MEDICINES CONTROL COUNCIL
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MEDIA RELEASE

October 1, 2004

Withdrawal of Vioxx® (rofecoxib) from the South African Market

The Medicines Control Council (MCC) was informed on 30 September that MSD would voluntarily be withdrawing its product Vioxx® (chemical name rofecoxib) from the South African market as part of a worldwide voluntary withdrawal of the drug.

The main reason for the withdrawal is because results of a study testing Vioxx® over three years showed that after 18 months of continuous use, the risks of heart attack (myocardial infarct or coronary thrombosis) and strokes had increased compared to placebo (non-active medication).

Vioxx® is mostly used in the treatment of arthritis.

Although the MCC has not yet itself had the opportunity to assess the data on which this decision was made, it supports MSD's decision to withdraw the drug from the market for safety reasons. Once the MCC has fully assessed the data, MSD will be notified should any further action be required.

The risk that an individual patient will suffer a heart attack or stroke as a result of taking Vioxx appears to be very small, but any patient who already has cardiovascular problems and is taking this medication should consult their doctors without delay. As Vioxx will no longer be available, the MCC encourages all people taking Vioxx to contact their doctors for advice on how to discontinue the use of Vioxx, and for information on what other options are available to them. In addition, patients are encouraged to make use of the special call centre set up by MSD for enquiries from patients and doctors. This number is 0800-003-576 .

Any person who has experienced an adverse reaction to Vioxx® is encouraged to ask their doctor to report this to the National Adverse Drug Events Monitoring Centre in Cape Town, on Tel: 021-447-1618.