

## MHRA signs MoU with CDSCO

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The Medicines and Healthcare products Regulatory Agency (MHRA) has signed a Memorandum of Understanding (MOU) with Central Drugs Standard Control Organisation (CDSCO) in India. This agreement will increase collaboration between the two countries in the area of medicines and medical devices with the aim of further improving public safety in the two countries.

This is the first MOU agreed with CDSCO, part of the Ministry of Health and Family Welfare of Republic of India and was signed by Dr Gyanendra Nath Singh, India's Drugs Controller General, and MHRA chairman, Professor Sir Michael Rawlins. It provides a formal agreement between the two organizations, and strengthens relations between the UK and Indian governments.

The central understandings of the agreement include promotion of each other's regulatory frameworks, requirements and processes. Significant outcomes will include the facilitation and exchange of information and opportunities for technical cooperation of mutual benefit, helping to ensure the regulators are better equipped to protect the health of their respective publics.

MHRA chairman, Professor Sir Michael Rawlins said, "We are committed to protecting the health of UK citizens and that's why we are continuing to formalize our collaborative efforts with key partners like India. We operate in a global environment and agreements such as these serve to further strengthen our ability to promote good practices and we look forward to working even closer with our Indian counterparts."

Dr Gyanendra Nath Singh said, "The MoU signed between MHRA and CDSCO is going to create a new platform where patients will be given utmost importance. Quality medicine, affordability and transparency will be the tools for making medicines available to the people of the two nations."

In 2014, MHRA carried out more than 550 inspections in the UK and 125 in non-EU countries, 49 of which were in India. The

India Brand Equity Foundation states that the Indian pharma sector accounts for about 2.4 percent of the global pharma industry and is the third largest in terms of volume.

Approximately 25 percent of UK medicines are made in India and each batch is tested on importation to ensure it is safe, of good quality and effective and it is important that MHRA assessors continue to inspect Indian sites to ensure Good Manufacturing Practice - a globally recognised regulatory framework.

Sir Michael Rawlins added, "It's essential that the commitment to good quality manufacturing comes right down from the top levels of management to those on the factory floor, and throughout the entire industry. Indian firms already accept and understand this, and the MOU is part of a concerted effort to ensure the UK and wider global public continue to have access to quality and safe medicines."

The signing of the MOU took place at CDSCO's headquarters in New Delhi and was followed by a series of meetings to discuss next steps.