Next Generation Policy for MDMA in Canada: A Regulatory Roadmap for Medical-Use Ecstasy

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Ecstasy (3,4-methylenedioxymethamphetamine (MDMA)) has a relatively low harm and low dependence liability. It is currently scheduled as an illegal in many jurisdictions. compound. It was first synthesized and patented by Merck in 1912 and is currently not covered by a patent. Before MDMA acquired its illegal status in the US in 1985, it was used by several dozen psychotherapists who believed it to be a valuable and effective neuroscience tool to augment the psychotherapeutic process. MDMA is legally controlled in most of the world under the UN Convention on Psychotropic Substances and other international agreements, although exceptions exist for research and limited medical use. In Canada, MDMA is listed as a Schedule 1 drug under the *Controlled Drugs and Substances Act* as it is an analogue of amphetamine.

However, in January 2022, the Government of Canada amended regulations to include MDMA (and other compounds) in the Special Access Program for drugs in instances when other therapies have failed, are unsuitable, or are unavailable in Canada. The Canadian Government stated: "*Given the growing scientific interest in certain restricted drugs, it is expected that Health Canada would eventually encounter a situation where scientific evidence supports the therapeutic use of a restricted drug within the context of the Special Access Program*." As a result, there is forming a novel regulatory roadmap for medical use MDMA in Canada. This will position Canada at the forefront of novel therapies using MDMA. This paper will outline the history, medical use value and regulatory options for MDMA in Canada. A detailed outline of first North America commercial legal cGMP value-chain for MDMA will be presented.