Promoting Illicit Drug Prevention Initiatives Nationally

September 2020

Therapeutic Goods Administration
PO Box 100,
Woden ACT 2606

Public Submission proposed amendments to Poisons Standards

PROPOSED NEW ENTRY IN POISONS STANDARD -
MDMA

Drug Free Australia notes that the Therapeutic Goods Administration (TGA) plans to weigh up the purported benefits of legalising the active ingredients in ecstasy and magic mushrooms, MDMA, for mental health treatment.

We would therefore like to bring to the attention of the TGA that Phase III studies in the United States are randomized controlled multicenter trials, on large patient groups (300–3,000 or more, depending upon the disease/medical condition studied) and are aimed at being the definitive assessment of how effective the drug is, in comparison with current 'gold standard' treatment.

It may be a requirement, due to the fact that MDMA has been listed as a dangerous illegal drug, that there would be at least two successful Phase III trials, demonstrating a drug's safety and efficacy, in order to obtain approval from the appropriate regulatory agencies such as FDA (US), or the EMA (European Union).

Once a drug has proved satisfactory after Phase III trials, the trial results are usually combined into a large document containing a comprehensive description of the methods and results of human and animal studies, manufacturing procedures, formulation details, and shelf life. This collection of information makes up the "regulatory submission" that is provided for review to the appropriate regulatory authorities in different countries. They will review the submission, and if it is acceptable, give the sponsor approval to market the drug.

Most drugs undergoing Phase III clinical trials can be marketed under FDA norms, with proper recommendations and guidelines through a New Drug Application (NDA) containing all manufacturing, preclinical, and clinical data. In case of any adverse effects being reported anywhere, the drugs need to be recalled immediately from the market. While most pharmaceutical companies refrain from this practice, it is not abnormal to see many drugs undergoing Phase III clinical trials in the market.

There is clear evidence that because of the addictive nature and history of MDMA the Therapeutic Goods Administration should delay changing the Schedule 4 MDMA down to a Schedule 3 substance.

Please note that harmful effects discovered by Phase IV trials may result in a drug being no longer sold, or restricted to certain uses; examples include cerivastatin (brand names Baycol and Lipobay), troglitazone (Rezulin) and rofecoxib (Vioxx).

A Phase IV trial is also known as post-marketing surveillance trial, or informally as a confirmatory trial. Phase IV trials involve the safety surveillance (pharmacovigilance) and ongoing technical support of a drug after it receives permission to be sold (e.g. after approval under the FDA Accelerated Approval Program). Phase IV studies may be required by regulatory authorities or may be undertaken by the sponsoring company for competitive (finding a new market for the drug) or other reasons (for example, the drug may not have been tested for interactions with other drugs, or on certain population groups such as pregnant women, who are unlikely to subject themselves to trials). The safety surveillance is designed to detect any rare or long-term adverse effects over a much larger patient population and longer time period than was possible during the Phase I-III clinical trials.

Drug Free Australia supports The College of Psychiatrists that gave the warning that there is not enough evidence these drugs are safe. During the present COVID-19 virus the Federal Government and all State Chief Medical Officers have made it crystal clear that they will use all means necessary to protect the safety of the Australian community.

Therefore Drug Free Australia sees the urgent need to bring to your attention this very important research.

Yours sincerely

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