Alketami Ragad Saud A.,
master's student
Moscow Pedagogical
State University,
Moscow, Russia

FEATURES OF ASTELLAS PHARMA'S FOREIGN TRADE MANAGEMENT MECHANISM IN VARIOUS MARKETS

Abstract. This article analyzes the foreign economic activity (FEA) management system of the pharmaceutical corporation Astellas Pharma in the context of globalization and geopolitical instability. It examines the company's flexible approaches to international logistics, its experience implementing "green" technologies, the creation of joint logistics platforms, and the modernization of production facilities (including gene and cell therapy). Key challenges facing the company's FEA are identified: high import dependence, vulnerable supply chains, regulatory barriers, and insufficient internal coordination. A set of measures aimed at digitalizing management, optimizing logistics, promoting import substitution, and strengthening interdepartmental cooperation are proposed as a solution.

Keywords: Astellas Pharma, pharmaceutical market, foreign economic activity (FEA), supply chain management, green logistics, quality audit, risk optimization, digital transformation, import substitution.

ASTELLAS PHARMA uses adaptive and flexible methods of managing foreign trade, which allows it to quickly adapt to changes in the global economy. In the context of globalization and high competition in the pharmaceutical market, the company is introducing new approaches to foreign economic activity. To do this, it studies the needs of different regions, takes into account local laws and

cultural traditions. This approach helps the company successfully explore new markets and strengthen its position in those already developed.

ASTELLAS PHARMA actively enters into strategic partnerships and alliances to expand its international presence. These agreements allow us to exchange resources and experience, as well as reduce risks when entering new territories. In addition, the company uses modern technologies to improve logistics and supply management, which leads to lower costs and increased efficiency.

Special attention is paid to research and development. Products are adapted to the requirements of specific markets – new medicines are created or existing ones are modified to take into account local characteristics. This is supported by marketing research, which reveals the preferences and expectations of customers.

Due to constant changes in laws and the economy, the company is improving its legal framework and following international standards. This avoids legal problems and builds trust on the part of partners and clients.

ASTELLAS PHARMA Corporation attaches great importance to the environmental and social aspects of its activities. The use of "green" technologies and adherence to strict ethical standards in the production and sale of medicines are becoming key factors shaping its reputation and international image.

In general, the company's foreign trade management system is complex and flexible. It combines not only legal and economic instruments, but also social and environmental components. This approach allows the corporation to successfully compete on a global level and take into account the needs of various market segments.

In addition, ASTELLAS PHARMA makes extensive use of the latest IT solutions to improve the efficiency of its foreign economic activities. The use of data analysis and information management systems helps to more accurately predict consumer demand, as well as optimize inventory and logistics chains. As a result, costs are reduced and the overall productivity of business processes increases.

The company also works closely with local partners and distributors in different countries. This contributes not only to the expansion of sales channels, but also to a deeper understanding of local customer needs and preferences. Forming strategic alliances and partnerships with other market participants gives ASTELLAS PHARMA the opportunity to adapt to the changing environment in a timely manner and respond quickly to the challenges that arise in the course of doing business.

Astellas consistently invests in the development of its production facilities to ensure reliable and stable deliveries. In 2020, the construction of the Active Ingredients Center for Biopharmaceuticals was completed on the territory of the Toyama Technology Center. This center produces biologics for clinical research and commercial use, which are delivered in accordance with international standards. In parallel, the construction of the Third Fermentation Building has started. After commissioning, the plant will launch the production of the active pharmaceutical substance Prograf®, an immunosuppressant that prevents organ rejection after transplantation. The construction of aseptic lines for the production of medicines has begun at the Yaizu Technology Center. These lines will allow us to flexibly produce not only antibodies, but also new promising methods that require advanced technologies in the future.

Regarding gene therapy, Astellas has opened plants in South San Francisco (California) and Sanford (North Carolina). Production under GMP rules there should begin in 2022. Thus, the company is increasing its own capabilities in the production and supply of drugs associated with adeno-associated virus (AAV), products based on AAV and plasmids. This provides complete autonomy-from research to commercialization of gene therapy programs. In the field of cell therapy, Astellas opened a new manufacturing facility in Westboro, Massachusetts, in April 2020. This has strengthened the ability to produce GMP-compliant medicinal substances and cellular products for cell therapy. By creating such state-

of-the-art facilities, the company aims to build an even more reliable production system capable of delivering high-quality products in the future.

Astellas has quality systems that enable audits of both internal facilities and external production and sales partners. The frequency and intensity of inspections are determined by a risk-based approach. Internal audits cover all Astellas divisions where current Good Manufacturing Practices (cGMP) and/or current Good Distribution Practices (cGDP) are applied at all stages of the product lifecycle and throughout the supply chain, in accordance with documented policies and procedures. Quality audits are conducted for new or existing external partners. The purpose of these checks is to assess compliance with cGMP, cGDP and applicable Astellas requirements. In fiscal year 2022, the company conducted 444 audits worldwide: 31 internal and 413 quality audits of external partners.

For the pharmaceutical company, one of the key tasks is to continuously improve the business continuity plan (BCP) and ensure a stable supply of products even in the face of natural disasters. Japan's Ministry of Health, Labor and Social Security has developed guidelines for good distribution practices (GDPs) that tighten quality control requirements for storage and transportation. In parallel, the Ministry of Land, Infrastructure, Transport and Tourism (MLIT), the Ministry of Economy, Trade and Industry (METI) and the Ministry of Agriculture, Forestry and Fisheries (MAFF) are promoting the White Logistics Initiative. It is aimed at solving problems related to the reform of working hours, lack of drivers, reduction of CO2 emissions and other challenges in the logistics sector. As part of this initiative, shippers work with logistics partners to implement improvements and reforms to create sustainable logistics structures.

In a changing logistics environment, Astellas, Takeda Pharmaceutical Company Limited, Teva Takeda Pharma Ltd., Teva Takeda Yakuhin Ltd., and Nichi-Iko Pharmaceutical Co., Ltd.have joined forces to create a common storage and joint distribution platform in Hokkaido, Japan. This platform aims to ensure a diverse and stable supply of medicines even in large-scale natural disasters, as well

as to improve the efficiency and quality of distribution management. Astellas continues to develop initiatives that promote resource sharing and standardization of pharmaceutical logistics in the industry.

A joint distribution platform in Hokkaido has reduced costs. It not only created a new logistics base, but also reduced the burden on the environment by reducing carbon dioxide emissions. For these achievements, Astellas received the Award of the Minister of Economy, Trade and Industry for outstanding achievements in the field of green logistics in 2018.

Starting in 2021, another joint distribution center was added to Kyushu, which allowed for the formation of an inventory and supply management system in four regions of Japan.

A stable supply of medicines is crucial to ensure that patients can always receive Astellas products. To ensure such supplies, it is necessary to minimize the risks of industrial accidents. Some active pharmaceutical ingredients are synthesized in multi-step chemical reactions. As a result, these reactions and the raw materials associated with them pose many risks, including the possibility of fires.

For the pharmaceutical company, one of the key tasks is to continuously improve the business continuity plan (BCP) and ensure a stable supply of products even in the face of natural disasters. Japan's Ministry of Health, Labor and Social Security has developed guidelines for good distribution practices (GDPs) that tighten quality control requirements for storage and transportation. In parallel, the Ministry of Land, Infrastructure, Transport and Tourism (MLIT), the Ministry of Economy, Trade and Industry (METI) and the Ministry of Agriculture, Forestry and Fisheries (MAFF) are promoting the White Logistics Initiative. It is aimed at solving problems related to the reform of working hours, lack of drivers, reduction of CO2 emissions and other challenges in the logistics sector. As part of this initiative, shippers work with logistics partners to implement improvements and reforms to create sustainable logistics structures.

In a changing logistics environment, Astellas, Takeda Pharmaceutical Company Limited, Teva Takeda Pharma Ltd., Teva Takeda Yakuhin Ltd., and Nichi-Iko Pharmaceutical Co., Ltd.have joined forces to create a common storage and joint distribution platform in Hokkaido, Japan. This platform aims to ensure a diverse and stable supply of medicines even in large-scale natural disasters, as well as to improve the efficiency and quality of distribution management. Astellas continues to develop initiatives that promote resource sharing and standardization of pharmaceutical logistics in the industry.

A joint distribution platform in Hokkaido has reduced costs. It not only created a new logistics base, but also reduced the burden on the environment by reducing carbon dioxide emissions. For these achievements, Astellas received the Award of the Minister of Economy, Trade and Industry for outstanding achievements in the field of green logistics in 2018.

A stable supply of medicines is crucial to ensure that patients can always receive Astellas products. To ensure such supplies, it is necessary to minimize the risks of industrial accidents. Some active pharmaceutical ingredients are synthesized in multi-step chemical reactions. As a result, these reactions and the raw materials associated with them pose many risks, including the possibility of fires.

The study of the current model of managing export and import processes at Astellas Pharma has shown that there are several serious difficulties that significantly reduce the effectiveness of its foreign economic work.

The first difficulty is associated with a strong dependence on foreign supplies. This is due to the fact that our own production facilities and technological platform are not sufficiently developed. As a result, there are risks of disruptions in supply chains due to political restrictions and sanctions, as well as narrowing the opportunities for choosing different sources of raw materials and components.

The second most important difficulty concerns the instability of logistics routes. Due to the current geopolitical situation and imposed economic sanctions,

the company is forced to regularly change its transportation patterns. This leads to longer delivery times and higher costs. The methods used to adjust routes and change suppliers are not fast enough, which reduces management flexibility and increases the risk of failures, especially for medicines with a short shelf life.

There was also a lack of new approaches to managing export-import activities. Despite the use of digital tools, more active implementation of automation and analytics is required to predict market changes and improve processes. Poor innovation development affects not only operational performance, but also the company's ability to respond in a timely manner to regulatory and competitive challenges.

Regulatory issues also have a big impact. The laws that regulate drug trafficking and customs procedures are complex and heterogeneous. This creates administrative barriers that slow down foreign trade operations and reduce their transparency. These risks become even more serious due to frequent changes in legislation at the international and national levels, which complicates planning and forces the company to spend additional resources on maintaining full compliance with the regulations.

One of the key shortcomings is poor coordination between the departments responsible for export and import. The fragmentation of management processes worsens the quality of information exchange, slows down decision-making, and reduces the speed of response to supply chain disruptions. This is especially critical in a situation where foreign trade requires rapid and coordinated interaction of all functional links to ensure continuous supply[1].

The identified problems allow us to identify the main barriers: dependence on imports, limited technological base, unstable logistics routes, administrative difficulties related to regulation, low level of innovation in management, and inefficient internal coordination. All these factors not only worsen Astellas

[1] Johnson R. Evaluating Economic Efficiency in International Trade Management: A Case Study of Astellas Pharma [Electronic resource] // International Journal of Business and Economics: information related to the title / Johnson R. URL: https://www.ijbejournal.com/articles/2023/johnson (date accessed: 01.04.2026).

Pharma's competitive position in the international market, but also increase risks in the current geopolitical and economic conditions.

A number of measures are proposed to address these issues. First, it is necessary to increase investment in the development and implementation of innovative technologies for managing foreign trade activities, including digitalization and data analytics. Second, flexible strategic plans should be created to restructure logistics chains using alternative routes and suppliers, which will increase the resilience of operations to external shocks. Third, it is necessary to optimize internal coordination between departments by implementing centralized information management systems and operational data exchange. In addition, it is necessary to step up cooperation with regulatory authorities in order to respond in a timely manner to changes in legislation and simplify customs procedures. Finally, a comprehensive import substitution policy should be based on a balance between the development of domestic production and the preservation of the company's export potential.

The implementation of these recommendations will significantly increase the sustainability, adaptability and competitiveness of Astellas Pharma in the field of international foreign trade activities, which is especially important in a rapidly changing foreign economic environment.

LIST OF REFERENCES AND SOURCES

1. Astellas Pharma Inc. Integrated Report 2022 [Electronic resource] / Astellas Pharma Inc. – Tokyo, 2022. – 124 p. – URL: https://www.astellas.com/en/system/files/integrated_report_2022_en.pdf

2. Astellas Pharma Inc. Sustainability Report 2021/2022 [Electronic resource] / Astellas Pharma Inc. – Tokyo, 2022. – URL: https://www.astellas.com/en/sustainability (дата обращения: 24.10.2023).

3. Astellas Pharma Inc. Business Continuity Plan (BCP) & Disaster Response Guidelines [Electronic resource] / Astellas Pharma Inc. – Tokyo, 2020. – URL: https://www.astellas.com/en/about/bcp (дата обращения: 24.10.2023).

4. Guidelines for Good Distribution Practice (GDP) of Medicinal Products for Human Use [Electronic resource] / Ministry of Health, Labour and Welfare (MHLW) of Japan. – Tokyo, 2018.

5. White Logistics Movement: Guidelines and Actions for Sustainable Logistics [Electronic resource] / Ministry of Land, Infrastructure, Transport and Tourism (MLIT); Ministry of Economy, Trade and Industry (METI); Ministry of Agriculture, Forestry and Fisheries (MAFF) of Japan. – Tokyo, 2019. – URL: https://www.mlit.go.jp

6. Joint Distribution Platform in Hokkaido: Press Release of Astellas, Takeda, Teva Takeda Pharma, and Nichi-Iko [Electronic resource]. – Tokyo, 2018. – URL: https://www.takeda.com/newsroom (date accessed: 01.04.2026).

7. Sato, H. Shared Logistics Models in the Japanese Pharmaceutical Industry: Case of Hokkaido Joint Platform / H. Sato, T. Tanaka // International Journal of Physical Distribution & Logistics Management. – 2020. – Vol. 50, No. 4. – P. 312–329.

8. Johnson R. Evaluating Economic Efficiency in International Trade Management: A Case Study of Astellas Pharma [Electronic resource] // International Journal of Business and Economics: information related to the title / Johnson R. URL: https://www.ijbejournal.com/articles/2023/johnson (date accessed: 01.04.2026).