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 2023

Course No.: 202208270J001
Course Period in Japan: From July 6, 2023 to August 11, 2023

In the context of the COVID-19 pandemic, please note that there is still a possibility the course period will be changed, shortened, or the course itself will be cancelled

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

JICA Knowledge Co-Creation Program (KCCP)
The Japanese Cabinet released the Development Cooperation Charter in February 2015, which stated, *"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."* JICA believes that this 'Knowledge Co-Creation Program' will serve as a foundation of mutual learning process.

I. Concept

Background

'Ensuring Access to Quality Medicines' is the essential element to strengthen health systems, to improve the basic health services, and to contribute 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 a prevalent example of the problem that may spread Antimicrobial Resistance (AMR) and quality problem of medicines, which eventually threatens people's health and public health services. Therefore, it is one of the top priorities of international cooperation to establish functional pharmaceutical regulatory systems worldwide.

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

For what?

This program is intended to help the participants' organizations (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 hospitals, 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 a pharmaceutical department or equivalent and who has responsibility for 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 (Course No.)
Regulatory Systems on Ensuring Access to Quality Medicines
(202208270J001)

2. Course Duration in Japan
July 6 to August 11, 2023

3. Target Regions or Countries
Bangladesh, Brazil, Egypt, Indonesia, Laos, North Macedonia, Saint Christopher and Nevis, Thailand, Timor-Leste

4. Eligible / Target Organization
National pharmaceutical regulatory authorities and relevant agencies.

5. Capacity (Upper Limit of Participants)
9 participants

6. Language
English

7. Objective
Participants summarize findings and applicable measures 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. Output and Contents
This course consists of the following components. Details on each component are given below.

(1) **Preliminary Phase in a participant's home country:** June 2023
Participating organization is required to prepare for the program in the respective country.

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: June 24, 2023 (Guideline of the Inception Report will be sent at the time of notification of acceptance).

(2) Core Phase in Japan: July 6, 2023 to August 11, 2023	
Expected Module Output	Subjects/Agendas
Output module 1 To be able to understand and compare pharmaceutical regulatory system in the health service system of Japan and participating countries. To understand trends of international collaboration among regulatory authorities.	➢ Health Medical Case System in Japan ➢ 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 ➢ Outline of Pharmaceuticals and Medical Devices Agency (PMDA)
Output module 2 To be able to understand regulatory management for access to quality medicines including inspection system.	➢ Overviewing 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
Output module 3 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.)
Output module 4 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, ➢ Improvement plan presentation

***After returning home countries, participants are expected to share the improvement plan with their supervisors and colleagues and discuss how to make use of results to their activities.**

<Tentative Program Outline>

	AM		PM	
July 6(Thu.)	Arrival in Japan			
July 7 (Fri.)	JICA Briefing		Introduction of JICA's health cooperation	Program Orientation
	July8(Sat.), July9(Sun.) free			
July 10 (Mon.)	Pharmaceutical Administration in Japan		Challenges of Japanese Pharmaceutical industry	
July 11 (Tue.)	Japanese Administration on Pharmaceutical Inspection and Guidance		Trade and Control of Active Pharmaceutical Ingredients and Intermediates	
July 12 (Wed.)	Drug Licensing and Approval Systems in Japan		Status and Challenges of generic drug	
July 13 (Thu.)	Overview of Post-marketing Safety Measures and Risk Management Plan		Health system in Japan	
July14 (Fri.)	Inception Report Presentation		Interim Review-(1) Review and Explanation on Improvement Plan Preparation	
	July 15(Sat.), July 16(Sun.) July17(Mon.) free			
July 18 (Tue.)	Insurance pharmacies and insurance preparations		Functions and the Roles of Pharmacist in Japan	
July 19 (Wed.)	Countermeasure against Counterfeit Medicines in Japan		Antidrug control in Japan(narcotic and stimulants)	
July 20 (Thu.)	Courtesy call to PMDA Outline of PMDA		Collection of Safety Information and Dissemination of Risk Communication during the Post-Marketing phase Evaluation of Safety Information Safety Measure and Risk Management Plan(RMP) （PMDA)	
July 21 (Fri.)	Case Study of reviewing on New Drug Application (with New Active Ingredient) (PMDA) GCP and GLP Inspection (PMDA)		Case Study of reviewing on Generic Drug, OTC, Quasi-drug Application (PMDA)	
	July 22(Sat.), free			
July 23 (Sun.)	☆ Study Trip to Toyama Tokyo ⇒ Toyama			
July 24 (Mon.)	Courtesy call to Toyama Prefectural Government	Pharmaceutical Administration in Toyama Prefecture	Outline of PMDA (GMP, International Activities, Relief System, etc.)	

July 25 (Tue.)	＜Study Visit＞TOA Pharmaceuticals Co.,Ltd. Pharmaceutical companies' Manufacturing Plants	
July 26 (Wed.)	＜Study Visit＞ Toyama Prefectural Institute for Pharmaceutical Research	＜Study Visit＞Traditional Medicine Museum
July 27 (Thu.)	Institute of Natural Medicine, University of Toyama / Tour for the Museum of Materia Medicine	＜Study Visit＞ Preparation of Japanese and Chinese Medicine in Pharmacy Dept. of the University-affiliated Hospital
July 28 (Fri.)	☆ Back to Tokyo Toyama ⇒ Tokyo	Interim Review-(2) Review on Study Trip to Toyama
	July 29(Sat.), July 30(Sun.) free	
July 31 (Mon.)	Japanese Pharmacopoeia and Standards	＜Study Visit＞ National Institute of Health Sciences
Aug 1 (Tue.)	Role of pharmacist in hospital	<Study Visit> National Center for Global Medicine Hospital
Aug 2 (Wed.)	<Study visit> Drug store, Chuo Pharmacy	<Study Visit> Hachioji Pharmaceutical Center
Aug 3 (Thu.)	Interim Review (3)	Vaccine Production and Quality Control (Lecture and Q&A)
Aug 4 (Fri.)	Countermeasure against Counterfeit Medicines	Presentation based on Theme Discussion
	Aug 5(Sat.), Aug 6 (Sun.) free	
Aug 7 (Mon.)	Infection Control and Therapeutic Management of Infectious Disease (1)	Infection Control and Therapeutic Management of Infectious Disease (2)
Aug 8 (Tue.)	Tokyo Customs	<Study Visit>Drug sales and Good Distribution Practice
Aug 9 (Wed.)	Preparation of Improvement Plan	
Aug10 (Thu.)	Improvement Plan Presentation	Evaluation Meeting Closing Ceremony
Aug 11 (Fri.)	Departure from Japan	

July 20-26 programs are offered by the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs in PMDA as a joint seminar specifically for JICA.

III. Eligibility and Procedures

1. Expectations to the Applying Organizations

(1) This course is designed primarily for organizations that intend to address specific issues or problems identified in their operation. Applying organizations are expected to use the program for those specific purposes.

(2) This course is enriched with contents and facilitation schemes specially developed in collaboration with relevant prominent organizations in Japan. These special features enable the course 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 official who is 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 to participate in the program in Japan. To reduce the risk of worsening symptoms associated with respiratory tract

infection, please be honest to declare in the Medical History (QUESTIONNAIRE ON MEDICAL STATUS RESTRICTION of the application form) if you have been a patient of following illnesses; Hypertension / Diabetes / Cardiovascular illness / Heart failure / Chronic respiratory illness.

(2) Recommended Qualifications

1) Age: be under fifty (50) years of age (when applying)
2) Gender Consideration: JICA promotes 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 overseas office (or the Embassy of Japan)**

* If you have any difficulties/disabilities which require assistance, please specify necessary assistances in the QUESTIONNAIRE ON MEDICAL STATUS RESTRICTION (1-(c)) of the application form. Information will be reviewed and used for reasonable accommodation.

(2) Photocopy of Passport: You should submit it 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.

*The following information should be included in the photocopy:
Name, Date of Birth, Nationality, Sex, Passport Number and Expiry Date

(3) English Score Sheet: to be submitted with the application form, if the nominees have any official English examination scores. (e.g., TOEFL, TOEIC, IELTS)

4. Procedures for Application and Selection

(1) Submission of the Application Documents

Closing date for applications: **Please confirm the local deadline with the JICA overseas office (or the Embassy of Japan).**

（All required material must arrive at **JICA Center in Japan** by May 7, 2023）

(2) Selection

Primary screening is conducted at the JICA overseas office (or the embassy of Japan) after receiving official documents from your government. JICA Center will consult with concerned organizations in Japan in the process of final selection. Applying organizations with the best intentions to utilize the opportunity will be highly valued.

The Government of Japan will examine applicants who belong to the military or other military-related organizations and/or who are enlisted in the military, taking into consideration of their duties, positions in the organization and other relevant information in a comprehensive manner to be consistent with the

Development Cooperation Charter of Japan.

(3) Notice of Acceptance

The JICA overseas office (or the Embassy of Japan) will notify the results not later than June 6, 2023.

5. Additional Document(s) to Be Submitted by Accepted Candidates

Inception Report -- to be submitted by June 24, 2023

Before coming to Japan, only accepted candidates are required to prepare an Inception Report. Detailed information 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 Improvement Plan 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 Participation

The participants of KCCP are required

(1) to strictly observe the course schedule,

(2) not to change the air ticket (and flight class and flight schedule arranged by JICA) and lodging by the participants themselves,

(3) to understand that leaving Japan during the course period (to return to home country, etc.) is not allowed (except for programs longer than one year),

(4) not to bring or invite any family members (except for programs longer than one year),

(5) to carry out such instructions and abide by such conditions as may be stipulated by both the nominating Government and the Japanese Government in respect of the course,

(6) to observe the rules and regulations of the program implementing partners to provide the program or establishments,

(7) not to engage in political activities, or any form of employment for profit,

(8) to discontinue the program, should the participants violate the Japanese laws or JICA's regulations, or the participants commit illegal or immoral conduct, or get critical illness or serious injury and be considered unable to continue the course. The participants shall be responsible for paying any cost for treatment of the said health conditions except for the medical care stipulated in (3) of "5. Expenses", "IV. Administrative Arrangements",

(9) to return the total amount or a part of the expenditure for the KCCP depending on the severity of such violation, should the participants violate the laws and ordinances,

(10) not to drive a car or motorbike, regardless of an international driving license possessed,

(11) to observe the rules and regulations at the place of the participants' accommodation, and

(12) to refund allowances or other benefits paid by JICA in the case of a change in schedule.

(13) To obtain valid vaccination certificates (3 doses) or certificate of testing for COVID-19. Detailed information is provided below. The policy is subject to change.
000997373.pdf (mhlw.go.jp)

IV. Administrative Arrangements

1. **Organizer (JICA Center in Japan)**
   (1) Center: JICA Tokyo Center (JICA TOKYO)
   (2) Program Officer: Ms. Shiho HIRANO (ticthdop@jica.go.jp)
   (3) URL: https://www.jica.go.jp/tokyo/english/office/
   <JICA Tokyo's Facebook Page> https://www.facebook.com/jicatokyo
   < Knowledge Co-Creation Program and Life in Japan (English ver.)>
   https://www.youtube.com/watch?v=SLurfKugrEw

2. **Implementing Partner**
   (1) Name: Japan International Corporation of Welfare Services (JICWELS)
   (2) URL: https://jicwels.or.jp/
   (3) Contact: Ms. Sachiko OCHIAI (jigyo@jicwels.or.jp)

3. **Travel to Japan**
   (1) Air Ticket: In principle, JICA will arrange an economy-class round-trip ticket between an international airport designated by JICA and Japan.
   (2) Travel Insurance: Coverage is from time of arrival up to departure in Japan. Thus traveling time outside Japan (include damaged baggage during the arrival flight to Japan) will not be covered.

4. **Accommodation in Japan**
   Basically, JICA will arrange the following accommodation(s) 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) Please refer to facility guide of JICA TOKYO at its URL, https://www.jica.go.jp/tokyo/english/office/index.html

   If there is no vacancy at JICA TOKYO, JICA will arrange alternative accommodation(s) for the participants.

5. **Expenses**
   The following expenses in Japan will be provided by JICA
   (1) Allowances for meals, living expenses, outfits, and shipping and stopover.
   (2) Expenses for study tours (basically in the form of train tickets).
   (3) Medical care for participants who become ill after arriving in Japan (the costs related to pre-existing illness, pregnancy, or dental treatment are not included).
   (4) Expenses for program implementation, including materials.
   (5) For more details, please see "III. ALLOWANCES" of the brochure for participants titled "KENSHU-IN GUIDE BOOK," which will be given before departure for Japan.

*Link to JICA HP (English/French/Spanish/Russian):
https://www.jica.go.jp/english/our_work/types_of_assistance/tech/acceptance/training/index.html

6. Pre-departure Orientation

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

For Your Reference

JICA and Capacity Development

Technical cooperation is people-to-people cooperation that supports partner countries in enhancing their comprehensive capacities to address development challenges by their own efforts. Instead of applying Japanese technology per se to partner countries, JICA's technical cooperation provides solutions that best fit their needs by working with people living there. In the process, consideration is given to factors such as their regional characteristics, historical background, and languages. JICA does not limit its technical cooperation to human resources development; it offers multi-tiered assistance that also involves organizational strengthening, policy formulation, and institution building.

Implementation methods of JICA's technical cooperation can be divided into two approaches. One is overseas cooperation by dispatching experts and volunteers in various development sectors to partner countries; the other is domestic cooperation by inviting participants from developing countries to Japan. The latter method is the Knowledge Co-Creation Program, formerly called Training Program, and it is one of the core programs carried out in Japan. By inviting officials from partner countries and with cooperation from domestic partners, the Knowledge Co-Creation Program provides technical knowledge and practical solutions for development issues in participating countries.

The Knowledge Co-Creation Program (Group & Region Focus) has long occupied an important place in JICA operations. About 400 pre-organized course 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 is being customized by the different target organizations to address the specific needs, 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, as the first non-Western nation to become a developed country, built itself into a country that is free, peaceful, prosperous and democratic while preserving its tradition. Japan will serve as one of the best examples for our partner countries to follow in their own development.

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 a process of adoption and adaptation, of course, has been accompanied by countless failures and errors behind the success stories.
Through Japan's progressive adaptation and application of systems, methods and technologies from the West in a way that is suited to its own circumstances, Japan has developed a storehouse of knowledge not found elsewhere from unique systems of organization, administration and personnel management to such social systems as the livelihood improvement approach and governmental organization. It is not easy to apply such experiences to other countries where the circumstances differ, but the experiences can provide ideas and clues useful when devising measures to solve problems.

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.

Contact Information for Inquiries

For inquiries and further information, please contact the JICA overseas 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