

SPEECH OF THE DIRECTOR, CBI ON THE OCCASION OF 1st INDO-FRENCH WORKSHOP ON 'COMBATING COUNTERFEIT MEDICINE'

June 23, 2015 at CBI HQ, New Delhi

Ladies and Gentlemen,

I feel privileged to welcome you all to this two days Workshop on Combating Counterfeit Medicine. This is a first such workshop being organised in collaboration with the esteemed French Embassy, Institute of Research Against Counterfeit Medicines, France, Central Office against Environmental & Public Health Violations, France and Central Fight Against Harm to the Environment And Public Health (OCLAESP). Summer in Delhi is a bit harsh. But, monsoon is on its way.

2. Two days before, the world celebrated International Day of Yoga, as the United Nations adopted without a vote, a resolution, declaring June 21st as International Day of Yoga, recognizing that Yoga provides a holistic approach to health and well being. Ayurveda is the science and yoga is the practice of the science. India is home to the oldest surviving system of medicine in the world, Ayurveda. Its origins have been traced back more than 5000 years. Maharishi Charak has described Ayurveda as an eternal science.

3. Drugs play a crucial role in saving lives, restoring health, preventing diseases and epidemics. When drug itself is counterfeit, it poses danger to the life of the patient.

4. Counterfeit drugs often contain the wrong amount of active ingredient . too little, too much or none at all . posing a major health risk. Fake drugs can kill, therefore the fight against pharmaceutical crime is crucial to protect global public health and safety.

5. Counterfeit medicines are difficult to detect. No region or country is immune from this problem. Apart from the very real direct dangers presented by the consumption of fraudulent medicines or use of fake medical devices there is also evidence showing that the trade in such products has over time become an important source of income for organized crime groupings . be they informal networks or the more traditional organized crime groups. These criminal networks are involved in all types of pharmaceutical crimes, such as falsifying, diverting, stealing or illicitly selling medicines over the Internet. According to an INTERPOL Report released in July, 2014,two types of Organised Criminal Groups seem to dominate this crime area: Highly organized, yet generally informal, international affiliate networks selling medicines via illicit online pharmacies as well as Small groups, not yet well established, of between 3-10 members, involved in various aspects of pharmaceutical crime.

6. The counterfeit medicine scenario the world over is alarming. According to an estimate of INTERPOL fake medicine kill more people in an year than those who have died in the past 40 years as a result of terrorism. Though the ramifications of this menace is worldwide but more pronounced in developing and under developed nations.

7. Large amounts of money are involved in these transnational criminal enterprises. For example, one illicit online pharmacy network, which was dismantled by US authorities in 2011, managed to earn USD 55 million during two years of operations.

8. Counterfeiting has become a global problem which now has attracted due attention of people from medical profession, Drug Enforcement Agencies and Law Enforcement Agencies like Customs and Police. Counterfeiters, who run this deadly trade undercover, use sophisticated technologies and tools and are well equipped.

9. Responding to the growing public health crisis of counterfeit drugs, in February 2006, many stakeholders, including the World Health Organization, launched the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). The taskforce, created in 2006, has been active in forging international collaboration to seek global solutions to this global challenge and in raising awareness of the dangers of counterfeit medical products.

10. Due to dire consequences on public health in view of circulation of spurious drugs, under the aegis of Central Drugs Standard Control Organisation, a systematic study was carried out to assess actual extent of spurious drug circulation in India. It was concluded that the extent of spurious drug in retail pharmacy is only 0.046 %.

11. Though the problem in India has not reached an alarming proportion, nevertheless we cannot ignore this global menace, which is slowly taking the shape of a transnational organised crime. Reputed brands are counterfeited and even exported by criminals. Most of these exports are to third world countries. The danger lies in not only the health risk involved to those people who are administered the medicines but also the reputation of the brand, as well as the country exporting the drug which takes a beating. Thus, counterfeit medicines also affect a country's economy.

12. To make the Drugs & Cosmetic Act, 1940 more stringent and in tune with the changing scenario, the Government of India had set up an Expert Committee under the Chairmanship of Dr. R.A. Mashelkar, the then DG (CSIR) in February, 2003 to recommend measures for strengthening the drug regulatory system in the country as well as tackling the problem of spurious drugs. The Committee which submitted its report in November, 2003 had recommended several changes in the penal provisions of the Drugs & Cosmetics Act. Consequent upon the recommendations given by the Mashelkar Committee, a bill was passed in both the houses of Parliament which had been notified as The Drugs and Cosmetics (Amendment) Act, 2008.

13. Drugs, Pharmaceuticals and Fine Chemicals have been the Fifth largest exported principal commodity from India accounting for 4.8% of India's Total Exports. In line with last two decades India's Pharmaceutical Industry, has achieved a positive trade balance and the initial estimates puts it around USD 9.0 to 10.0 billion.

14. As per the latest periodic statistics released by Director General of Commercial Intelligence & Statistics (DGCIS), Kolkata, India's Exports of Drugs, Pharmaceuticals for the period April 2013 to March 2014 stood at USD 15,045 million recording a growth rate 2.5%. USA remains the top export destination with a share of 26.73 % amounting to \$ 4022 million and a growth of 7.9%. Among the top 25 destination countries, exports to Ethiopia, Uganda & Tanzania, have grown exceptionally in comparison to the average growth.

15. It is high time that we pull up our socks and take the issue of counterfeit medicines head-on. INTERPOL's Medical Product Counterfeiting and Pharmaceutical Crime (MPCPC) unit has coordinated a series of transnational operations codenamed Operation Pangea to dismantle the criminal networks behind this form of crime. To effectively tackle this problem requires a united effort, by law enforcement, the private sector, health agencies and most importantly the public. It is only through working together that we can address this growing menace. INTERPOL cooperates

with multiple international and regional organizations, the scientific community, academia and partners from the private sector to tackle all strategic, operational and technical aspects of fighting pharmaceutical crime. INTERPOL has also built a global Single Point of Contact (SPOC) network, with specialized points of contact in health and enforcement units around the world. On a regional level, INTERPOL coordinates the Storm Enforcement Network, which aims to strengthen collaboration in enforcement activities among agencies and key partners to combat pharmaceutical crime in the Asia-Pacific region. It is pertinent to note that INTERPOL and the Health Sciences Authority (HSA) of Singapore have signed a cooperation agreement on investigation and testing training for law enforcement officers battling counterfeit medical products and pharmaceutical crime.

16. The Enforcement Agencies in India, the Federal Drug Control Authorities at the Centre and the States as well as the Customs and Police have to be adequately sensitised. Their capacity is required to augmented, so that they can investigate cases of counterfeit drugs professionally. It is in this background that several agencies of the Govt. of India and the Government of the Republic of France have joined hands to organize this work-shop.

17. I am glad to know this two day event covers almost every aspect of investigation of such offences, be it the relevant legal provisions, Investigation tools, asset recovery methods and tracking online pharmacies of counterfeit drugs have been included in the agenda. I reiterate that any effective action against this activity would require continuous surveillance by the regulators and active co-operation from the Police, Health, Regulatory and Customs officials. International cooperation is another aspect which needs to be addressed due to transnational ramifications of this crime. As designated National Central Bureau of India, CBI is ever willing to assist the agencies of India and abroad in combating transnational crime.

18. I express my sincere gratitude to His Excellency Mr Francois Richier for taking out time to grace the occasion. I am thankful to Mr Wilfrid Roge, Director (Training) Institute of Research against Counterfeit Medicines, France, Dr GN Singh, the Drug Controller General of India and Mr P.K. Das, Commissioner, Central Excise and Customs for providing the best resource persons for this workshop. I am sure the objectives of this work shop would be fully realized and all of you would be greatly benefitted professionally. With these words, I formally inaugurate this Work-shop and wish it a grand success.

Thank You
