

- Dr. Jagadish Prasad, DGHS, Ministry of Health and Family Welfare,
- Mr. K. B. Aggarwal, Additional Secretary, Ministry of Health and Family Welfare,
- Dr. Kazuhiro Shigetoh, Executive Director, Pharmaceuticals and Medical Devices Agency (PMDA)
- Mr. Koji Nakao, Chairperson, The Japan Federation of Medical Devices Associations (JFMDA)
- Distinguished Guests,
- Ladies and Gentlemen,

1. Opening

I am very pleased and honoured to be here today at the inaugural session of India-Japan Medical Products Regulation Symposium.

2. Progress of the cooperation between Japan and India in the field of healthcare

- (1) In recent years, the relationship between Japan and India has significantly expanded. Ties have been deepened in various fields, and healthcare cooperation has advanced greatly. I would like to point out a few evidential facts:
- (2) During Prime Minister Modi's visit to Japan in September 2014, the Memorandum of Cooperation in the Field of Healthcare was signed in Tokyo as a comprehensive framework of the dialogue and cooperation in this sector.
- (3) Subsequently, during Prime Minister Abe's visit to India in December last year, the Memorandum of Cooperation on

Pharmaceutical Affairs Regulation Dialogue and Cooperation Framework was signed in New Delhi. Based on this framework, the Health Ministries of Japan and India are holding this symposium today.

(4) And last month, Honorable Health Minister of India, Mr. Nadda, visited Tokyo to attend the “Tokyo Meeting of Health Ministers on Antimicrobial Resistance (AMR) in Asia.” In this meeting, it was confirmed that every country in Asia would take forward the measures for AMR in cooperative manner. In addition, during Mr. Nadda’s visit, the Letter of Intent on AMR research was signed in Tokyo between Indian Council of Medical Research and Japan’s National Institute of Infectious Diseases.

3. Significance of the cooperation in medical products and this symposium

Pharmaceutical and medical device is one of the most important areas of cooperation in healthcare. I am confident that this symposium will be the first and a great step for strengthening the ties of both countries in this sector in three aspects.

(1) Enhancement of the partnership between industries of both countries

① The first aspect is the enhancement of the partnership between industries of both countries and the promotion of trade between India and Japan.

In June 2015, the Government of Japan set the target of raising the share of generic medicines in the market to 80% at the earliest possible date between FY 2018 and 2020. The current share is 56.2% as of February 2015.

② In this context, the joint statement issued at the summit

meeting in December 2015 states, “Prime Minister Modi expressed that the target regarding quantitative share of generic medicines in Japan would be an excellent opportunity for collaboration between Japanese and Indian pharmaceutical companies.”

- ③ Japanese generic drug manufacturers are now expanding their manufacturing capacity and also trying to reduce the cost. Indian pharmaceutical industry is one of possible partners with the greatest potential as it has the advantage of low cost manufacturing with quality.
- ④ Indian pharmaceutical industry has high technology, therefore their products can meet the standard in Japan. In fact, since the Japan-India Comprehensive Economic Partnership Agreement entered into force in 2011, the export of Indian drugs to Japan is rapidly increasing. In addition, not only APIs (active pharmaceutical ingredient) and generic medicines, but also a bio-similar of insulin manufactured by BIOCOM was approved for marketing in Japan in March, 2016 under the partnership with Fuji Film Pharma.
- ⑤ I expect that this symposium will enhance the mutual understanding and strengthen the partnership among industries of both countries. This will contribute to boosting the trade of various medical products between India and Japan.

(2) Expectation on trade promotion

- ① The second aspect is the increase in investment.

During Prime Minister Modi’s visit to Japan in September 2014, both Prime Ministers committed to double Japan’s foreign direct investment and the number of Japanese companies in India within five years.

Prime Minister Abe expressed his intention to achieve 3.5 trillion Yen of public and private investment and financing from Japan in five years.

Prime Minister Modi underlined his determination to further improve the business environment in India to boost investment.

② In pharmaceutical sector, there is huge potential for mutual investment. Japanese pharmaceutical and medical device industry has advantage in innovative technology and marketing in Japan. Indian industry has advantage in low-cost research and development and manufacturing with quality. Therefore, the partnership in investment can complement each other.

(3) The contribution for creating regulatory system in India and the improvement of mutual credibility on regulation

① The third aspect is to improve mutual credibility on regulation.

② It is essential to improve the quality of products which can meet the requirement of a high standard market. I understand that, to promote “Make in India” in the medical device sector, the Government of India is now considering introducing new regulation for medical devices and regenerative medicine.

③ Through sharing our experiences and by providing opportunities of capacity building of regulators, Japan would like to support India in creating a highly credible regulatory system. I am sure that such efforts will also contribute to “Make in India” campaign.

4. Closing

I wish a great success of this symposium. I strongly hope that partnership among regulators and industries of both countries will be further advanced and that it will consequently benefit patients in both countries. Thank you.