



Toward the Establishment of a Supply-Chain System to Secure a Stable Domestic Supply of Antibacterial Drugs

– Certification of “Plan for Stable Supply of Antibacterial Substances” by Ministry of Health, Labour and Welfare –

OSAKA, Japan, August 1, 2023 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that the Ministry of Health, Labour and Welfare (MHLW) has certified an application relating to the plan for the stable supply of antibacterial substances (hereafter "this supply securing plan") submitted by Shionogi Pharma Co., Ltd. (Head Office: Osaka, Japan; President & CEO: Akira Kato; hereafter "Shionogi Pharma") and their joint venture company Pharmira Co., Ltd. (Head Office: Hyogo, Japan; President & CEO: Masanori Nishiwaki; hereafter "Pharmira").

Antibacterial substances (hereafter, antibacterial drugs), especially β -lactam antibacterial drugs including cephem antibiotics^{*1} focused on this supply securing plan, are not only used for the treatment of infectious diseases, but for the prevention of infection associated with surgical operations as a recommended drug in clinical guidelines. That means it has extremely high medical need. Nevertheless, almost 100% of its raw materials are dependent on imports from overseas and has been pointed out as a risk that affects the stable supply of antibacterial drugs to clinical practice in Japan. In fact, a long-term supply shortage happened about cefazolin sodium, which is widely used as a β -lactam antibacterial drug, in 2019 due to manufacturing problems in China, which accounts for the largest proportion of its suppliers. And it occurred that had a serious impact on the medical care service in Japan. Considering these supply chain issues, antibacterial drugs have been designated as "specified important materials" based on the provisions of Article 7 of the Act on Economic Security Promotion Bill, and considerations are underway, led by MHLW, to secure a stable supply of antibacterial drugs for domestic use.

^{*1} A general term for antibiotics with a β -lactam ring in the molecule, classified into penicillins, cepheems, carbapenems, etc.

Shionogi and its manufacturing subsidiary, Shionogi Pharma, have been working on the establishment of a manufacturing system for active pharmaceutical ingredients of antibacterial drugs while receiving support through MHLW's stable supply project for pharmaceuticals²⁻⁴. With this certification, we will further strengthen our supply chain system for the stable domestic supply of antibacterial drugs and develop more efficient and safe manufacturing methods using serial production technology, which is one of Pharmira's strengths.

Shionogi is committed to the principle "Protecting people worldwide from the threat of infectious diseases" as our key focus, and is promoting tackling antimicrobial resistance (AMR) and the three major infectious diseases and acute infections including COVID-19. As the global supply shortage of pharmaceuticals has become apparent due to the pandemic caused by the COVID-19, we will promote initiatives to secure a stable supply of antibacterial drugs as a leading company in the field of infectious diseases.

[Summary of certification of supply securing plan]

Authorized business	Shionogi Pharma Co., Ltd., Pharmira Co., Ltd.
Specified Important Materials Initiatives	Cefazolin sodium, Cefmetazole sodium Introduce manufacturing equipment for active pharmaceutical ingredients, etc., and develop a stockpiling system
Certification date	July 28, 2023

References (Only Japanese)

1. Effort Policy for Securing Stable Supply of Antimicrobial Substances
<https://www.mhlw.go.jp/content/001039660.pdf>
2. Pharmaceutical Stable Supply Support Project Public Recruitment for Implementing Operators (First Public Recruitment) https://www.mhlw.go.jp/stf/newpage_12086.html
3. Pharmaceutical Stable Supply Support Project Public Recruitment for Implementing Operators (Second Public Recruitment) https://www.mhlw.go.jp/stf/newpage_17823.html
4. Pharmaceutical Stable Supply Support Project Public Recruitment for Implementing Operators (Third Public Recruitment) https://www.mhlw.go.jp/stf/newpage_25875.html

■ About Shionogi Pharma Co., Ltd.

Shionogi Pharma, which is responsible for the production-related functions of the SHIONOGI Group, started operations on April 1, 2019, with the mission of becoming a "technology development-oriented manufacturing company" that provides new manufacturing methods and products globally. We have established a system that allows us to provide a full range of services, including development of manufacturing methods for active pharmaceutical ingredients, development of formulations, and commercial production, as well as development of analytical methods and equipment design support using pharmaceutical engineering technology. For more information, please visit: <https://www.shionogi-ph.co.jp/en/>

■ About Pharmira Co., Ltd.

Aiming to transform the manufacturing technology of pharmaceutical ingredients and intermediates, companies with specialized technology and functions gather to conduct development and manufacturing business using both experienced batch manufacturing technology and innovative continuous manufacturing technology. Established in November 2021 and started business in April 2022. For more information, please visit: <https://www.pharmira.co.jp/en.html>

Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

For Further Information, Contact:

SHIONOGI Website Inquiry Form : <https://www.shionogi.com/global/en/contact.html>