Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: **29 August 2022** Our Ref: MDR-010-07-2022-CA

Dear Healthcare Professional,

(Bumetanide 1 mg tablets) **MA084/0040**

Batch Number	Expiry Date	Pack Size	First Distributed
87997	Jun-25	30 tabs	26/08/2020
82806	Jul-24	30 tabs	12/02/2020

Re: Bumetanide 1mg Tablets - Recall

(Marketing Authorisation Number: MA084/00401, Date of first authorization: 15/11/2006)

This is to inform you that following EMA / CMDh Guidelines on nitrosamines, Remedica Ltd performed confirmatory testing for detection of nitrosamine impurities in Bumetanide 1mg Tablets.

The results of the confirmatory testing showed that the n-nitroso-bumetanide was above the acceptable limits (detailed report will be provided as soon as the external laboratory provides it).

Based on the above facts, Remedica Ltd decided to proceed with recall of batches of Bumetanide 1mg Tablets that have not expired yet.

Recall Category: II

Possibility to cause temporary or medically reversible health damage.

Level: 2

From wholesales, representatives, hospitals, pharmacies and any other places of sale.

The MAH (Vivian Corporation) has already been informed and they will proceed with all relevant actions.

Yours faithfully

ChristopherAttard

Medicines Authority Distribution (if applicable):
Licensing Authority
Superintendent of Public Health