7%	0.5%
14	-	LOZAP	4.8	3.8%	0.5%
15	2	CANEPHRON	4.5	9.8%	0.5%
16	-1	NAIZ	4.4	2.8%	0.4%
17	-1	LINEX	4.3	3.7%	0.4%
18	2	LORISTA	4.2	10.6%	0.4%
19	-1	VOLTAREN	4.0	-3.1%	0.4%
20	2	JEX	3.8	4.3%	0.4%

系统疾病的药物”（14.1%）。这一组领先的品牌是Detralex，Konkor和Lozap。

俄罗斯商业领域销售额领先的20大品牌

TOP-20品牌占据了11.1%的市场份额。商业领域领先品牌排名发生许多重大变化。前三名中首位仍是镇痛药Nurofen，市场份额为0.8%。直接作用抗凝血药Xarelto（上升11位）升至第二位，为TOP-20品牌中增幅最大的品牌（+50.9%）。Detralex静脉营养和保护药为第三位。

根据实物计的指标，“传统”的廉价药品“杀菌膏药”，Citramon和乙酰水杨酸继续保持领先。TOP-20以包装计排名中只有四种药物呈负增长：Citramon（-6.6%），活性炭”（-6.0%），缬草（-5.8%），伐力多,（-3.8%）。增幅最高的有：Taufon（+150%），“依那普利”（+40%）和Rhinostop（+27%）。值得注意的是，以实物计的药店销售额中TOP-20品牌占比21.3%，比以价值计的占比高。

RATING 排名	CHANGE 变化	MANUFACTURER 制药厂	VALUE VOLUME, RUB BN 2018 总金额十亿卢布 2018年	INCREASE IN VALUE VOLUME 金额增幅	SHARE 份额
1	-	BAYER	45.0	-0.4%	4.5%
2	-	SANOFI	41.5	0.2%	4.2%
3	-	NOVARTIS	41.5	6.3%	4.2%
4	-	TEVA	36.9	-5.3%	3.7%
5	-	SERVIER	34.3	5.0%	3.5%
6	-	OTCPHARM	34.2	7.7%	3.4%
7	-	TAKEDA	30.0	8.3%	3.0%
8	1	GLAXOSMITHKLINE	26.8	0.6%	2.7%
9	1	BERLIN-CHEMIE	26.7	2.2%	2.7%
10	1	GEDEON RICHTER	26.7	5.0%	2.7%
11	-3	STADA	26.1	-4.4%	2.6%
12	1	KRKA	25.2	16.8%	2.5%
13	-1	ABBOTT	23.4	7.5%	2.4%
14	-	JOHNSON & JOHNSON	20.2	-2.8%	2.0%
15	-	FARMSTANDART	19.4	2.0%	2.0%
16	-	ASTELLAS PHARMA	17.3	10.0%	1.7%
17	-	DR.REDDY'S LABORATORIES	16.7	7.3%	1.7%
18	1	POLPHARMA	16.5	19.9%	1.7%
19	-1	VALENTA PHARM	15.5	3.4%	1.6%
20	-	PFIZER	14.0	2.6%	1.4%

(+150%), Enalapril (+40%) and Rhinostop (+27%). Let us note that the TOP-20 brands in physical terms account for 21.3% of pharmacy sales, meaning their concentration is higher than in value volume terms.

THE TOP-20 MANUFACTURERS IN SALES VALUE TERMS ON THE RUSSIAN COMMERCIAL MARKET

There are markedly fewer changes in the rating of manufacturers and they are less material. As traditionally, Bayer retains the top position at year end in terms of sales volumes in the pharmacy segment, though its sales volumes in this segment dropped by 0.4%. Sanofi was in second place, with a minimal sales growth of 0.2%, and Novartis (+6.3%) took third place.

Changes in the rating were up or down by three places. Four of the TOP-20 companies demonstrated negative dynamics. The biggest drop in sales was experienced by the manufacturer STADA (-4.4%) as a result of lower sales of the antiviral medicine Lavomax (-14%) and the Snup spray (-14%).

Foreign companies are represented most in the rating: only three of the companies are Russian. The biggest share belongs to OTCPharm: 3.4%, in position 6.

CONCLUSIONS

The medicine retail segment is the driver of the Pharmaceutical market's development in Russia. Its current share is about 70% (government-financed medicine use accounts for only 30%). Despite the decreasing population's purchasing ability due to the financial and economic instability in the country and the decreasing in their real incomes, the pharmacy segment is maintaining positive dynamics. The main market growth factor is not, however, the price factor but the increase in the market in terms of packs.

Over the last few years, several trends have taken shape on the market that are inherent in 2019 dynamics, too:

- Consumers switching to generic medicines;
- The consumption structure is greatly dependent on the epidemiological situation in the country;
- The market in terms of packs retaining its positive dynamics.

The DSM Group forecast is that in 2019 the pharmacy segment will grow by at least 5%. Such dynamics are confirmed by the market volume for January-February this year when a sales surge of "seasonal" medicines was observed. ■

俄罗斯商业市场销量领先的前20家制药厂

制药厂排名无明显变化，且变化不大。药店销售年度排名第一位仍为Bayer，其药店销售额下降了0.4%。Sanofi位列第二，产品销售额最低增幅为0.2%。Novartis排名第三（+6.3%）。

排名变化在±3名以内。TOP-20中的四家公司呈现负增长。因抗病毒药物Lavomax（-14%）和喷雾Snoop（-14%）销量下降，Stada制药厂（-4.4%）的销售额下降最多。

制药厂排名榜中多为外国公司，只有三家公司俄罗斯公司，其中OTCPharm公司所占份额最大，为3.4%，排名第6。

结论

药品零售领域是整个俄罗斯医药市场发展的推动力。其份额约70%（其中30%为国家对药物需求的拔款）。尽管居民购买力因国家金融和经济不稳定影响有所下降，实际收入减少，药店销售仍保持积极态势。市场增长的主要因素不是价格因素，而是实物销量增加。

过去几年市场已形成以下趋势，这些趋势在2019年仍将持续：

- 消费者转为购买仿制药；
- 消费结构高度依赖本国流行病的发病趋势；
- 以实物计的市场销量保持增长。

DSM集团预测，2019年药店领域销售额增长至少为5%。今年1月至2月该领域的交易量已证实了预测，“季节性”药物的销售量出现激增。■

GMP Is Not Standards,

It Is Philosophy and Culture of Production

19 April 2019

Association of International Pharmaceutical Manufacturers
Ассоциация международных фармацевтических производителей

Interview with Vladimir Shipkov, Executive Director, Association of International Pharmaceutical Manufacturers (AIPM)

Vladimir Shipkov
AIPM Executive Director

弗拉季米尔 •希普科夫
AIPM执行主席

AIPM today is the most numerous Association uniting pharmaceutical manufacturers in the Russian Federation. What activities of association contribute to the effective work of your members on the Russian pharmaceutical market?

Indeed, our Association today brings together more than 60 companies. The localization factor does not affect whether the company may or may not be a member of the Association. At the same time, the majority of our member companies have localized or in the process of localizing its manufacturing activities in Russia in various forms and volumes: it is either investments in greenfield manufacturing projects (more than 20 plants have been built), or technology transfer partnerships, or joint ventures with Russian drug manufacturers under contract production projects, or the acquisition of Russian assets with modernization of existing production bases, and etc. The companies' desire to become AIPM members underlines our relevance and credibility in the industry, professionalism of our staff. We see our mission not in protecting the interests of specific companies, oddly enough it sounds, but in upholding the interests of Russian patients. When a company turns to me with business problems, I might do not react. However, if, due to the current situation in the company, Russian patients are suffering, I will definitely involve. Our priority task is to ensure the assortment availability of modern, effective and high-quality products manufactured by our members for Russian citizens. A proactive position, effective interaction with regulators and responsible market players allow us to remain one of the most influential and respected organizations on the local pharmaceutical market for the last 25 years.

Being a full-fledged member of a number of European and global pharmaceutical manufacturers associations, we have the opportunity to analyze not only what is happening in Russia, but also, engage in cooperation with the leading international pharmaceutical industry experts and transfer the best world experience and practices into the market of the Eurasian Economic Union (EAEU) and Russian market.

Your Association conducts systematic educational and publishing activities. Is this part of AIPM's mission?

Unfortunately, in our industry, few people are doing this and can compete with us. Within our capabilities as a non-profit organization, we are doing our utmost to implement a significant number of educational initiatives, publish and make available to all market participants global regulatory initiatives and

GMP不是标准，

是生产的哲学和文化

2019年4月19日

国际药物制造商协会（AIPM）执行主席 弗拉季米尔•希普科夫专访

AIPM目前是俄罗斯联邦境内药品制造商会员的协会。协会的哪些活动有助于会员在俄罗斯医药市场展开高效的工作？

是的，协会现在共有60多家会员公司。本地化因素不会影响公司能否成为会员。目前大多数会员都有不同形式和规模的本地化项目。比如有些是已建成的工厂，有些与俄罗斯公司是基于合同制造的技术转让或产品生产的伙伴关系，有些成员在俄罗斯收购资产等。从公司希望成为AIPM会员的意愿中可以看出整个行业对协会的需求和认可，以及协会工作人员的专业性。我们认为协会的使命不是保护某个公司的利益，而是要维护俄罗斯患者的利益，这听起来似乎很奇怪。当一家公司因业务问题向我求助时，我通常不会做出反应。但如果某个公司让俄罗斯患者遭受痛苦，我肯定会介入。协会的首要任务是确保每位俄罗斯公民都能用上协会会员生产的高效和高品质的药物。协会成立25年以来，以积极的立场与监管机构和有责任心的协会会员进行有效的互动，成为制药行业内最具影响力和最受尊敬的组织之一。

作为多个欧洲和全球制药企业协会的正式会员，我们不仅有能力分析俄罗斯市场的现状，还可以与行业主要国际专家合作，将全球最好的实践经验推广到欧亚经济联盟（EAEU）国家的市场上。

协会经常举办教育活动，发行出版物。这也是协会的使命吗？

很遗憾，行业内很少有人从事这项工作与我们竞争。这样做首先是为制定欧亚联盟国家市场的统一方法，作为一家非营利组织，我们在能力范围内尽最大努力落实教育措施，向所有市场参与者发布和提供全球监管措施和最佳实践经验。这样做不仅是为了协会的会员，他们已拥有了在全球市场运营必须的知识和能力，这样做也是为了包括监管机构在内的所有市场参与者的利益—确保最好的世界经验与俄罗斯执法实践间有效的沟通。这不是一种比喻。这是我们参与制定欧亚药物统一市场监管措施的结果，该措施主要监管生物技术药物、类似药或生物仿制药的生产和流通领域。我们将所有英文监管文件翻译成俄文，供EAEU（欧亚经济联盟）所有会员国的所有市场参与者、部委和部门使用。我们的“多卷”图书有药品注册和鉴定、药监部门和其它生产良好规范等内容，已成为那些计划将药品推向欧亚联盟统一市场公司必备的手册。还有重要的一点，我们将主要文件集翻译成英文，向全球行业社团展示俄罗斯符合世界标准的生产规范和监管标准。这样做公司就能够切实评估自身能力和前景。俄罗斯公司在向第三国市场出口时也需要翻译成英文的文件。我们的出版物是实用的工具，通过它不仅能了解进入国外市场的条件，还能使国内企业遵照国际标准工作。很多工作的结果和价值今天可能无法全部显现，但一定会得到下一代的认可。

您是否认为俄罗斯制药行业已过渡到GMP标准或者仍然存在需要解决的问题？

尽管监管机构和市场参与者在很短时间内做出

On February 28, 2019, Pharmaceutical Vestnik announced results of the "Rating of the most influential subjects of the Russian pharmaceutical market – 2018". The data issues based on independent survey prepared by Ipsos Comcon with the assistance of the Russian branch of audit, tax and advisory services firm KPMG. The rating traditionally recognizes the most important persons, organizations, companies, medicines and media that made outstanding input into the development of the modern pharmaceutical market in Russia. AIPM was awarded as the Most Influential Association following the decision of almost 400 experts from all market segments.

"This year AIPM celebrates the 25th anniversary. We are grateful to our colleagues and opponents for this high assessment of our work. Building modern advanced healthcare cannot be implemented without constantly improving access to high-quality treatment, including new drugs and new healthcare technologies. The latest very ambitious goals and priorities of the Russian Federation in healthcare require new solutions. And we hope that our contribution will add value further to achieving these goals putting a strong accent on improving access to modern treatments for patients in our country", – said **Vladimir Shipkov**, AIPM Executive Director.

best practices, primarily to form common approaches to the market of the Eurasian Union countries. It is important that we do this not so much for members of our Association, who possess all the necessary knowledge and competencies being presented on global market, but for the benefit of all market participants, including regulators, ensuring effective connection of the best world experience with its enforcement in Russia. And this is not a figure of speech. This is the result of our participation in the development of regulatory landscape of the single Eurasian pharmaceutical market, including such complicated areas as the regulation of manufacturing and circulation of biotech drugs or biosimilar. We have translated almost all regulatory documents from English into Russian, and now it has become available to all market players, ministries and other authority bodies of all EAEU member-countries. Our "multivolume book" on the registration and examination of drugs, pharmacovigilance and other good practices has become a reference edition for companies that are planning to bring their drugs to the single market according to the requirements of the Eurasian Union. There is another important aspect. We also translated the main set of EAEU documentation into English, in order to show the world professional community what a modern and balanced regulatory standards we have in the Eurasian Union now, which take into account the best international practices and the world regulatory standards. This allows companies realistically assess their capabilities and prospects. All these documents are also in demand by Russian companies, including those ones translated into English; especially when they export their products to the markets of third countries. Our publications are a practical tool that allows not only to understand the conditions for entering foreign markets but also to work according to the actual international standards. We have done a lot of work, the result and value of which may not be so obvious today, but they will be certainly appreciated by the next generations.

Do you think the transition of the Russian pharmaceutical industry into GMP standards has already taken place or there are still problems that need to be solved?

Despite the fact that in a very short time, both the regulators and market participants did a great job, the Russian Federation, in my opinion, is only at the very beginning of the journey. The peculiarity of the process to transfer to GMP standards lies in the fact that the adoption of a regulatory act in itself is only the start of a complex, multidisciplinary process that must be constantly upgraded. GMP is not just a set of standards; it is a philosophy and a culture of production and, from this point of view, much remains to be done. Our Association in its time played and has continued to play its role in adapting in the Russian industry the standards by which the world community has been working for more than 50 years. We consider the introduction of GMP standards as a means of increasing competitiveness, above all, of the Russian pharmaceutical industry. Our members have already invested heavily in localization. Therefore, it is important for us that more and more Russian companies meet international requirements and can act as partners for international companies on the Russian market. At the same time, according to the legislation, Russian manufacturers turned out to be a priori compliant with GMP requirements. International manufacturers that operate in global markets have to confirm this correspondence constantly. Of course, the Russian inspectorate in recent years has made a huge step forward in the quality and number of inspections, and the professionalism of the FSI "SID & GP" staff has significantly increased. Nevertheless, the Association continues to analyze the results of inspections in order to avoid possible distortions in law enforcement and administration.

How would you describe the effectiveness of the Russian regulatory policy in the pharmaceutical industry?

The regulatory system in all countries is conservative, and in Russia, it can be even more so. However, I am optimistic about the future, and the part of the reason for this is my perception that our regulators has started increasingly more listening to the opinion of the professional community. The Russian Minister of Healthcare Veronika Igorevna Skvortsova once called me the main critic of her governing body. Nevertheless, I see it otherwise. We are trying to become a reliable partner who is ready to use all its capabilities and competencies to improve the healthcare system and ensure the availability of drugs for Russian patients. When there is enough time to prepare legislative initiatives, which are taking into account the opinions of experts, the adopted documents not only remove barriers for the industry but also contribute to its active development. An example is the regulation of a single Eurasian market. Our Association is not the only professional association that participated in the work of its creation. As a result – we have the modern legislative of the Eurasian Economic Union, corresponding to the best international practices. From the very beginning, we believed in the Eurasian integration, we were inspired by the far-reaching will of the presidents of our countries, who made a very correct decision. In a single national regulatory framework, we

了一定的成绩，但在我看来，俄罗斯联邦仍处于这项工作的起点。向GMP标准过渡的特殊性在于通过监管法案本身就是一个需不断完善的复杂多学科的起点。GMP不是标准，是生产的哲学和文化，从这个角度看，还有许多工作要做。协会曾参与修订国际社会已遵循了50多年的标准，以后还将继续发挥作用。我们将引入GMP标准视为提高竞争力的手段，这点对俄罗斯制药业而言尤为重要。协会会员（AIPM的参与者）已经为本地化投入了大量资金。越来越多的俄罗斯公司符合国际要求，成为国际公司在俄罗斯市场的合作伙伴，这一点对我们来说非常重要。依据法律俄罗斯制造商先天已符合GMP要求。在全球市场运营的国际制造商必须不断验证是否符合要求。毋庸置疑，近年来俄罗斯监察局在质量和数量检查工作上迈出了一大步，联邦预算机构"国家药物和GP）研究院"工作人员的专业水平显著提高。但协会仍会继续分析检查结果，以避免执法和行政管理中可能出现的偏差。

您如何评价俄罗斯联邦制药行业现行监管政策的效率？

所有国家的监管体系都是保守的，在俄罗斯更是如此。但我对未来持乐观态度，因为我们的监管机构越来越善于倾听行业社团的意见。卫生部长韦龙妮卡·伊戈列弗娜·斯克沃勒措娃曾称我为卫生部的批评家。我对此有不同的解释。我们正在努力成为一个可靠的，而不是冷漠的合作伙伴，我们希望利用所有的机会和能力来改善医疗保健系统，为俄罗斯患者提供药物。如果有足够的时间制定法律措施，并能考虑到专家的意见，这样所通过的法律文件不仅能消除行业壁垒，还能促进行业积极发展。举个例子，我们的协会不是唯一参与建立欧亚市场统一监管的专业协会，工作成果是欧亚经济联拥有符合国际最佳惯例的现代法律。受到各国总统超前意愿的启发，我们从一开始就相信欧亚一体化进程，总统们作出了非常正确的决定。我们很难在如此短的时间内在单独的国家监管框架内实现这一目标。顺便说一句，我们协会的会员根据欧亚要求已提交了第一份注册申请。GlaxoSmithKline公司已获得符合欧亚联盟要求的首个注册证书，Pfizer公司已取得第一个欧亚GMP证书。很遗憾，第一份注册文件不是在俄罗斯联邦提交的，欧亚GMP检查并不是俄罗斯监察人员完成的。但我看到了某些积极因素，这些因素不仅可提高申请人及监察机构的专业水平，引入监管机构的良性竞争，最终还能让每方都从中受益，尤其是那些希望获得更好质量、功效和安全性药物的患者。

众所周知，俄罗斯目前正在制定制药业新的发展战略"制药业2030年"。该战略的重要措施之一是扩大药物出口。您如何评估大幅增加出口背景下俄罗斯公司的前景？

我们当然对该计划的实施寄予厚望，并希望在引入现代技术和完善知识产权保护机制的基础上进入崭新的发展阶段。《制药业2020年》计划实施期间，协会成为国家和工贸部可靠和重要的合作伙伴。经专家评估，全俄有超过20家国际制药公司在运营，它们对俄罗斯经济的贡献超过300亿美元。我们向全球系统地推广了《制药业2020年》规划。通过建立重要的合作关系以确保投资回报，保护知识产权、清除创新产品上市的障碍，建立对本地化的信任是我们希望在该计划结束时看到的成果。中国在这方面已颇有经验，自2017年以来，中国政府采取了一系列非常重要和正确的举措，使得人们对

2019年2月28日制药公报公布了《2018年俄罗斯医药市场最具影响力企业评级》结果。行业主导报纸每年根据Ipsos Comcon编写的独立调查报告，在审计，税务及咨询公司毕马威（KPMG）俄罗斯分公司的协助下公布数据。按照惯例该排名发布的是对俄罗斯现代医药市场发展做出杰出贡献的重要的个人，组织，公司，药品和媒体。AIPM被市场各个领域近400名专家评为最具影响力的协会。

AIPM执行主席弗拉基米尔·希普科夫谈到："今年是AIPM成立25周年纪念。感谢同行和评论员对我们工作的赞赏。只有持续改善医疗品质，包括提高新药和新的医疗卫生技术，才可能建立一个现代的先进医疗体系。建立现代化医疗体系是俄罗斯联邦卫生领域宏伟的目标和核心工作，它需要新的决策方案。我们希望能为实现该目标做出贡献，将工作重点放在如何让我国更多患者享受到先进的治疗服务上。"

would hardly have achieved this in such a short period of time. By the way, members of our Association were the first who filed applications for registration in accordance with Eurasian requirements. GlaxoSmithKline has already received the first registration certificate issued according to the requirements of the Eurasian Union, and Pfizer – the first Eurasian GMP certificate. Unfortunately, the first registration documents were submitted not in the Russian Federation, and Russian inspectors did not carry out the Eurasian GMP inspections. Anyway, I see certain positive aspects in this. Not only the level of professionalism of the applicants rises, but also of the inspectorates does, a healthy competition of regulators appears. Eventually, everyone will benefit from this, and above all patients, who will receive drugs of better quality, efficacy and safety.

According to experts, the contribution of international pharmaceutical companies to the Russian economy is estimated at more than $30 billion; more than 20 factories built from greenfield stage are already operating

Everyone knows that today a new strategy for the development of the pharmaceutical industry in Russia "Pharma 2030" is being drafted. One of the priorities of this strategy is to increase the export of drugs. How do you assess the prospects of a significant increase in exports by Russian companies?

We are certainly optimistic for the implementation of this program and hope that this will be a qualitatively new stage based on the introduction of modern technologies and the improvement of mechanisms for the protection of intellectual property rights. The Association has already proved itself as a reliable and serious partner of the Government and separately of the Russian Ministry of Industry and Trade during the implementation of the Pharma-2020 program. According to experts, the contribution of international pharmaceutical companies to the Russian economy is estimated at more than $30 billion; more than 20 factories built from greenfield stage are already operating. In addition, we systematically promoted the brand "Pharma-2020" around the world. Growing trust in localization through the building a serious partnerships, ensuring return on investment, protecting intellectual property rights, and removing barriers for innovative products to enter the market are the aspects that we would like to see in the final version of the updated program. In this regard, indicative is the experience of China, which since 2017 has taken a number of very significant and strong steps that have allowed achieving a major change in the attitude towards the innovative drugs. Based on the systematic analysis of Chinese regulators' data, it was concluded that during last 10 years, 415 new molecules were introduced to the global market, but none of them were registered in China. Excessive protectionism of local manufacturers, the requirements for conducting duplicating local clinical trials and other measures created serious obstacles for the introduction of new innovative medicines to the Chinese market, especially for the treatment of cancer, diabetes, HIV, etc. Having determined the list of a top priority medicines, the Chinese government in a short time developed and implemented a series of effective measures that made it possible to provide Chinese patients with access to many innovative drugs recognized throughout the world during less than a year period. Resetting import duties to zero level, a significant increase in intellectual property rights protection, a ban on the production of generics and biosimilars during the patent protection period, removal of the requirement to conduct local clinical trials, the rapid inclusion of drugs in the lists for reimbursement – this is an incomplete list of measures that allowed to achieve such a great results. In addition, I would very much like to hope that the Russian Federation, having studied the experience of China, would select the correct regulatory approaches to further improve our own industry outlook, which will be reflected in the Pharma-2020 program extended currently until 2024. As for exports, we welcome the innovative trend of development of the domestic pharmaceutical industry. Moreover, if case local Russian scientists and manufacturers develop world-class blockbusters in the future, we are ready to help these products to be launched on the leading global markets, and I assure you that we will do this much faster, more efficiently and with mutual benefit for all participants.

Very recently, the Russian-language version of regulatory guide MedDRA became available. How can you evaluate the importance of this document?

Indeed, since March 20, Russian-language MedDRA dictionary, which is the single standard for coding of the medical information on drug safety reporting, has become available. It is a real breakthrough on the way of harmonization of the regulatory system of pharmacovigilance in the Russian Federation and a platform for further integration of the entire EAEU space into the global system for monitoring the safety of drug use. The dictionary allows professionals who speak 12 different languages to operate with the same concepts and exchange standardized data, despite local differences in the names and classifications of medical conditions. In my opinion, the most important reason for the need to standardize concepts and data is the possibility of analyzing big data, which is extremely important in the field of pharmacovigilance and safety monitoring. The joint work of international experts and the team of representatives of the Russian regulatory authorities on translation and validation has lasted more than a year, and a significant role in this belonged to our Association. In the future, the integration of the Russian-language version of MedDRA with the Pharmacovigilance base of the Automated Information System of Roszdravnadzor will allow receiving messages from both domestic and foreign specialized software products. In addition, it will support the possibility of information exchange with WHO and the use of modern statistical data analysis methods for the benefit of all players, including, above all, patients. ■

创新药物的态度发生了根本性的改变。对中国监管机构数据进行系统分析后我们得出结论，10年来全球有415种新分子（药物）投入市场，但没有一种在中国注册。对当地生产企业的过度保护，药品注册需进行反复临床试验及其他要求，使得新型创新药物进入中国市场困难重重，特别是治疗癌症，糖尿病，艾滋病等的新型药物。中国政府在确定最优先药物清单后，在短时间内制定并实施了一系列有效措施，使中国患者在半年内就能用上世界公认的创新药物进行治疗。免除进口关税，大力保护专利，在专利保护期内禁止生产类似药和生物仿制药，取消对本地临床试验的要求，将药物迅速列入报销范围内—以上可能不完整的措施清单最终取得了成果。我非常希望联邦政府在研究了中国的经验后，可以选择正确的监管方法进一步改善制药行业，这些监管方法将会出现在延长至2024年的《制药业2020年》计划中。

我们支持国内医药行业在出口领域的创新发展趋势。我们愿将俄罗斯的科学家和世界级制造商研发出的药品推向庞大的全球市场，我向您保证，我们会行动地更快，更有效，与此过程中所有参与者互利共赢。

不久前新闻称有了俄文版的MedDRA。您如何评价这份文件的重要性？

实际上3月20日国际监管指南MedDRA就有了俄文版，该指南是药物安全信息编码的唯一标准。俄文版MedDRA的出现是俄罗斯联邦药监部门协调药物监管体系方法的重大突破，也是将整个EAEU（欧亚经济联盟）进一步整合到全球药物使用监测安全系统的平台。尽管医疗条件的名称和分类存在局部差异，但该词典有12种不同语言的版本，专业人员可使用相同的概念工作，交换标准化数据。在我看来，使用标准化概念和数据的重要性在于大数据分析能力，这点在药监部门和安全监测领域极为重要。国际专家和俄罗斯监管机构的代表们在翻译和验证工作方面的合作持续了一年多，协会在这一过程中发挥了重要作用。将来，俄文版MedDRA和俄罗斯卫生监督局自动信息系统药监部门的数据库将整合在一起，这样可接收和处理来自国内外专业软件产品的信息，它将支持与世卫组织的信息交换，使用现代统计数据分析方法符合所有利益攸关方的利益，当然首先是让患者受益。■

Pharmasyntez:
by All GMP Standards

10 April 2019

Pharmasyntez Group is a Russian pharmaceutical company engaged in the development and production of modern, high-quality, affordable medicines. It presents on the drug market since 1997 and has established itself as a reliable manufacturer of drugs for the treatment of socially significant diseases such as tuberculosis, HIV infection, oncology, diabetes, hepatitis.

Since 2014, the company is in the top-10 Russian pharmaceutical companies ranked by drug production volumes. Since 2015, Pharmasyntez in one of three fastest growing Russian pharmaceutical companies.

Pharmasyntez group has extensive experience in promoting its medicines and building effective relationships with medical communities and patient organizations, thereby occupying a leading position in the health care segment of the Russian pharmaceutical market.

Pharmasyntez has a powerful modern production base. The group includes five modern high-tech factories: in St. Petersburg, Tyumen, Bratsk, Irkutsk and Ussuriysk. Here Pharmasyntez produces more than 145 types of drugs in various dosage forms and dosages: capsules, tablets, granules, ointments, suppositories, infusion solutions, sterile powders for injection, lyophilisates and solutions for injection.

Drugs are manufactured on high-tech equipment from the world's best manufacturers, such as Bausch+Ströbel (Germany), GEA Belgium, Romaco (Germany), Bosch (Germany), Shanghai Tofflon Science & Technology Co. Ltd (China), ACG Pharma Technologies PVT LTD (India), and others.

Pharmasyntez
符合GMP所有标准

2019年4月10日

Pharmasyntez集团公司是一家俄罗斯制药公司，致力于研发和生产高品质、价格合理的药品。自1997年成立以来它就成为药品市场上可靠的制药商，主要生产治疗结核病、艾滋病毒感染、肿瘤、糖尿病、肝炎等社会重大疾病的药物。

自2014年起，公司药品产量进入俄罗斯十大制药公司之列。2015年成为俄罗斯增长最快的三家制药公司之一。

Pharmasyntez集团公司在药物推广，与医疗社团和患者组织建立高

Pharmasyntez Group is the holder of the largest portfolio of glucose-lowering drugs for the treatment of type 2 diabetes (8 trade names) and the most comprehensive range of anti-tuberculosis drugs in Russia.

One of the main tasks that Pharmasyntez sets itself is to meet high international standards. All Pharmasyntez enterprises operate according to unified international GMP rules. The quality system at the company's enterprises cover all issues that, individually or in aggregate, can affect product quality. At all stages of production, there is a complete control of all processes – from the purchase of raw materials to packaging.

Standards of the Rules of Good Manufacturing Practice imply continuous training of personnel directly influencing the quality of medicines. Pharmasyntez built a system of training and staff development. Personnel entering the production undergo compulsory primary training, internal and external training programs has been developed for all departments of the company, thus each employee must undergo certification.

Compliance with GMP standards allows Pharmasyntez to compete on equal terms with global manufacturers of drugs and boost exports.

Pharmasyntez carries out several large investment projects that are already at the design stage in line with international standards. One of the most ambitious projects is the creation of a pharmaceutical industrial complex for the production of active pharmaceutical substances and finished pharmaceutical products in the city of Usolye-Sibirskoye. It is planned, that in the future the Usolsky plant will produce almost a third of all drugs produced in Russia for the treatment of socially significant diseases.

Another project is the construction of the production of hormonal drugs, which is carried out by Pharmasyntez-Tyumen. The plant is expected to be launched by mid-2020; it will be the largest in Europe. The planned annual production of hormonal drugs will reach up to 4.8 million packages per year.

In 2017, the company launched the Pharmasyntez-Nord-based production of anticancer drugs in the form of liquid and lyophilized injectable preparations in vials. The second phase of construction scheduled for May 2020 and timed to SPIEF-2020 (St. Petersburg International Economic Forum) will increase production capacity.

Pharmasyntez constantly brings to the market the original drugs, which are praised by the experts for their quality and effectiveness. Thus, an original drug for the treatment of diabetes mellitus type 2, Satereks® (INN Gozogliptin), which is included in the list of Vital and Essential Drugs, is being launched on the pharmaceutical market. Pharmasyntez carries out a full cycle of production of

效联系等方面拥有丰富的经验，在俄罗斯医药市场医院领域一直处于领先地位。

Pharmasyntez集团公司拥有强大的现代化生产基地。集团公司下属五家高科技企业，分别位于圣彼得堡、秋明、布拉茨克、伊尔库茨克和乌苏里斯克。公司生产超过145种不同剂型和剂量的药物：胶囊、片剂、颗粒、软膏、栓剂、输注液、无菌注射粉末、冻干剂和注射用溶液。

公司使用全世界最好的设备制造商，如：Bausch+Ströbel（德国），GEA比利时，Romaco（德国），Bosch（德国），Shanghai Tofflon Science & Technology Co. Ltd（中国），ACG Pharma Technologies PVT LTD（印度）等出品的高科技设备生产药物。

Pharmasyntez集团公司是俄罗斯最大的生产治疗2型糖尿病（8种商品名）降血糖药和最全结核病药物的厂家。

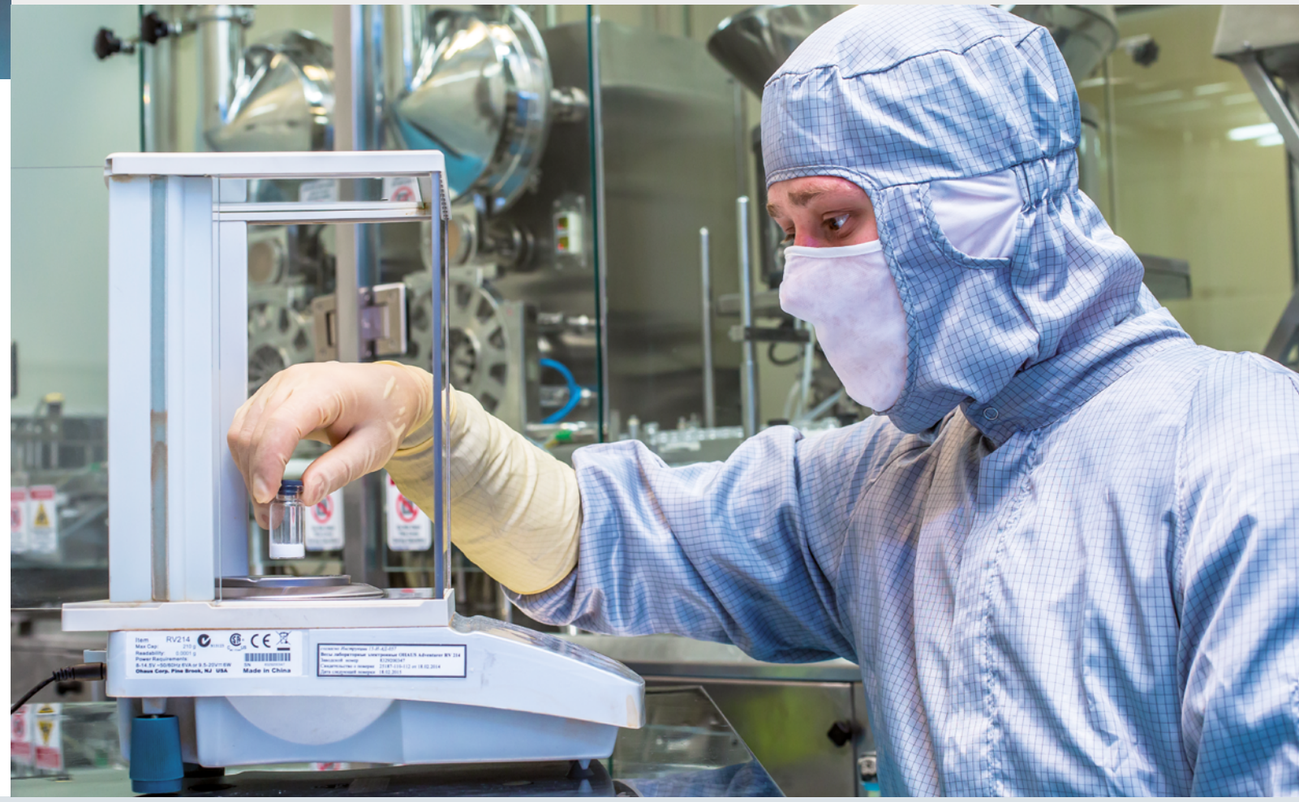
Pharmasyntez为自己制定的主要任务之一是符合国际标准。其下属所有企业均按照统一的GMP国际标准生产。企业质量管理体系涵盖所有可能影响产品质量的个别或全局性问题。在生产各个阶段都可以完全控制从原材料采购到包装的所有流程。

“良好生产规范”标准意味着要对长期直接影响药品质量的人员进行培训。公司已制定员工培训和发展体系。从事生产的人员必须接受强制性初级培训，公司所有部门都制定了内部和外部培训计划，每个员工必须通过考核上岗。

Pharmasyntez集团公司遵循GMP标准，与全球制药商平等竞争，扩大出口机会。

Pharmasyntez公司已落实多个符合国际标准，处于设计阶段的大型投资项目。其中最大的项目是在西伯利亚乌索利耶市建造一个生产活性药物和成品药的制药工业综合体。乌索利耶工厂的计划产量将占全俄治疗社会重大疾病药物总量的三分之一。

另一个项目是建设“荷尔蒙药物生产线”，该项目是在Pharmasyntez-秋明工厂进行的。2020年中期投产后工厂将成为欧洲同类项目中最大的。计划每年生产激素类药物480万包。



the drug, ranging from the synthesis of pharmaceutical substances at the plant in Bratsk to the release of the finished dosage form at the plant in Tyumen.

Soon a new generation drug, Epolong, is expected to enter the market; it will be used in outpatient treatment of people with severe impairment of the kidneys awaiting hemodialysis and transplantation surgery. Pharmasyntez will develop the drug in conjunction with another Russian company. Such a combination is necessary for the successful implementation of projects aimed not only at joint development, but also at the production and commercialization of innovative medicines with world export potential, in both Russia, the EAEU, and other global markets.

The development of innovative drugs and their introduction into production are performed in the company R&D center, which is equipped with an analytical laboratory and an experimental-industrial workshop. The company annually invests up to 500 million rubles in scientific research, constantly working on the search for new chemical molecules to combat tuberculosis, HIV and other diseases. The company annually synthesizes from 300 to 500 new molecules.

Pharmasyntez is interested and invites for cooperation Russian and foreign partners; the cooperation will be aimed at joint development, conducting preclinical and clinical studies, the production of high-quality medicines in Russia and ensuring the availability of innovative, biotech medicines. ■

COMPANY PROFILE– PHARMASYNTEZ GROUP, RUSSIA

- Product portfolio: more than 145 drugs
- Geography: five plants in Russia
- Staff: more than 2000 highly qualified professional staff members
- Turnover (2018): 16.8 billion rubles
- Production: more than 50 million packages per year
- Investment volume in the 2019-2021 period: ≥ 20 billion rubles

PHARMASYNTEZ.COM

2017年在Pharmasyntez-诺德工厂建成小瓶液体和冻干注射制剂抗癌药物的生产线。为提高产能，工厂二期预计在2020年5月投入生产（恰逢2020年彼得堡经济论坛）。

Pharmasyntez公司不断向市场推出自主研发的原药，其质量和治疗效果获得专家们的高度赞誉。目前向医药市场推出的治疗2型糖尿病的原药Satereks®（INN Gozogliptin）已被列入日常必备重要药品清单。Pharmasyntez集团公司拥有完整的生产线，从布拉茨克工厂的药物合成到秋明工厂出产成品药。

新一代药物Epolong很快将投放市场，可在门诊治疗肾脏严重受损，等待血液透析和移植手术的患者。该药物是Pharmasyntez公司与另一家俄罗斯公司合作研发的。无论是在俄罗斯，EAEU（欧亚经济联盟）还是在全球其他市场，为顺利实施共同开发的项目，与全球极具出口潜力的企业合作生产新型药物并商业化是十分必要的。

公司研发中心完成新型药物的研发并将其投入生产，该中心配备分析实验室和实验工业车间。公司每年投入高达5亿卢布的科研费用，不断致力于寻找新型化学分子，以对抗结核病，艾滋病毒和其他疾病。研发中心每年合成300至500个新型分子。

Pharmasyntez公司有意邀请国内外合作伙伴共同参与研发，进行临床前和临床研究，以期在俄罗斯境内生产出高品质的药品，实现新型生物技术药物的普及应用。■

公司资料 – 俄罗斯PHARMASYNTEZ集团公司

- 产品线：超过145种药品名称
- 地理位置：俄罗斯境内有5家工厂
- 员工编制：超过2000多名高素质技术人才
- 2018年营业额：168亿卢布
- 产量：每年超过5000万包
- 2019-2021年期间的投资额：≥200亿卢布

Launching Production

of Russian Vaccines in Latin America

10 April 2019

Press service of SPbSRIVS

MECHNIKOV Institute, created as part of the Russian-Nicaraguan project in Managua, has begun production of commercial batches of influenza vaccine

MECHNIKOV Institute has launched the production of commercial vaccine batches in Managua (Nicaragua). The launch of the production lines was attended by the advisor for investments of the Government of Nicaragua **Laureano Ortega**, Deputy Minister of Health of the Russian Federation **Sergey Kraevoy**, President of the Nicaraguan Institute of Social Insurance **Dr. Roberto Lopez**, Head of Federal medical and biological agency of Russia (FMBA) **Viktor Uiba** and Director of the Saint-Petersburg scientific research institute of vaccines and serums of the FMBA of Russia (SPbSRIVS) **Viktor Trukhin**. The project has been implemented pursuant to the Instruction of **Vladimir Putin**, the President of the Russian Federation.

MECHNIKOV Institute has become a new stage of the collaboration of Russia with Latin American countries and a new brand with Russian participation in Central America opening the window of opportunities to improve the health care level in the whole region. The project has been implemented in close cooperation and with the support of the Pan American Health Organization (PAHO). As Director of the Saint-Petersburg Scientific Research Institute of Vaccines and Sera of Federal Medical and Biological Agency of Russia (SPbSRIVS), **Viktor Trukhin** said that by 2020 they are planning to complete the transfer to Nicaragua of another drug, Tuberculin.

Sergey Kraevoy noted that the facilities of the MECHNIKOV Institute allow producing up to 300 thousand doses of influenza vaccine per day during two-shift work.

Vaccine production in Managua has been established in record-breaking time. According to UNIDO, the cycle from designing such a plant to launching production in developing countries can take up to 7 years. The construction of the production building of MECHNIKOV Institute was completed in less than a year, in October 2016. It took more than two years to fit out the production facility with modern equipment and complete the procedures for qualifying premises, critical engineering systems, validating technological processes, as part of the technology transfer process, and also validating transportation of the finished product in the cold chain conditions from Russia to Nicaragua and from Nicaragua to Cuba. In 2018, the company

2019年4月10日

圣彼得堡疫苗和血清科学研究所新闻中心

俄罗斯疫苗在拉丁美洲投产

俄-尼两国马那瓜项目已建成的梅奇尼科夫研究所投产商用系列流感疫苗

位于马那瓜（尼加拉瓜）的梅奇尼科夫研究所开始生产商用系列疫苗。尼加拉瓜国家投资和出口促进局顾问劳列安诺·奥尔捷佳，俄罗斯联邦卫生部副部长谢尔盖·克拉耶沃，尼加拉瓜社会保障局主席罗别尔托·洛佩斯博士，俄罗斯联邦医疗生物机构（FMBA）所长弗拉季米尔·维巴和俄罗斯医疗生物机构下属圣彼得堡疫苗和血清科学研究所（SPbNIIVS）所长维克托·特鲁欣出席了投产仪式。该项目是由俄罗斯联邦总统弗拉基米尔·普京授权实施的。

梅奇尼科夫研究所的成立使俄罗斯与拉丁美洲的合作进入新阶段，它是俄罗斯参与国家级合作的新典范，也是提高中美州地区卫生保健水平难得的机会。该项目是在与泛美卫生组织的密切合作下落实的。俄罗斯医疗生物机构下属圣彼得堡疫苗和血清科学研究所（SPbNIIVS）所长维克托·特鲁欣

underwent certification for compliance with GMP requirements, which was conducted by the Cuban CECMED center, which has the highest (fourth) level in terms of the PAHO qualification.

Not less important and time-consuming process, carried out during this period, was the registration of the Russian vaccine for the prevention of influenza in Cuba and Nicaragua with the subsequent delivery of the drug and use as part of vaccination of the population of these countries.

Government investments in construction and equipment of the Institute MECHNIKOV amounted to USD 33.5 mln, and 34% of the amount were the expenditures of the Nicaraguan party.

MECHNIKOV Institute equipment alone costs more than USD 18 mln. The managing company of the MECHNIKOV Institute is a Nicaraguan one, the Russian party represented by SPbSRIVS FMBA of Russia holds a share in its capital.

Production of the influenza vaccine is very important for the Latin American

MECHNIKOV Institute is developing at a quick rate. This is a modern technological production, built to the latest standards. The joint Inspectorate of CECMED and the national regulator of Nicaragua carried out GMP inspections, tested validation series of vaccines, including the results of accelerated stability, which is very important for this type of product. In February 2019, the first profile on the drug "influenza inactivated split vaccine" was submitted.

Mikhail Murashko

the Head of the Federal Service on Surveillance in Healthcare (Roszdravnadzor)

梅奇尼科夫研究所正快速发展。研究所的工艺生产流程建立在最现代的标准之上。2019年2月CECMED联合监察机构和尼加拉瓜国家监管机构对研究所进行了GMP检查，对疫苗系列进行了加速稳定性等测试，这些检查和测试对该类产品非常重要。之后提交了一份《灭活分裂流感疫苗》制剂档案。

米哈伊尔•穆拉什科

俄罗斯联邦卫生监督局局长

称，2020年计划向尼加拉瓜再转让一种药物—结核菌素。

谢尔盖·克拉耶沃强调，梅奇尼科夫研究所每天双班制的产量可达30万剂流感疫苗。

马那瓜疫苗生产线在很短时间内建成，创造了此类项目的建设纪录。根据UNIDO的数据，在发展中国家建设这样的工厂从设计到投入生产的周期需要5-7年。2016年10月，梅奇尼科夫研究所生产大楼在不到一年的时间建成。之后两年多的时间内生产线完成设备配套，房屋和主要工程系统完成鉴定，技术转让的工艺流程完成验证，冷链条件下从俄罗斯到尼加拉瓜，再从尼加拉瓜到古巴的运输过程也得以确认。2018年，研究所通过GMP要求的符合性认证，由具有泛美卫生组织最高级别（第四级）资格的古巴CECMED中心进行认证。

在此期间同时在古巴和尼加拉瓜注册俄罗斯流感预防疫苗，这也是最重要和耗时的工作，最终交付药物，为这些国家的居民进行疫苗接种。

政府为梅奇尼科夫研究所的建设和设备投资近3350万美元。其中34%为尼方的费用。仅梅奇尼科夫研究所的设备成本就超过1800万美元。研究所的管理公司是尼方公司，由俄罗斯医疗生物机构下属圣彼得堡疫苗和血清科学研究所代表俄方投入资本。

生产流感疫苗是拉丁美洲国家迫切的需求。该地区每年流感疫苗的缺口达1亿剂，加之2022年欲将居民流感免疫水平提高到30%

The launch of the Latin American biotechnology Institute MECHNIKOV is a successful example of the transfer of the Russian high-tech production of immunobiological drugs. This is an example that the creation of full-cycle production of drugs, especially vaccines, is possible far beyond the parent company. It is doubly pleasant that it was made by the Russian company. The project to provide residents of Nicaragua and the entire Latin American region with influenza vaccine is highly supported at the government level – it is implemented within the framework of the decisions of the Russian-Nicaraguan intergovernmental Commission, as well as in accordance with the Instructions of the President of the Russian Federation, Vladimir V. Putin and the order of the Government of the Russian Federation. As representatives of the Russian GMP Inspectorate, we tried to support and promote this project, we worked together with colleagues from CECMED in October last year, during one of the stages of GMP inspection of the plant.

Vladislav Shestakov

Director of FSI "SID & GP" of the Ministry of Industry and Trade of Russia, Deputy Head of the Russian State GMP Inspectorate

拉丁美洲梅奇尼科夫生物技术研究所的成立是俄罗斯高科技免疫生物制剂生产转让的成功范例。它是在母公司之外建造完整的生产线，特别是疫苗生产线的成功案例。非常荣幸，俄罗斯公司做到了。

项目得到了政府的高度支持，它旨在为尼加拉瓜乃至整个拉丁美洲地区的居民提供流感疫苗，项目依据俄-尼政府间委员会决定实施，符合俄罗斯联邦总统V.V.普京的命令和俄罗斯联邦政府令。去年10月我们作为俄罗斯GMP监察机构的代表与CECMED的同行们一起对工厂进行了GMP的阶段检查

弗拉迪斯拉夫•谢斯塔科夫称

俄罗斯工贸部下属联邦预算机构国家药物和GP研究院院长，俄罗斯国家GMP监察机构副局长

countries. At present, the deficit of the influenza vaccine in the region is up to 100 million doses annually, and, considering the plans to raise the level of influenza vaccination of the population to 30% by 2022, the deficit will be increasing. Based on the PAHO/WHO data, influenza and pneumonia cause 4.6% of all deaths in Nicaragua. In Brazil – 8.12%, in Columbia – 4.2%, in Mexico – 3.97%, and in Cuba – 7.14%.

The market of pharmaceutical and immunobiological drugs of the countries of Latin America and the Caribbean Basin (LAC) exceeds USD 96 bln. In total, the aggregate market of these countries, with a population exceeding 600 million people, is about 8% of the global pharmaceutical market. The growth dynamics is about 12% annually, which exceeds the indicators of the Russian market.

As of the year-end 2018, FSUE SPbSRIVS FMBA of Russia has exported 104,068 of packages inactivated vaccine for influenza prophylaxis for a total amount of about 109.5 mln RUB, and practically increased supplies twofold, in comparison with 2017

All the largest manufacturers of influenza vaccines are represented in the markets of Latin America, in particular, the French Sanofi Pasteur, the British GSK and the South Korean Green Cross, as well as local manufacturers of Brazil, Mexico and Argentina.

Today, the MECHNIKOV Institute is the only biotechnological facility in Central America and has the status of a regional manufacturer.

Considering that the social support of the population in the countries of the Latin American region is high, the public health sector in most countries of the region is interested in long-term cooperation based on the procurement of a sufficient number of drugs at fixed prices. MECHNIKOV Institute plans to sell its products, in particular, the influenza vaccine, at a competitive price, which will be determined depending on the volume of supply and the terms of contracts to be concluded.

MECHNIKOV Institute is a prime example of successful international cooperation, in which one has already become interested in Ecuador and Venezuela. This experience attracts attention not only from Latin American countries and companies: on March 29, 2019, the management of the largest pharmaceutical company in Ethiopia, Addis Pharmaceutical Factory, visited the production site of Institute MECHNIKOV. Unique technological solutions used in the construction of the Russian and Nicaraguan enterprise were presented to the guests from Ethiopia by the specialists of the Indian company Fabtech, who acted as a partner and general contractor in the construction of a plant of the MECHNIKOV Institute in Nicaragua.

In the future, it is planned to transfer production technologies and other immunobiological drugs to the site of MECHNIKOV Institute.

The head of the FMBA of Russia, **Vladimir Uiba**, notes that the development of MECHNIKOV Institute will proceed in three areas. First of all, this is the production of a vaccine for the prevention of influenza and the expansion of its sales markets. Also, MECHNIKOV Institute will provide technology transfer for production of topical drugs for the region, in particular, for Hepatitis

A vaccine and recombinant erythropoietin, the development of another institute of the FMBA of Russia – the National Research Institute for High Purity Biologicals. Another area of development will be researched in various areas, as well as training and vocational guidance among young people, in particular, in the framework of the BioNica project. ■

的计划，该赤字定会增加。泛美卫生组织/世界卫生组织称，流感和肺炎占尼加拉瓜死亡总人数的4.6%。巴西占比为8.12%，哥伦比亚占比为4.2%，墨西哥占比为3.97%，古巴占比为7.14%。

拉丁美洲和加勒比流域（LAC）药物和免疫生物制剂的市场规模超过960亿美元。这些国家的人口总数超过6亿，占全球医药市场的8%左右。每年的增长态势约为12%，超过俄罗斯市场的指标。

2018年的报告中指出，俄罗斯联邦医疗和生物机构下属联邦国家单一企业“圣彼得堡疫苗和血清科学研究所”共出口104068包预防流感的灭活疫苗，总计约1.095亿卢布。销量比2017年增加了1倍。

拉丁美洲国家市场上生产流感疫苗的厂家均为大型制药厂，如法国的Sanofi Paster（赛诺菲帕斯特），英国GSK和韩国的Green Cross（绿十字），以及巴西，墨西哥和阿根廷的本土生产商。

目前梅奇尼科夫研究所是中美洲区域生产商中唯一的生物技术企业。

拉丁美洲地区各国人口的社会保障率较高，该地区大多数国家公共卫生部门愿与制药企业长期合作，以固定价格采购药物。梅奇尼科夫研究所计划以极具竞争力的价格销售包括流感疫苗的药品，产品价格将取决于供货量和合同期限。

梅奇尼科夫研究所是开展国际合作的成功典范，厄瓜多尔和委内瑞拉对这种合作模式表示出兴趣。成功经验引起了拉丁美洲国家和诸多公司的注意，2019年3月29日，埃塞俄比亚最大的制药公司Addis Pharmaceutical Factory的管理层参观了梅奇尼科夫研究所的生产基地。印度Fabtech公司的专家们向来自埃塞俄比亚的客人们介绍了研究所项目独特的建设方案，Fabtech公司是梅奇尼科夫研究所的合作伙伴和总承包商。

未来计划将其他免疫生物制剂的生产技术转让给梅奇尼科夫研究所。

俄罗斯联邦医疗生物机构（FMBA）所长弗拉季米尔·维巴指出，梅奇尼科夫研究所有三个发展方向。首先是生产流感疫苗及扩大其销售市场。将为梅奇尼科夫研究所提供生产该地区急需药物，特别是甲型肝炎疫苗和重组促红细胞生成素的技术转让，以及生产俄罗斯联邦医疗生物机构下属另一个研究所“国家特别净化制剂科研所”研发产品的技术转让。另一个发展方向是在各个领域的研发工作，以及BioNica项目框架内对年轻人的培训和职业指导工作。■

New Plant of Obolenskoe

is Created by All International Standards

On February 7, 2019, a new solids manufacturing facility was launched by the "Obolenskoe Pharmaceutical Enterprise" in the Serpukhov district, Moscow region (village Obolensk). The manufacturing complex will allow for an annual production output of 120 million packs of non-sterile solid dosage forms and will secure availability of high-quality Russian medicines not only in Moscow and in the Moscow region, but will satisfy the existing demand in locally produced medicines throughout Russia. The total investment in the new plant site amounted to **3 billion rubles**.

First Deputy Minister of Industry and Trade of the Russian Federation, **Sergey Tsyb**, congratulated the leaders of the PE "Obolenskoe" and the guests on the launch of the new plant, noting that the use of advanced technologies in the new plant site will allow to keep the highest quality of medicines with large volumes of output.

"In accordance with the introduction of the latest quality standards, the plant will make a due contribution to the implementation of the Pharma-2020 strategy and to the new pharmaceutical industry development strategy – Pharma-2030", – said Sergey Tsyb.

Within the territory of the facility having the most advanced manufacturing

新“奥博连斯基”制药厂根据国际标准建造

2月7日在莫斯科州奥博连斯基区（奥博连斯克村）新奥博连斯基制药厂完成了交付仪式。该工业园区每年将生产1.2亿包有菌固体药剂，不仅可为莫斯科州和首都居民提供高质量的药品，还将满足俄罗斯全体居民对国产药品的基本需求。新生产线总投资额达30亿卢布。

俄罗斯联邦工贸部第一副部长谢尔盖·齐布向奥博连斯基的管理团队和嘉宾们表示祝贺，庆祝新工厂投产，他特别指出，新生产线使用的先进技术可保证在高产的同时产出高品质产品。

谢尔盖·齐布强调说：“引入最新的质量标准，工厂将为《制药业2020年》战略实施以及制药业2030年新发展战略规划做出应有的贡献。”

新生产线将引进直接混合、非喷射等先进技术，以及可与疏水性药物和光敏药物一起加工的技术。

technologies for the production of solid dosage forms, there is state-of-the-art equipment for direct mixing, non-spray techniques as well as the techniques for handling hydrophobic and light-sensitive pharmaceutical substances.

"Today we witness a historic event not only for the Moscow region but for the country on the whole. The pharmaceutical company with 25 years of experience behind and a vast portfolio of drugs manufactured is giving a start to a new manufacturing complex. It is noteworthy that this new facility has been designed according to international GMP standards. We can see the implementation of such current trends as a transition to automation, which excludes risks of contamination due to a closed-type production line without open dusting, with automated CIP, WIP systems for equipment cleaning. And on top of that the facility already has the most advanced packaging lines with the system of labelling with control (identification) symbols", – emphasized the Director of FSI "SID & GP" **Mr. Vladislav Shestakov** in his congratulatory speech towards the "Obolenskoe Pharmaceutical Enterprise".

A large-scale manufacturing line designed according to GMP and ISO standards including the system of medicines monitoring from the plant to the pharmacy and ultimately to the end user by means of labelling solutions will bring the facility to the level of the leading European drug manufacturers.

"The plant is equipped with all necessary equipment for applying a code with cryptographic protection. Currently, three lines operate at 250 packs per minute. Together with the Center for the Development of Industry and Commerce, we conducted a successful test packaging lines with the system of labelling. The result shows that the application corresponds to digital labelling requirements. The labelling is designed to increase the transparency of drug accounting and eliminate illegal circulation of medicine. Due to the introduction of labelling, citizens will be confident in the quality of purchased drugs, nothing will threaten their life and health", – said General Director of the "Obolenskoe Pharmaceutical Enterprise" **Andrey Mladentsev**.

"Testing on the application of code on the site of the new pharmaceutical enterprise "Obolenskoe" showed that the crypto-protected code doesn't complicate the process of labelling drugs. The crypto-protection doesn't allow forging a code and minimizes the risks of illegal drug trafficking in such a socially important industry as pharmaceuticals", – commented the head of Pharma Department of the Center for the Development of Industry and Trade **Anton Kharitonov**.

The new enterprise was built in the framework of the agreement with the government of the Moscow region, signed in May last year at the St. Petersburg International Economic Forum.

The government of the Moscow region allocated subsidies for the creation of engineering infrastructure in the amount of more than 83 million rubles. It is assumed that the company will have 350 jobs. At present, 130 jobs have already been created.

The territory on which the plant is located is 6 hectares, and production facilities occupy 14 thousand square meters. The potential of the enterprise is 1.3 tons of products per year. The production capacity involves the production of 1.6 billion tablets, 120 million capsules, 15 million sachets per year.

There will produce medicines of the main therapeutic directions: drugs affecting the digestive tract and metabolism substances; for the treatment of diseases of the cardiovascular system; antimicrobials for systemic use; drugs for the treatment of diseases of the musculoskeletal and nervous system;

联邦预算机构"国家药物和GP研究院"院长弗拉斯拉夫·谢斯塔科夫在工厂开幕式发言："今天我们见证的不仅是莫斯科地区的历史，也是整个国家的历史。有着25年历史和丰富产品线的制药公司启动了一个新的制药厂。新工厂按照GMP国际标准建造。工厂处于向自动化生产过渡阶段，封闭式无露天粉尘的生产线，自动CIP，WIP设备清洗系统排除了污染风险。更重要的是新企业的包装线引进了CIZ标签系统。"

根据GMP和ISO标准建成的大规模生产线所使用的标签系统可实现药品从工厂到药房柜台和最终用户手中的流动监控系统，这点工厂已与欧洲大型制药厂商同步。

奥博连斯基制药企业总经理安德列·姆拉坚采夫称："企业配备了标识加密代码的所有设备。目前，三条生产线的运行速度为每分钟250包。我们与"先进技术发展中心"一起顺利完成测试，标识符合数字标记的要求。数字标记提高了药品统计的透明度，避免了产品的非法流通。它的推出使居民对药品质量充满信心，因为没有任何东西会威胁到他们的生命和健康。"

"先进技术发展中心"产品线负责人安东·哈里通诺夫补充道："对奥博连斯新制药厂进行的代码制作测试表明，加密保护代码并不会使标记药物的过程复杂化。加密保护无法伪造代码，最大限度地降低了像制药业这样重要行业内产品非法流通的风险。

新工厂按照去年5月在圣彼得堡国际经济论坛与莫斯科州政府签订的协议建造。

莫斯科州政府以金额超过8300万卢布的工程基础设施建设补贴提供支持。工厂将产生350个新工作岗位。目前已有130个工作岗位。

工厂占地面积6公顷，生产车间占地1.4万平方米。每年产能为1.3吨。每年可生产16亿片剂，1.2亿粒胶囊，1500万包药品。

工厂生产的主要药物：促进消化和新陈代谢的药物；治疗心血管系统疾病的药物；全身使用的抗菌剂；治疗肌肉骨骼和神经系统疾病的药物；治疗感觉器官和呼吸系统疾病的药物以及其他医疗药物。

位于谢尔普霍夫的奥博连斯基制药厂成立于1994年，其前身为全俄应用微生物研究所，曾参与前苏联细菌武器研发计划。公司生产片剂和胶囊，是俄罗斯国内12大制药厂之一。

2018年12月底，俄罗斯多元化公共控股公司Sistema收购了奥博连斯基制药厂股份。由俄罗斯联邦对外贸易银行和OBL Pharm管理层共同从Alvansa公司收购，Alvansa公司的主要股东为俄罗斯天然气工业银行和UFG Private Equity。

此次收购的目的是在奥博连斯基制药厂与Binnofarm股份公司（Sistema集团的成员）合并后成立一家俄罗斯大型制药公司。2019年上半年两家公司（奥博连斯基制药厂和Binnofarm股份公司）合并后将成立联合公司，联合公司将成为俄罗斯商业领域十大制药公司之一。其产品多样化，包括200多种药物。联合公司的产能为莫斯科和莫斯科州四家制药厂的总量。 ■

for treatment of diseases of the sense organs and respiratory system and a number of other medicines.

"Obolenskoe Pharmaceutical Enterprise" in Serpukhov was established in 1994 on the premises of the former Research Institute of Applied Microbiology, which participated in Soviet programs for the development of bacteriological weapons. The enterprise produces tablets and capsules. The company is in the top 12 of domestic manufacturers.

At the end of December 2018, Public Joint-stock financial corporation Sistema (Russian diversified public holding company) acquired a package of shares of "Obolenskoe Pharmaceutical Enterprise". The shares were purchased jointly with the VTB Bank and the management of the OBL Pharm from company Alvansa Ltd, the main shareholders of which are Gazprombank and UFG Private Equity.

The purpose of the transaction is to create a leading pharmaceutical holding in Russia after the merger of Obolenskoe with Binnopharm JSC, a member of Sistema group. On the basis of these two companies (Obolenskoe and Binnopharm), in the first half of 2019, a joint company will be created, which will enter the top 10 Russian pharmaceutical companies in the commercial segment. The diversified product portfolio includes about 200 drugs. The production facilities of the United company will be represented by four pharmaceutical plants in Moscow and the Moscow region. ■

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WERTEKS Sees the Future in Global Markets

20 April 2019

Russian manufacturer of drugs and cosmetics, WERTEKS, connects long-term successful cooperation with Chinese partners – the largest suppliers of active pharmaceutical substances and excipients. In particular, thanks to it, for almost 16 years from obtaining the first license for production, the company has increased its competence in the domestic market and the markets of some countries of the Eurasian Economic Union and created a competitive portfolio in demand. It mainly includes original combined drugs, a lot of generics and cosmetics of own brands – more than 250 items (SKU). Therefore, today WERTEKS is ready to consider options for expanding the market and finding reliable partners in China to offer its medicinal, cosmetic products and biologically active additives to Chinese citizens. A number of cosmetics for skin, hair and oral cavity produced by the company is also intended for children.

Objectively, in the last few years, the Asian market and its main representative in East Asia, China, is attractive for Russian exporters and investors due to its economic growth, advanced technologies, market volume and rapid development.

"PRC and pharmaceutical company WERTEKS have a similar view on the

WERTEKS看到了新市场的前景

2019年4月20日

俄罗斯药品和化妆品制造商与中国伙伴保持着长期稳定的合作关系，中国伙伴是公司活性药物和辅料的最大供应商。

从获得第一个生产许可证后近16年，通过与中国伙伴的合作，公司提高了其在俄罗斯及欧亚经济联盟多个国家市场的运营能力，生产了一系列受欢迎且极具竞争力的产品。

主要包括：组合原药，仿制药和自有品牌的化妆品，共超过250种（SKU）。目前WERTEKS准备扩大市场，在中国境内寻找可靠的合作伙伴，向中国居民提供药品，化妆品和膳食补充剂。公司生产的系列化妆品，如面霜，护发产品和口腔护理产品也适用于儿童。

客观讲过去几年亚洲市场及东亚主要代表—中国经济、先进技术及市场规模的快速发展吸引了俄罗斯出口商和投资者。

制药公司WERTEKS首席执行官格奥尔吉·波别良斯基评论道：“中国和WERTEKS制药公司对经济发展持有相同的看法。我们努力奉行积极增长战略，与潜在的中国合作伙伴步伐一致。尽管文化，传统、思维方式仍存在差异，某些时候交流有障碍，但我希望我们能找到一种共同语言-商业语言。”

WERTEKS自2015年以来一直是俄罗斯药房销售领域增长率最高的大型制药企业，2018年底，公司被评为大型制药企业药房零售增长最快的公司（DSM Group，俄罗斯联邦专业营销机构）。自2015年以来公司年收入增长率高达30%。

attitude to economic development. We also strive to match an active growth strategy and therefore are on the same wavelength with potential Chinese partners. Despite the differences in culture, traditions, mentality, and some of the complexities of verbal communication, I hope we can find a common language – the language of business", – comments **Georgy Pobelyanskiy**, CEO of pharmaceutical company WERTEKS.

Since 2015, WERTEKS has been the leader in terms of growth among all the largest pharmaceutical manufacturers in Russia in terms of sales in pharmacies, and by the end of 2018, it was recognized as the fastest growing company among the largest domestic producers of medicines in pharmacy retail (data from the leading specialized marketing Agency in the Russian Federation DSM Group). Since 2015, the annual growth of the company is up to 30%, if we assess the dynamics of revenue.

PRODUCTION

The company's portfolio is a balanced combination of innovative products, modern popular generics and commercially successful cosmetic brands. WERTEKS is in the top-3 Russian manufacturers of cosmetics and top-7 Russian manufacturers of medicines by the share of sales in pharmacies of the Russian Federation, according to the analytical Agency DSM Group retail prices in 2018.

In 2018, WERTEKS brought to market two new original combined medicines for use in otorhinolaryngology (over-the-counter spray FRINOZOL (rus. – ФРИНОЗОЛ®)) and cardiology (KONSILAR®-D24), which has no analogues. Thus, there are already four innovative products in the company's portfolio: the first is for use in gynecology and dermatovenerology ELGINA (rus. – ЭЛЬЖИНА®) appeared in 2016, the second, for use in dermatology Tetraderm (rus. – ТЕТРАДЕРМ®), in 2017. The development of such drugs requires up to 8-10 years of research and significant investments.

Branded medicines and generics pharmaceutical companies cover about 20 areas of application from cardiology to neurology.

The main types of dosage forms:

- Solid – tablets, capsules, powders
- Semisolid – creams, gels, ointments
- Liquid – non-sterile solutions, sprays

Also, the company has five own brands with the main cosmetic range:

产品

公司产品主要为创新产品、现代流行仿制药和拥有商业品牌的化妆品。根据2018年DSM Group分析机构公布的零售价格，WERTEKS在俄罗斯联邦药店销售份额中位列俄罗斯药品和化妆品制造商前五位。

2018年WERTEKS向市场推出了两种适用于耳鼻喉科（OTC喷雾－FRINOZOL（俄－ФРИНОЗОЛ®））和心脏病科的（Konsilar®-D24）新组合原药，它们没有类似产品。公司已拥有四个创新产品：第一个是2016年研发的适用于妇科、皮肤病和性病的ELGINA（俄－ЭЛЬЖИНА®），第二个是2017年研发的皮肤病用药TETRADERM（俄－ТЕТРАДЕРМ®）。研发这些药物需要长达8-10年的时间和大量的资金支持。

制药公司药物和仿制药的品牌涵盖了从心脏病学到神经学的约20个应用领域。

主要制剂类型：

- 固体－片剂，胶囊，粉末。
- 软体－面霜，凝胶，软膏
- 液体 －有菌溶液，喷雾剂

公司拥有五个自有品牌的化妆品：

ALERANA®－刺激头发生长，防止脱发，强化和改善发质（除化妆品外，还有两种药物和一种膳食补充剂）；

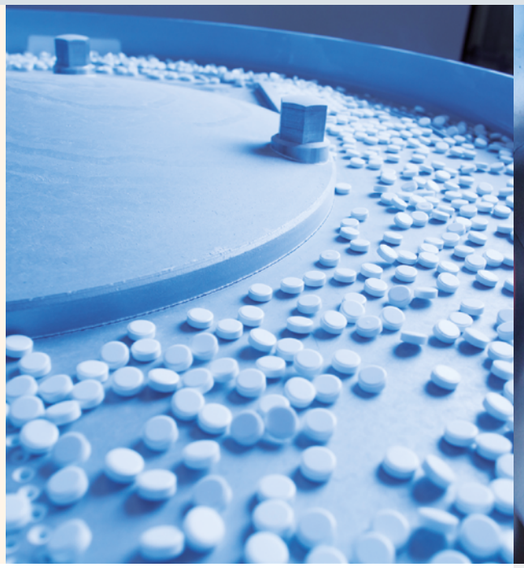
LA-KRY®－系列含天然成分的非激素消炎产品，呵护秀发，护理容易出现干燥、发红、刺痒的皮肤（儿童同样适用）；

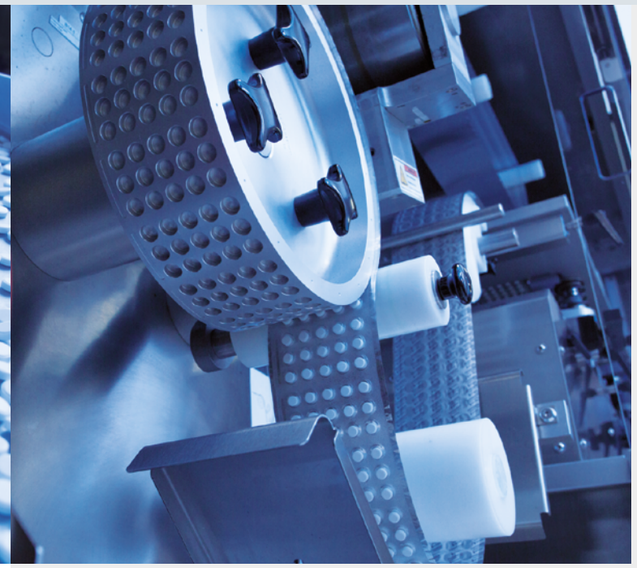
ACEPTA（俄－ACEПTA®）预防牙周炎症的口腔药物，已证实对口腔护理有效，益生菌复合物（BAA）和儿童用品；

JSC WERTEKS

- Russian pharmaceutical company from St. Petersburg will celebrate 20 years from the date of foundation in 2019. In 2003, it received the first license for the production of drugs.
- Laureate of the Russian Government prize in the field of quality in 2017 Among the 10 winners – the only pharmaceutical manufacturer, as well as the leader among all participants of the competition on the criterion of "Processes, products and services". The award was presented by Prime Minister Dmitry Medvedev in the Russian Government house.
- Full production cycle from development to product packaging

COMPANY SITE: HTTPS://VERTEX.SPB.RU/
GENERAL EMAIL ADDRESS: VERTEX@VERTEX.SPB.RU





ALERANA® for stimulating growth and preventing hair loss, as well as their strengthening and improvement (in addition to cosmetics, there are two drugs and one dietary supplement in the line);

LA-KRY® is a series of anti-inflammatory non-hormonal products based on natural ingredients for hair and skin care, prone to dryness, redness, irritation and itching (permitted for children use as well);

ACEPTA (rus. – АСЕПТА®) – products for the oral cavity, including: for the prevention of inflammatory periodontal diseases and oral care with proven efficacy, probiotic complexes (BAA), as well as products for children;

GINOKOMFORT® – intimate gel for women;

Normaven® – venotonic remedies.

In total, the brands include about 60 types of cosmetics, their types: shampoos, creams, gels, emulsions, toothpastes, mouthwash, lip balms, etc.

In 2019, it is planned to include more than 50 new products in the range, including medicines for use in neurology, cardiology, allergology, cosmetic products, etc.

CAPACITY DEVELOPMENT

The most large-scale industrial and investment project of the company is an innovation and production complex in the St. Petersburg Special Economic Zone, Novoorlovskaya Site. The first stage of the plant was opened in 2015. The total floor area of approximately 22,000 m² with a potential capacity of approximately 100 million packages of products per year.

Since 2018, the implementation of projects of the second and third phases of the pharmaceutical complex began. In the spring of 2019, WERTEKS began operation of the second stage building, launching a new warehouse, which occupies the prevailing part of the new facility. The built warehouses allowed doubling the storage volume of the entire plant. It is also planned to place research laboratories in the building. The total area of the four-storey building with a technical floor is about 7,300 m².

The third stage is the production building with a total area of more than 28,000 m². At the new facilities of the third stage, it is planned to place the production of solid and semisolid dosage forms and cosmetics. At the moment, the works on closing the perimeter of the building (construction of frames, facades, floors, etc.) have been completed, as well as 50% of the work on the arrangement inside the object and the main equipment of the clean premises of the site for the production of dosage forms.

Taking into account the three phases, the total area of the pharmaceutical complex will be about 58,000 m². The design capacity of the third stage is about 110 million packages of products per year, thus, the expected increase in the volume of production of the entire pharmaceutical complex is more than twice. The potential production volume of the plant, taking into account the three stages, is further estimated at more than 200 million packages per year. The construction and operation of the three phases will require the total investment in the project at more than 7 billion rubles by the end of 2019, at the moment it reaches 6.47 billion rubles. ■

GINOKOMFORT® – 女性私密处护理凝胶；

NORMAVEN® – 静脉药。

约有60个品牌化妆品，包括洗发水，面霜，凝胶，乳液，牙膏，漱口水，唇膏等。

2019年计划增加超过50个新产品，包括适用于神经病学，心脏病学，变态反应学的药物和化妆品等。

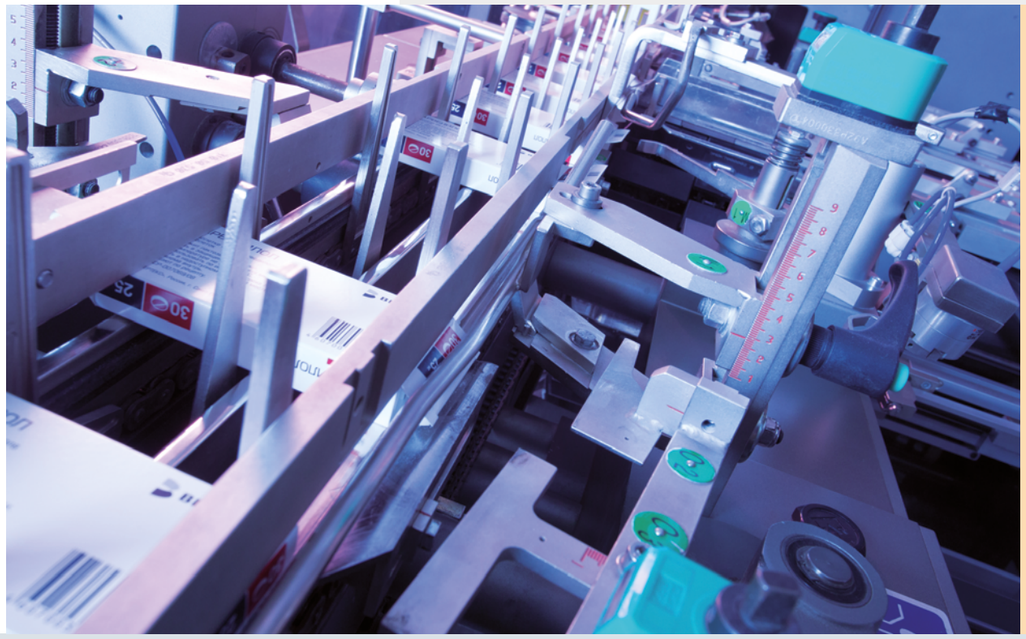
提高产能

公司最大的工业和投资项目是在圣彼得堡经济特区新奥尔洛夫区的创新型生产厂。厂房一期于2015年运营。项目总面积约22,000平方米，每年潜在产能约为1亿包产品。

2018年药厂二期和三期开始建设。预计2019年春WERTEKS二期厂房开始运营，新项目主要部分—新仓库将投入使用。内置仓储空间使厂区的存储容量翻倍。厂房内计划配备研发实验室。四层厂房的建筑总面积约为7300平方米。

三期生产大楼总面积超过28000平方米。三期工程将新添生产固体、软体药物和化妆品的设备。目前厂房周边工程（建造构架、厂房外墙，天花板等）已完工，厂房内部药品生产车间设备安装工程已过半。

制药厂三期工程总面积约58000平方米。第三期设计产能为每年约1.1亿件产品，因此，整个制药厂的预期产量增长将超过一倍。三期工程结束后工厂潜在产量为每年超过2亿件产品。到2019年底三期建设和运营的投资总额估计超过70亿卢布，目前为64.7亿卢布。■



WERTEKS股份公司

- 位于圣彼得堡的俄罗斯制药公司，2019年是公司成立20周年纪念，2003年获得第一个药品生产许可证。
- 获得俄罗斯联邦政府奖项“2017年质量奖”，是10位获奖者中唯一的制药厂家，在“流程，产品和服务标准”竞赛中名列前茅，该奖项由俄罗斯联邦总理德米特里·梅德韦杰夫在俄罗斯联邦政府大楼颁发。
- 拥有从产品研发到包装的完整的生产周期。

公司网站: HTTPS://VERTEX.SPB.RU/
电子邮件: VERTEX@VERTEX.SPB.RU

GENERIUM – Leader in the Orphan Segment of Russian Biotech

26 April 2019

GENERIUM occupies a strong position in the Biotech segment, being the key Russian manufacturer of genetic engineering products for the treatment and diagnosis of rare and socially significant diseases.

The history of GENERIUM began in 2009. At that time, Russia needed to create a modern biotechnological center with its own scientific research and production. Today, GENERIUM is a unique infrastructure facility in Russia, which combine a world-class biotechnological research center and a full-cycle innovative production, organized according to international GMP standards.

Thanks to innovative production technologies, GENERIUM made a significant contribution to the implementation

GENERIUM–俄罗斯生物技术孤儿病领域的领导者

2019年4月26日

GENERIUM公司在生物技术发展领域处于领先地位，它是俄罗斯重要的基因工程产品制造商，其产品多用于治疗和诊断罕见的社会重大疾病。

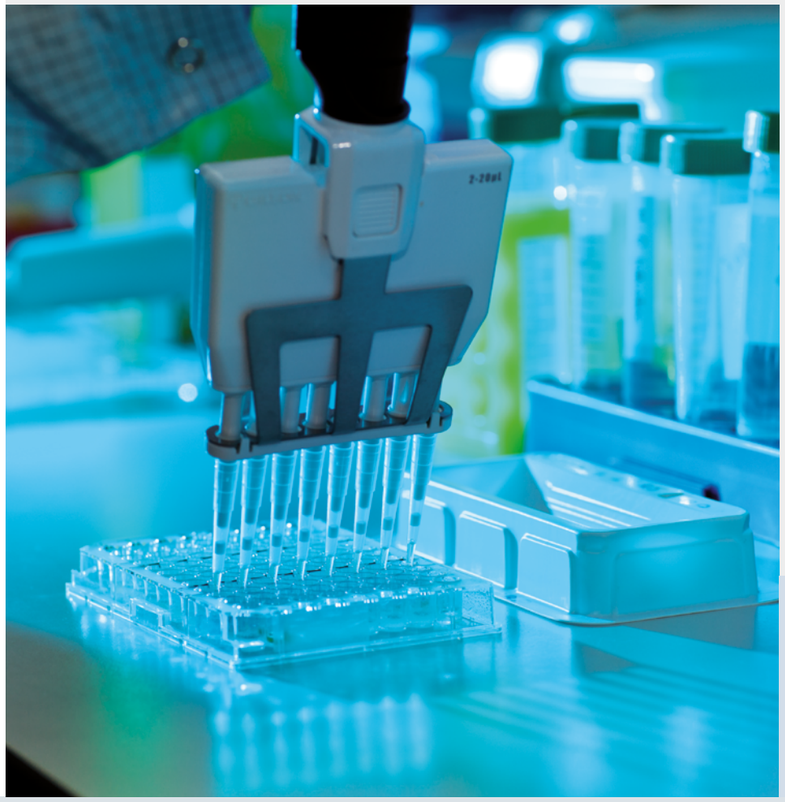
GENERIUM公司成立于2009年，当时俄罗斯正需要建立一个拥有自主科技和生产的现代生物技术中心。目前GENERIUM是俄罗斯境内唯一的拥有世界一流生物技术研究中心和符合

of the strategy of import substitution in the Russian Federation. After the introduction of the company's products to the market, a reduction in prices was achieved, which made the treatment more accessible for Russian patients. On the territory of the Biotech Park, a project was implemented to create the production of biomedical cell products. The key areas of company's specialization are autoimmune therapy, orthopedics, and plastic surgery. The company also actively develops exports in Latin America, the Middle East and Southeast Asia. ■

CONTACT
COMPANY SITE: GENERIUM.RU
EMAIL: BD@GENERIUM.RU

The company's portfolio includes the following drugs
公司产品线包括以下药物

TRADE NAME 商品名	INN （国际非专利药品名称）	INDICATIONS 适用症
Coagil VII®	recombinant blood coagulation factor VIIa	Hemophilia Inhibitor Form 血友病抑制型
Octofactor®	recombinant blood coagulation factor VIII	Hemophilia (type A) 血友病（A型）
Elizaria®	eculizumab	Paroxysmal nocturnal hemoglobinuria + atypical hemolytic uremic syndrome 阵发性睡眠性血红蛋白尿+非典型溶血性尿毒症综合征
Glurazyme®	imiglucerase	Gaucher disease 高歇病
Tigerase®	dornase alfa	Cystic fibrosis 囊肿性纤维化
Revelise®	alteplase, tPA	Myocardial infarction, acute ischemic stroke 心肌梗塞，急性缺血性中风
Genolair®	omalizumab	Bronchial asthma 支气管哮喘



GMP国际标准的完整创新生产线的基础工程。

GENERIUM公司凭借创新生产技术为俄罗斯联邦实施进口替代战略做出了重大贡献。公司产品进入市场后降低了药品价格，使更多的俄罗斯患者可以接受治疗。在生物技术园区内还实施有生物医学细胞产品生产项目。公司重点关注自身免疫疗法，矫形外科和整形外科。公司积极拓展出口业务，向拉美、中东和东南亚国家出口产品。 ■

联系方式
公司网址: GENERIUM.RU
电子邮件: BD@GENERIUM.RU

BIOCAD Prepares for Expanding

to the Chinese Pharmaceutical Market

10 April 2019

Dmitry Morozov, CEO of BIOCAD, over the past few years has been talking about the need for domestic producers to look for opportunities to expand abroad. The domestic market is becoming increasingly crowded for the growing Russian pharmaceutical industry. At the same time, only on the global market, in tough competition and versatile cooperation, Russian companies will be able to fully realize their potential.

The first shipment of BIOCAD drugs abroad took place in 2015. In the next three years, the company signed export agreements worth $850 million. Today, BIOCAD exports to 21 countries, and over the next five years, about 50 more countries will join this list.

For a Russian biotech company, the issue of increasing export earnings is one of the key issues. The company plans to increase the share of exports in turnover by 2023 to 50%, and one of the most

BIOCAD准备进军中国医药市场

2019年4月10日

BIOCAD Biotechnology Company

BIOCAD总经理德米特里·莫罗佐谈到过去几年国内生产商寻求机会进入国际市场的紧迫性。随着国内制药业不断增长的产能，国内市场日渐缩小。俄罗斯公司只有在竞争激烈的国际市场上与多方合作，才能充分发挥自己的潜力。

2015年BIOCAD向远邻国家出口第一批药物。三年后公司签订了价值8.5亿美元的出口协议。现在BIOCAD的产品共出口21个国家，未来五年计划出口增加至50个国家。

提高出口收入是俄罗斯生物技术公司面临的关键问题。公司计划到2023年将出口额占营业额的比例提高至50%，出口中国的销量在该增长比例中占据了重要地位。

经国际分析公司Evaluate Pharma评估，中国医药市场规模为1230亿美元，是目前世界上仅次于美国的第二大国。预计到2022年将增至1450-1750亿美元。其中进口份额占比25%以下。中国医疗领域投融资计划和居民收

important roles is assigned to China.

The international analytical company, Evaluate Pharma, estimates the Chinese pharmaceutical market to be worth $123 billion. Today, it's the second largest market in the world after the United States. By 2022, it is expected to reach $145-175 billion. At the same time, the share of foreign suppliers is 25%.

The main factors for the growth are the program of state financing of the country's health care and national income growth. Since 2017, China has consistently simplified the procedure for introduction of new drugs to the market, which simplifies the access of foreign pharmaceutical companies to the Chinese market. In particular, the requirements for conducting repeated clinical trials on the territory of the People's Republic of China have been abolished. In addition, an eight-fold increase in the number of employees involved in reviewing applications for the admission of drugs for sale in the country reduced the time for consideration of applications from one year to several months.

Biotechnology company BIOCAD is able to offer Chinese consumers drugs based on monoclonal antibodies used in modern therapy of oncological and severe autoimmune diseases such as chronic lymphocytic leukemia, colorectal cancer, lung cancer, breast cancer, psoriasis, ankylosing spondylitis, and others.

According to the analytical agency Globocan, China is the world leader in the number of newly identified patients diagnosed with lung cancer, breast cancer, cervical cancer, and colorectal cancer. Besides, the availability of drugs based on monoclonal antibodies is not so high. The rising costs of government programs motivate the state to look for new solutions that allow spending less on healthcare system projects without harming patients and the quality of the therapy they receive. Joint projects with the Russian business can become a solution.

China massively invests in the development of health care and improvement of drug provision, including expensive drugs, through the creation of partnerships between parastatal structures and private foreign companies able to provide modern therapy. For example, on September 12, 2018, Shanghai Pharmaceuticals Holding Ltd. and BIOCAD signed a preliminary agreement on the establishment of a joint venture to co-finance clinical research, registration, production and promotion of drugs based on monoclonal antibodies in China. The portfolio of the new enterprise will include both several biosimilars and the latest original preparations created by BIOCAD. The terms of the final contract are currently being negotiated.

Creating an internationally competitive portfolio of original products is one of the strategic initiatives of BIOCAD. The company is actively developing new drugs: from the search for a molecule to the production of packages. Now at different stages of development are about 40 original products. One of them, a monoclonal antibody to interleukin-17, has already been registered in Russia and in the very near future will be able to compete for the bestseller title. ■

入增长是市场增长的主要因素。自2017年以来中国政府致力于简化新药进入市场的程序，特别是废除了在中国境内进行反复临床试验的要求，这为外国制药公司进入中国市场开辟了道路。此外，从事境内药品销售申请审查的员工人数增加了七倍，将申请的审议时间从一年减少到几个月。

BIOCAD生物技术公司愿为中国患者提供单克隆抗体类药物，这些药物以现代手段治疗肿瘤及严重的自身免疫疾病，如慢性淋巴细胞增多症，结肠直肠癌，肺癌，乳腺癌，牛皮癣，强直性脊柱炎等。

分析机构Globocan称，中国新确诊的肺癌，乳腺癌，宫颈癌，结直肠癌患者数量位列世界前位。同时单克隆抗体药物较易获取。国家计划费用的增长促使政府寻求新的即可以减少医疗系统开支，同时又不会影响患者治疗质量的解决方案。与俄罗斯企业合作正是这样的解决方案。

通过半国营机构与能够提供现代化治疗的外国私营公司间的伙伴关系，中国政府在积极投资发展医疗卫生行业，改善和保障居民用药，包括昂贵药品。2018年9月12日，上海医药集团股份有限公司（Shanghai Pharmaceuticals Holding Ltd.,）和BIOCAD就建立合资企业签署了初步协议，旨在共同资助中国单克隆抗体药物的临床研究、注册、生产和推广。新企业的产品将包括多种生物仿制药和BIOCAD自主研发的最新制剂。目前正在商谈判最终合同的条款。

生产具有国际竞争力的自主研发产品是BIOCAD的战略举措之一。公司积极研发新药，自主完成从寻求分子到生产包装的全过程。目前约40种原药处于不同研发阶段。其中白细胞介素-17单克隆抗体已在俄罗斯注册，相信在不久的将来能够成为热卖药品。■

Each employee contributes a piece of their energy to the common cause.

At the end of 2017, Sotex took the 1st place in the rating of employers in terms of "Personnel Involvement" among all employers in Russia.

1 April 2019

PRODUCTION CAPACITY

In 2005, the Sotex plant for the production of injectable drugs, the first production site of the PROTEK Group of companies, was opened in Sergiev Posad district of the Moscow region.

It was one of the first enterprises built in Russia in full compliance with GMP EU requirements.

The production capacity of the Sotex plant is 143 million ampoules and 13 million pre-filled syringes per year.

In 2011, the company Anvilab entered the production segment of PROTEK group. The deal has expanded Sotex's product portfolio, providing

2019年4月1日

生产能力

2005年，位于莫斯科州马林斯基波萨德区的Sotex工厂开始生产注射用药物，这里是PROTEK集团公司的第一个生产基地。

该基地是俄罗斯首批完全符合欧盟GMP标准要求的企业之一。

工厂每年的产能为1.43亿安瓿瓶和1300万个预装式注射器。

2011年，AnviLab公司并入PROTEK集团的生产部门，AnviLab的加入不仅丰富了Sotex的产品线，也使公司生产非处方药成为可能。

2017年，PROTEK集团收购Rafarma制药厂，集团的生产部门再次扩大。

Rafarma股份公司生产以下剂型的15种药物：固体（片剂，胶囊），软体（凝胶，软膏，栓剂）和无菌剂型（小瓶）。

Rafarma生产的无菌抗癌药物符合欧盟GMP标准。

Sotex拥有33种品牌药物，可治疗肿瘤学、神经学、风湿病学、精神神经学等领域的疾病。

Rafarma加入Sotex集团公司后，有助于大力发展集团生产部门的抗癌药物产品线。

为俄罗斯患者生产创新抗癌药物是整个俄罗斯医疗保健体系的战略任务。

每位员工都在为共同的事业贡献力量。

截至2017年底，Sotex公司“员工参与性”指标在俄罗斯雇主公司排名中位列第一。

capability of development of over-the-counter direction.

In 2017, the segment "Production" of GC PROTEK significantly expanded due to the acquisition of the pharmaceutical plant Rafarma.

JSC "Rafarma" produces drugs in 15 dosage forms: solid (tablets, capsules), soft (gels, ointments, suppositories) and sterile dosage forms (vials).

Sterile forms of cancer drugs Rafarma are in accordance with the GMP EU standard.

The Sotex company portfolio includes 33 branded drugs in the directions of oncology, neurology, rheumatology, psychoneurology and so forth.

With the entry of Rafarma into Group of companies, Sotex had the opportunity to actively develop the oncology portfolio of the Group manufacturing segment.

The production of innovative anticancer drugs available to Russian patients is a strategic task that is relevant for the entire Russian health care system.

CONTRACT MANUFACTURING

Cooperation with foreign pharmaceutical manufacturers in the framework of contract production of drugs is one of the most important activities of the Sotex company. Among the long-term partners of the Russian enterprise, there are such giants of the pharmaceutical industry as Sanofi, Bayer, Takeda, Novartis, Pierre Fabre, etc.

Sotex makes a significant contribution to the development of contract production at the Rafarma plant.

Today Rafarma is registered as a platform for production of 18 drugs of eight pharmaceutical companies.

INNOVATIVE DRUG

Sotex is the first company in Russia to start production of recombinant erythropoietin in a full cycle in the form of a syringe with an automatic needle protection device. Eralfon® has received a number of professional awards.

In 2012 the company brought to market an injectable form chondroitin sulfate – Chondrogard® drug. Years later, the sales turnover of the drug exceeded 1 billion rubles. The drug occupies a leading position among Russian chondroprotectors.

In 2014, the company Sotex has brought to the Russian market a new dosage form of meloxicam, the drug Amelotex gel®. The unique technology of the outer dosage form of meloxicam is patented by the company.

EXPORT

An important milestone in the development of the Sotex export direction was the receiving of the EU GMP certificate in 2016.

In 2017, the drug manufactured by Sotex was registered in the Czech Republic.

In 2018, there was the first shipment of the company's products to the EU countries.

Today, the company's products are exported to more than 15 countries. Among the importers are Latin America, Montenegro, Portugal, Poland, Slovakia, Mongolia. The number of partner countries is constantly growing. ■

合同制造

与国外制药厂以合同制造药品方式合作是Sotex公司最重要的业务领域。公司的长期合作伙伴有众多的制药业巨头企业，如Sanofi, Bayer, Takeda, Novartis, Pierre Fabre等公司。

Sotex为Rafarma工厂拓展合同制造业务做出了重大贡献。

目前Rafarma已注册成为八家制药公司生产18种药物的工厂。

创新药物

Sotex是俄罗斯第一家生产注射用重组促红细胞生成素的公司，注射器针头有自动保护装置。Eralfon®赢得了许多行业奖项。

2012年公司推出注射用硫酸软骨素—Chondrogard®。该药物近几年的销售额超过10亿卢布。在俄罗斯软骨保护剂中占据领先地位。

2014年，Sotex向俄罗斯市场推出美洛昔康的新剂型Amelotex gel®。公司已获得美洛昔康外用剂型独特技术专利。

出口

2016年获得GMP欧盟认证是Sotex出口业务的重要里程碑。

2017年，Sotex出品的药物在捷克共和国注册。

2018年，公司产品首次运往欧盟国家。

如今公司产品已远销15个国家。进口商遍及拉丁美洲，黑山，葡萄牙，波兰，斯洛伐克，蒙古等国。合作国家的数量仍在不断增加。■

Rafarma Implements Import Substitution Strategy

Rafarma was merged into manufacturing segment of PROTEK Group of companies in April 2017, there is no doubt that one of the most promising innovative pharmaceutical plants in Russia will achieve its full industrial potential soon. The company has ambitious plans for cranking contract manufacturing up and expanding its own product portfolio, primarily by production of oncology products. Vladimir Ilyushin, General Manager of JSC Rafarma, told how do things stand at the Rafarma plant.

After JSC Rafarma entered PROTEK Group's manufacturing segment in April 2017, the plant obviously underwent significant changes. What are the results achieved by Rafarma at the beginning of 2019?

Today, Rafarma actively executes the strategy of import substitution. For this purpose, the innovative onco drugs and antibiotics plant was set up in Lipetsk region, with the support of the Ministry of Health and the Ministry of Industry and Trade of the Russian Federation.

From the moment the plant entered PROTEK's production segment, we began to work on the transfer of Sotex oncology products to our site. At the same time, we started to build our own oncological portfolio. By the beginning of 2019, Rafarma plant has already been manufacturing four anticancer drugs: two of them were produced on a contract basis, while the other two were part of Rafarma's portfolio. A number of products, including antineoplastic drugs and antibiotics, are at various stages of obtaining

Rafarma实施的进口替代战略

Rafarma公司总经理弗拉季米尔·伊柳申在回答工厂主要工作时称：公司2017年4月加入PROTEK集团公司生产部门后，成为俄罗斯最具前景的创新制药厂商，生产潜力将在短期内实现。公司计划增加合同制造产品，同时将扩大自有产品线，首先是抗癌药物。

Vladimir Iliushin
the General Manager of JSC Rafarma

弗拉季米尔•伊柳申
Rafarma公司总经理

marketing authorizations. Seven of them are anticancer drugs – the first generics of imported original products.

By 2023, Rafarma's portfolio will include about 30 innovative drugs, mainly oncological ones for export as well as for domestic market.

How the contract manufacturing direction is developing?

The enterprise's production facilities were designed to comply with GMP standard, so they meet the most exacting requirements of both Russian and European contract manufacturing customers. Clean contained areas with isolated water- and air-treating systems, hightech production facilities and laboratory equipment from leading European manufacturers, and team of highly-skilled professionals experienced in technology transfer and laboratory developments scaling – all these make our plant an attractive site for foreign companies. And not only in regards to localization for taking part in Russian public procurement but also for manufacturing products for export to Europe and the EEU countries.

Today, six drugs on a contract basis are manufactured in Terbuny. Our enterprise regularly undergoes audits by potential customers from Russia and other countries. Even though Rafarma plant is highly-demanded as a production site, we are still open to dialogue with new partners.

Rafarma and Sotex are the foundation for the production segment of PROTEK Group. What are advantages of these two brands' symbiotic relationship?

As Rafarma entered the production segment of PROTEK Group, it got the opportunity to offer a unique range of services to its partners. We are able to accomplish a full cycle of product launching from the ground up, implement a full-cycle pharmaceutical development in the R&D sector, from the initial concept stage to manufacturing procedure, provide a complete range of services for obtaining marketing authorization, set up the manufacturing process, as well as marketing, logistics and distribution.

The background of Sotex includes long-term partnership with pharma giants like Bayer, Sanofi, Novartis, Pierre Fabre, and others. Based on it we plan to develop contract manufacturing with leading global pharmaceutical companies. The Sotex ampoules and pre-filled syringes plant has had its GMP EU certificate since 2016. Products of the company are authorized for use and sell in countries of European Union. They are currently conquering markets of Latin America, Asia and the Pacific region.

Rafarma's own products are actively exported to the CIS countries. At the end of 2018, Rafarma became the first Russian company to enter the Afghan market. Rafarma is currently getting ready for certification under the European GMP standard so the products are to be exported worldwide in the long term.

Rafarma and Sotex take part in the largest industry exhibitions as CPhI Worldwide in Frankfurt. The international pharma community's recognition is an important driver for both potential contract customers and the growing number of buyers of Rafarma and Sotex's ready-made drugs. ■

2017年4月宣布Rafarma股份公司加入PROTEK集团生产部门后，工厂显然发生了很大变化。到2019年初，Rafarma已取得哪些成果？

如今Rafarma已在直接实施进口替代战略。在卫生部和俄罗斯联邦工贸部的支持下，Rafarma在利佩茨克州成立了一个生产抗癌药物和抗生素的新工厂。

工厂产品包括日常必备和基本药物清单的18种药物－抗生素、口服降糖药，心血管和肺结核药物和其他药物。

加入PROTEK生产部门后，Sotex的抗癌药品就转移到我们的工厂生产。与此同时，我们也开始研发抗癌药物。2019年初，Rafarma工厂已生产四种抗癌药物－两种为合同制造形式，两种是自有药物。许多产品如抗癌药物和抗生素处于注册阶段，其中7种抗癌药物是进口原药的首批仿制药。

到2023年，Rafarma的产品组合将包括约30种创新药物，主要以不仅供应国内市场，还提供出口的抗癌药物为主。

如何发展合同制造业务？

早在设计阶段就已考虑工厂生产设施是否符合俄罗斯工厂及合同制造欧洲客户最严格要求—GMP标准。欧洲主要制造商生产的封闭式水气处理车间，技术设备，生产和实验室设备，在技术转让和大型实验室研发方面具有丰富经验的高素质专家团队—这一切使外国公司对我们的厂区很感兴趣。因此工厂产品除满足俄罗斯市场本地化国家采购需求外，还向欧洲和欧亚经济联盟国家出口。

目前捷尔布内的工厂以合同制造形式生产6种药物。我们不断通过俄罗斯和外国潜在客户的审核。Rafarma工厂是非常热门的生产基地，但我们仍然欢迎与新伙伴合作。

Rafarma和Sotex现在是PROTEK集团生产部门的基础。这种品牌共生现象有哪些优势？

Rafarma进入PROTEK集团公司生产部门后，我们可以为合作伙伴提供更为个性化的服务。我们可以从零开始完成整个药物营销过程，包括：药物的全程研发，理念和技术应用在工业生产中，完成全部注册，安排生产，市场营销，物流运输和分销网络。

Sotex丰富的经营经验为其赢得了很多长期合作伙伴，如制药巨头：Bayer（拜耳）、Sanofi、（赛诺菲）、Novartis（诺华）、Pierre Fabre（皮埃尔法布尔）等，我们计划与全球领先制药公司开展合同制造业务。2016年Sotex工厂生产的安瓿瓶和预装式注射器获得GMP EU认证，公司产品在欧盟国家注册销售，正在开发拉丁美洲，亚洲和东南亚地区的市场。

Rafara自有产品已出口到独联体国家，2018年底，Rafarma成为第一家进入阿富汗市场的俄罗斯公司。为将产品出口到世界各地，Rafarma已着手进行GMP欧洲标准认证。

Rafarma和Sotex多次参加大型的行业展会，如法兰克福的CPhI Worldwide。国际专业组织的认可是Rafarma和Sotex获得更多潜在合同客户和成品药顾客的一个重要因素。■

supported by PHARMASYNTEZ

RAFARMA

Rafarma Product Portfolio

Antibiotics
- Azithromycin
- Ceftriaxone
- Ceftazidime
- Ciprofloxacin
- Clarithromycin
- Levofloxacin
- Meropenem
- Ofloxacin

Oncology products
- Bendamustin (Rozustin®)
- Pemetrexed (Pemelan®)

Sugar lowering drugs
- Glimepiride
- Metformin

Cardiovascular products
- Bisoprolol
- Clopidogrel

Anti–TB drugs
- Sodium para–aminosalicylate

Antipsychotics
- Risperidone

Other groups
- Betahistine
- Ibuprofen

PARTNERSHIP ADVANTAGES

- Availability of production facilities for contract manufacturing and area for additional construction
- Local production and technology transfer experience
- Integrated business approach: production, distribution and promotion of medicines

REGARDING CONTRACT PARTNERSHIP:

YURII MIKHAILOVICH KALMYKOV
Head of Department of Development and Strategic Marketing

«SOTEX» PHARM FIRM»
+7 (495) 730-16-60, доб. 25-13
y_kalmykov@sotex.ru

Sotex PharmFirm Portfolio

Neurology
- Aminophenylbutyric acid (Anvifen®)
- Tolperisone + Lidocaine (Calmirex®)
- Choline alfoscerate (Cereton®)
- Dexketoprofen (Flamadex®)
- Ketoprofen (Flamax®)
- Meldonium (Idrinol®)
- Memantin (Memantal®)
- Citicoline (Neipilept®)
- Nimesulide (Nemulex®)
- Ethylmethylhydroxypyridine succinate (Neyroks®)
- Meloxicam (Amelotex®)
- Vitamin B complex (CompligamB®)
- Ketorolac (Dolomine®)
- Thioctic acid (Lipothioxon®)
- Diclofenac

Rheumatology
- Chondroitin sulfate (Chondroguard®)
- Glucosamine (Sustaguard Artro®)

Oncology
- Bortezomib (Bartizar®)
- Epoetin alfa (Eralfon®)
- Iron (III) hydroxide sucrose complex (Likferr 100®)

Nephrology
- Epoetin alfa (Eralfon®)
- Ketoanalogues of aminoacids (Ketoaminol®)
- Sevelamer (Selamerex®)

Gastroenterology
- Octreotide (Oktretex®)
- Ornithine (Ornilatex®)
- Tranexamic acid (Hemtranix®)

Cardiology, Surgery, Phlebology
- Enoxaparin sodium (Enixum®)
- Bosentan (Bosenex®)

Surgery, Anesthesiology
- Bupivacaine (BloccoC®)
- Atracurium besilate (Ridelat–C®)

Therapy of influenza and cold
- Paracetamol+ Ascorbic acid + Rimantadine + Loratadine (AnviMaks®)

Anti–histamine
- Chloropyramine®

Food supplements
- Bifistim®
- Hepaguard®

sotex

IMCoPharma Expands

its Logistics and Distribution Network

22 March 2019

IMCoPharma keeps looking for solutions to become as close to its customers as possible by applying the services of high quality. Expanding the possibilities of logistics and distribution, the company seeks to minimize the delivery time and to increase the range of pharmaceutical products stored in its own warehouses at the same time. The aim is to provide its customers with a wide range of pharmaceutical substances, excipients and materials in the CIS countries and to organize effective trade with an end-consumer.

IMCoPharma's warehouses are located throughout the CIS. The Central warehouse with an area of about 600 m^2 is located in

IMCoPharma

扩展物流和分销网络

2019年3月22日

IMCoPharma继续寻求解决以服务质量尽可能接近客户的方案。该公司扩大了物流量和配送量，缩短了交货时间，同时增加了储存在自己仓库的药品品种。目标是在独立国家联合体内为客户提供各种药物、辅助物质和材料，并与最终用户组织有效的贸易。

IMCoPharma仓库遍布独立国家联合体。中央仓库面积约600平方米，位于捷克共和国公司总部附近。仓库完全符合经销GDP的要求，并由政府机构定期监控。高质量的设备和技术设备不仅为仓库内部的货物运输提供了最大的效率和安全，而且为所有的进出口运输提供了最大的保障。

We strongly believe that investing in logistics to provide efficient and timely services to our customers at a professional level should be one of our priorities and will be positively appreciated by all business partners, supliers and customers.

Ivan Mikes
the General Director of IMCoPharma

我们坚信，在物流方面的投资，以有效及时地为我们的客户提供服务，是我们的首要任务之一，我们的任务将受到所有商业伙伴、供应商和客户的好评。

伊万•米克什
IMCoPharma的总经理

the Czech Republic near the main office of the company. The warehouse is fully compliant with good distribution practise (GDP) and is regularly controlled by state authorities for drug control. High-quality equipment and technical fit-out ensure maximum efficiency and safety not only for the movement of commercial products in the warehouse but also for all types of transportation in the framework of export-import operations.

Thanks to the certification of AEO (Authorized Economic Operator) IMCoPharma received priority opportunities in the passage of customs procedures, which are an integral part of exports to the CIS countries. In order to respond quickly to the growing needs of the market, the company has additionally invested in an area of about 7300 m^2 near the main office, where it is planned to build another logistics centre, in the near future.

As already mentioned, in addition to the Central warehouse in the Czech Republic, IMCoPharma has other warehouses in the CIS, including Russia and Ukraine. These warehouses also meet the requirements of state authorities and are certified for the storage of medicines and pharmaceutical products. The planned expansion of storage facilities is also underway in Kazakhstan and Uzbekistan.

As for Russia, IMCoPharma's warehouses' space in the Moscow region, Gribki, is 1600 m^2. The opening of this warehouse is associated with the need to ensure more efficient logistics processes and maximum satisfaction of the company's customers' needs. Since the warehouse is certified, its mandatory components are reception area, main storage area, expedition area, area for the storage of hazardous products, area for the storage of substandard products, the quarantine zone. All phramaceutical produts are stored at preset and controlled values of temperature and humidity in the warehouse. Two ramps of the warehouse provide separate reception and delivery of goods.

The expansion also bears on the warehouse in Ukraine, in the Kiev region. Here IMCoPharma currently has up to 550m^2 of the area for storage of products. As well as all others, this warehouse is certified for a storage of pharmaceutical products and meets all requirements for the quality of rooms and the equipment. ■

由于AEO（经认证的经营者）的认证，IMCoPharma在海关程序中获得了优先条件，海关程序是向独立国家联合体出口的过程主要部分。为了迅速响应日益增长的市场需求，公司增加了额外资金，在总部附近购买了约7300平方米面积的土地，并计划在不久的将来建造另一个物流中心。

如前所述，除了捷克共和国的中央仓库以外，IMCoPharma还在独立国家联合体有其他仓库（其中包括俄罗斯和乌克兰）。这些仓库也符合国家机构的要求，并经过药品和药品储存认证。计划在哈萨克斯坦和乌兹别克斯坦扩大仓库。

俄罗斯莫斯科州Gribki村的IMCoPharma仓库面积为1600平方米。该仓库的建造的目的是确保更高效的物流流程，并尽可能满足公司客户的需求。由于仓库经过认证，该仓库组成部分为：验收区、主要储存区、探险区、危险品储存区、劣质储存区、检疫区。库存中的所有药品都以设定和受控的温度和湿度值储存。两个仓库斜坡提供单独的验收和交付货物。

乌克兰基辅州的仓库也被扩大了。那里的IMCoPharma的存储面积为550平方米。该仓库与其他仓库一样为存储药品认证的，并符合房屋和设备质量的所有要求。■

Chinese Exhibition

of World's Pharmaceutical Substances

10 April 2019

China remains a region with unmatched growth potential, and companies globally are attempting to capitalize on the plethora of investment opportunities that have arisen in recent years. The rise in the number of innovative China-based biotechs – coupled with the easing of regulatory pathways and an emerging CDMO sector – is fueling a significant growth in manufacturing across China.

With the Chinese pharma growing at a ferocious pace, CPhI China, taking place at the Shanghai New International Expo Center (SNIEC) on 18-20th June 2019, is expected to welcome 70,000 attendees in its 19th edition – a year-on-year increase of 55% – which is further indicative of the buoyancy of the Chinese market. The event is also expected to see a 6% increase in exhibitors, with more than 3,200 from over 120 countries in attendance.

The demand for innovative treatments in China is driven by the increasing burden of disease with an increase in activity from China-based firms locally. For international pharmaceutical companies, there are a number of immediate strategies being taken. These include acquiring or merging with local manufacturing companies, securing a network of distributors, targeting the emerging biological markets, and moving R&D facilities to China.

Wider market data also supports this ongoing boom, with the China's pharmaceutical market projected to grow strongly from 115.2bn USD in 2016 to 159.4bn USD by 2021 and 234.2bn USD by 2026. This represents a 10-year compound annual growth rate of 8.8% in local currency terms and 7.3% in US dollar terms. Similarly, bioprocessing in China has been on a trajectory of rapid growth, with a 39% growth in facilities, and total capacity is growing ≥8% annually, with biosimilars offering the largest growth potential. In fact, The pilot plan for the Marketing Authorization Holder (MAH) system is a revolutionary process in the development of biopharmaceutical innovation in the country.

世界制药原料中国展

2019年4月10日

中国的发展潜力仍然是无可匹敌的，全球众多公司正在努力把握近年来出现的大量投资机遇。中国的创新生物科技公司数量不断增长，加上监管途径的放松以及新兴的合同研发生产服务（CDMO）行业，共同促进中国广泛而显著的生产增长。

在中国制药领域飞速发展的大背景下，“世界制药原料中国展”（CPhI China）将于2019年6月18至20日在上海新国际博览中心（SNIEC）举办，届时预计有70,000人参加此次第19届展览会；此届人数同比增长55%，进一步显示出中国市场的上涨趋势。此次活动的参展者将增加6%，共3,200多位，来自120多个国家/地区。

持续增长的疾病负担，以及中国当地企业的活跃程度增长，共同造就了中国境内创新治疗的需

The system allows the license holders of a drug to sell in China using a contract manufacturer, instead of manufacturing the drug themselves. This makes it easier for the growing number of Chinese biotech's to progress their own products through clinical development, as they are no longer required to invest in their own manufacturing facilities. However, it also means that foreign drug license holders can now use contract facilities in China, providing much easier access to the market.

Taking place concurrently with CPhI China is the 13th edition of P-MEC China, Asia's leading pharma machinery event, providing access to pharmaceutical manufacturing machinery, pharma packaging machinery & material, pharma cleanroom machinery and machinery suppliers from China and overseas. A who's who of exhibitors at P-MEC include Shinva Medical, Truking, IVEN Pharmatech, Tofflon, Canaan, Saideli, Highfine, Jiangxi Chunguang Pharmaceutical, Rommelag, and De Dietrich.

Finally, CPhI & P-MEC China 2019 will also see the introduction of bioLIVE – the new bioprocessing and manufacturing exhibition – which has evolved from the previous BioPh China and will run adjacent to the event. This exposition is in response to the large molecule trend within the industry, and arrives at a particularly prominent moment. Within the last year, there has been a proliferation of biosimilars and double-digit approvals of biologics – as well as a host of investments taking place in contract services.

The third edition of China Pharma Week will take place alongside CPhI & P-MEC China on 17 – 21 June 2019 focusing on Leadership, Business, Networking, Innovation, Recognition and Knowledge. Activities will include plant visits, a networking dinner, women in leadership forum, summits and the Innovation Gallery Tours, giving a deeper work floor insight and dedicated industry conferences on different sectors. ■

求。国际制药公司正在采取一系列即时策略。其中包括收购或合并当地制造公司，确立分销商网络，以新兴生物市场为目标，以及将研发机构迁移至中国。

更为广泛的市场数据也支持这一持续繁荣趋势，中国制药市场预计会持续强劲增长，从2016年的1152亿美元增长到2021年的1594亿美元，到2026年增长到2342亿美元。这代表着10年的年均复合增长率以当地货币计算为8.8%，以美元计算为7.3%。与此类似地，中国的生物工艺也在快速增长，机构增长为39%，总产量年增长≥8%，其中生物仿制药增长潜力最大。实际上，药品上市许可持有人（Marketing Authorization Holder, MAH）制度的试点计划正是中国生物制药创新发展中的一个革新性进程。这一制度允许药品许可持有人通过合同制造商在中国销售药品，不需自行生产药品。这样以来，不断增多的中国生物技术公司不再需要投资自己的制造机构，能够更容易地通过临床研发推进自己的产品。但是，这也意味着国外药品许可持有人现在能够利用中国境内的合同机构，更容易打入市场。

第13届“世界制药机械，包装设备与材料中国展”(P-MEC China）与“世界制药原料中国展”(CPhI China）同期举行；前者是亚洲领先的制药器械展览会，展出各种制药器械、药品包装设备与材料、药品洁净室设备等，汇聚来自中国和海外的众多器械供应商。P-MEC知名参展者包括新华医疗、楚天、埃文制药、东富龙、迦南、赛德力、昊帆、江西春光药业、罗姆来格以及德地氏等。

最后，2019年度CPhI与P-MEC展览会还将迎来“世界生物医药科技展”(bioLIVE）－它是全新的生物工艺与制造展览会，从之前的“生物制药与技术中国展”(BioPh China）升级而来，举办时间紧挨上述展会。这一展会是在业内大分子趋势下应运而生，在至关重要的时机举办。在上一年度中，生物仿制药大量增长，几十种生物制剂得到批准－在合同服务方面也有大量投资。

第三次“China Pharma Week”主题活动周将于2019年6月17至21日与CPhI China和P-MEC China同步举办，聚焦于Leadership（领导力）、Business（业务）、Networking（关系网）、Innovation（创新）、Recognition（嘉奖）和Knowledge（知识）六大主题。活动包括参观工厂、联谊晚宴、女性领导力论坛、峰会与Innovation Gallery Tours（创新荟萃游览），带来更深刻的工作场所洞察，以及各行业专属的业内会议。■

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In autumn 2010, the first issue of the industry magazine "GMP news" was published. The printed edition is primarily addressed to the professional community, heads of pharmaceutical companies, experts in the pharmaceutical industry as well as a non-specialist audience. The main purpose of the magazine is dissemination of information about the main events on the pharmaceutical market of Russia, the EAEU and CIS countries. The magazine introduces readers to the achievements in the field of GMP standards implementation. Particular attention is paid to the localization of pharmaceutical products, technology transfer, contract manufacturing.

Media partnership is one of the ways to cooperate with "GMP news" project

We offer media cooperation to everyone who works in the field of medicine manufacturing, to pharmaceutical industry specialists and experts, press services of organizations and companies.

Today our project consists of GMPnews.ru news portal (in Russian) and GMPnews.net (in English) as well as printed publications – magazines "Новости GMP" (GMP News) and "CIS GMP news".

We are always happy to cooperate!
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第一期《GMP新闻》杂志在2010年秋天出版。印刷版主要提供给专业论坛、制药公司负责人、药剂学专业圈子内的专家，以及广泛的读者群。该期刊的目的是传播有关俄罗斯、欧亚经济联盟和独联体国家药品市场的主要信息以及实施GMP标准的成就。尤其关注药品的本地化、技术转让以及合同制造信息。该杂志自2017年起使用《CIS GMP NEWS》的名义出版英文版，并自2019年以来以双语进行出版：英文-阿拉伯文、英文-中文和英文-德文。

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