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Cabinet approves MoU with UK for medical product regulation

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It would facilitate better understanding of the regulatory aspects between the two sides



The Union Cabinet, chaired by the Prime Minister Narendra Modi, has given its approval for signing a Memorandum of Understanding (MoU) between the Central Drugs Standard Control Organisation (CDSCO), India and the United Kingdom Medicines and Healthcare Products Regulatory Agency (UK MHRA) on cooperation in the field of medical product regulation.

The MoU will help in establishing a framework for fruitful cooperation and exchange of information between CDSCO and UK MHRA of United Kingdom in matters relating to Medical products regulation in line with their international responsibilities.

The main areas of cooperation between the two regulatory authorities include the following:

a) Exchange of safety information, including Pharmacovigilance where there is a particular safety concern related to the other party. This includes safety concerns relating to medicines and medical devices.

b) Participation in scientific and practical conferences, symposia, seminars and fora organised by India and the United Kingdom.

c) Exchange of information and cooperation on Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) and Good Pharmacovigilance Practices (GPvP).

d) Capacity building in mutually agreed areas.

e) Promote an understanding between the Parties of each other's regulatory framework, requirements and processes; and to facilitate future regulatory strengthening initiatives for both Parties.

f) Exchange of information on laws and regulations regarding medicines and medical devices.

g) Information exchange to support efforts to control unlicensed exports and imports.

h) Coordination at the international fora.

It would facilitate better understanding of the regulatory aspects between the two sides and could help in increased cooperation in the field of medical products regulation and better coordination in international fora.