



CODEINE CARE INITIATIVE

INTRODUCTION

There is widespread concern about the 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 prescription in South Africa, whilst most neighbouring countries have either banned codeine-containing cough medicines or up-scheduled 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, despite the current schedules making such export subject to Schedule 6 restrictions.

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.

On the basis of the above, the South African Health Products Regulatory Authority (SAHPRA) is currently in the process of reviewing the scheduling status of codeine and codeine-containing medicines.

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SAHPRA has noted and takes cognisance of the opinion and comments of industry on the most effective method to control access to codeine-containing medicines. Up-scheduling codeine is likely to be inadequate to address the abuse problem in its entirety. Persons who are currently misusing, overusing or abusing codeine are unlikely to change behaviour and use, based only a scheduling change. Scheduling would also not address the potential diversion of codeine-containing medicines from regulated distribution channels.

Industry, through various associations, has previously proposed a Codeine Care Initiative (CCI) as a tool to identify and curb the illicit abuse of codeine-containing products.

SAHPRA RECOMMENDATION

SAHPRA, through previous industry engagement, has reviewed and highlighted concerns with the initial proposal of the Codeine Care Initiative. Areas of concern highlighted were:

- the requirement for purchasers to submit information not required in terms of the existing law;
- the reliance on identity documents, which some legitimate purchasers may not have at hand or be in possession of;
- potential breaches of the Protection of Personal Information Act (No. 4 of 2013);
- the inability to include licensed sellers other than community pharmacies that are connected electronically; and
- the ability of the Initiative to address diversion from regulated channels.

SAHPRA therefore invites the various industry and professional associations to submit proposals for the amendment and strengthening of the intervention and to make legally enforceable proposals regarding alternatives to re-scheduling codeine to prescription-only status.

Input to be provided to Ms Momeena Omarjee at momeena.omarjee@sahpra.org.za by the 29 February 2020.

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