*My Dear Dr. Gyanendra Nath Singh, the Drug Controller General of India
*Mrs. Patricia Grollet, Intelligence Officer from the Interpol Medical Product Counterfeit Pharmaceutical Crime Sub-Directorate, Lyon.
*Distinguished Guests from Drug Control Organization and Various State Police Organizations
*Faculty & colleagues from CBI
*Ladies and Gentlemen.

I feel privileged to welcome you all to this three day's Training on 'Investigation of Trafficking of Spurious Medical Products'. I am extremely grateful to the Drug Controller General of India for joining hands with us in conducting this immensely useful training programme. I am also thankful to Mr. Ronald Noble Secretary General and the INTERPOL Medical Product Counterfeit Pharmaceutical Crime Sub-Directorate for choosing CBI to jointly host this event. In fact during the last two years Interpol and CBI have jointly organized three training programmes on varied topics, this is the fourth partnership towards capacity building. I congratulate Dy Director, IPCC Shri Sai Manohar and Director of the academy Dr G.K Goswami for the interest they have shown in organizing this training.

We all know that the production, trafficking, and distribution of counterfeit drugs threatening the health and lives of the people across the globe, particularly in developing countries. According to World Health Organization, out of the 193 Member States, only about 20% are known to have well-developed medicine regulation and enforcement. 50% of the Member States implement regulations at various levels and 30% have no or limited pharmaceutical drug regulation in place that is hardly enforced.

Building effective regulatory systems for pharmaceuticals in developing countries is

a major challenge, because resources and technical expertise are scarce, and many other pressing health needs are competing for priority. In many countries, the underlying legal framework is non-existent, weak or outdated. Counterfeiting is often treated only as a trademark violation & unscrupulous racketeers who play with people's lives are able to escape from the penalties that such horrendous offence should invite. The law enforcement agencies are not equipped fully to recognize counterfeit medicines from genuine ones. Corrupt public officials are sometimes bribed by counterfeiters and the officials may collude with the counterfeiters to let them out of jail after a short time. At the international level, the issue is surrounded by confusion regarding the definition of counterfeit medicines.

In the recent past, The Interpol has taken the lead in busting this organized crime by conducting joint operations with member countries across the world. The highly successful operations like Storm (Southeast Asia), Mamba (Eastern Africa) and Pangea (targeting the Internet) have left a great impact and taken the war to the strong hold of the drug tycoons in their home turf. Successive joint raids on illicit markets have shown improved results in terms of seizures, arrests, convictions and the closure of illicit websites. Such successful operation could not have been possible without a fully trained drug and law enforcement officers in the countries were these operations were conducted. Capacity building is an integral part of any successful operation. I would like to express my sincere appreciation for INTERPOL for taking measures not only to ensure capacity building of member countries in this highly specialized area but also to enhance coordination and in promoting international cooperation in countering organized crime of spurious drugs.

In India this menacing problem has started knocking at our doors. According to the statistics of the year 2011-12 (upto March 2012) of Ministry of Health and Family

Welfare, out of 48082 drugs tested across 35 States of the country 133 turned out to be fake, which translates to roughly 0.27%. However, the second part of the statistics throws up some interesting facts. It says that prosecution was launched only in 0.43% of these 133 cases and only 0.23% of accused persons who were found involved in the manufacture of these fake drugs were arrested. Failure to prosecute an accused could be due to several factors including lack of expertise on the part the investigating officers to gather evidence to implicate the accused. Low detection rate could be due to lack of an efficient intelligence collection apparatus or awareness among the stake holders. The NCRB statistics for 2012 show that counterfeiting cases constitute only 0.1% of total reported crimes and criminal prosecution could only be taken up in 51.1% of the cases registered. As against this homicide constituted 1% of total crimes and criminal prosecution was launched in as much as 86% of the cases registered. These figures, therefore, prove that counterfeiting cases that are detected and investigated are not prosecuted, perhaps due to certain weaknesses in investigation. Needless to say that the investigating capability of investigating officers is required to be beefed up. Imparting Professional training and adopting good practices in this sphere is therefore the need of the hour.

It has been difficult to assess the extent of the problem of counterfeit medicines in many settings because of the lack of resources/skills to detect counterfeit medicines, the absence or weak medicines regulatory systems, the different definitions of counterfeit medicines in different countries worldwide, as well as the variations in the distribution systems. As such the actual extent of the problem may vary from country to country. Monitoring of, and control over pharmaceuticals ought to be much more stringent since it concerns the health of the citizens and the harm that spurious drugs can cause is far more serious than that caused by any other consumable good.

The Supreme Court of India and the National Human Rights Commission too have

expressed their concern about improving the drug regulatory system. In response to this growing concern, the Central government constituted an expert committee under the chairmanship of R. A. Mashelkar, Director-General of the Council for Scientific and Industrial Research (CSIR), to examine all aspects of the regulatory infrastructure. The committee was also required to evaluate the extent and problem of spurious and substandard drugs in the country.

Among the recommendations made by the Committee, the one recommending enhanced maximum punitive action for manufacture or sale of spurious drug from life imprisonment to death penalty has attracted greater attention. But, in arriving at this recommendation the Committee has noted that there is a discernible trend of organised crime taking over the manufacture and sale of counterfeit and spurious medicines and that so far not a single prosecution has resulted in life imprisonment. The committee felt that only an enhanced punishment can serve as a deterrent and instill fear among offenders.

According to the Report, interestingly, there is no mention of spurious drug offences in the Indian Penal Code. Also, the existing provisions are bailable and cognizable and are not in consonance with the provisions of the drugs and cosmetics act. It has been recommended that manufacture and sale of counterfeit drugs be made non-bailable and cognizable.

The Committee noted that most of the cases relating to spurious drugs remained undecided for years and has suggested a separate provision for speedy trials of such offences. Even though the menace of fake drugs has been around for decades and is widespread in the country, it is indeed startling that there is no authentic data on the extent of the problem. The Committee in one of its recommendations noted that there

was a great need to train officers enforcing the drug laws.

Spurious drugs are global phenomena with inter-state and transnational ramifications and CBI has acquired expertise in investigation of such cases.

In this context, I would recall that we registered a case in 2006 against a notorious spurious drug counterfeiter and our officers seized a huge quantity of spurious medicines, which included products of multinational companies like Glaxo Smithkline and Alkem. The case is currently under trial.

The Association of Indian Drug Manufacturers may also like to partner with Law Enforcement Agencies of the States and the Center to address this menace as otherwise it can tarnish the image of the industry as India is one of the major exporters of Medicinal Drugs to Asian and African countries.

To conclude, I once again like to express my sincere appreciation to INTERPOL for taking measures not only to ensure Capacity Building of member countries in this highly specialized area but also to enhance coordination in promoting international cooperation in countering organized illegal trade in spurious medicines. With these words, I formally inaugurate this training programme and wish it a grand success.

****