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India to develop blueprint to curb fake drugs

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New Delhi: Imagine if you come to know that the pill you just popped down to get relief from a bad ailment is a fake. The first reaction would be fear followed, of course, by anger and pain. Over a long period of time, the menace of spurious drugs has been a major headache for the union and state governments. However with the Indian media raising giving prominence to the issues in recent times, the government has got serious again about the matter that concerns directly with the health of the masses.

Keeping this in view, the Ministry of Health, Government of India; the World Health Organization (WHO), and the partnership for safe medicine (PSM) have joined hands for international consultation on developing blueprint to combat spurious drugs with use of technology. This will entail a robust detection and authentication mechanism based on modern technologies to identify genuine quality and safe medicines from spurious and unsafe medicines in the supply chain. Also high on agenda is the prompt action against manufacturers and dealers trading with fake and unsafe medicines and violating existing mandatory standards and provisions of the law under the Drugs & Cosmetics Act, 1940 (amended until 2008).

Visible stepped up efforts!

The decision to collaborate came in the backdrop of an international workshop 'Patient Safety and Drug Detection Technology' held at New Delhi on September 10, 2012. The participating governments and NGOs decided that India will collaborate to find an effective mechanism to ensure patients safety prevail over commercial interest and regain consumer confidence in the existing supply chain. Also highlighted was the need for the use of user-friendly technologies to make detection of spurious medicines in the supply chain.

Participants included key government officials, regulatory bodies and leading civil society groups working in India in the interest of the patients and consumers. Key dignitaries included Shri P K Pradhan, IAS, secretary to the Government of India, Ministry of Health and Family Welfare; Dr Jagdish Prasad, director general of health services, Government of India; Shri C P Singh, IAS, chairman, National Pharmaceutical Pricing Authority (NPPA), India.

Other dignitaries included Dr Arun Kumar Panda, joint secretary to the Ministry of Health and Family Welfare, Government of India; Dr Nata Menabde, WHO Representative to India; Dr Michael Deats (WHO HQ) and Dr Madhur Gupta, (WHO India Country Office); Dr G N Singh, Drug Controller General of India; Mr Anil Rajput, chairman, FICCI CASCADE. Shri Sudip

Bandyopadhyay, Hon'ble Minister of State for Health and Family Welfare, Government of India, who was the chief guest at the event, inaugurated the workshop.

"The partners will work closely to develop a blueprint with a specific timeline to design a strategy to implement the use of detection and authentication technologies to make spurious and unsafe medicines
easily detectable and take prompt action against all such manufacturers who violate the laws and standards of our country by working closely with the State Regulators and law enforcers," said Mr Bejon Misra, founder director, Partnership for Safe Medicines (PSM) India.

Mr Jeffrey Gren, director, office of health and consumer goods, US Department of Commerce, said that, "No doubt technology can play a major role to track and trace the menace of spurious drugs but the need of the hour is to evolve a more holistic approach that ensures involvement of all stakeholders in the supply chain."

WHO clarifies on media reports

Denying that it had ever released a report on the spurious drugs in India, the WHO made it clear that no survey has been carried out by it. The denial came after the issue was repeatedly highlighted by various speakers at the international workshop. A section of Indian press had earlier reported while quoting WHO, that the spurious drugs in India stood somewhere between 35 percent-to-40 percent of the total available medicines in the market.

Dr Madhur Gupta, representative, WHO India Country Office while reacting to the same commented, "WHO has not issued any such figure on Indian spurious drugs and that infact is not possible without an extensive survey. The clarification in this regard has been communicated to the ministry of health."

Although there are contradictory reports on the fake drugs, there is no consensus at the mechanism to tackle the menace. Therefore WHO is working closely with the government on host of issues such as GMP, Audits and other things. After the Mashelkar committee report, now the Tandon committee report has also pointed out that there is no authentic figure on the number of manufacturing labs and something requires to be done on that front." added Dr Gupta.

The various officials of health ministry, government of India, World Health Organization and Partnership for Safe Medicine (PSM) have called the figure as misleading and creating a bad name for the nation internationally.

Earlier a countrywide survey had been done by the Central Drug Standards Control Organization (CDSCO) in 2008-09 based on statistical methodology of determining the sample size advised by Indian Statistical Institute, Hyderabad. Dr D Roy, deputy drug controller general of India, said, "Data generated on the legal samples drawn by drug inspectors throughout India above shows the extent of spurious drugs vary between 0.3 percent-to-0.4 percent. A survey funded by WHO & carried out by SEARPharm Forum in 2007 showed 3.1 percent counterfeit suspects during visual inspection but 0.3 percent did not meet the pharmacopia standards during lab analysis."

Setting the things right!

Various stakeholders agree on the need to develop a common framework under which such drugs can be studied in detail and also bringing clarity on the definition of spurious, which will be acceptable globally. The increased use of the internet worldwide has indeed been providing an anonymous marketplace for criminal counterfeiters trading and advertising spurious medicine. It is also alleged that a few countries were illegally using brand India to market such drugs overseas in their own interest. Experts caution that unless checked this could undermine the image and credibility of the pharmaceutical manufacturing companies, especially the small and medium scale companies, who are the biggest contributor to low cost medicines, not only in India but across the world.

PSM India also will be conducting a study in the coming months by engaging with all the stakeholders, especially Government of India on making a comprehensive report on the level of spurious medicines in supply chain in India. This will be based on an agreed methodology arrived at and outlined by former president of India, Dr AP J Abdul Kalam at an event on October 03, 2011, organized by PSM India.

Acknowledging that the laws in India were adequate to deal with counterfeiters, officials were of the view that the regulators and industry needed to work in tandem to safeguard public health by availing latest technologies that facilitate consumers to make informed choice and access to quality medicine. Current technologies available to detect spurious medicines include serialization, non-clonable packaging and 2 D barcoding to name a few.

For its part, Government of India has demonstrated its commitment within the framework of World Health Organization and has started upgrading the capacity of the State Governments by equipping the State Drug Testing Laboratories with modern technology and latest rapid testing equipments. It has also considered giving price advantage to companies if they make their

technology public beyond the 74 medicines notified in the DPCO that are subject to bar coding and regulatory tracing and tracking system.

The drug controller general of India, Dr G N Singh also pointed out to BioSpectrum that there is a need for a much bigger survey involving the civil society and the other agencies for finding the exact percentage of the spurious drugs. "CDSCO is working on various new initiatives and we will surely take some concrete measures in the coming months." added Dr Singh.

It is highly imperative for the authorities at helm to realize the seriousness of an issue that is a matter of life and death for patients on deathbed. Therefore sending a strong message to those who indulge in counterfeit drugs is necessary and for giving teeth to enforcement laws is a must.