

Knowledge Co-Creation Program (Group & Region Focus)

GENERAL INFORMATION ON

Regulatory Systems on Ensuring Access to Quality Medicines

課題別研修「適正な医薬品の供給・品質管理・
使用に向けた薬事行政」

JFY 2019

NO. J19-04310 / ID. 1984415

Course Period in Japan: From June 30, 2019 to August 2, 2019

This information pertains to one of the JICA Knowledge Co-Creation Program (Group & Region Focus) of the Japan International Cooperation Agency (JICA), which shall be implemented as part of the Official Development Assistance of the Government of Japan based on bilateral agreement between both Governments.

‘JICA Knowledge Co-Creation (KCC) Program’ as a New Start

In the Development Cooperation Charter which is released from the Japanese Cabinet on February 2015, it is clearly pointed out that *“In its development cooperation, Japan has maintained the spirit of jointly creating things that suit partner countries while respecting ownership, intentions and intrinsic characteristics of the country concerned based on a field-oriented approach through dialogue and collaboration. It has also maintained the approach of building reciprocal relationships with developing countries in which both sides learn from each other and grow and develop together.”* We believe that this ‘Knowledge Co-Creation Program’ will serve as a center of mutual learning process.

I. Concept

Background

'Ensuring Access to Quality Medicines' is the essential element to strengthen health system, to improve the basic health services, and to realize universal health coverage (UHC).

However when a pharmaceutical regulatory system (authorization, post-marketing surveillance, inspection, etc.) is insufficient, there are many difficulties in implementing proper production and sales distribution. In such circumstances, the safety, efficacy and quality of medicine is not assured. Distributed substandard and falsified medicine is prevalent example of the problem that may spread Antimicrobial resistant (AMR) which threatens people's health and public health services eventually. Therefore, it is one of the top priorities of the international cooperation to establish functional pharmaceutical regulatory systems in the world.

In this program, participants will learn 1) regulatory related systems on pharmaceuticals, 2) supply chain systems for quality assured medicines through lectures, and site-visits. Also, participants are expected to analyze the country's prioritized issues and discuss the applicable measurements for improving proper access to quality medicines in their own countries.

For what?

This program is intended to help participants' organization (national pharmaceutical regulatory authorities and/or tertiary level hospitals) to enhance its capacity for ensuring proper access to quality assured medicines.

For whom?

This program is offered to the following (1) or (2);

- (1) Government officials who are engaged in making policies on pharmaceutical affairs and/or planning/implementation of pharmaceutical regulatory services, or
- (2) Senior pharmacists of tertiary level hospital, who are engaged in management of supply and rational use of medicines and human development. It is required that he/she is a director of pharmaceutical department or equivalent, who has a responsibility of collaboration with national pharmaceutical regulatory authorities and its relevant agencies.

How?

Participants shall have following opportunities in Japan to ensure program effectiveness.

1. Lectures on an overview of health system in Japan including pharmaceutical legislation and administration
2. Observations and site visits to local governments, pharmaceutical production companies, hospitals, research institute, and pharmacy
3. Discussions with Japanese/international experts and participants
4. Development and presentation of reports

II. Description

1. **Title (J-No.):** Regulatory Systems on Ensuring Access to Quality Medicines (J19-04310)
2. **Course Period in JAPAN:**
June 30, 2019 to August 2, 2019
3. **Target Regions or Countries:**
Afghanistan, Azerbaijan, Georgia, Indonesia, Iraq, Laos, Liberia, Myanmar, Thailand, Timor-Leste, Uganda, Venezuela
4. **Eligible / Target Organization :**
National pharmaceutical regulatory authorities and relevant agencies
5. **Course Capacity (Upper limit of Participants) :**
12 participants
6. **Language to be used in this program :** English
7. **Course Objective :**
Participants summarize findings and applicable measurements for improving access to quality assured medicines in their own countries through better understanding of experiences in both Japan and participating countries.
8. **Overall Goal:**
Access to quality assured medicines will be improved in participating countries.
9. **Expected Module Output and Contents:**
This program consists of the following components. Details on each component are given below:

(1) Preliminary Phase in a participant's home country: June 2019 <i>Participating organization is required to prepare for the program in the respective country.</i>	
Expected Module Output	Activities
To formulate an Inception report	Current situation and issues on pharmaceutical regulatory services in participant's organization are preliminary identified. Submission due date: <u>June 21, 2019</u> (Guideline for the Inception Report will be sent at the time of notification of acceptance).

(2) Core Phase in Japan: June 30, 2019 to August 2, 2019

Participants dispatched by the organizations attend the Program implemented in Japan.

Expected Module Output	Subjects/Agendas	Methodology
<u>Output module 1</u> To be able to understand and compare pharmaceutical regulatory system in the health service system of Japan and participating countries, as well as to understand trends of international collaboration among regulatory authorities.	➤ Overview of pharmaceutical regulatory system in Japan (Legislation, Pharmaceutical approval system, Good Manufacturing Practices(GMP), Health insurance system and drug price listing, Safety measures, etc.), ➤ Inception report presentation and discussion	-Lecture -Report presentation
<u>Output module 2</u> To be able to understand regulatory management for access to quality medicines including inspection system.	➤ Overseeing role of stakeholders to ensure quality-assured medicines (Activities by importers, manufacturing companies, wholesalers, hospitals and pharmacies), ➤ Pharmaceutical inspection system (Collaboration with local government, etc.), ➤ Trends in international cooperation among regulatory authorities	-Lecture -Observation -Discussion
<u>Output module 3</u> To be able to understand actual operations both in governmental and medical institutions for ensuring quality of medicines.	➤ Field trip to Toyama prefecture (Local government, Pharmaceutical manufacturer and Pharmaceutical Research Institute), ➤ Observations at pharmaceutical companies, and pharmacy, ➤ Lectures on countermeasures against counterfeit medicines, ➤ Observations at hospitals and pharmacies (Roles of pharmacists in wards and R&D, Dispensing, Pharmaceutical products management, etc.)	-Field trip -Lecture -Observation -Discussion

<u>Output module 4</u> To be able to clarify challenges from the view point of administrators and pharmacists in participants' workplace through sharing experiences and discussions.	➤ Summing-up discussion, ➤ Feedback session of group programs, ➤ Final report making and presentation	-Report developmen t/presentatio n -Workshop -Discussion
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***After returning home countries, participants are expected to share the final report within their supervisors and colleagues and discuss how to make use of results to their activities.**

<Program Outline in 2018> Please refer to the last year schedule.

	AM		PM
July 8 (Sun.) Arrival in Japan			
July 9 (Mon.)	JICA Briefing		Programme Orientation
July 10 (Tue.)	Pharmaceutical Administration in Japan (MHLW)	Drug Licensing and Approval Systems in Japan (MHLW)	Case Study of New Drugs' Review (PMDA)
July 11 (Wed.)	Post-marketing Safety Measures for Drugs (MHLW)	Collection of Safety Information and Dissemination of Risk Communication during the Post-Marketing phase (PMDA)	Japanese Administration on Pharmaceutical Inspection and Guidance (MHLW)
July 12 (Thu.)	Challenges of Japanese Pharmaceutical Industry		Market and Outline of Regulatory System on Generic Medicines in Japan
July 13 (Fri.)	Japan's Medical Insurance System and Drug Price Standard (MHLW)		Inception Report Presentation
July 14-16 (Sat., Sun. & Mon.) free *July 16: National Holiday -Marine Day			
July 17 (Tue.)	Trade and Control of Active Pharmaceutical Ingredients and Intermediates		Study Visit to National Institute of Health Sciences
July 18 (Wed.)	Evaluation of Safety Information •Safety Measure and Risk Management Plan (RMP)		Case Study of Risk Management (PMDA)
July 19 (Thu.)	Insurance Pharmacies and Insurance Preparations (MHLW)		Interim Review-(1) Review and Explanation on Improvement Plan Preparation
July 20 (Fri.)	Countermeasures against Counterfeit Medicines - Improvement for Quality Assurance of Pharmaceuticals		Countermeasure against Counterfeit Medicines in Japan
July 21 (Sat.) free			
July 22 (Sun.)	☆ Study Trip to Toyama prefecture 11:24 Tokyo St. <Shinkansen, Hakutaka> ⇒13:57 Toyama St.		< Study Visit> Traditional Medicine Museum
July 23 (Mon.)	Courtesy call to Toyama Prefectural Government	Pharmaceutical Administration in Toyama Prefecture	< Study Visit> Toyama Prefectural Institute for Pharmaceutical Research
July 24 (Tue.)	Outline of PMDA (GMP, International Activities, Relief System, etc.)		Case Study on GMP Inspection
July 25 (Wed.)	< Study Visit > Production Line of Oral Solid Formulations		< Study Visit > Production Line of Eyedrops and External Medicines
July 26 (Thu.)	< Lecture & Study Visit > Institute of Natural Medicine, University of Toyama / Tour for the Museum of Materia Medica		< Study Visit> Preparation of Japanese and Chinese Medicine in Pharmacy Dept. of the University-affiliated Hospital ☆ Back to Tokyo 16:33 Toyama St. <Shinkansen, Hakutaka> ⇒19:12 Tokyo St.
July 27 (Fri.)	Interim Review-(2) Review on Study Trip to Toyama		Study Visit to Pharmaceutical Center
July 28-29 (Sat. & Sun.) free			
July 30 (Mon.)	Hospital Pharmacy Programme (Lecture, Study Visit and Q&A)		
July 31 (Tue.)	Infection Control and Therapeutic Management of Infectious Disease		Introduction of Japanese Society of Hospital Pharmacists and Roles of Pharmacists in Disaster Medical Care
Aug. 1 (Wed.)	Interim Review-(3)		Tuberculosis and BCG
Aug. 2 (Thu.)	Wholesaler of Drug in Japan (Lecture, Study Visit and Q&A)		JICA's Role & Activities toward UHC

Aug. 3 (Fri.)	Presentation based on Theme Discussion		
Aug. 4-5 (Sat. & Sun.) free			
Aug. 6 (Mon.)	Functions and the Roles of Pharmacist in Japan	<Study Visit> Drug store	
Aug. 7 (Tue.)	Improvement Plan Presentation Overall Review		Evaluation Meeting Closing Ceremony
Aug. 8 (Wed.)	Departure from Japan		

MHLW: Ministry of Health, Labour and Welfare
PMDA: Pharmaceuticals and Medical Devices Agency

III. Conditions and Procedures for Application

1. Expectations from the Participating Organizations:

- (1) This program is designed primarily for organizations that intend to address specific issues or problems identified in their operation. Participating organizations are expected to use the project for those specific purposes.
- (2) This program is enriched with contents and facilitation schemes specially developed in collaboration with relevant prominent organizations in Japan. These special features enable the project to meet specific requirements of applying organizations and effectively facilitate them toward solutions for the issues and problems.

2. Nominee Qualifications:

Applying Organizations are expected to select nominees who meet the following qualifications.

(1) Essential Qualifications

1) Current Duties:

who qualify (A) or (B) below;

(A) be a government officials who are engaged in making policies on pharmaceutical affairs and/or planning/implementation of pharmaceutical regulatory services, or

(B) be a senior pharmacists of tertiary level hospital, who is engaged in management of supply and rational use of medicines and human development. It is required that he/she is a director of pharmaceutical department or equivalent, who has a responsibility of collaboration with national pharmaceutical regulatory authorities and its relevant agencies.

2) Occupational Qualification / Background:

have more than 3 years' experience of the above-mentioned fields.

3) Language: Be proficient* in spoken and written English which is equal to TOEFL iBT 79 or more (Since this course includes active participation into discussions, report development and presentation, high English competency is required. If applicants have official certification of English language e.g. TOEFL, TOEIC etc, please attach it for selection purpose).

*Conversational accuracy & fluency in wide range of situations: discussions, short presentations & interviews. Compound complex sentences. Extended essay formation.

4) Health: must be in good health, both physically and mentally, to participate in the Program in Japan. Pregnant applicants are not recommended to apply due to the potential risk of health and life issues of mother and fetus.

(2) Recommendable Qualifications

- 1) Age: be under fifty (50) years of age (when applying)
- 2) Gender Consideration: JICA is promoting Gender equality. Women are encouraged to apply for the program.

3. Required Documents for Application :

(1) Application Form: The Application Form is available at **the JICA office (or the Embassy of Japan)**.

* If you have any difficulties/disabilities which require assistance, please specify necessary assistances in the Medical History(1-(d)) of the application forms. It may allow us (people concerned in this course) to prepare better logistics or alternatives.

(2) Photocopy of passport: to be submitted with the application form, if you possess your passport which you will carry when entering Japan for this program. If not, you are requested to submit its photocopy as soon as you obtain it.

*Photocopy should include the followings:

Name, Date of birth, Nationality, Sex, Passport number and Expire date.

(3) Nominee's English Score Sheet: to be submitted with the application form. If you have any official documentation of English ability. (e.g., TOEFL, TOEIC, IELTS)

4. Procedures for Application and Selection:

(1) Submission of the Application Documents:

Closing date for applications: **Please inquire to the JICA office (or the Embassy of Japan)**.

(After receiving applications, the JICA office (or the Embassy of Japan) will send them to **the JICA Center in JAPAN** by **May 8, 2019**.)

(2) Selection:

After receiving the documents through proper channels from your government, the JICA office (or the embassy of Japan) will conduct screenings, and then forward the documents to the JICA Center in Japan. Selection will be made by the JICA Center in consultation with concerned organizations in Japan. *The applying organization with the best intention to utilize the opportunity of this program will be highly valued in the selection.* Qualifications of applicants who belong to the military or other military-related organizations and/or who are enlisted in the military will be examined by the Government of Japan on a case-by-case basis, consistent with the Development Cooperation Charter of Japan, taking into consideration their duties, positions in the organization, and other relevant information in a comprehensive manner.

(3) Notice of Acceptance:

Notification of results will be made by the JICA office (or the Embassy of Japan) **not later than May 31, 2019**.

5. Document(s) to be submitted by accepted candidates:

(1) Inception Report -- to be submitted by June 21, 2019

Before coming to Japan, only accepted candidates are required to prepare an Inception Report. Detailed information on the guideline for the "Inception Report" will be provided to the participant upon notification of the acceptance to the program.

* Please note that the presentation session of both the Inception Report and the Final

Report will be attended by a small number of Japanese observers. It is for the purpose of promoting public awareness and support of JICA's activities.

6. Conditions for Attendance:

- (1) to strictly adhere to the program schedule.
- (2) not to change the program topics.
- (3) not to extend the period of stay in Japan.
- (4) not to be accompanied by family members during the program.
- (5) to return to home countries at the end of the program in accordance with the travel schedule designated by JICA.
- (6) to refrain from engaging in any political activities, or any form of employment for profit or gain.
- (7) to observe Japanese laws and ordinances. If there is any violation of said laws and ordinances, participants may be required to return part or all of the training expenditure depending on the severity of said violation.
- (8) to observe the rules and regulations of the accommodation and not to change the accommodation designated by JICA.

IV. Administrative Arrangements

1. Organizer:

(1) **Name:** JICA TOKYO, Human Development and Operational Coordination Division

(2) **Contact:** Ms. Yoko JOGENJI (ticthdop@jica.go.jp)

2. Implementing Partner:

(1) **Name:** Japan International Corporation of Welfare Services (JICWELS)

(2) **URL:**

<http://www.jicwels.or.jp/files/2013E5B9B4JICWELSEFBE8AEFBE9FEFBE9DEFBE8CEFBE9AEFB.pdf>

(3) **Contact:** Ms. Hiroko FUJIMORI (jigyo@jicwels.or.jp)

3. Travel to Japan:

(1) **Air Ticket:** The cost of a round-trip ticket between an international airport designated by JICA and Japan will be borne by JICA.

(2) **Travel Insurance:** Coverage is from time of arrival up to departure in Japan. Thus traveling time outside Japan will not be covered.

4. Accommodation in Japan:

JICA will arrange the following accommodations for the participants in Japan:

JICA Tokyo Center (JICA TOKYO)

Address: 2-49-5 Nishihara, Shibuya-ku, Tokyo 151-0066, Japan

TEL: 81-3-3485-7051 FAX: 81-3-3485-7904

(where “81” is the country code for Japan, and “3” is the local area code)

If there is no vacancy at JICA TOKYO, JICA will arrange alternative accommodations for the participants.

Please refer to JICA Tokyo at its URL, <https://www.jica.go.jp/tokyo/english/office/>

< Facility and Service Guide >

https://www.jica.go.jp/tokyo/english/office/c8h0vm00009uld4m-att/facilities_service_guide.pdf

<JICA Tokyo's Facebook Page >

<https://www.facebook.com/jicatokyo>

5. Expenses:

The following expenses will be provided for the participants by JICA:

(1) Allowances for accommodation, meals, living expenses, outfit, and shipping

(2) Expenses for study tours (basically in the form of train tickets.)

(3) Free medical care for participants who become ill after arriving in Japan (costs related to pre-existing illness, pregnancy, or dental treatment are not included)

(4) Expenses for program implementation, including materials

For more details, please see “III. ALLOWANCES” of the brochure for participants titled “KENSU-IN GUIDE BOOK,” which will be given before departure for Japan.

6. Pre-departure Orientation:

A pre-departure orientation will be held at the respective country's JICA office (or Japanese Embassy), to provide participants with details on travel to Japan, conditions of the workshop, and other matters.

For Your Reference

JICA and Capacity Development

The key concept underpinning JICA operations since its establishment in 1974 has been the conviction that “capacity development” is central to the socioeconomic development of any country, regardless of the specific operational scheme one may be undertaking, i.e. expert assignments, development projects, development study projects, training programs, JOCV programs, etc.

Within this wide range of programs, Training Programs have long occupied an important place in JICA operations. Conducted in Japan, they provide partner countries with opportunities to acquire practical knowledge accumulated in Japanese society. Participants dispatched by partner countries might find useful knowledge and re-create their own knowledge for enhancement of their own capacity or that of the organization and society to which they belong.

About 460 pre-organized programs cover a wide range of professional fields, ranging from education, health, infrastructure, energy, trade and finance, to agriculture, rural development, gender mainstreaming, and environmental protection. A variety of programs are being customized to address the specific needs of different target organizations, such as policy-making organizations, service provision organizations, as well as research and academic institutions. Some programs are organized to target a certain group of countries with similar developmental challenges.

Japanese Development Experience

Japan was the first non-Western country to successfully modernize its society and industrialize its economy. At the core of this process, which started more than 140 years ago, was the “*adopt and adapt*” concept by which a wide range of appropriate skills and knowledge have been imported from developed countries; these skills and knowledge have been adapted and/or improved using local skills, knowledge and initiatives. They finally became internalized in Japanese society to suit its local needs and conditions.

From engineering technology to production management methods, most of the know-how that has enabled Japan to become what it is today has emanated from this “*adoption and adaptation*” process, which, of course, has been accompanied by countless failures and errors behind the success stories. We presume that such experiences, both successful and unsuccessful, will be useful to our partners who are trying to address the challenges currently faced by developing countries.

However, it is rather challenging to share with our partners this whole body of Japan’s developmental experience. This difficulty has to do, in part, with the challenge of explaining a body of “tacit knowledge,” a type of knowledge that cannot fully be expressed in words or numbers. Adding to this difficulty are the social and cultural systems of Japan that vastly differ from those of other Western industrialized countries, and hence still remain unfamiliar to many partner countries. Simply stated, coming to Japan might be one way of overcoming such a cultural gap.

JICA, therefore, would like to invite as many leaders of partner countries as possible to come and visit us, to mingle with the Japanese people, and witness the advantages as well as the disadvantages of Japanese systems, so that integration of their findings might help them reach their developmental objectives.



CORRESPONDENCE

For enquiries and further information, please contact the JICA office or the Embassy of Japan. Further, address correspondence to:

JICA Tokyo Center (JICA TOKYO)

Address: 2-49-5 Nishihara, Shibuya-ku, Tokyo 151-0066, Japan

TEL: +81-3-3485-7051 FAX: +81-3-3485-7904