

## **PoongLim Vaccine Syringe Receives FDA Approval, Exports on the Horizon**

- ❶ With the Food and Drug Administration (FDA) approval granted on February 17, PoongLim Pharmatech Inc. will be exporting “LDS Vaccine Syringes with Safety Device” to pharmaceutical companies in the United States, Japan, Europe, etc.
  - An additional production system for 10 million units on a monthly basis is set to be installed in the new factory in March to produce and export over 20 million units per month.
  - A total of 127,000 LDS vaccine syringes will be donated in line with Pfizer’s local vaccination.
- ❷ On February 18 (Thursday), the Minister of SMEs and Startups Kwon Chil-seung visited the PoongLim Pharmatech production site to provide support for LDS vaccine syringe production and export and held an on-site conference with SHINA Corporation and Doowon Meditec, the vaccine syringe manufacturers.
  - Last year, K-Quarantine products saw an increased export volume by six times, and testing kits were exported 30 times more, rising as a new export drive for SMEs.

The Ministry of SMEs and Startups (Minister Kwon Chil-seung, hereafter MSS) announced on February 18 that, the day before, Minister Kwon visited the PoongLim Pharmatech production site for low dead space

(LDS) vaccine syringes that received FDA approval and inspected the Smart Factory and encouraged the employees.

Poonglim Pharmatech has established a mass-production system to manufacture more than 10 million LDS Vaccine Syringes with Safety Device per month through a mutual-growth Smart Factory built by MSS and Samsung Electronics. In cooperation with Samsung Bioepis and Samsung Biologics, the company also applied for the FDA approval of the syringe on January 18.

With the FDA approval, PoongLim Pharmatech will begin its negotiation with US-based pharmaceutical companies for product export.

In addition, PoongLim announced that orders are rushing in from pharmaceutical companies in the United States and Japan to export 180 million syringes and 80 million LDS vaccine syringes, respectively.

The new third factory that is ongoing construction will also establish an additional Smart Factory where the company can produce more than 10 million LDS vaccine syringes per month (March 2021). Through this production site, PoongLim is set to own the largest LDS vaccine syringe factories in the world, producing a total of 20 million syringes per month.

After the site inspection, Minister Kwon held a conference for vaccine manufacturers to receive opinions from SHINA Corporation and Doowon Meditec on LDS vaccine syringe manufacture and export.

In this conference, the companies announced that, since last year, they had established a sufficient vaccine syringe supply system by securing additional manufacturing facilities in preparation for the soaring vaccine supply and a seamless vaccination.

In particular, PoongLim Pharmatech announced that it would make an initial donation of 127,000 LDS vaccine syringes for 60,000 shots of the Pfizer vaccine and cooperate with the Korea Disease Control and Prevention Agency for their local supplies.

At the conference, Minister Kwon announced that the Ministry would establish Smart Factories for other vaccine syringe manufacturers based on the private-public cooperation and performance of PoongLim Pharmatech. He also said that MSS would promote specialized Smart Factories for pharmaceutical and medical companies to foster manufacturing innovation in K-Quarantine-related SMEs.

Furthermore, according to Minister Kwon, MSS will provide tailored support, such as consulting, acquisition of certificates/standards, and overseas marketing packages throughout the whole process of export and will offer broad support for the exhibition connecting online and offline for these companies to enter the global online market.



**Note****Companies at the conference****(1) PoongLim Pharmatech Inc.**

- **Date of establishment:** July 13, 1999 (First established as Koryo Chemical Company in 1979, supplying environmental treatment chemicals for wastewater and later transformed into a medical device specialist in 1999)
- **Address:** 21, Jayumuyeok 1-gil, Gunsan-si, Jeollabuk-do
- **Key business areas:** Supply of medical devices and equipment used in pharmaceutical companies and clinics, sterilized injection needles, various specialized syringes, and vials (sterilized glass containers for injections)
- **Current business status**

(KRW 100 million, person)	2018	2019	2020
Sales (exports <sup>1</sup> )	251 (25)	301 (31)	360 (36)
No. of employees <sup>2</sup>	71	80	205

<sup>1</sup>Including indirect exports from local pharmaceutical companies / <sup>2</sup>Employed only 15 staff upon entry to the Gunsan Free Trade Zone in 2008

□ **Major products**

Category	Product name	Description
	EZ-Injec (169 types)	○ <b>[Sterilized injection needles]</b> Sterilized single-use product used to inject medical substances or sample body fluids
	LDV*, Kopac	○ <b>[Syringe]</b> A device used in injecting medical substances or fluids into the body or sampling blood. Our products offer minimal residual injection substances.

\* The **product name** of the vaccine syringe is represented as **Low Dead Volume**, not **Low Dead Space**, to emphasize the minimized residual injection substances.



(2) Shina Corporation Co., Ltd.

- **Date of establishment:** September 1, 1987 / **Address:** 8-26, Bojeokdong-gil, Useong-myeon, Gongju-si, Chungcheongnam-do
- **Key business areas:** Supply of medical devices and equipment used in pharmaceutical companies and clinics, including LDS and insulin syringes
- **Current business status**

(KRW 100 million, person)	2018	2019	2020
Sales (exports)*	176 (160)	204 (190)	156 (138)
No. of employees	147	123	97

\*Including indirect exports through local pharmaceutical companies

- **Major products**

Category	Product name	Description
	<b>LDS Syringe</b> * Domestic supply	○ A syringe that minimizes the residual vaccine left in the syringe and allows up to six injections per vial for COVID-19 vaccines
	<b>Single-Use LDS Safety Syringe</b> * Overseas export	○ A syringe that allows up to six injections per vial by minimizing the residual injection substance for COVID-19 vaccines given by international institutions, such as Centers for Disease Control and Prevention (CDC), and prevents unintentional stabs through a safety cover, thereby preventing infections (to be supplied to CDC)




(3) DOOWON MEDITEC Co., Ltd.

- **Date of establishment:** July 4, 2000
- **Address:** (Yeongmun-ri) 15, Seokseong-ro 1069beon-gil, Pogok-eup, Cheoin-gu, Yongin-si, Gyeonggi-do
- **Key business areas:** Medical devices, including single-use syringes, intravenous sets, blood transfusion sets, etc.

□ **Current business status**

(KRW 100 million, person)	2018	2019	2020
Sales	217	223	180
No. of employees	47	46	50

□ **Major products**

Category	Product name	Description
	Vaccine Syringe	○ Available for use immediately after filling with the injection; a medical device that minimizes substance losses unlike regular syringes and allows for a set dose of vaccine
	Intravenous Set	○ Medical equipment used to inject substances into a vein
	Blood Transfusion Set	○ Blood transfusion set used for blood sampling