

Republic of Azerbaijan

Ministry of Economy (Sumgait Chemical Industrial Park LLC)

Ministry of Health

Republic of Azerbaijan

**Collaboration Program with the Private Sector
for Disseminating Japanese Technology for
Good Manufacturing Practice(GMP) for
Generic Pharmaceuticals
Final Report**

May 2018

JGC Corporation

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Table of Contents

List of abbreviations.....	iii
Functions of Organizations in this program	iii
1. Executive Summary.....	1
1.1. Executive Summary	1
1.1.1 Background	1
1.1.2 Purpose and targeted goals	1
1.1.3 Contents	2
1.1.4 Current prospects for business development	2
1.2. Concept of the program	3
2. Program Overview	4
2.1. Targeted goals	4
2.1.1. Specific goals for the industrialization of the pharmaceutical sector in Azerbaijan.....	4
2.1.2. Specific goals to overcome business circumstance issues in Azerbaijan	5
2.1.3. Formation for program implementation.....	6
2.1.4. Program Implementation schedule	7
2.2. Assessment of activities for the industrialization of the pharmaceutical sector in Azerbaijan	7
2.2.1. Goal 1 “Recognition of the importance to introduce the Global GMP standard into the pharmaceutical industry in the country”	7
2.2.2. Goal 2 “Recognition of the Global GMP standard and Japanese pharmaceutical technology ”	8
2.2.3. Goal 3 “Support to promote the rapid development of institutional design for pharmaceutical industry in the country”	10
2.3. Achievement through the program in business development.....	10
2.3.1. Goal 4 “Improvement of pharmaceutical manufacturing and sales environment”	10
2.3.2. Goal 5 “Selection of generic pharmaceuticals imported from Japan”	11
2.3.3. Goal 6 “Recognition of the application and approval process in order to import pharmaceuticals into Azerbaijan”	12
2.3.4. Goal 7 “Recognition of regulations in order to build and operate Pharmaceuticals Manufacturing facilities in Azerbaijan”	12
2.3.5. Goal 8 “Creation of a Joint Business Team enables the materialization of successful business development”.....	12
2.4. Outstanding issues to be overcome.....	13
2.4.1. Solution to the issue of Goal 4 “Improvement of pharmaceutical manufacturing and sales environment”	13
2.4.2. Solution to the issue of Goal 5 “Selection of generic pharmaceuticals imported from Japan”	14

2.4.3. Solution to the issue of Goal 8 “Creation of a Joint Business Team to enable the materialization of successful business development”	14
3. Plan for Business Development after the program.....	15

List of abbreviations

Abbreviation	Description
AEC	Analytical Expertise Center
AIC	Azerbaijan Investment Company
GMP	Good Manufacturing Practice
JGC	JGC CORPORATION
MHLW	The Ministry of Health, Labour and Welfare of Japan
MOE	The Ministry of Economy of the Republic of Azerbaijan
MOH	The Ministry of Health of the Republic of Azerbaijan
MOU	Memorandum of Understanding
NPP	NIPRO PHARMA CORPORATION
OTC	Over The Counter Pharmaceuticals
PIC/S	The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PMDA	Pharmaceutical and Medical Device Agency
SCIP	Sumgait Chemical Industrial Park
SCIP LLC	Sumgait Chemical Industrial Park LLC

Functions of Organizations in this program

Name	Role
(Azerbaijan)	
MOE	Ministry in Azerbaijan. It is engaged in the task of achieving the industrialization of the pharmaceutical sector.
MOH	Ministry in Azerbaijan. It is engaged in the regulation of the medical devices and pharmaceuticals.
SCIP LLC	Subsidiary of MOE. It has the mission of developing the industrial park for non-oil and gas business and to be a one-stop service window for foreign investors.
AIC	Subsidiary of MOE. It takes the role of being a financial supporter and consultant for foreign investors.
AEC	Organization established under the initiative of MOH in order to regulate the pharmaceutical sector.
AVROMED	The largest pharmaceutical distribution company in the country. It is a potential business partner in Azerbaijan.
(Japan)	
JGC	Engineering and Construction company. It carries out overall coordination in this program.
MHLW	Ministry in Japan. It provides appropriate advice and consultation to support the program.
NPP	A leading pharmaceutical company, especially in the field of contract manufacturing and generic pharmaceuticals manufacturing. It engages in the selection of pharmaceuticals and technology transfer for manufacturing.
PMDA	Japanese regulatory agency belonging to MHLW. It organizes GMP seminars.

1. Executive Summary

1.1. Executive Summary

1.1.1 Background

Since its independence from the Soviet Union in 1991, the Republic of Azerbaijan, an oil and gas-producing country, has continued high economic growth synchronizing with rising oil prices. Meanwhile, market demand for pharmaceuticals in the country is increasing in accordance with the economic growth. The country does not have sufficient pharmaceutical manufacturing facilities in the country to respond to the demand and depends on the importation of expensive pharmaceutical products from neighboring countries such as Russia, Turkey, Europe and Iran. This system places a serious load on the state treasury of the country. In addition, an increase of imported pharmaceuticals sometimes makes the domestic pharmaceutical supply system unstable, particularly in the case of supply shortage in emergencies such as rapid expansion of viral infections, as well as a risk to the national healthcare system caused by distribution of low quality pharmaceuticals, some of which are counterfeit products, which can adversely affect human health.

Also, industrialization of the non-oil and gas sectors is an important issue for the country. The state has engaged in encouraging foreign capital by developing industrial parks for the non-oil and gas sectors, mainly conducted by SCIP LLC established under the MOE.

1.1.2 Purpose and targeted goals

The purpose of this program is to define the initial process for the industrialization of an internationally competitive pharmaceutical industry complying with the Global GMP standard through promotion activities of technologies to produce high-quality generic pharmaceuticals and supporting actions to introduce the type of advanced pharmaceutical manufacturing and distribution system which exists in the pharmaceutical industry of Japan.

Since it is indispensable to set up institutional design which plays an important role to guarantee the reliability of pharmaceuticals in the industrialization process, supporting work for improving the pharmaceutical manufacturing and distribution system is included in this program.

The targeted goals of this program are as follows:

1) Contribution to the industrialization of the pharmaceutical sector in Azerbaijan

- Goal 1 Recognition of the importance of introducing the Global GMP standard into the pharmaceutical industry in the country
- Goal 2 Recognition of the Global GMP standard and Japanese pharmaceutical technology
- Goal 3 Support to promote the rapid development of institutional design for the pharmaceutical industry

2) Business development

- Goal 4 Improvement of the pharmaceutical manufacturing and sales environment
- Goal 5 Selection of generic pharmaceuticals imported from Japan
- Goal 6 Recognition of the application and approval process in order to import pharmaceuticals into Azerbaijan
- Goal 7 Recognition of regulations in order to build and operate Pharmaceuticals Manufacturing facilities in Azerbaijan

Goal 8 Creation of a Joint Business Team to enable the materialization of successful business development

1.1.3 Contents

In the Republic of Azerbaijan, JGC and NPP carried out the program to promote the production of high quality generic pharmaceuticals compliant with the Global GMP standard, with the organizations in Azerbaijan such as MOE, SCIP LLC, MOH, AIC, and AVROMED.

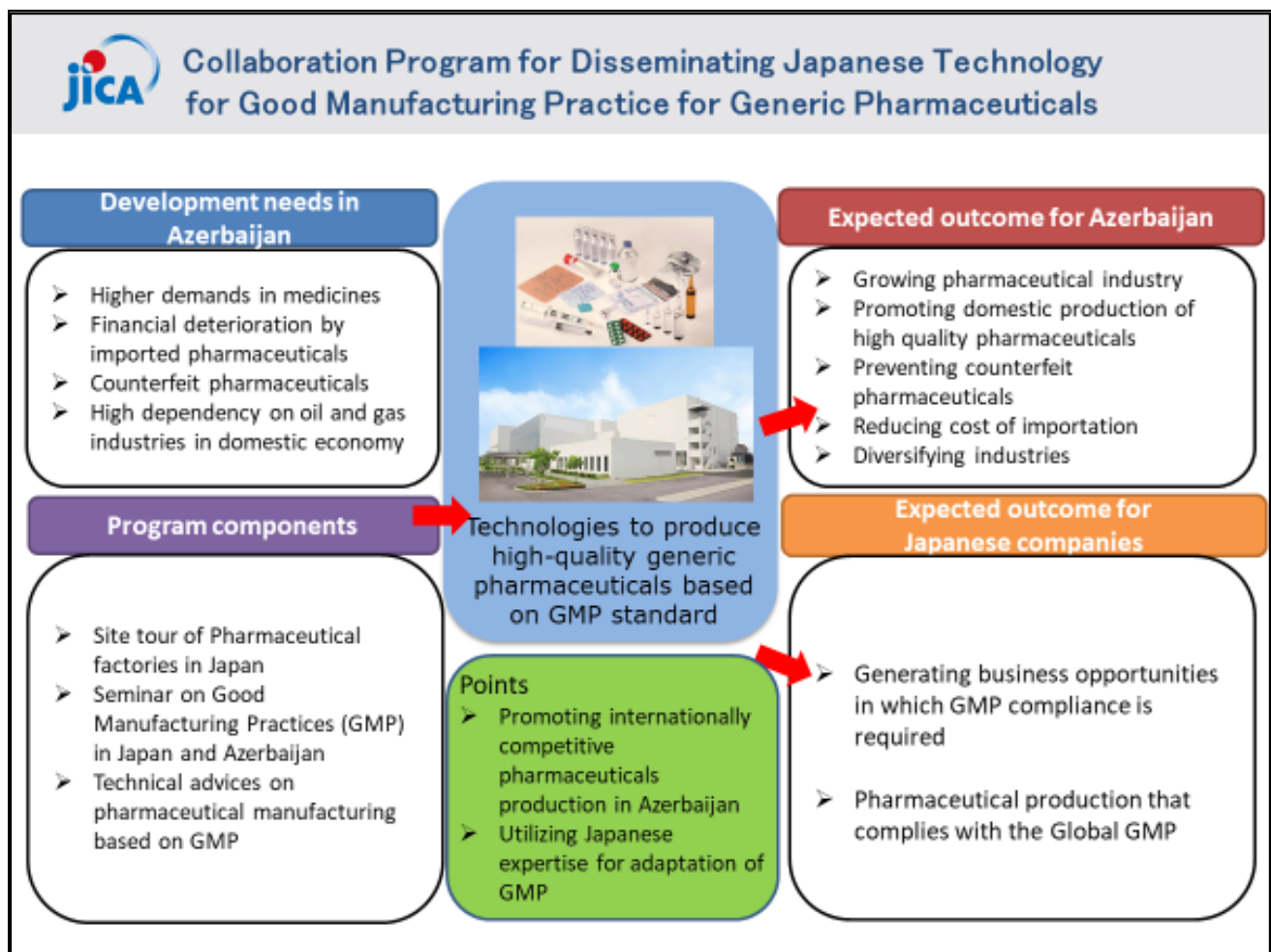
In this program, JGC and NPP provide MOE and MOH with support to develop pharmaceutical manufacturing industry taking advantage of Japanese knowledge, and proceeded dialogues with SCIP LLC and AVROMED to collect business information in Azerbaijan such as markets, investment incentives and relevant governmental application/approval processes for investors, aimed toward successful investment in the future.

1.1.4 Current prospects for business development

Since business development on the premise of factory investment is difficult to be realized at this stage, a new business development, to import and sell Japan brand pharmaceuticals, conducted by the pharmaceutical distribution company in Japan is proposed as an alternative plan.

The business development accompanying factory investment is regarded as feasible after the success of the above importation and sales business.

1.2. Concept of the program



2. Program Overview

2.1. Targeted goals

2.1.1. Specific goals for the industrialization of the pharmaceutical sector in Azerbaijan

Goal 1 Recognition of the importance of introducing the Global GMP standard into the pharmaceutical industry in the country

Through close dialogues with MOE and MOH about the concept of this program, the following results were expected to be understood respectively:

- 1) As an opportunity for initial technology transfer and arrangement of industrial infrastructure, this program helps Azerbaijan to understand the importance of the Global GMP standard, particularly PIC/S GMP, as a significantly effective tool in enabling the establishment of an internationally competitive pharmaceutical sector.
- 2) A successful approach and short-cut path for Azerbaijan to be a member of PIC/S through which Japan-oriented technologies and know-how can be taken advantage of since Japan is already a member of PIC/S. In terms of pharmaceutical manufacturing and distribution system, the Japanese system is one of the best practices in the world which has grown appropriate technologies and know-how under PIC/S regulation.

Goal 2 Recognition of the Global GMP standard and Japanese pharmaceutical technology

By way of the following functional program to the officials of the MOH (AEC) and SCIP LLC:

- 1) Technical seminar to encourage appropriate understanding on the Global GMP standard and pharmaceutical technology
- 2) The GMP Inspection Seminar organized by PMDA of Japan
- 3) Site visit to pharmaceutical-related facilities in Japan including a tableting and packaging plant, a distribution center and machine/equipment fabrication factories,

And then, the following effects are expected to be enjoyed by the Azerbaijan government:

- a) Outline and trends of the Global GMP standard
- b) Overview of PIC/S GMP
- c) Overview of Japanese pharmaceutical technology, including NPP's technologies enable the production of high quality pharmaceuticals
- d) Outline of the supply-chain system which enables the production of high quality pharmaceuticals in Japan, including the processes followed in manufacturing, packaging, distribution and sales

Goal 3 Support to promote rapid development of institutional design for a pharmaceutical industry in the country

Besides providing the opportunity to attend the seminars in Goal 2 above stated, PIC/S accession by Azerbaijan is promoted through a timely consultation by MHLW to support the institutional design of an appropriate industrial infrastructure for pharmaceutical manufacturing and distribution.

2.1.2. Specific goals to overcome business circumstance issues in Azerbaijan

In order to realize a business to manufacture and sell Japan branded pharmaceuticals in Azerbaijan, the following goals are clearly clarified for the successful business development.

Goal 4 Improvement of pharmaceutical manufacturing and sales environment

In the Azerbaijan market, it is observed that it is not easy for Japanese companies to definitively indicate the quality advantages of Japan branded products for the reasons as below:

- 1) In the existing industry, the pharmaceutical GMP is NOT widespread
- 2) The industrial infrastructure for pharmaceutical manufacturing is NOT well-developed
- 3) The market presence of Japan brand pharmaceuticals is VERY SMALL

In order to overcome those difficulties and to show the quality advantages of Japan brand pharmaceuticals, it aims to enhance acknowledgement to the pharmaceuticals with achievement of the goals mentioned in 2.1.1. above.

Goal 5 Selection of generic pharmaceuticals imported from Japan

It is proposed that the business be divided into 3 phases as follows:

- Phase 1 : Japan brand pharmaceuticals to be imported and sold locally in Azerbaijan
- Phase 2 : A pharmaceuticals packaging plant to be constructed and operated locally in Azerbaijan
- Phase 3 : Secondary manufacturing plant such as tableting and capsule manufacturing to be constructed and operated locally in Azerbaijan

After confirming the marketability and feasibility of the business with AVROMED, candidate pharmaceuticals to be imported from Japan will be selected. Just as an assumption now, the criteria for selection is based on the following points:

- 1) Whether competitive prices can be set in terms of price and quality
- 2) Whether sales volume in Azerbaijan can be expected to be more than the minimum manufacturing lot size at the existing supplying source in Japan.

Goal 6 Recognition of the application and approval process in order to import pharmaceuticals into Azerbaijan

Through communication with MOH and AVROMED, the entire process of application and approval in order to import and sell Japan brand pharmaceuticals in Azerbaijan will be confirmed.

Goal 7 Recognition of regulations in order to build and operate Pharmaceutical Manufacturing facilities in Azerbaijan

Through the communication via SCIP LLC with concerned government bodies such as MOE, MOH, the Ministry of Emergency Situations and other bodies, the entire process of governmental application and approval to build and operate pharmaceutical plants in Azerbaijan will be confirmed

Goal 8 Creation of a Joint Business Team enables the materialization of successful business development

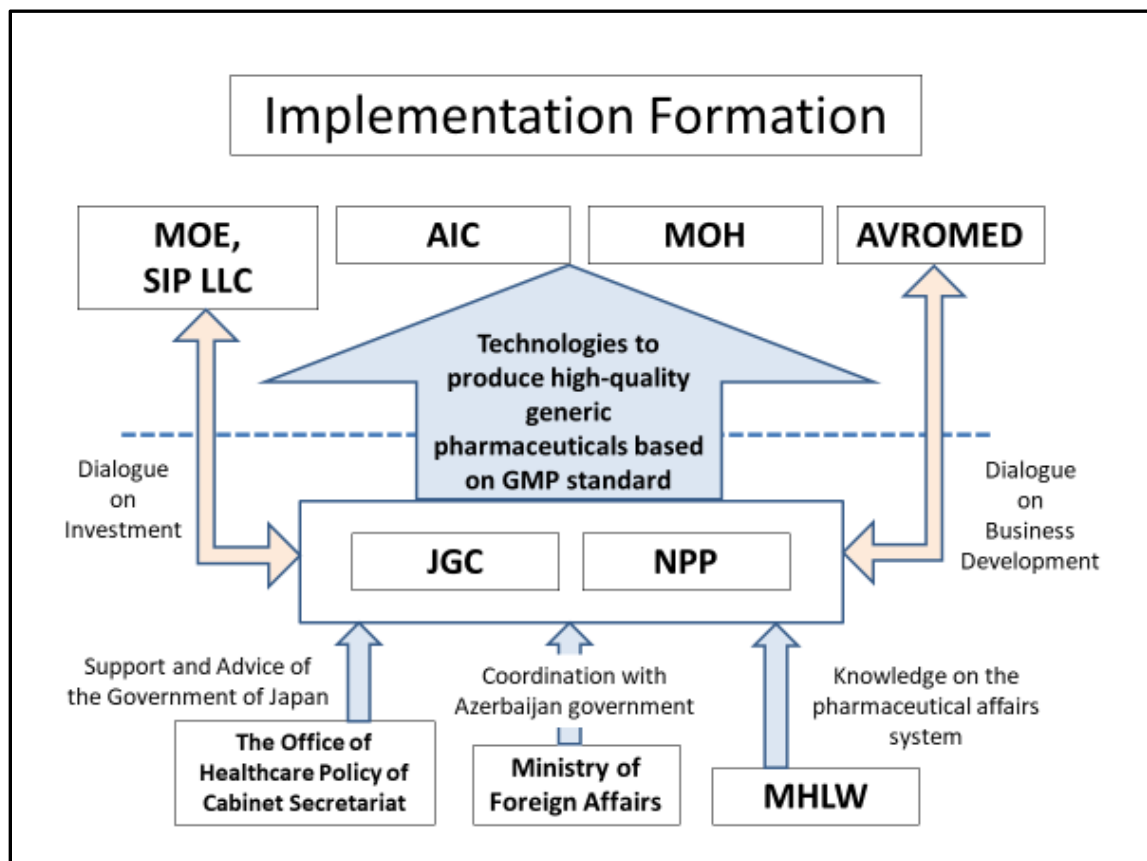
In order to define an ideal business scheme, project formation and respective functions in the team is discussed with SCIP LLC and AVROMED. The progress of the discussion overlaps with the progress of activities of the above stated Goal 5 “Selection of generic pharmaceuticals imported from Japan”.

2.1.3. Formation for program implementation

In the republic of Azerbaijan, MOE has engaged in a task to achieve the industrialization of the pharmaceutical industry through their subsidiary SCIP LLC whose mission is to be the one-stop service window for foreign investors. They have developed industrial parks in the country for foreign investors. MOH has jurisdiction over medical and pharmaceutical regulatory administration. In addition to the above organizations, AIC, also a subsidiary of the MOE, takes a role to be a financial supporter and consultant for the foreign investors in the business implementation stage, and AVROMED which is the largest pharmaceutical distribution company in the country join this program,

With the above organizations from Azerbaijan, JGC and NPP jointly carry out the program for promotion to manufacture and sell Japan branded high quality generic pharmaceuticals in Azerbaijan.

In Japan, the government bodies including the Office of Healthcare Policy of the Cabinet Secretariat, MHLW and the Ministry of Foreign Affairs support this program by means of instructions and advice in a timely manner.



2.1.4. Program Implementation schedule

The detailed program for the implementation is as follows:

Date	Activity
19 th Aug. 2016	Concluded the contract with JICA and started program
29 th Aug. 2016 to 2 nd Sep. 2016	1 st Field activity ① Meeting with Deputy Prime Minister, Abid Sharifov, other Government officials and Japanese ambassador ② Discussion and MOU signing ceremony with SCIP LLC ③ Discussion and Facility inspection with AVROMED ④ Holding GMP seminar for MOE, MOH, SCIP LLC and AVROMED
5 th Dec. 2016 to 9 th Dec. 2016	1 st Invitation activity ① Tour of Japanese pharmaceutical manufacturing sites ② Inspection of manufacturer of pharmaceutical machinery ③ Meeting on business development
20 th Feb. 2017 to 25 th Feb. 2017	2 nd Field activity ① Holding GMP seminar for MOE, MOH, SCIP LLC and AVROMED ② Interview with officials of MOH ③ Tour of local packaging, printing factory and industrial park for pharmaceutical industry ④ Meeting on business development
31 st July. 2017 to 5 th Aug. 2017	2 nd Invitation activity ① PMDA seminar for officials of MOH
25 th Sep. 2017 to 29 th Sep. 2017	3 rd Invitation activity ① Tour of Japanese medicine delivery center ② Exchanging opinions with pharmaceutical-related companies in Hokuriku centering on Toyama ③ Inspection of packaging material supplier ④ Pharmacy tour ⑤ Meeting on business development
27 th Nov. 2017 to 2 nd Dec. 2017	3 rd Field activity ① Activity report to related organizations in Azerbaijan ② Implementation of a workshop on the manufacture and sale of generic drugs ③ Holding seminar about the outline of various theories of PIC/S GMP ④ Meeting on business development

2.2. Assessment of activities for the industrialization of the pharmaceutical sector in Azerbaijan

2.2.1. Goal 1 “Recognition of the importance to introduce the Global GMP standard into the pharmaceutical industry in the country”

In the program, opportunities for courtesy calls to the former Deputy Prime Minister Abid Shalifov, Deputy Minister of Economy Niyaji Safarov and Deputy Minister of Health Elsever Aghayev were arranged and a briefing about this program and future business development was carried out by JGC and NPP. In the meeting, strong messages to encourage any investment in Azerbaijan by Japanese companies were expressed respectively.

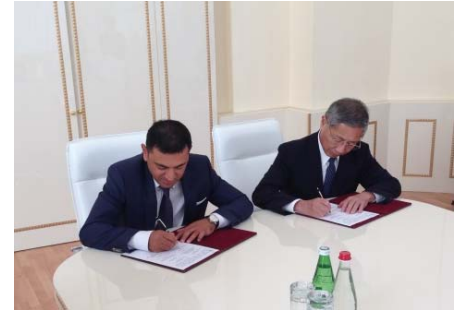
Through the remarks by such high-level governmental representatives, it was confirmed as follows:

- 1) There is no pharmaceutical manufacturing facility in Azerbaijan and it is a social issue to be immediately resolved in order to mitigate their national health care risk caused by shortage of supply in emergencies, as well as state treasury risk to be affected by increase in imported pharmaceuticals.
- 2) For the foreign investors, the marketing strategy to target only the domestic market is not sufficient to make the business feasible and, therefore, a strategy to target the neighboring areas via Azerbaijan as a business hub is recommended.
- 3) Any opportunity for GMP training for concerned officials in Azerbaijan is truly appreciated.



4) The highest degree of confidence by Azerbaijan consumers in the Japanese technology and products was expressed.

Taking the opportunity of a courtesy call to the Deputy Minister of Economy Niyaji Safarov, the signing ceremony on the MOU, in which cooperation in this program and future business development with SCIP LCC and JGC was confirmed, was arranged.



2.2.2. Goal 2 "Recognition of the Global GMP standard and Japanese pharmaceutical technology "

The following opportunities were arranged to the concerned governmental organizations, including MOE, MOH, AEC, SCIP LLC, AIC and AVROMED.

(1) Seminar on the Global GMP and pharmaceutical technology

Mr. Robert Tribe of GMP consultants, who is the former PIC/S chairman, Dr. Noriko Katori of the National Institute of Health Sciences in Japan, JGC and NPP, taking advantage of their expertise, lectured on the following contents on Global GMP and Japanese pharmaceutical technology.



- Outline and trends of the Global GMP standard
- Overview of PIC / S GMP
- Overview of Japanese pharmaceutical technology, including NPP's technologies enabling the production of high quality pharmaceuticals
- Outline of the supply-chain system enabling the production of high quality pharmaceuticals in Japan, including the processes followed in manufacturing, packaging, distribution and sales

As the result of above training seminars, it was observed that appropriate knowledge and information on the Global GMP standard were deepened among the participants. All participants expressed their special thanks to the organizer for the arrangements.



(2) Opportunities to participate in GMP Inspection Seminar organized by PMDA

An opportunity for an AEC official, Mr. Rauf Afandiyev of Quality Manager and head of GMP inspection in AEC, to participate in a GMP training seminar, was arranged. It was organized by PMDA at Yamaguchi Prefecture in Japan.

The following assessment was concluded as a result of his participation in the seminar.

- It was organized on a high level and all lecturers were professionals of their area and the content of presentations were simple and easy to follow.

- It was worth participating not only to learn valuable knowledge and participate in the practice exercises but also to build up human network with inspectors from different countries and to share their experiences.
- Since the pharmaceutical industry is going to emerge in Azerbaijan, all the information obtained from this seminar is to be fully shared in the country.
- Resource development of the GMP inspector is an urgent issue in Azerbaijan and it is expected that the opportunity for those officials involved in the GMP issues to participate in such training course will be increased in Azerbaijan.



(3) Site visit to Japanese pharmaceutical related facilities

Taking the opportunities of the dispatch of a delegation to Japan from SCIP LLC and AVROMED, site visits to the facilities of companies representing the Japanese pharmaceutical industry, including the following were arranged. It is concluded that they could recognize Japanese high-quality pharmaceuticals manufacturing technology and innovative system for pharmaceuticals distribution system.

- Solid Dosage Manufacturing Plant of Sumitomo Dainippon Pharma

A fully automated facility, preventing cross contamination in the plant operation in accordance with the Global GMP standards and achieving high efficiency and economics, was observed by the delegates. They deepened their understanding on the pharmaceutical plants for high-quality manufacturing.



- Pharmaceutical Distribution Center of Alfresa Corporation

For delegates to have a certain image how Japanese companies achieve the delivery system which enables them to maintain customer satisfaction, safe operation and reliability in the daily pharmaceutical supply in Japan, a pharmaceutical distribution center was observed. It is concluded that the delegates observed the state of art technologies to smoothly handle pharmaceuticals, such as a highly accurate system to eliminate mis-delivery and allow 24 hours delivery, well-known as the TOYOTA Automobile Just In Time System. Also, it is a duplexed system designed to quickly recover from any delivery troubles.

- Pharmacy

For delegates to have a certain image how the drugs are delivered to the consumers at the Japanese drug stores, a large-scale pharmacy was observed. They recognized how the product flow in the supply-chain is monitored by means of a barcode system



- Packaging material manufacturer facility of Asahi Printing Co., Ltd.

For delegates to have a clear image of how Japan achieves the quality control system to manufacture the high-quality packaging material, a factory of one of the biggest packaging material manufacturers in Japan was observed. By confirming strict quality control to manufacture the packaging material, prescription leaflet, the recognition of the importance of packaging and labeling quality was deepened.

- Machinery factories of FREUND Corporation, CKD Corporation and Airex Co., Ltd.

To deepen their understanding of the Japanese machinery industry, machinery factories were visited. They observed the pharmaceutical machinery such as powder handling machines, packaging equipment, sterile/containment isolators. At each factory, it was explained about the mechanical composition of the machines, the operation method and the point of compliance with the GMP standard. The delegates inquired about the materials of the machines and the difference from the manufacturers in other countries such as China. They understood the sophisticated and delicate fabrication process of the machines required to fully satisfy the quality requirement from the machinery users.



2.2.3. Goal 3 “Support to promote the rapid development of institutional design for pharmaceutical industry in the country”.

As a result of arrangements of the above mentioned GMP training courses as well as opportunities of dialogue with MOE and MOH to develop a suitable industrial infrastructure of pharmaceutical manufacturing and distribution industry in Azerbaijan, it is concluded that MOE and MOH understood the necessity to join PIC/S in future and they built up the communication channel with PIC/S and MHLW.

Despite the result of network setting with PIC/S, no concrete activities for PIC/S accession have been commenced yet in this program. As for communication access to MHLW, it is concluded that a certain contact window in MHLW has been opened for Azerbaijan since the participation in the GMP Inspection Seminar organized by PMDA.

2.3. Achievement through the program in business development

2.3.1. Goal 4 “Improvement of pharmaceutical manufacturing and sales environment”

Due to the reasons given below, in Azerbaijan, it was observed that it is not easy to launch the Japan brand pharmaceuticals which have advantages in terms of high-quality particularly to prevent the spread of illegal counterfeit pharmaceuticals into the market as well as its reasonable pricing:

- 1) In the existing industry, the pharmaceutical GMP is NOT widespread
- 2) The industrial infrastructure for pharmaceutical manufacturing is NOT well-developed
- 3) The market presence of Japan brand pharmaceuticals is VERY SMALL

In order to resolve these barriers to market entry, concentration on the promotion of understanding on the Global GMP standard and Japanese qualities and technologies through dialog with concerned parties involved in this program from Azerbaijan should be continued.

Despite the result through this program in which all concerned parties showed their keen interest in the manufacturing technologies of the Japan brand generic pharmaceuticals, there was no way to take concrete action toward PIC/S accession at this stage due to the lack of GMP standard in the country. Therefore, as it was concluded that it is not easy to show quality advantage of Japan brand pharmaceuticals without PIC/S accession, Goal 4 was not achieved with a fully satisfactory result.

2.3.2. Goal 5 “Selection of generic pharmaceuticals imported from Japan”

With a strong support by AVROMED, the market demand for pharmaceuticals in Azerbaijan was sufficiently confirmed and then an examination to select the candidates from among Japan brand pharmaceuticals to be imported was carried out. In this selection, only the marketable products in terms of competitive price and feasible lot size in the factory of NPP in Japan were selected as the candidates.



As a result, no candidates were found among a wide range of products of NPP mainly due to the reason that the demanded lot size in Azerbaijan is much smaller than the feasible supplied lot size in Japan.

In order to seek other candidates' products provided by any other Japanese companies as a substitute of NPP, “Life Science Market Development Forum for the Caucasus and Central Asia region” in Toyama was arranged by JGC. It was a business seminar to encourage business investment in Azerbaijan by any potential investors, as well as a strategy to find Japanese potential investors to replace NPP, since Toyama prefecture is a well-known place in terms of its pharmaceutical industry. Especially, Toyama is the place there is a certain number of small and medium sized pharmaceutical companies which have manufacturing plants. Therefore, it was assumed that any potential companies to meet the small lot size demand in the pharmaceutical market in Azerbaijan might be found.

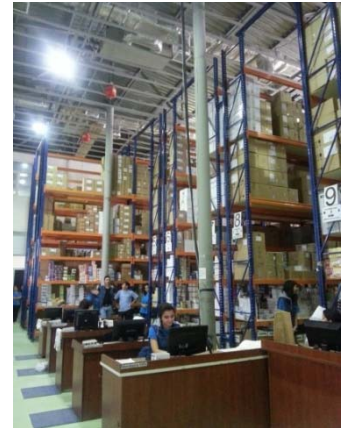


As a result of the Forum, five pharmaceutical companies showed their interest in the business to export their products to Azerbaijan. The candidate products provided by these five companies include not only generic pharmaceuticals but also OTCs, traditional herbal medicines and food supplements. Apart from the program, market study for these five companies is currently ongoing with the support by AVROMED.

2.3.3. Goal 6 “Recognition of the application and approval process in order to import pharmaceuticals into Azerbaijan”

Through the following activities to collect information, a certain degree of progress for recognition of the local application and approval process in order to import pharmaceutical into Azerbaijan was achieved:

- 1) Meeting with MOH, AVROMED and a potential investor of the foreign pharmaceutical company already announced their investment plan in Azerbaijan.
- 2) Mission tours to the distribution center and chain pharmacies owned by AVROMED



2.3.4. Goal 7 “Recognition of regulations in order to build and operate Pharmaceuticals Manufacturing facilities in Azerbaijan”

Through the following activities to collect information, particularly on the regulatory issues affecting the investment cost and project schedule in the future, a certain amount of progress in the recognition of the local application and approval process in order to build and operate the pharmaceuticals manufacturing facilities in Azerbaijan was achieved:

- 1) Meeting with SCIP LLC, MOH, AVROMED, local construction companies and a potential investor of the foreign pharmaceutical company
- 2) Mission tour to visit a distribution center owned by AVROMED and the industrial park developed by SCIP LLC at Pirallahi island in Baku.



2.3.5. Goal 8 “Creation of a Joint Business Team enables the materialization of successful business development”

When the program was started, it was assumed that a scheme based on the investment of a plant construction could be built up through the program. However, it was concluded that any candidates of generic pharmaceuticals among NPP’s products could not be manufactured in Azerbaijan, due to the reason of above stated Azerbaijan market and business circumstance issues.

In spite of withdrawal of NPP from the program, through the discussion with potential business partners, the following information was collected for future business development:

(1) Function of AVROMED

As the biggest pharmaceuticals distribution company in Azerbaijan, it seems that the involvement of this company in this business could be an essential aspect of the process. The following functions are expected to be covered by them:

- a) Marketing, distribution and sales

- b) Application of imported products and registration of Japan brand products in the market
- c) Export to neighboring countries from Azerbaijan

(2) Packaging material supplier in Azerbaijan

In the program, an opportunity to visit the fabrication factories to AZERSUN, BESTPACK and ALOPRINT, all are suppliers of packaging materials such as cartons and sheets of prescription leaflets in Azerbaijan, was arranged. As for the quality of their products, it was confirmed that they have a certain level to satisfy the quality demand in the local market and they have the potential to raise their quality to satisfy GMP requirements after suitable GMP training. For the packaging materials which require high quality such as plastic film and PTP, it could be imported from foreign countries.



(3) Local construction resources

In the program, meetings with AFZEN, which is one of the biggest construction companies in Azerbaijan, and USTAY, which is a Turkish company and has experiences of facilities construction in Azerbaijan, were arranged. As the outcome of meetings with them, the information about the procedure for application for the construction license was collected and other application processes related to governmental bodies required for the construction companies were clarified.

As it is expected that the governmental application process for the construction business in Azerbaijan could be complicated for the foreign companies, involvement of a local construction company could be mandatory in the phase of facility construction.

(4) A candidate location for pharmaceutical plant

The industrial park in Pirallahi island developed by SCIP LLC is recommended as a candidate to establish the facility. With reference to the Pirallahi industrial park, HAYAT Pharma, joint venture company by R-Pham, a Russian company and a local company, Caspian Pharma, joint venture company by TIPICO of Iranian and a local company, have announced their project to build the pharmaceuticals manufacturing facilities in the same industrial park.



2.4. Outstanding issues to be overcome

As stated above, the following 3 goals remain as the outstanding issues to be overcome:

- Goal 4 Improvement of pharmaceutical manufacturing and sales environment
- Goal 5 Selection of generic pharmaceuticals imported from Japan
- Goal 8 Creation of a Joint Business Team to enable the materialization of successful business development

In order to mitigate outstanding issues and move the project forward, the following ideas are proposed:

2.4.1. Solution to the issue of Goal 4 “Improvement of pharmaceutical manufacturing and sales environment”

Since Azerbaijan has not become a member of PIC/S yet, the difficult situation for Japanese companies has not been resolved. However, the government of Azerbaijan has developed the dedicated industrial park for the pharmaceutical industry in Pirallahi island, in which SCIP LLC has encouraged the foreign pharmaceutical sector to invest, and the deepened recognition of the importance of PIC/S accession. In

fact, an initial but a certain effort toward the successful PIC/S accession have been in progress by MOH, particularly by AEC.

In addition, since it seems that the announcements about the investment by Hayat Pharm and TIPICO in the Pirallahi industrial park also encourage the government toward their PIC/S accession and it could be achieved in the near future.

From Japan, support such as invitations to the PMDA seminar and delivery of information regarding updates about PIC/S accession in the neighboring countries could be continuously arranged.

2.4.2. Solution to the issue of Goal 5 “Selection of generic pharmaceuticals imported from Japan”

As a result of the investment forum arranged in the process of this program, five new potential investors who can replace NPP have emerged and currently the market study is on-going. They are planning to launch their products into the market and the products are not only generic pharmaceuticals but also OTCs, traditional herbal medicines and food supplements. Since they have not found any successful business scenario to manufacture pharmaceuticals, they are concentrating on the study to export their products from Japan to Azerbaijan.

2.4.3. Solution to the issue of Goal 8 “Creation of a Joint Business Team to enable the materialization of successful business development”

It is expected that the successful teaming-up with AVROMED and Japanese investors will be a key strategy in order to achieve the future business development. For the purpose of maintaining smooth communication between the parties, it is recommended that a Japanese distribution company, which is familiar with the business of exporting pharmaceuticals from Japan to foreign countries, to be involved for a successful business materialization in the future as the coordinator between five companies and AVROMED. By means of involvement of such a Japanese distributor, in addition to import to the Azerbaijan market, it can target further business development of exports via Azerbaijan to the neighboring countries.

3. Plan for Business Development after the program

Through this program, it has turned out that business development on the premise of investment in pharmaceutical manufacturing by Japan brand generic pharmaceuticals is not easy, but also confirmed that there are Japanese pharmaceutical companies who showed their intention to sell their products in the market of Azerbaijan.

As stated, their marketing study is on-going. Candidate products include not only generic pharmaceuticals but also OTCs, traditional herbal medicines and supplemental foods. Since they have already constructed a business network with AVROMED through this program, it can be expected that business development taking advantage of Japanese technology in Azerbaijan will be materialized in the near future.

Business development accompanying factory investment could be regarded as feasible by the success of this import sales business. Therefore, although the above business strategy focuses on the import of Japanese brand pharmaceuticals, it could be expected that factory investment will be materialized beyond as a further step.

In addition, it was confirmed, as industrially and socially concerned issues respectively in Azerbaijan and Japan, that the following issues must be resolved for sustainable growth of each company:

Azerbaijan)

- 1) Financial deterioration by an increase of the imported pharmaceuticals into the country
- 2) An increase of counterfeit pharmaceuticals which adversely affects national healthcare
- 3) Delay in the achievement of industrialization of non-oil and gas industries such as the pharmaceuticals manufacturing industry which contribute to a new employment and human resources development

Japan)

- 1) Shrinking of the pharmaceutical market as the population decreases in Japan
- 2) Severe cost reduction requirement by the government order to control drug prices and tougher domestic competition caused by this

Considering the circumstances of each country, the investment in the pharmaceuticals manufacturing business by Japanese companies in Azerbaijan can be a realistic solution to break through the status of the above issues in the two countries.