"Project Formulation Survey" under the Governmental Commission on the Projects for ODA Overseas Economic Cooperation in FY2012

Summary Report

India

The research to improve the transportation quality of vaccines, specimens and clinical samples by high-performance isothermal transportation container

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SUGIYAMA-GEN Co., Ltd. and
Tokyo Medical Consulting Co., Ltd.

This report is a summary of a project formulation survey conducted by the contractor, under the Governmental Commission on the Project for ODA Overseas Economic Cooperation, commissioned by the Ministry of Foreign Affairs of Japan in Fiscal Year 2012. It does not necessarily represent the official views of the Ministry of Foreign Affairs of Japan.

Introduction

It is important to transport the various temperature sensitive medical substances under the appropriate temperature control for the benefit of people's health, these include, temperature sensitive pharmaceuticals, clinical investigational pharmaceuticals and also clinical trial related specimens for new drug development and diagnostic specimens.

The feasibility study was triggered in our estimation, that there must be room for improvement in the temperature controlled transportation systems within the medical fields of India, this is because India has a vast various natural environment and resources with a broad range in the standard of living.

Because of this we conducted a feasibility study regarding the deployment of BioBox Plus which brings a stable temperature controlled transportation system for extended periods of time with relative simplicity and without the need for costly electricity. We also conducted another feasibility study for the desired implementation of stable temperature controlled transportation systems for vaccines within India. These systems have to be able to transport substances with low stable temperatures and also for extended periods of time.

Purposes of our feasibility study outlined below.

- Needs regarding precise temperature controlled transportation systems for vaccines, clinical investigational pharmaceuticals, clinical trial related specimens and diagnostic specimens.
- Exchange of thoughts among various relevant parties regarding ODA application based on current environment and the features of our various products.
- Study regarding the various relevant regulations, IPR-Intellectual Property Rights, partial localization of BioBox Plus and projected future plans.

Previously, we conducted a study in Japan followed by a physical feasibility study in India conducted last December and January of this year. The main focus and target audience during those visits, were of central and local governments, the private sector, transportation haulage companies and also hospitals.

I . Description of the current situation and development needs of the concerned development issues within India

India has the second largest population in the world, and has been steadily expanding economy since 1990. Also the range of disposable house income has gradually widened and development in many areas has been progressively widened. There is a gap between infrastructure readiness and economic development. Thus the Indian government has targets of gross growth and equal development among the population, and is taking action particularly on village development, the thorough support of socially impoverished layers, for example women's rights and the needs of the poor, unemployment and transparency of governmental

organizations with a particular emphasis and focuses on vaccination programs within the healthcare field.

India is a country of pharmaceutical manufacturing and development and is the central hub of low cost vaccine manufacturing. It is also leading the development of innovative and low cost vaccines for the market of developing countries, and has a very important role in supplying vaccines to not only the developing local market but also the international overseas market.

The supply of vaccines has also been steadily expanding; currently, annually 20% of infants do not have access to fundamental vaccinations for the prevention of fatal diseases in the world. This is mainly due to a low vaccination rate. As of 2010, India is among the bottom 10 countries where many children are simply not vaccinated.

To combat the spread of disease, which the vaccine can prevent, it is very important to have a program in place to reduce the number of infected children. It is vitally important to properly manufacture, transport and implement the vaccines. Almost all vaccines require storage and transportation under temperature control, in other words it requires cold chain management. As stated India is a large country and its infrastructure in certain areas is not well maintained, it has limited refrigeration technology and the power grid supply is not stable. This creates a problem in transportation and also a challenge in the development of transportation systems. This equally applies to clinical investigational pharmaceuticals and for clinical specimens for new drug development.

Our feasibility study revealed that Indian government officers are very knowledgeable in the field of healthcare. They have excellent vaccination programs and instruct the various state governments, UNCIEF, NGOs and so on to carry out the execution of these programs. However, the knowledge and understanding on how well the program has been carried out is behind in this respect.

This fact is proven in the report 'Vaccine Wastage Analysis" (2010) of UNICEF. This report states that, critically, gross vaccine wastage is extremely high.

The actual responsibility in the execution of the programs sits mainly on the state governments shoulders, but due to a lack of human resources it now results in the heavy dependence on many of the NGOs.

Presently UNICEF is supporting vaccinations at the end of the cold chain, for example, training regarding cold chain management, but is not directly involved in the vaccination process itself. The government only receives aid from limited aid supply countries and organizations however it demonstrates strong initiatives for policy execution. It promotes co-ordination among the various donors.

Along with the UN and the World Bank with co-ordination under UNICEF, the Japanese government has donated polio vaccine for over 10 years now. A free flow of information and idea exchange exists among all of the various donors.

Next, is the process of the law in India as it pertains to the population. The implementation of law and the protection of its workforce vary heavily depending on the workers/non workers status.

In India there is the labor law, which was established by the central government, and furthermore labor laws established by the local governments as well. There are no real differences between these

laws. There is a fundamental important Shop & Establishments law. This is a state law and sets a standard for fundamental work conditions.

In order to have a valid recognition of patent licenses in terms of a judicial aspect, it is mandatory to register license for a contract on the patent. The registration of a trademark is not mandatory because it is a requirement to duly assert against 3rdparties. There is no registration system on sales confidentiality.

Looking at the relationship between Japan and India, Japan is the largest donor for India. Since 2003 India is the largest recipient of loans from Japan. India sits in a very important geological position in terms of securing sea passage for Japan. India has been increasing its status and international relationships through economic development and also its active foreign diplomacy, and it demonstrates a large influence on South Asia countries. Certainly from Japans' perspective it is vitally important to establish a good relationship with India through economic cooperation in order to secure sustainable growth. This is very important for peace and the stability of south Asia and ultimately for the whole of Asia.

II. Possible applicability of the SME's products and technologies, and the prospects for future business development

BioBox Plus made by Sugiyama-Gen is a high performance temperature controlled transportation box with vacuum insulation panels. It can maintain inside storage temperatures of between 2-8℃ (the majority of vaccines and temperature sensitive pharmaceuticals must be kept within this range) for over 10 days under severe ambient fluctuating temperatures. The box has an advantage over competitors' in that the box is entirely frost free. Substances to be transported within this box are mainly vaccines, clinical investigational pharmaceuticals and clinical specimens. The company has the desire to establish a transportation container system which will become a worldwide.

BioBox Plus has been very popular and has an excellent user base which includes many public organizations and has established an excellent reliability rating because of its success working closely with Japan businesses the company has started deployment of the product in Asia.

The Indian market occupies a very important role in the international market. There are several container manufacturers and competition is quite strong. However we believe that we will be able to take a reasonable share in the market by finding the various weak points of currently available containers in India whilst offering a product that will be continually refined and improved whilst maintaining cost reduction.

BioBox Plus is a product that will improve the transportation conditions of vaccine, clinical investigational pharmaceuticals and clinical samples. It is the product that will benefit the health of the Indian populace.

As an ODA scheme, the company will begin sales of the product and deploy the technology needed within India. In doing so the company will understand appropriate specifications and cost answering needs recognized in India. The company has a strategy to make BioBox Plus the defect standard in India through continued research and development.
In the initial stages the point of sale will be through local agents, moving forward localization of the products will result in the increase of local employment.

III. Expected development impact and effect on business development of the proposing SMEs in the surveyed country through proposed ODA projects

Once vaccines have been frozen, they must be discarded due to loss of potency, they must be not used.

There are many areas in India, where vaccines have a risk of exposure due to very high temperature. UNICEF warned of the risk of potency loss due to freezing. An official Indian report also describes the risk due to freezing.

This information was obtained from an NGO that undertakes vaccination programs. They state that the procedure for the screening of frozen vaccines, before the actual vaccination, is not carried out particularly well.

Concerning cold chain management of vaccines, frozen ice packs are used after preconditioning in the refrigerator. Cold chain handlers have to follow procedures to avoid freezing. Current boxes do not implement a function to avoid freezing.

However, the concern is, is that there are many cold chain handlers for management, transportation and the vaccination process. We have obtained information that manuals are not been adhered to all of the time.

The temperature control function of BioBox Plus reduces the risk of high temperature exposure and eliminates the risk of low temperature exposure as well resulting in no freezing. The use of BioBox Plus requires very little preparation and operation therefore training in use of the product is very simple. For this reason the introduction of BioBox Plus will contribute to a definite improvement in the cold chain management for vaccines.

The trend now is of an increase in temperature sensitive pharmaceuticals and the activation of global clinical trials in India. Once our product has been accepted and well integrated within India, the company can enjoy an increase in international demand.

IV. Proposals for formulating ODA projects

We will take advantage of grassroots, human safety related free grant[tn1] s as part of the ODA scheme.

Our counterpart is an Indian NGO named Karuna Trust. This is a registered NGO in FCRA that has been well established for over 25 years. The main focus of its activity is in health care and sanitization. It covers 75 health units in India and its primary location is in southwest India and undertakes vaccinations every day.

The Karuna Trust has a particular concern that the problem of temperature deviation exists on the high side and probably on the lower side as well. The latter may not be recognized or may be ignored altogether consequently frozen vaccines with potency loss are been used within the chain. It is quite probable that these cases are not been reported.

Our plan is to clarify the actual temperature control conditions of vaccines to carry out vaccination of correct temperature controlled vaccines. At the same time our plan is to replace the existing old cold chain equipment by BioBox Plus. Our plan will focus on wastage reduction due to frozen vaccines. To renew the procedure and concept of vaccination, our plan is to train vaccine handlers using an easy to understand training manual.

An ODA project application will be completed mid next fiscal year and they will kick off the project at the end of the next fiscal year utilizing individuals from the NGO, Sugiyama-Gen and Tokyo Medical Consulting.

As a backup plan, our project currently has 2 NGOs.

Japan's Grant Assistance for Grassroots Projects (GGP)
India, The research to improve the transportation quality of vaccines, specimens and clinical samples by high-performance isothermal transportation container

SMEs and Counterpart Organization

- Name of SME: SUGIYAMA-GEN Co., Ltd. and Tokyo Medical Consulting Co., Ltd.
- Location of SME: Hongo 2-34-9 Bunkyo-ku, Tokyo, Japan
- Survey Site・Counterpart Organization: The Ministry of Foreign Affairs, Karuna Trust (Local NGO)

Concerned Development Issues

- Vaccine disposal problem due to freezing and temperature deviation
- UNICEF education manual for vaccine handlers should be complied with, but often it is not paid attention of the end of the Cold Chain Management
- Supply of the cold box is insufficient

Products and Technologies of SMEs

- This container has very high performance and can maintain the inside temperature at +2 ℃ ~ +8 ℃ about four days at ambient temperature of 48 ℃.
- Vaccine never froze in the box, so it is highly effective on prevention of vaccine disposal

Proposed ODA Projects and Expected Impact

- Take advantage of Japan's Grant Assistance for Grassroots Projects (GGP) as ODA scheme
- To promote secure implementation of vaccination and to reduce the waste disposal of vaccines

Future Business Development of SMEs

- Perform selection and training of the local distributor and conduct market research in major cities of India
- During research and sales activities, search for and select local sub-contractors and prepare to start local production if situation allows