Recall Guidelines for Chinese Medicine Products

Chinese Medicines Board
Chinese Medicine Council of Hong Kong
Compiled in September 2005
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1. **Introduction**

1.1

These guidelines have been prepared by the Chinese Medicines Board (“Medicines Board”) of the Chinese Medicine Council of Hong Kong, to assist the wholesalers of Chinese herbal medicines, the wholesalers of proprietary Chinese medicines, and the manufacturers of proprietary Chinese medicines to set up an efficient system of recall for Chinese medicine products, which will, so far as practicable, enable the rapid recall of any Chinese medicine products sold or distributed by them. In addition, the Medicines Board also wishes that the setting up of a recall system will help to ensure the quality and safety of the Chinese medicine products available in the market, to protect the health of the public and enhance confidence in using Chinese medicines.

1.2

These guidelines do not cover the recall of Chinese medicine products on commercial grounds such as the recall of a product which is about to expire, or which has obtained approval for change to its agent, label, packing or registration particulars.

1.3

These guidelines only provide a guide to recalling Chinese medicine products and do not cover all the details of relevant regulations and practising requirements. For practising requirements for wholesalers and manufacturers, please refer to the “Practising Guidelines for Wholesalers of Chinese Herbal Medicines”, the “Practising Guidelines for Wholesalers of Proprietary Chinese Medicines” and the “Practising Guidelines for Manufacturers of Proprietary Chinese Medicines”, all issued by the Medicines Board. A manufacturer of proprietary Chinese medicines who has obtained the certificate for manufacturer (GMP) may also refer to the “Hong Kong Good Manufacturing Practice for Proprietary Chinese Medicines”.

1.4

Chinese medicines traders should also comply with the Chinese Medicine Ordinance (“the Ordinance”) and its subsidiary legislation. The contents of the relevant provisions shall be subject to the relevant legislation. According to the Ordinance, the Director of Health may, by order in writing for issuance of the Chinese medicine safety
order, do either or both of the following –

(a) prohibit the sale of a Chinese medicine or related product;

(b) direct that a Chinese medicine or related product that has been sold be recalled and specify the way in which, and the period within which, the recall is to be conducted.

The making of a Chinese medicine safety order is in the common interest of the industry, the Government and, in particular, the consumers. While it is an effective and powerful tool to remove from the market any deficient Chinese medicine products, it is always in the best interest of both the trade and the consumers for the relevant traders to suspend the sale or carry out recalls voluntarily. A voluntary recall, which is much more common than a mandatory one in different overseas jurisdictions, is a fundamental way for any responsible trader to ensure that the deficient Chinese medicine product is not consumed.
2. **Interpretation**

“proprietary Chinese medicine”

means, in accordance with the Chinese Medicine Ordinance, any proprietary product:
(a) composed solely of the following as active ingredients:
   (i) any Chinese herbal medicines; or
   (ii) any materials of herbal, animal or mineral origin customarily used by
        the Chinese; or
   (iii) any medicines and materials referred to in subparagraphs (i) and (ii)
        respectively;
(b) formulated in a finished dose form; and
(c) known or claimed to be used for the diagnosis, treatment, prevention or
    alleviation of any disease or any symptom of a disease in human beings, or for
    the regulation of the functional states of human body.

“intermediate product”

means, in accordance with the Chinese Medicines Regulation, a substance or
compound generated in the course of manufacture of a proprietary Chinese medicine
and which is to be used in further preparation or production process of the medicine.

“listed Chinese herbal medicine”

means any of the substances specified in Schedule 1 or Schedule 2 of the Chinese
Medicine Ordinance.

“herbal medicine”

means a “listed Chinese herbal medicine” and any materials of herbal, animal or
mineral origin customarily used by the Chinese for medical treatment.
“Chinese medicine product”

(a) in relation to a wholesaler of Chinese herbal medicines, means a herbal medicine or single Chinese medicine granules for prescription which is sold or distributed by the wholesaler;
(b) in relation to a manufacturer of proprietary Chinese medicines, means a proprietary Chinese medicine or an intermediate product of a proprietary Chinese medicine which is sold or distributed by the manufacturer;
(c) in relation to a wholesaler of proprietary Chinese medicines, means a proprietary Chinese medicine which is sold or distributed by the wholesaler.

“Chinese medicines trader”

means a wholesaler of Chinese herbal medicines, a manufacturer of proprietary Chinese medicines or a wholesaler of proprietary Chinese medicines, as the case may be, who is licensed under the Chinese Medicine Ordinance.

“single Chinese medicine granules for prescription”

means any single Chinese medicine granules manufactured by way of extraction and which are dispensed only on a prescription from a Chinese medicine practitioner.
3. Recall System

3.1

Wholesalers and manufacturers of Chinese medicine products shall, for the purpose of complying with the provisions of the Chinese Medicines Regulation, set up and maintain a recall system. This system will enable the rapid and, so far as practicable, complete recall of any Chinese medicine products sold or distributed by them.

3.2

The recall system should be revised from time to time in the light of the actual situation. In the course of a recall, a wholesaler or a manufacturer should take into consideration practical factors such as its scope of the business, the nature of the Chinese medicine product concerned and the needs of customers as well as changes in relevant conditions and undertake suitable corresponding action.

3.3

The recall system should be clearly set out in writing and notified to the personnel performing a recall. The relevant trader should also inform its personnel concerned of the latest changes to the recall system. A Chinese medicines trader is required to take necessary steps to ensure that the details of the latest recall system are promulgated and that the affected personnel are notified that the arrangement is in place.
4. Responsibility

4.1

The prime responsibilities of a Chinese medicines trader are to decide whether to recall a deficient Chinese medicine product, to assign personnel to carry out a recall, and to determine the scope of a recall, having regard to the danger that the product may cause.

4.2

The Medicines Board will assume a role in communication and coordination in the course of a recall, and it will monitor the recall actions and assess their progress and effectiveness. If necessary, the Medicines Board may discuss recall strategy with the Chinese medicines trader and undertake corresponding action.
5. **Grounds for Recall**

5.1

For a Chinese herbal medicine, there are reasonable grounds to believe that — 

(i) the medicine has been sold or dispensed in contravention of section 109(1) or 111(1) of the Ordinance; 

(ii) the medicine has been sold or distributed in contravention of section 109(2) or 111(2) of the Ordinance; 

(iii) the medicine is dangerous or injurious to health, or unfit for use by human beings; or 

(iv) the recall is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health.

5.2

For a proprietary Chinese medicine, there are reasonable grounds to believe that — 

(i) the medicine has been sold or dispensed in contravention of section 119(1), 143 or 144 of the Ordinance; 

(ii) the medicine has been sold or distributed in contravention of section 134 of the Ordinance; 

(iii) the medicine has been manufactured in contravention of section 131 of the Ordinance; 

(iv) the medicine is dangerous or injurious to health, or unfit for use by human beings; or 

(v) the recall is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health.

5.3

For an intermediate product, there are reasonable grounds to believe that — 

(i) the product is dangerous or injurious to health, or unfit for use by human beings; 

(ii) the recall is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health.
6. Recall Procedures

6.1 – Receipt of Complaints

6.1.1

A Chinese medicines trader should keep on file a record of any complaint received about its Chinese medicine products (including reports on its products of the Medicines Board, such as a test report) alleging that its products are found to be deficient. The records may contain the following information:

(1) Details of the problem
   (i) name, telephone number, facsimile number and email address (if any) of the person reporting the problem;
   (ii) date of report;
   (iii) physical location and nature of the problem;
   (iv) number of similar reports received;
   (v) investigation results and test result of suspected and other samples; and
   (vi) other relevant factors.

(2) Details of the product
   (i) product name and description including batch number, expiry date (if any) and date of manufacture (for proprietary Chinese medicine only);
   (ii) quantity and date of the product released;
   (iii) sales network (e.g. for local sale or for export);
   (iv) number of complaints received;
   (v) registration number or receipt number of application for proprietary Chinese medicines registration (for proprietary Chinese medicine only);
   (vi) contact number, facsimile number and email address (if any) of the manufacturer/supplier.

6.1.2

The Chinese medicines trader should assign or appoint appropriate personnel to handle the complaints and make available to them the details of the complaints.
6.2 – Assessment of Recall

6.2.1

The responsible person as assigned or appointed by the Chinese medicines trader should determine promptly whether or not to initiate a recall after assessing the potential hazard or danger the deficient product may cause to users based on the nature of complaint.

6.2.2

In assessing a deficient product, the responsible person should consider whether the deficient product would, when used by or in contact with human beings, cause short-term, curable or minor health problems to them or cause severe adverse effect on human bodies or even lead to death. The responsible person may seek expert opinion in making this assessment.

6.2.3

The responsible person should classify the recall of a product (an example of “Classification of Recall” is provided at Appendix 1) according to the extent of hazard posed by the product when determining to initiate recall actions as below:

Class 1: when a product is potentially life-threatening, or could cause a serious risk to health;

Class 2: when a deficient product could cause illness or inappropriate treatment, but does not fall within Class 1;

Class 3: when a deficient product may not cause significant hazard to health, but withdrawal may be initiated for other reasons.

6.2.4

When a single batch of a product is found to be deficient, the responsible person should consider whether products of other batches are to be examined, to ascertain if they have been affected.
6.3 – Recall Actions

6.3.1

Once a Chinese medicines trader has decided to initiate recall actions, he should promptly notify the Medicines Board by telephone at 2319 5119 and then inform the Medicines Board of the details of the actions by facsimile (Facsimile number: 2319 2664).

6.3.2

The Chinese medicines trader should deliver a recall notice containing the following information to the Medicines Board (an example of a “Recall Notice” is provided at Appendix 2):

(i) name, position and telephone number or facsimile number of the person responsible for the recall;
(ii) date of complaint first received, and date of decision made to initiate recall actions;
(iii) name, address and telephone number of the complainant (if these can be provided);
(iv) name of the product to be recalled;
(v) registration number or receipt number of application for proprietary Chinese medicines registration of the product to be recalled (for proprietary Chinese medicine only);
(vi) description of the complaint;
(vii) scope of distribution of the product;
(viii) plan and logistics of the recall;
(ix) expected time of completion of recall actions;
(x) “Classification of Recall”; and
(xi) any other relevant information.
6.3.3

The Chinese medicines trader should notify in writing all organizations or parties to which the recalled product has been supplied directly. The notification should be written in the following manner:

(i) be concise and comprehensive;
(ii) clearly specify the name, dose form or type, pack size and batch number (if any) of the product, and any other information which may help to identify the product;
(iii) specify the registration number or receipt number of application for proprietary Chinese medicines registration of the product (for proprietary Chinese medicine only);
(iv) contain a warning for immediate removal of the product from supply or use;
(v) specify the “Classification of Recall” and clearly explain the reason(s) for the recall and the hazard(s) involved (if any);
(vi) suggest that if any of the recalled products could have been re-supplied to another organization, such organization and the manufacturer and/or wholesaler concerned should be notified of the recall;
(vii) explain how the product can be returned to the Chinese medicines trader.

If the Chinese medicines trader considers it necessary, he may make a wider publication of the recall actions (e.g. by making announcements through the media).

6.3.4

The Chinese medicines trader may send personnel to contact the organizations or parties concerned to assist in returning the product to the suppliers;

6.3.5

The Chinese medicines trader should set up telephone and facsimile hotlines to answer enquiries.

6.4 - Supervision of Recall

The relevant Chinese medicines trader should monitor the effectiveness and progress of the recall, to ensure that the deficient product is recalled within the proposed period of time.
6.5 – Recall Report

6.5.1

In the course of a recall, the parties concerned should, upon the request of the Medicines Board, submit an interim report (an example of an “Interim Report” is provided at Appendix 3) to enable the Medicines Board to assess the progress and effectiveness of the recall actions. The interim report should contain the following information:

(i) the number of organizations which have been supplied with the product, and the quantity of the product supplied;
(ii) the quantity of the product recalled;
(iii) the date and method of notification to such organizations;
(iv) the number of organizations which have responded;
(v) the names of those organizations which have not responded; and
(vi) the estimated proposed time schedule for completion of the recall.

6.5.2

On completion of a recall, the Chinese medicines trader should compile a final report (an example of a “Final Report” is provided at Appendix 4) and submit that to the Medicines Board. The final report should contain the following information:

(i) the names of organizations or parties being requested to return the recalled product;
(ii) the quantity of the product distributed;
(iii) the quantity of the product recalled;
(iv) the results of the investigation into the causes of the deficiencies of the product;
(v) their decision(s) on handling the recalled product; and
(vi) the measures to be taken to prevent any recurrence of similar problem(s).

6.5.3

In the course of a recall, the Chinese medicines trader should appropriately handle any commercially sensitive information and personal data. The Chinese medicines trader should also maintain properly the relevant documents and/or records for inspection, when necessary.
7. Conclusion

7.1

These Guidelines are intended to provide assistance to Chinese medicines traders to conduct an effective recall of Chinese medicine products. These Guidelines are subject to amendment in the light of actual experience in operation and changes to the social environment.

7.2

Each recall action is a unique exercise. In preparing a recall strategy, there are a number of factors that need to be considered, including the nature of the problem, the number of complaints received, customer safety, sales or distribution networks, recall procedures and resources.

7.3

The Chinese medicines trader should maintain good communication and cooperation with the Medicines Board, to enable effective and rapid recall of a deficient Chinese medicine product with a view to ensuring the quality and safety of the Chinese medicine products available in the market and to protecting public health.

The Chinese Medicines Board of the Chinese Medicine Council of Hong Kong
April 2018
Appendix 1

Example of “Recall Classification”

The purpose of stating a “Recall Classification” is to foster better understanding among the Chinese medicines traders and between the Chinese medicines traders and the Medicines Board of the seriousness of the problem that gave rise to a recall. According to the extent of hazard posed by a deficient Chinese medicine product, recalls may be generally classified as follows:

Class 1

When a product is potentially life-threatening, or could cause a serious risk to health.

Examples:
- wrong product (its label and ingredients are of a different product)
- right product but of wrong quantities of ingredients, which may result in serious medical consequences
- proprietary Chinese medicine with wrong active ingredients which may result in serious medical consequences.

Class 2

When a deficient product could cause illness or inappropriate treatment, but does not fall within Class 1.

Examples:
- with labelling errors, such as incorrect or incomplete information on the label description
- omission or incorrect information on the package insert
- deviation from the quality specification.

Class 3

When a deficient product may not cause significant hazard to health, but withdrawal may be initiated for other reasons.
Examples:

- with packaging errors, such as mistakes or omissions are found in the batch number or expiry date
- discoloration which does not affect the efficacy of the product or where the seal of the package is damaged.
Appendix 2: Example of “Recall Notice for Chinese Medicine Product”

To: Chinese Medicines Board of the Chinese Medicine Council of Hong Kong
   (Fax Number: 2319 2664)

Our company has decided to initiate the recall of________________________. Details of this recall are as follows:

(1) Details of the Company

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Licence number of Chinese medicines trader:</td>
<td></td>
</tr>
<tr>
<td>(2) Name of Chinese medicines trader:</td>
<td></td>
</tr>
<tr>
<td>(3) Name and position of person responsible for the recall:</td>
<td></td>
</tr>
<tr>
<td>(4) Telephone number:</td>
<td></td>
</tr>
<tr>
<td>(5) Facsimile number:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>E-mail address / website (if any):</td>
</tr>
<tr>
<td>(6) Enquiry hotline (if any):</td>
<td></td>
</tr>
</tbody>
</table>

(2) Background information on the recall

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Date and time of receipt of complaint:</td>
<td></td>
</tr>
<tr>
<td>(2) Details of the organization or person which made the complaint (subject to consent of the complainant):</td>
<td></td>
</tr>
<tr>
<td>(3) Description of complaint:</td>
<td></td>
</tr>
</tbody>
</table>

(1 of 2)
(3) Details of recalled product

<table>
<thead>
<tr>
<th>(1) Name of product:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(2) Type of product</td>
</tr>
<tr>
<td>(put a ✓ in the appropriate box):</td>
</tr>
<tr>
<td>Chinese herbal medicine</td>
</tr>
</tbody>
</table>

(3) Registration number or receipt number of application for proprietary Chinese medicines registration (for proprietary Chinese medicine only):

(4) Package specifications:

(5) Scope of distribution, in brief:

(4) Details of recall actions

<table>
<thead>
<tr>
<th>(1) Batch number of affected product (if applicable):</th>
</tr>
</thead>
<tbody>
<tr>
<td>(2) Quantity supplied before the recall:</td>
</tr>
<tr>
<td>(3) Reasons for recall:</td>
</tr>
<tr>
<td>(4) Classification of recall (put a ✓ in the appropriate box):</td>
</tr>
<tr>
<td>Class 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(5) Plan and logistics of recall actions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(6) Expected time of completion of recall:</td>
</tr>
<tr>
<td>(7) Other relevant information:</td>
</tr>
</tbody>
</table>

(if the space provided is insufficient, supplementary sheets may be added.)

(2 of 2)

__________________________
Signature of responsible person

Date: ______________________

__________________________
Company chop
Appendix 3: Example of “Interim Report on Recall of Chinese Medicine Product”

To: Chinese Medicines Board of the Chinese Medicine Council of Hong Kong  
(Fax Number: 2319 2664)

Our company hereby submits this interim report on the recall of ______________ by virtue of the information provided below:

(1) Details of the Company

<p>| | |</p>
<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Licence number of Chinese medicines trader:</td>
<td></td>
</tr>
<tr>
<td>(2) Name and address of Chinese medicines trader:</td>
<td></td>
</tr>
<tr>
<td>(3) Name and position of the person responsible for the recall:</td>
<td></td>
</tr>
<tr>
<td>(4) Telephone number:</td>
<td></td>
</tr>
<tr>
<td>(5) Facsimile number:</td>
<td></td>
</tr>
<tr>
<td>E-mail address / website (if any):</td>
<td></td>
</tr>
<tr>
<td>(6) Enquiry hotline (if any):</td>
<td></td>
</tr>
</tbody>
</table>

(2) Details of recalled product

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Name of product:</td>
<td></td>
</tr>
</tbody>
</table>
| (2) Type of product  
(put a ✓ in the appropriate box): | Chinese herbal medicine ☐ Proprietary Chinese medicine ☐ ☐ others __________ |
| (3) Registration number or receipt number of application for proprietary Chinese medicines registration (for proprietary Chinese medicine only): |   |
| (4) Package specifications: |   |

(3) Details of progress of the recall

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Number of organizations supplied with the product:</td>
<td></td>
</tr>
<tr>
<td>(2) Quantity of product supplied:</td>
<td></td>
</tr>
<tr>
<td>(3) Date and method of notification to the above organizations:</td>
<td></td>
</tr>
<tr>
<td>(4) Number of organizations which have responded:</td>
<td></td>
</tr>
<tr>
<td>(5) Quantity of product recalled:</td>
<td></td>
</tr>
<tr>
<td>(6) Name of organization which have not responded:</td>
<td></td>
</tr>
<tr>
<td>(7) Time schedule for recall actions, and expected time of completion:</td>
<td></td>
</tr>
</tbody>
</table>

(If the space provided is insufficient, supplementary sheets may be added.)

Date: _______________________________  
Company chop and signature of responsible person
Appendix 4: Example of “Final Report on Recall of Chinese Medicine Product”

To: Chinese Medicines Board of the Chinese Medicine Council of Hong Kong
   (Fax Number: 2319 2664)

Our company hereby submits this final report on the recall of ________________
by virtue of the information provided below:

(1) Details of the Company
   (1) Licence number of Chinese medicines trader:
   (2) Name and address of Chinese medicines trader:
   (3) Name and position of person responsible for the recall:
   (4) Telephone number:
   (5) Facsimile number:
       E-mail address/website (if any):
   (6) Enquiry hotline (if any):

(2) Details of recalled product
   (1) Name of product:
   (2) Type of product (put a ✓ in the appropriate box):
      Chinese herbal medicine ☐ Proprietary Chinese medicine ☐ ☐ others __________
   (3) Registration number or receipt number of application for proprietary Chinese medicines registration (for proprietary Chinese medicine only):
   (4) Package specifications:

(3) Summary of the recall
   (1) Number of organizations or person requested for return of product:
   (2) Total quantity of product distributed:
   (3) Total quantity of product recalled:
   (4) Results of investigation into the cause(s) for deficient product:
   (5) Method(s) of disposal for the recalled product:
   (6) Measures to prevent recurrence of similar problem:

(If the space provided is insufficient, supplementary sheets may be added.)

_________________________  ___________________________
Date:                      Company chop and
                           signature of responsible person