Pharmaceutical Products Recall Guidelines

Version March 2024

Pharmacy and Poisons Board of Hong Kong

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A. INTRODUCTION AND DEFINITIONS

Introduction

When pharmaceutical products are suspected of being potentially harmful to users due to their defective quality, safety or efficacy, they may be subjected to a recall and all related information must be report to the Drug Office, Department of Health, HKSAR.

The Pharmaceutical Products Recall Guidelines (the 'Guidelines') intended to ensure that in the event of a necessary recall, the recall operations are effectively and efficiently carried out by the manufacturer, importer, distributor or certificate holder of pharmaceutical product (hereafter known as the 'Licensee') in order to safeguard public health.

Regulation 28(8) & 33(5) of the Pharmacy and Poisons Regulations require a holder of a wholesale dealer licence and a manufacturer to set up and maintain a system of control that will enable the rapid and, so far as practicable, complete recall of any lot or batch of a pharmaceutical substance or product from sale to the public in the event of the pharmaceutical substance or product being found to be dangerous or injurious to health. It is mandatory that all licensees comply with Pharmacy and Poisons Ordinance and associated Regulations. Any person who is guilty of an offence under the above provisions of regulation is liable on conviction to a fine of $100,000 and to imprisonment for 2 years.

The Guidelines represent Department of Health current stance on this topic. They are recognized by the licensing authority as being appropriate to the specialized requirements for the recall of pharmaceutical products and are the licensing condition for all licences issued by the licensing authority. Any licensee has failed to comply with the conditions or has been convicted of an offence under the Ordinance/ Regulations, the licensing authority may revoke or suspend the licence for a period as it thinks fit.

The role of the Drug Office of the Department of Health in a recall is to assess the adequacy of the Licensee's decision on the recall of the product and to monitor the progress and effectiveness of the recall. The Drug Office may alert the public of the product problem and instruct the Licensee to recall and dispose of the product according to the circumstances.

Definitions

Licensee-
Licensee is the person or business that has the primary responsibility for the supply. The Licensee could be the manufacturer, importer, distributor or the certificate holder of a pharmaceutical product.

Pharmaceutical product-
Under the Pharmacy and Poisons Ordinance, pharmaceutical product

(a) means a substance, or combination of substances that –
    (i) is presented as having properties for treating or preventing disease in human beings or animals; or
    (ii) may be used in or administered to human beings or animals with a view to -
        (A) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or
        (B) making a medical diagnosis; and
(b) includes an advanced therapy product*.

Recall-
A process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/ or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, wholesale dealer licence holder, or Department of Health.

** "advanced therapy product"*

means any of the following products that is for human use—

(a) a gene therapy product;

(b) a somatic cell therapy product;

(c) a tissue engineered product.

B. STAGES OF RECALL PROCEDURE

The procedure is divided into six stages, which are set out below, with a reference to the Section in which detailed information is given.

Recall Stage		See Section
1.	**Receipt of Pharmaceutical Product Problem Report** **Notification to the Department of Health** Information on problem of pharmaceutical products, see sample of Pharmaceutical Product Problem Report Form (Part 1) at Appendix ONE.	C
2.	**Initiation of a Recall** **Information Required for Assessment of Recall** Information on product, problem and distribution is required, see also sample of Recall Notification Form (Part 2) at Appendix ONE.	D
3.	**Assessment of Recall** The classification, level and strategy of recall are determined depending on the potential hazard of the defective product and the extent of product distribution.	E
4.	**Recall** Letters and press release where applicable are dispatched to relevant firms for notifying on the recall. See sample of Recall Reply Form at Appendix TWO.	F
5.	**Progress of Recall and Report** Progress reports and final report are submitted to the Drug Office. See sample of Final Report Form at Appendix THREE.	G
6.	**Evaluation of the Recall** The effectiveness of the recall is monitored by the Drug Office.	H

C. NOTIFICATION OF A PHARMACEUTICAL PRODUCT PROBLEM

Recall might be initiated as a result of reports or complaints on quality, safety or efficacy on a pharmaceutical product referred to the Licensee from a variety of sources. The reports or complaints may be referred by manufacturers, wholesalers, retailers and hospital pharmacies, research institutes, medical practitioners, dentists and patients, recall might also be initiated as a result of analysis and testing of samples of pharmaceutical products by the manufacturers and by the Department of Health. Recall of pharmaceutical products manufactured overseas might be initiated by the local or overseas health authorities, or from information received directly from such authorities.

Certain information is essential to permit the assessment of the validity of the report of quality defects, safety or efficacy problem with pharmaceutical products, the potential danger to consumers and the action appropriate to the situation. A Pharmaceutical Product Problem Report Form (Part 1) is used to report problems to the Department of Health, the sample of the form is provided at Appendix ONE.

Serious problems which may lead to recall of Class I or Class II (refer to recall classification at Section E) must be reported to the Department of Health within 24 hours after receipt of the complaint or report for investigation. The Pharmaceutical Product Problem Report Form (Part 1) (see sample of the form at Appendix ONE) together with opinions on toxicological or therapeutic hazards and the action proposed by the authorities/ organization (if any) should be referred on to the Senior Pharmacist (LC-W) of the Department of Health. For less serious problems would result in a Class III recall, the Pharmaceutical Product Problem Report Form should be sent to Department of Health no later than 72 hours after receipt of complaint or report of a problem.

It should be noted that the Licensee has to send the Pharmaceutical Product Problem Report Form (Part 1) to Department of Health prior to their decision on recall.

When the need for recall has been established, additional information is required so that an appropriate recall strategy may be devised. A summary of the information required is provided in Section D.

Licensing and Compliance Division of Drug Office,
Department of Health
Hong Kong SAR, China
Room 2001-2002, 20/F, Dah Sing Financial Centre,
248 Queen's Road East, Wan Chai, Hong Kong
Telephone (852) 3107 3498
Fax (852) 3107 0221
E-mail product_recall@dh.gov.hk
Website www.drugoffice.gov.hk

D. INITIATION OF RECALL/ INFORMATION REQUIRED FOR ASSESSMENT OF RECALL

When the Licensee decides to initiate a recall on a pharmaceutical product, it is required to notify the recall situations with the Recall Notification Form (Part 2) (see sample of the form at Appendix ONE) including information outlined below to the Department of Health immediately after the decision to recall is made and the Senior Pharmacist (LC-W), Department of Health is notified (refer notes of Appendix ONE on the contact information of Senior Pharmacist (LC-W)). The Licensee shall not wait to submit this information until ALL applicable information is prepared and assembled prior to notification to the Department of Health. This “early” notification is necessary to allow the Department of Health to review and comment on the written notification and to offer guidance and assistance in the recall process.

The information required may include:

Details of the Problem

- name, telephone fax number and email address of the person reporting the problem;
- date of report;
- physical location of the problem;
- nature of the problem;
- number of similar report received;
- results of tests and other investigations on suspect or other samples.

Details of the Product

- name of the product and description including active ingredients, dosage from, strength, registration no, pack size or type;
- batch number(s) and expiry date;
- manufacturer/ distributors and contact telephone, fax numbers and email address;
- date manufactured, date released or imported to Hong Kong;
- quantity of the batch, date and amount manufactured, released or imported to Hong Kong;
- local distribution list;
- oversea distribution list of product exported from Hong Kong;
- whether the product is meant to be sterile.

Health hazard evaluation and proposed action

- type of hazard, and evaluation of health hazard to user;
- action proposed by the Licensee;
- proposed recall classification and level;
- availability of alternative product; and
- method of recall communication.

E. ASSESSMENT OF RECALL

Recall Strategy

Each recall is a unique exercise. There are a number of factors common to all recalls that need to be considered in tailoring an appropriate recall strategy. These include the nature of the deficiency in the product, the incidence of complaints, public safety, distribution networks, recovery procedures, resources for corrective action and availability of alternative products.

In determining the recall strategy, the Licensee should consider the factors which may affect the duration of the recall action and should inform the Department of Health. The recall should be completed by the date as directed by the Department of Health.

When the required information (Section D) is available, the appropriate strategy should be proposed by the Licensee to Department of Health. The proposed recall strategy should be agreed by the Department of Health before implementation. The actual implementation of the recall includes use of the basic steps which are summarized in Section B and these will be common to all strategies.

In the recall strategy, the Licensee should mention the followings:

- Indicate the proposed level in the distribution chain to which the recall is extending (see level of recall below), if the recall only extends to the wholesale level, the rationale of not recalling to retail level should be explained;
- In case of *consumer level* recall, additional information should be mentioned-
    - Indicate the location of recall spots for consumers (preferably not less then 10 recall spots covering different district in Hong Kong), their operation time and duration (at least 7 days);
    - Indicate the hotlines number(s) for enquiry and the corresponding operating hours;
    - Indicate the proposed refund mechanism at the recall spots, the conditions of refund (applicable to opened products, expired products or parallel-imported products) and methods of refund (by means of money, credit notes or product replacement etc.);
- Indicate the method of notification (e.g. mail, phone, Fax, email);
- Indicate how the message of recall will be delivered to customers including but not limited to press release, recall letters, healthcare professional letter etc;
- If the Licensee has a website, it should consider posting the recall notification on it as an additional method of recall notification;
- Report on what have the customers been instructed to do with the recalled product;
- It is necessary for recalling firms to know the name and title of the recall contact person for each of its consignees. Addressing a recall letter to a recall contact person will expedite the recall process and reduce the potential for the recall letter

to get misdirected;
- If product is to be returned, explain the mechanics of the process;
- Explain if the recall will create a market shortage that will impact on the consumer;
- Determine and provide the course of action for out-of-business distributors;
- Provide a proposed disposal plan of the recalled products, whether they would be destroyed, reconditioned or returned to overseas manufacturer; and
- Inform Department of Health before product destruction, the proposed method of destruction would be reviewed and Department of Health may choose to witness the destruction.

Classification

Recalls are classified according to the following system:

Class I recalls occur when products are potentially life-threatening or could cause a serious risk to health.

Examples of Class I Defects

- Wrong Product (label and contents are different products)
- Correct product but wrong strength, with serous medical consequences
- Microbial contamination of sterile injection or ophthalmic product
- Chemical contamination with serious medical consequences
- Mix up of some products ('rogues') with more than one container involved
- Wrong active ingredient in a multi-component product with serious medical consequences

Class II recalls occur when product defects could cause illness or mistreatment, but are not Class I.

Examples of Class II Defects

- Mislabeling e.g. wrong or missing text or figures
- Missing or incorrect information- leaflets or inserts
- Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences
- Chemical/ physical contamination (significant impurities, cross contamination, particulates)
- Mix up of products in containers ("rogues")
- Non-compliance with specification (e.g. assay, stability, fill/ weight or dissolution)
- Insecure closure with serious medical consequences (e.g. cytotoxics, child resistant containers, potent products)

Class III recalls occur when product defects may not pose a significant hazard to health, but withdraw may be initiated for other reasons.

Examples of Class III Defects

- Faulty packaging e.g. wrong or missing batch number or expiry date
- Faulty closure
- Contamination- microbial spoilage, dirt or detritus, particulate matter

Class I or Class II recalls are considered to be urgent safety-related recalls. They must be reported to the Department of Health for further evaluation and investigation.

Class III recalls are considered to be non safety-related recalls.

Note: Each recall is a unique exercise and there may be occasions when the scope of a recall can be narrowed to particular customer groups. The classification is determined by the Department of Health. Expert advice might be sought where the nature of the hazard or its significant is not clear.

The Guidelines do not apply to the recall of pharmaceutical products related to regulatory issues (e.g. approved change of agent, labeling, package insert or other registered particulars). The Licensee should follow the instruction as provided by the Drug Evaluation and Import/Export Control Division of Department of Health and take reference from the Guidelines.

Level

As with classification, the level (or depth) of a recall is to be assigned by Department of Health. In determining the recall level, the principal factors to be considered are the significance of the hazard (if any), the channels by which the pharmaceutical products have been distributed, and the level to which distribution has taken place. Again, expert opinion may be necessary to determine the significance of the hazard.

There are three levels of recall: wholesale, retail and consumer.

Wholesale level includes:

- All parties involved in wholesale distribution and may include wholesalers and retail pharmacies.

Retail level includes:

- All public and private hospital pharmacies;
- Retail pharmacies;
- Clinical investigators and the institutions in which clinical investigations are performed;
- Medical, dental and other health care practitioners;
- Nursing homes and other related institutions;
- Other retail outlets e.g. medicine shops, supermarkets and health food stores; and
- **Wholesale level.**

Consumer level includes:

- Patients and other consumers; and
- **Wholesale and retail levels.**

F. COMMUNICATION TO PUBLIC

Recall letters

In case of a recall, the Licensee may prepare letters with a factual statement of the reasons for the recall of the product, together with specific details that will allow the product to be easily identified. The letter may be sent by mail, Fax or e-mail to the clients.

The recall letter should use company letterhead; include date and name and title of signatory. The text of recall letter may include:

a. **Description of the pharmaceutical product:** name of the product; Hong Kong registration number; name of manufacturer, pack size; dosage form; batch number(s) and expiry date;
b. **Hazard associated with the product:** The reason for the recall should be concisely explained. It should be made clear that further distribution or use of the product should cease immediately.
c. **Instruction for recall of the product:** The method of return, disposal or correction and refund mechanism of the product. There should be a request for a response to confirm receipt and understanding of the action to be taken e.g. pre-addressed cards, telephone replies or a form to complete and return by fax or e-mail. The Licensee should clearly identify a hotline for enquiry.

For retail level recall, the Licensee should have confirmation for returning all the stock on hand from the consignees using the Recall Reply Form (please refer to the sample of the form at Appendix TWO).

If safety to the public is involved and distribution is limited, the Licensee may contact the clients of the information listed above by telephone and followed by a recall letter.

Press Release

Rapid alert to public is usually reserved for hazards classified as Class I, and where appropriate Class II, or situation where other means for controlling the hazard appear inadequate. Rapid alert to public may be issued through appropriate channels which include press release by the Licensee and in addition, to be uploaded on the company website where applicable.

G. RESPONSIBILITIES OF LICENSEES

Licensee has responsibilities in relation to recall of pharmaceutical products in three general areas:

a. in maintaining records and establishing procedures which will assist in facilitating recall should such action become necessary;
b. in taking the prime responsibility for implementing recall in the situation where it is necessary; and
c. Provide the DH with a full Investigation and Corrective Action Preventive Action ("CAPA") reports containing the Licensee's comments on the implementation of CAPA and the conclusion of the incident after self-assessment.

Records

The Licensee should maintain records for all the pharmaceutical products manufactured or distributed by them in accordance with the followings:

For manufacturers

- A system should be in operation whereby the complete and up-to-date histories of all batches of products from the starting materials to the finished products are progressively recorded;
- The system should allow the determination of utilization and disposal of all starting materials and bulk products.

For distributors

- Records of all sales or distribution (including professional samples and export to overseas countries) of pharmaceutical products should be retained or kept readily accessible to permit a complete and rapid recall of any lot or batch of a pharmaceutical product.

The complete records pertaining to manufacturing and distribution should be retained for two years after the date of transaction or one year after the expiry date of the batch whichever longer.

Besides, the Licensee should retain records of problem reports received about each product. Problem reports should be evaluated by competent personnel and appropriate action taken. The evaluation of each report and the action taken should be shown in the records.

All the above records should be readily available and easy to follow so as to expedite recall whenever necessary. A copy of manufacturing/ import and distribution records should be sent to Department of Health when a recall is implemented.

Recall Procedure

As mentioned in Section B, Licensee should prepare procedures for recall action which are consistent with the Guidelines and which are applicable to their own operations. All senior personnel should be familiar with their responsibilities in connection with the procedure and of the records system for pharmaceutical products.

Problem Reporting

Where evaluation of a problem report concerning pharmaceutical products indicates that recall may be necessary, the report must be conveyed with the least possible delay to the Department of Health, including pharmaceutical products that have been exported-only and not supplied in Hong Kong. Any batch of a formulated product that has been distributed, or any batch of a starting material that is found not to comply with the approved product specifications or a relevant standard of PICS, must also be reported if it has been used in a distributed products.

Recall

Licensee has the prime responsibility for implementing recall action, and for ensuring compliance with the recall procedure at its various stages (Section B). However, no recall, regardless of level, should be undertaken without consultation with the Department of Health.

A responsible officer for recall should be appointed to coordinate the recall and his/her name and contact phone number should be notified to Department of Health. In addition, this officer has to report the progress of recall regularly to the Department of Health.

For Class I recall, Licensee should notify its clients within 24 hours upon the decision of recall. The company personnel may be utilized to immediately disseminate information on the recall. This includes telephone advice to quarantine stock pending recall or possible recall followed by recall letters if necessary. A Recall Reply Form (please refer to the sample of the form at Appendix TWO) should be sent to all consignees to confirm quantity of stock on hand and have all of them returned. The reply form should be kept for inspection by Department of Health. All Class I recall should complete within a time as found suitable for the case agreed by Department of Health.

For consumer level recall, the Licensee should set up sufficient recall spots for collection of recalled products. Information of location of the recall spots, their operating hours and duration, conditions of refund as well as method of refund should be noticed to consumers by effective means.

Company representatives may be utilized to recover stock which is the subject of recall, providing the provisions are observed in relation to unauthorized possession of certain stock, e.g. dangerous drugs.

Licensee may also be required to notify overseas recipients of recall actions that affect them.

Refund Mechanism

Licensee should set up a refund mechanism for the recalled products.

Post-recall

After the timeframe directed by Department of Health to complete the recall, or at other agreed times, the Licensee is to provide the Department of Health with an interim report during recall process for the monitoring of progress within 7 days after initiation of recall. The interim report should contain the following information:

- the number of organizations or persons to whom the defective product has been supplied;
- the date and means of notifying them of the recall;
- the number of responses received from them;
- the names of the non-responders;
- the quantity of stock returned;
- the quantity of stock has been off shelves pending return to Licensee;
- the estimated time frame for the completion of the recall .

A final report (refer Final Report Form at Appendix THREE) contain the following information should be submitted to Department of Health within 14 days after commencing of the recall:

- the circumstances leading to the recall;
- the consequent action taken by the Licensee;
- the extent of distribution of the relevant batch in Hong Kong and overseas;
- the result of the recall
    - the quantity of stock returned, corrected, outstanding;
    - the quantity of stock used by the consignees and;
    - the quantity of stock not located;
    - date of recall completion;
- confirmation using the Recall Reply Form (please refer to the sample of the form at Appendix TWO), where practicable, the retailers have returned all the recalled products to the Licensee and the customers have received the recall letter;
- the method of destruction or disposal of the recalled products; and

The licensee should report to Department of Health with relevant explanation and obtain its approval if the final report cannot be submitted within 14 days after commencing of the recall.

After completion of the recall, a report on investigation results on the problem and the action proposed to be implemented in future to prevent a recurrence of the problem should be submitted to Department of Health in a timely manner. The report shall contain the Licensee's comments on the implementation of CAPA and the conclusion of the incident after self-assessment.

These reports establish the effectiveness of the recall and unless satisfactory reports are received, further recall action may have to be considered.

H. EVALUATION OF THE RECALL

The evaluation consists of a check on the effectiveness of the recall and an investigation of the reason for the recall as well as the remedial action taken to prevent a recurrence of the problem.

Check on the Effectiveness of Recall Action

It is the Licensee responsibility to assure that the recall is effective.

The Department of Health examines the recall reports and the signed Recall Reply Forms submitted by the Licensee and assesses the effectiveness of the recall action. Recall records may be inspected and in some case the Department of Health may contact a percentage of customers in the distribution list as a means of assuring the Licensee is carrying out its recall responsibilities. If Department of Health finds the recall to be ineffective, the Licensee will be asked to take appropriate steps, including re-issuing recall letters.

Investigation of the Reasons for Recall and Initiation of Remedial Action

On completion of a recall, the Licensee is requested to provide a report with investigation on the problem and details of the remedial action proposed to prevent a recurrence of the problem which gave rise to the recall (Section G). Where the nature of the problem and appropriate remedial action are not apparent, investigation and in some cases Good Manufacturing Practice audits may be necessary.

Where a recall is initiated following a report submitted by a party from overseas health authorities, the reporter is to be provided with an outline of the results of investigation and a summary of the recall.

Whether it is a locally initiated recall or a recall action based on a report submitted by a party from overseas health authorities, the investigation report and the CAPA report provided by the Licensee shall contain the Licensee’s comments on the implementation of CAPA and the conclusion of the incident after self-assessment.

I. REINSTATEMENT OF SUPPLY

The quality of the products shall conform specific requirements before resuming the supply to public. The Licensee must seek approval from Department of Health for **reinstatement of the pharmaceutical product previously "totally recalled"**.

Implementation of Remedial Action

The Licensee shall identify the root cause of the problem and implement the corrective action accordingly. Furthermore, preventive action shall be imposed to prevent recurrence of the problem in the future.

Submission of Analytical Report

After implementing the remedial action and subsequent manufacturing or importing the new batch of the product, the Licensee shall submit analytical report(s) of the new batch tested by external accredited laboratory to Department of Health as a proof of product quality. The submitted report(s) will be evaluated by the Hong Kong Government Laboratory via Department of Health. After evaluation, Department of Health would inform the Licensee whether the submitted reports are satisfactory. The documents relating to submission of analytical report are summarized in Appendix FOUR.

Sampling

When Department of Health satisfies the submitted reports, sample of the first three batches of the product (being manufactured by the local manufacturer / being imported) will be collected for examination by the Hong Kong Government Laboratory. The Licensee shall notify Department of Health **(Please contact Senior Pharmacist (LC-W) at 3107 3498 (telephone), 3107 0221 (fax) or product_recall@dh.gov.hk (email address). For emergence notification during off hours, please contact Senior Pharmacist (LC-W) at 9125 6378)** once the product is ready for sampling. The product can be put on the market only upon approval for reinstatement from Department of Health is obtained.

APPENDIX ONE

PHARMACEUTICAL PRODUCT PROBLEM REPORT FORM/ RECALL NOTIFICATION FORM

Note:

- **Part 1** of this form should be used to report problem of pharmaceutical products on quality, safety or efficacy, which are thought to have arisen during manufacture, storage, or handling. Problems of this nature are usually found in a single batch of a product and may require laboratory investigation by the Department of Health.

- **Part 2** of this form should be filled when decision of recall is established.

- When the reported problem may lead to Class I or II recall, it should be reported to Senior Pharmacist (LC-W) Department of Health ***within 24 hours by telephone*** and following by fax or email of this form (Part 1 only).

- If Class I or II recall is required, Part 1 & 2 of this form should be reported to Senior Pharmacist (LC-W) of Department of Health immediately by telephone and followed by fax or email.

- The Licensee shall NOT wait to submit this information until ALL applicable information in **Part 2** of this form is prepared and assembled prior to notification to the Department of Health.

- For problem may lead to Class III recall, Part 1 of the form should be returned by fax or by email to Senior Pharmacist (LC-W) ***no later than 72 hours***. When Class III recall is required, the form (both Part 1 & 2) should submitted by fax or email to Senior Pharmacist (LC-W).

- **Please contact Senior Pharmacist (LC-W) at 3107 3498 (telephone), 3107 0221 (fax) or product_recall@dh.gov.hk (email address). For emergence notification during off hours, please contact Senior Pharmacist (LC-W) at 9125 6378.**

- Use separate form for each pharmaceutical product reported.

- Please save and submit these forms in electronic format.

Drug Office
Department of Health
The Government of the Hong Kong Special Administrative Region

Attn: Senior Pharmacist (LC-W)
Fax Number: 3107 0221
E-mail: product_recall@dh.gov.hk

[Sample Form]

PHARMACEUTICAL PRODUCT PROBLEM REPORT FORM (PART 1)

DETAIL OF THE PROBLEM			
Reporting Company (company reporting the problem of Pharmaceutical Product to DH)			
Name of contact			Position/ Occupation
Organization			
Address			
E-mail address			
Tel	(office)	(mobile)	Fax
Pharmaceutical product problem occurred in Hong Kong? If not, location of problem:			
Nature of the problem			
Date of receiving complaint			
Source of Complaint	☐ Patient ☐ Customer ☐ Retailer ☐ Self-inspection ☐ Other: _____		
Number of similar reports received			
Description of the problem (use separate sheet if space is inadequate)			
Results of tests/ investigation on suspect or other samples			
Has manufacturer/ distributor been contacted? ☐ No ☐ Yes (please write down their names)			
Other relevant information (attach photos, package insert and press release of oversea authority of the product if any)			

DETAILS OF THE PRODUCT			
Name of the product (as in product registration certificate)		HK Registration number	
Active Ingredients & Strength			
Indications			
Dosage form		Pack size	
Batch number		Expiry date	
Distribution of products ☐ HA ☐ Private hospitals ☐ Pharmacies ☐ Medicine stores ☐ DH ☐ Private doctors ☐ Others (specify)			
Manufacturer			
Name			
Address			
Tel	Fax	Manufacture date	
Quantity of the batch manufactured		Date and quantity released	
Quantity on hold		Quantity distributed: local overseas	
Importer			
Name			
Address			
Tel	Fax	Import date	
Quantity of the batch imported		Date and quantity released	
Quantity on hold		Quantity distributed: local re-exported	
Local Distributors (please attach distribution list)			
No. of local distributors			
Name			
Address			
Contact Person		Tel (office & mobile)	
Quantity on hold		Quantity distributed: local re-exported	
Exporter			
Has the product been exported outside Hong Kong? ☐ Yes ☐ No If yes, specify the exported countries.			

Name of Reporter: _____ Post: _____

Contact no. (mobile): _____ Date: _____

Signature of Reporter: _____

Attn: Senior Pharmacist (LC-W)
Fax Number: 3107 0221
E-mail: product_recall@dh.gov.hk

[Sample Form]

RECALL NOTIFICATION FORM (PART 2)

RISK ASSESSMENT				
Type of hazard ☐ Safety	☐ Quality	☐ Labeling	☐ Compliance Issue	☐ Other (specify)
Evaluation of Health Hazard to users (e.g. effects on users, possibility of occurrence) (attached expert advice if any)				
Proposed recall classification	☐ Class I	☐ Class II	☐ Class III	

PROPOSED ACTION (WITH AGREEMENT OF DEPARTMENT OF HEALTH PRIOR ACTION)			
Recall start date		Proposed recall end date	
Hotline(s) for enquiry			
Hotline(s) operating hours:	Mon- Fri	Sat	Sun & PH
Link of company website			
Responsible officer of recall		Tel (office & mobile)	
Proposed recall level	☐ Wholesale	☐ Retail	☐ Consumer
Location of recall spots *(For Consumer level recall only)*			
Operating hours and duration of the recall spots *(For Consumer level recall only)*			
Means of Refund at the recall spots	☐ Money	☐ Credit Note	☐ Replacement ☐ Other
Conditions of Refund at the recall spots			
Proposed recall strategy (use separate sheet if space is inadequate)			

Name of Reporter: _____ Post: _____

Contact no. (mobile): _____ Date: _____

Signature of Reporter: _____

APPENDIX TWO

RECALL REPLY FORM

Note:

- Please save and submit the form in electronic format.

[Sample Form]

Recall Reply Form

To : _____

Attention : _____

E-mail : _____

Telephone No. : _____

Postal Address : _____

Subject : _____

From : _____

Contact person : _____

Telephone No. : _____

E-mail : _____

We do/ do not * have stock which is subject to this recall.

We have reported and returned all the stock on hand to _____

(please delete as appropriate)* (Licensee Name)

Stock received:

Batch No. _____ Quantity _____

Batch No. _____ Quantity _____

Batch No. _____ Quantity _____

Unused stock subject to recall (currently in quarantine):

Batch No. _____ Quantity _____

Batch No. _____ Quantity _____

Batch No. _____ Quantity _____

Any other relevant details:

_____

_____

I declare that the information provided by me in this reply form is complete and true to the best of my knowledge.

Signature: _____ Date: _____

APPENDIX THREE

FINAL REPORT

Note:

- Use separate form for each pharmaceutical product reported.
- This report should be returned by fax or by email to Senior Pharmacist (LC-W), Department of Health within 14 days after commencing of recall.
- Please save and submit the form in electronic format.
- **Please contact Senior Pharmacist (LC-W) at 3107 3498 (telephone), 3107 0221 (fax) or product_recall@dh.gov.hk (email address).**

Drug Office
Department of Health
The Government of the Hong Kong Special Administrative Region

Attn: Senior Pharmacist (LC-W)
Fax Number: 3107 0221
E-mail: product_recall@dh.gov.hk

[Sample Form]

FINAL REPORT FORM

Details of the recalled products	
Name of the product	HK Registration number
Active ingredients & strength	
Dosage form	Pack size
Batch number	Expiry date
Reasons for recall	
Extent of Distribution	
Imported/ manufactured quantity	
Quantity exported	Countries of Export
Quantity distributed in HK	No. of Consignee
Action taken by the Licensee	
Result of Recall	
Quantity of stock returned	Quantity of stock outstanding
Quantity of stock used or sold by the consignees	
Quantity of stock not located	
No. of Recall Reply Form received from consignees on all stock returned/ reported	
Disposal Plan	
Method of Disposal ☐ Destroy ☐ Return to overseas manufacturer ☐ Others, please specify:	
Details of the disposal method	

Licensee Name : _____

Name of Recall Officer : _____ Signature : _____

Date : _____

APPENDIX FOUR

DOCUMENTS RELATING TO THE SUBMISSION OF ANALYTICAL REPORT

Accredited Test

The laboratory performed the tests should obtain accreditation on the specific test method in accordance with the international standards e.g. ISO 17025 by third parties such as the Hong Kong Accreditation Service (HKAS) in Hong Kong or other Mutual Recognition Agreement (MRA) partners to ensure the its competence in performing pharmaceutical product testing. The Licensee shall submit the raw data and QC data for the tested samples to substantiate the validity of test results. These data could facilitate the Government Laboratory in evaluating the data in the analytical reports.

- List of laboratories which are accredited under the category of pharmaceutical products in Hong Kong are available in the HKAS websites: *https://www.itc.gov.hk/en/quality/hkas/conformity_assessment_bodies/hoklas.html*
- List of the HKAS MRA partners are available in the HKAS websites: *http://www.itc.gov.hk/en/quality/hkas/doc/common/mramla/MRA_HOKLAS_en.pdf*

Non-accredited Test

In case accreditation of the specific test could not be arranged, the analytical report might be considered acceptable if the laboratory has obtained appropriate accreditation in the area of pharmaceuticals or pharmaceutical products and be able to provide necessary documents to prove its competence in respect of their quality control and technical aspects in performing the specific chemical tests.

Basically the information should include, but not limited to, the following:

- Detailed method (including standard preparation procedure, sample preparation procedure, instrument parameters, and quality control procedure in details);
- Raw data and QC data for all tested samples shown in the report (including chromatograms, mass spectra and calculation);
- Validation summary for the method used (including method linearity, limit of detection, limit of quantitation, method bias, precision, and measurement uncertainty);
- Reference material used and purity verification summary; and
- Relevant proficiency test participated.

Licensee may refer to Technical Criteria for Laboratory Accreditation (HOKLAS 003) and Supplementary Criteria No. 1, No. 2 and No. 20 published by The Hong Kong Laboratory Accreditation Scheme (HOKLAS) via the HKAS website at *https://www.itc.gov.hk/en/quality/hkas/publications/hoklas_pub.html*

For non-chemical tests, other equivalent technical criteria listed in the website shall be followed and should be considered on case-by-case basis.