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31 July 2015

Dear Health Care Professional

## Class I

Class I is for defective/dangerous/potentially lifethreatening medicines that predictably or probably could result into serious health risk/adverse events or even death.

## Type B

A type B recall is designed to reach wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorised prescribers and dispensers.

## **URGENT MEDICINE RECALL**

Class: I

Type: B

We hereby inform you that we are recalling the following batch of Lethyl 30 mg Tablets:

Product	Reg. Number	Pack size	Batch Number	Expiry Date
Lethyl 30mg Tablets	B1163 Act 101 of 1965	1000's	A846868	10/2016

This recall is initiated as a result of a product quality complaint logged with Aspen Pharmacare due to the discoloration of Lethyl 30 mg Tablets. During the investigation of the complaint, additional samples obtained within the market were subjected to testing and OOS (Out-of-Specification) microbiological results identified the presence of two organisms on the tablets i.e. *Penicillium spp.* and *Chaetomium spp.* 

We request that you immediately return the affected batch of Lethyl 30 mg to your supplying wholesaler or distributor for full credit.

## For further product information or medical queries, please call:

Aspen Pharmacare's Medical Information Line: 0800 118 088

We would like to thank you for your co-operation and apologise for any inconvenience this may have created.

Yours Sincerely,

l orraine Hill

Responsible Pharmacist

NOTE: Kindly retain this letter in a prominent position for one month, in case there is still stock in transit and inform your customers where possible.