

17 November 2011

Dear Colleague,

This communication is a follow-up on my previous letter in October 2011.

You would have seen numerous media reports regarding the latest court ruling on the issue of the sale of Dextropropoxyphene (DPP)-containing medicines by the Company. The court has re-instated the 'Dear Healthcare Professional' Letter issued by the Medicines Control Council (MCC) on 28 September 2011, withdrawing DPP-containing products from the market in South Africa. As a response, the Company is immediately suspending the sale of products containing DPP pending the outcome of the appeal process.

In the best interests of patients requiring analgesia, we have called on the Department of Health to expedite the appeal committee process into the review of products containing DPP. We believe that this appeal process remains the most competent channel in resolving any arguments for, or against, the continued availability of products containing DPP and that an expedited process is in the best interests of all parties involved. Critical to this is an understanding that no scientific evidence exists to substantiate potential risks surrounding the continued sale and use of these products.

We reject in the strongest possible terms any arguments that DPP-containing products are so called "killer drugs" and fervently maintain that an accelerated MCC appeal process will correctly position the available scientific data in support of these objections.

Adcock Ingram maintains that the study used by the MCC as the basis for its actions is not credible enough to substantiate its actions in respect of DPP-containing products as this study made use of a single non-representative sample of six patients. We replicated the study conducted by the FDA through an independent CRO, but with increased patient numbers, in order to fully outline the suspected risks with Synap Forte, the results of which did not detect any negative medical signals, and were comparable to placebo.

DPP products remain in use in both the UK and Europe with tighter controls on scheduling and availability. These conditions already exist in South Africa.

In addition to this, we have clinical and epidemiological data that supports the safety of our DPP-containing products. These products have been used safely for over 30 years and are still used in 39 countries and DPP use in South Africa represents less than 1 % of global use by value, according to IMS.

It is important to note that DPP containing drugs tested overseas are not the same formulation as those used in South Africa. Critically, there is no evidence of cardiotoxicity in SA safety data.

Given the fact that the court has re-instated the MCC's 'Dear Healthcare Professional' Letter dated 28 September, 2011 which stated that all DPP- containing products be withdrawn from the market in South Africa over a three-month period to allow time for the transfer of patients to appropriate alternative therapies, healthcare professionals should therefore:

- Stop prescribing and dispensing dextropropoxyphene-containing products to patients in a phased-out process
- Discuss alternative pain management strategies with patients currently using dextropropoxyphene

Adcock Ingram will uplift all remaining stock of Synap Forte®, Lentogesic® and Doxyfene® by 28 December, 2011.

We place the health of patients at the centre of our business. At no stage would we ever compromise on this ethic.

We will continue to keep you apprised of new developments with dextropropoxyphene, and in particular, Adcock's DPP-containing products, and thank you for your continued support.



**DR AB KHOELE**  
**MEDICAL EXECUTIVE**