

URGENT MEDICINE RECALL

Code	English Name	PIN YIN	ARTG number	Pack size	Batch
164 164C	Ginseng, Ophiopogon & Schizandra	Sheng Mai San	11705	50g bottle 200 pills bottle	All batches within expiry
172 172C	Gastrodia & Gambir Combination	Tian Ma Gou Teng Wan	351363	50g bottle 200 pills bottle	All batches within expiry

Sponsor Ref: RC0012024

TGA Ref: RC-2024-RN-01007-1

Date: 08/11/2024

Dear [recipient],

Following consultation with the Therapeutic Goods Administration (TGA), Cathay Herbal Laboratories is undertaking a Consumer Level Recall of the above product/s. We are contacting you as our records indicate the potentially affected product has been supplied to your organisation.

ISSUE	<ul style="list-style-type: none">When taken at the recommended dose on the label of 24 pills per day, the daily lead exposure from Tian Ma Gou Teng Wan-(Gastrodia & Gambir Combination) and SHENG MAI SAN - [Ginseng, Ophiopogon & Schizandra Formula] is well above the permitted daily exposure (PDE) limit for lead of 5 mcg.
HAZARD	<ul style="list-style-type: none">Long-term use may cause elevated blood lead levels. When taken at or above the dosage stated on the product label, there is a potential for consumption of higher than acceptable levels of lead. Exposure to high levels of lead can result in a range of adverse effects depending on how much lead has been consumed and for how long. This can include high blood lead levels with no obvious symptoms, up to lead poisoning after higher or longer exposure. Pregnant women and children are at a greater level of risk from lead poisoning.

<p>INSTRUCTIONS FOR USERS</p>	<p><u>Distributors:</u></p> <ul style="list-style-type: none"> Inspect inventory and quarantine any remaining stock of the products listed above. Cathay Herbal Laboratories will contact you to arrange return of stock. Ensure any customers who have been supplied stock from this batch are made aware of this recall by providing them a copy of this letter. <p><u>Retailers/Practitioners:</u></p> <ul style="list-style-type: none"> Please inspect your stock and quarantine any units of the affected products. Complete the supplied Acknowledgement Form and return in order to arrange for affected stock to be recovered and a credit note issued. Please complete this form even if you do not have any stock which is subject to this recall as Cathay Herbal Laboratories still requires this information in order to reconcile this process. Ensure any customers who have been supplied stock from this batch are made aware of this recall by providing them a copy of this letter. <p>Consumers:</p> <p>Please check your product to identify if you have an affected batch and immediately stop using the product. Return the product to the place of purchase for a refund.</p> <p>If any of the affected stock has been transferred from your facility to another location, immediately inform the other location of this recall by providing a copy of this letter and advise them to contact Cathay Herbal Laboratories on +61 2 8345 6588 to return the product.</p>
<p>CONTACT INFORMATION</p>	<p>For questions regarding this letter, please contact:</p> <p>+61 2 8345 6588 - Robert Que</p> <p>robert@cathayherbal.com</p>

We apologise for any inconvenience caused to your organisation.

Kind Regards,

Robert Que

Customer acknowledgement form

Please complete this form *even if you do not have any affected stock.*

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Affected product/s on the list below supplied by [Cathay Herbal Laboratories Pty Ltd.]

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On behalf of this organisation I acknowledge receipt of the Urgent Medicine Recall notice date [08/11/2024] relating to the above product.

FROM:

Organisation	
Position	
Name	
Email or fax no.	
Telephone no.	
Date	
Signature	

Affected Stock

If you have **no affected** stock, tick this box:

If you have affected stock, please complete the stock details table below.

Product	Batch/Lot/Date	Quantity of stock received	Quantity of unused stock subject to recall (currently in quarantine)

Total affected product			
Other Relevant Details:			

Other organisations

Has your organisation supplied potentially affected product to any other organisation?

No

Yes I/we will forward all the recall information to the suppliers/distributors/customers

OR

Yes (please supply names and contact information of the organisations)

Return completed forms by fax or email to:

Name	
Position	
Organisation	
Address	
Email	
Subject of email	[Heading as noted above] of [Product details and description including batch/lot details]
Fax no.	
Telephone no.	