



POLYMERS IN HEALTHCARE

One of the challenges the medical products market faces today is the lack of adapted polymer brands that could be used to produce high quality and safe medical supplies. At the *Plastics in Medicine Industry 2018* exhibition SIBUR presented **PP R015 BM**, its new polypropylene brand for medical packaging, and a number of solutions for disposable syringes production.

According to the Ministry of Industry and Trade, the domestic production of medical supplies in Russia has increased by over 15% since 2015. Currently domestic companies occupy 18.5% of this market, while the international benchmark for imports is 50–60%. According to the industry development strategy, by 2020 Russia should achieve a 40% share of domestic products.

“The significant volume of imported polymer-based medical products suggests that there is a development potential for the domestic production to replace the imports”, said Rafael Grigoryan, Director General of INVENTRA (the exhibition host). However, the event participants admit that currently the industry faces both a deficit in domestic materials and challenges in standardisation of the finished products.



Rafael Grigoryan, Plastics in Medicine Industry 2018 conference hosted by INVENTRA (part of CREON (<http://www.creonenergy.ru/>)).

The monitoring system needs improvement

“Unfortunately, the current system of monitoring the quality and safety of medical supplies employed by Rospotrebnadzor (Federal Service for the Oversight of Consumer Protection and Welfare) and Roszdravnadzor (Federal Service for Surveillance in Healthcare) is not effective enough,” said Denis Mishin, CEO of Gassteril.

1.1 BILLION

OF DISPOSABLE MEDICAL SYRINGES WERE MANUFACTURED IN RUSSIA IN 2017, WHICH IS 42% OF THE TOTAL RUSSIAN MARKET. THE REMAINING 58% WERE IMPORTED (MAINLY FROM GERMANY, SPAIN AND CHINA). RUSSIA'S IMPORTS OF DISPOSABLE SYRINGES REDUCED BY 3% OVER THE PAST YEAR.

“Both validation and sterilisation of medical products are complex processes, and so far there is no general understanding of what a validation report should include. Industrial sterilisation methods are undeveloped, and since, for example, it is known that polymers are destroyed by radiation, the dose of irradiation treatment would often be deliberately reduced, undermining the quality of sterilisation.

Denis Mishin suggested that polymer producers conduct tests of gas and irradiation sterilisation impact on polymers which are most frequently used for medical supplies, particularly measure the toxicity of polymers after irradiation treatment. Valeriy Panarin, Senior Product Marketing Expert at SIBUR's Basic Polymers Division, supported the idea. He also pointed out to the participants that SIBUR offers special solutions for production of disposable medical syringes, sample containers and other medical supplies manufactured by polypropylene injection moulding.

The toxicity testing results obtained for high MFI moulded polypropylenes, such as PP H452 IM, PP H552 IM, or PP H558 IM, confirm that these brands are of high purity and suitable for production of medical supplies indirectly contacting milieu intérieur and blood.

Competition requires modern packaging

Valeriy Panarin also presented PP R015 BM, SIBUR's new medical grade polypropylene brand for blow moulding, that can be used to

manufacture infusion vials. This brand is fully compliant with the European Pharmacopoeia requirements and can substitute for expensive imported counterparts.



Valeriy Panarin presents SIBUR's new medical grade polypropylene brand.

51% (DOWN FROM 89%)

IS THE REDUCED SHARE OF GLASS VIALS USED FOR INFUSION SOLUTIONS IN RUSSIA (2004 TO 2017).

According to Valeriy Panarin, Russia today has excessive capacity for infusion solutions. Approximately 375 million standard packages of infusion solutions are consumed in Russia annually, of which 350 million are produced domestically, with the remaining 25 million imported. However, Russian companies can produce a total of 515 million standard packages per year. This excess results in a significant competition among the manufacturers and requires that they use cutting-edge materials.

The main advantage of polymer packaging for infusion solutions is that fully finished products can be made on a single automated line (the Blow-Fill-Seal technology), the vials are of high quality and small weight, shatter-proof and resistant to mechanical impacts, highly protected from counterfeiting and absolutely airtight, which ensures full sterility. Additionally, polymer packaging is cheaper and handier than glass, with its use posing minimum risk of trauma.



Polymer packaging is cheaper and handier than glass.

FOR FULL DETAIL ON HOW POLYMERS ARE USED IN HEALTHCARE AND WHAT KIND OF TASKS THE MEDICINE OF TOMORROW POSES TO THE PETROCHEMICAL INDUSTRY, PLEASE REFER TO OUR PREVIOUS ISSUE ([HTTPS://MAGAZINE.SIBUR.RU/RU/ARTICLE/FOCUS/HEALTHCARE-OF-THE-FUTURE/](https://magazine.sibur.ru/ru/article/focus/healthcare-of-the-future/)).

Safe materials register needed

A document currently being drafted by Roszdravnadzor and Rospotrebnadzor shall include all the requirements for validation reports. Elena Astapenko, Head of Department of State Control and Registration of Medical Devices, spoke about it at the exhibition.

Denis Mishin emphasised the meaning of cooperation for the medical products industry – the manufacturers, the sterilisation services and the government institutions supervising the medical products market should work together.

Elena Astapenko added that Roszdravnadzor and the Ministry of Industry and Trade consider creating a register of medical-grade materials that have been tested and proved safe. Valeriy Panarin said that such a register of approved medical-grade materials is vital because it would protect consumers from any products that fail to comply with the strict healthcare standards.

Source: RCC.