REQUEST FOR SALES DATA
CODEINE-CONTAINING MEDICINES

INTRODUCTION

There is widespread abuse of codeine-containing preparations nationally and globally. In South Africa and neighbouring countries, the abuse of codeine-containing cough preparations specifically amongst the youth, is concerning. These preparations are available without a prescription in South Africa, whilst most neighbouring countries have either banned codeine-containing cough medicines or up-scheduled all codeine-containing medicines to prescription-only status.
It is alleged that the cough preparations registered and available OTC in South Africa are finding their way, illicitly, onto the market in neighbouring countries. This is despite the fact that the current Schedules assign Schedule 6 status to all codeine-containing medicines intended for export.

Globally, there is also a trend towards up-scheduling codeine to prescription-only status, on the basis that there are safer, more effective alternative products available over-the-counter which do not contain codeine, and many non-drug options to manage pain. It is also noted that there are also several over-the-counter medicines available for treating cough, cold and flu symptoms which do not contain codeine. Research has shown that current over-the-counter low-dose codeine-containing medicines for pain relief offer very little additional benefit but high health risks, when compared to similar medicines without codeine.

SOUTH AFRICAN APPROACH

The South African Health Products Regulatory Authority (SAHPRA) is currently in the process of reviewing the schedule status of codeine and codeine-containing medicines.

There is a paucity of data on the sale of codeine-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 future regulatory steps, SAHPRA therefore requests manufacturers, wholesalers and distributors to submit sales data (domestic, import and export) of all codeine-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