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India and US agree to cooperate on regulations, medical products

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The Union Minister for Health, Mr Ghulam Nabi Azad met Ms Margaret Hamburg, managing director, Commissioner of Food and Drugs, USA, on February 10, 2014. A statement of intent on Cooperation in the field of medical products was signed between the Food and Drugs Administration, USA and the ministry of health and family welfare, India. Present at the occasion were Keshav Desiraju, secretary-health, Dr G N Singh, Drug Controller General of India (DCGI) and Ms Nancy Powell, US Ambassador to India and other higher officials from India and USA.

Speaking on the occasion, Mr Ghulam Nabi Azad mentioned that the Statement of intent between the two countries will go a long way in enhanced cooperation between the two countries in framing and strengthening frameworks for transparency and capacity building through seminars, workshops etc.

Ms Margaret Hamburg, M.D., Commissioner of Food and Drugs, USA congratulated India for its success in polio eradication. She commended India's leadership and powerful presence in the Pharma industry. She said that India is the second largest exporter of drugs to USA, and has a significant contribution in medical equipments and devices. But there is huge expectation and dependence of public on the regulator to ensure the quality of what the people consume through drugs and food, and also whether there are barriers being created to new opportunities, Ms. Hamburg stated. While she stated that quality regulation can go a long way in strengthening the robustness of the clinical industries, she also noted that India has made very serious commitment to strengthen regulatory framework to enhance transparency. India and USA need to be effective partners and work on transparency, she further added, as there are common goals and aspirations and both are world leaders in the field of medicines. There should be common set of standards so that people have quality, safe and efficacious drugs, she noted. She said that the Statement of Intent will enhance the transparency in the field of medicine.

The focus of the Statement of Intent between the two countries, signed today is

-- Sharing of information relevant to lack of compliance with accepted current good manufacturing practices, good clinical practices, or good laboratory practices, as appropriate, by manufactures and sponsors of medical products and manufacturers of cosmetics, in one another's country, or any other information as mutually decided upon.

-- Engaging collaboratively as observers in medical and cosmetic product and inspections conducted by the other country as per specific terms to be agreed and as time and resources allow.

-- Informing the respective regulatory authorities before undertaking inspections, so that host-country inspectors may join inspections as observers.

-- Collaborating in relevant scientific meetings, symposia, seminars, and other appropriate venues that may be organized either in the United States of America or the Republic of India.

-- Facilitating each other's holding (in persons or by teleconference) periodic discussions, possibly once every three (3) months, to report and assess progress on current collaborations and implementation of this Statement of Intent, to address concerns and resolve issues leading to strengthening and improving the bilateral relationship, and to identify new areas for collaboration.

-- Facilitating information-sharing between the two countries as appropriate and allowable by law, in support of public health and product safety, quality, and effectiveness, as appropriate.