REQUEST FOR SALES DATA
MEPROBAMATE-CONTAINING MEDICINES

INTRODUCTION

The South African Health Products Regulatory Authority is concerned about the potential misuse and abuse of meprobamate-containing preparations in South Africa. According to the International Narcotic Control Board (INCB) drug use statistics, South Africa is the third largest user of meprobamate globally. This high usage is attributed to the irrational prescribing and use of meprobamate-containing analgesics, not the use of meprobamate as a sedative/hypnotic.

Additionally, data provided by the South African Police Service (SAPS) shows a large quantity of meprobamate-containing medicines being found and confiscated during random seizures.

Globally, there is a trend towards banning meprobamate-containing medicines. The European Medicines Agency (EMA) suspended all marketing authorisations for meprobamate-containing oral medicines due to the serious side effects associated with the medicines, in 2016.

SOUTH AFRICAN APPROACH

The South African Health Products Regulatory Authority (SAHPRA) is currently in the process of reviewing the scheduling status of meprobamate and meprobamate-containing medicines.
There is a paucity of data on the sale of meprobamate-containing medicines at all levels of the supply chain i.e. manufacture, wholesale, distributor, retail.

In terms of Section 19(2) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965),

(2) "*The Authority may by notice in writing require any person who manufactures or sells medicines, medical devices or IVDs or administers or prescribes any medicine, medical devices or IVDs or on whose direction any medicine is administered to furnish it, within a period stipulated in such notice, with any information which such person has in his or her possession or which such person is in a position to obtain regarding such medicine, medical device or IVD.*"

In order to inform further regulatory steps, SAHPRA therefore requests all manufacturers to submit sales data (domestic, import and export) of all meprobamate-containing preparations for the time period January 2018 to date, within 60 days from publication of this notice. Information submitted should include the date; registration number; proprietary name of medicine; dosage form; quantity sold; purchaser's name; and purchaser's address, on the template, accessible here

Consolidated sales data should be submitted to Ms Momeena Omarjee at momeena.omarjee@sahpra.org.za.

MS P NKAMBULE
ACTING CHIEF EXECUTIVE OFFICER