8th July, 2014

First WHO- CDSCO International Workshop

WHO- CDSCO International Workshop on Reviewing Good Regulatory Practices for National Regulatory Authorities (8 – 10 July 2014)

The World Health Organization (WHO) along with the Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Government of India organized the first workshop on reviewing Good Regulatory Practices (GRP) in the area of regulation of health products and technologies.

Being held with the technical support of regulators from both developed and developing countries, the workshop is scheduled to take place in New Delhi from 8-10 July 2014.

The increase in number of central drug inspectors from 12 in 2008 to around 200 in 2014 conveys the strong commitment of the Indian government to ensure the quality of medicines" added Dr Arun Kumar Panda, Joint Secretary, Ministry of Health and Family Welfare emphasizing the importance of quality of drugs and this workshop.

"Access to essential medicines can be improved by improving the quality of API and the finished pharmaceutical products. Indian pharmaceutical industry being a forerunner in terms of volume and value globally has the responsibility to ensure the quality and efficacy of all medicines manufactured in the country", said Dr G N Singh, Drugs Controller General of India (DCGI).

Speaking about the importance of the workshop, Dr Nata Menabde, WHO Representative to India said, "The deliberations are aimed at developing a road map for the WHO GRP strategy, which will help strengthen NRAs." "The workshop is expected to improve the skills set of the NRA staff in reviewing the good regulatory practices in the regulatory systems of India, Indonesia, Mexico, France, Australia and China," she added.

"The aspect of affordability and access of medicinal products, transparency of drug regulatory authorities and flexible regulatory framework, among other issues would be deliberated in this GRP workshop", said Mr Lahouari Belgharbi, Group Leader, Regulatory System Strengthening, WHO Geneva.

The discussions in the workshop are expected to pave the way for developing the first draft of WHO Guideline on GRP, which would be reviewed and endorsed for submission to WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECPS) and Expert Committee on Biological Standardization (ECBS).

The WHO Country Office for India has developed a GRP toolkit for perusal of drug regulatory authorities participating in the workshop. The GRP Toolkit is a one-stop reference source for quality control assurance tools (QC/QA) of all key WHO guidelines for pharmaceuticals, vaccines, medical devices, diagnostics and others. The toolkit would also serve as a ready reckoner for international standards on quality, safety and efficacy of medicines.

The workshop is being attended by the international team of experts from WHO and regulatory agencies of developed and developing countries. Key officials from the central and state drug regulatory authorities in India (CDSCO) and its affiliated institutions, including drug testing laboratories and state drug controllers, participated in the deliberations.