

<b>STANDARD OPERATING PROCEDURE</b>		
Title <b>Product Recalls</b>		
SOP No.: <i>XXX</i>	Revision No.: <b>001</b>	Effective Date <i>DD-MMM-YYYY</i>

## 1.0 Purpose

- 1.1 To establish the procedure for prompt and efficient recall of products known or suspected to be defective, from the market.

## 2.0 Scope

- 2.1 This SOP applies to all types of recalls either initiated by *XXX company* voluntarily or by the *National Regulatory Authority*.

## 3.0 Responsibility

- 3.1 The *designated responsible person* shall ensure that product recall can be executed effectively and promptly upon receiving the recall instruction from the *Managing Director* or recall order from any Regulatory Authority.

## 4.0 Procedure

- 4.1 Recall can be initiated in the following situations:

- 4.1.1 A recall instruction decision from the Managing Director in response to a complaint received, where serious product quality problem was detected in product and/or product was found to have potentially caused adverse reactions in consumers;
- 4.1.2 A recall instruction decision from the Managing Director in response to any in-house detected defective products;
- 4.1.3 A recall order from any Regulatory Authority

the *designated responsible person* shall consult the Regulatory Authority and Management to determine the extent and nature of recall.

- 4.2 Recalls are classified into the following categories:

### *Class 1 Recall*

*Initiated when the product defect poses a life-threatening situation to users. Some examples of defects that will result in Class 1 recall*

<b>STANDARD OPERATING PROCEDURE</b>		
Title <b>Product Recalls</b>		
<b>SOP No.:</b> <i>XXX</i>	<b>Revision No.:</b> <b>001</b>	<b>Effective Date</b> <i>DD-MMM-YYYY</i>

*are contamination with toxic substances and products with major labelling errors.*

*Such recalls shall be accorded with highest urgency and reported to NRAs immediately.*

*Class 2 Recall*

*Initiated when the problem or defect is unlikely to cause serious harm to users. Some examples of defects that will result in Class 2 recall include products with minor labelling errors or products which fail to meet product specification or pharmacopoeia standards but are likely to cause minimal hazard to users.*

- 4.3 The *designated responsible person* shall inform the sales/marketing department or inventory control section to generate the distribution records of the affected batch.
- 4.4 All sales of defective products will be ceased immediately and the *designated responsible person* shall instruct the storekeeper to immediately remove any balanced stock of the affected batch from the warehouse and quarantine the goods at designated quarantine area.
- 4.5 All recipients of the affected product shall be notified the nature of the recall by telephone. For end-user recall, means of appropriate mass media communication should be considered.
- 4.6 A recall letter will be prepared by the *designated responsible person* to be sent to all recipients of the affected batch listed in the distribution record to inform them that recall operation is activated, and to stop selling and remove the affected product from the racks with immediate effect.
- 4.7 The *National Regulatory Authority* and Overseas Regulatory Authorities for which the affected product batch is exported should be notified of the recall in situations 4.1.1 and 4.1.2. Report must be made to the Officer of *National Regulatory Authority* within 24 hours from the receipt of the defective reports.

<b>STANDARD OPERATING PROCEDURE</b>		
Title <b>Product Recalls</b>		
<b>SOP No.:</b> <i>XXX</i>	<b>Revision No.:</b> <b>001</b>	<b>Effective Date</b> <i>DD-MMM-YYYY</i>

- 4.8 The *designated responsible person* shall instruct the delivery personnel to collect the recalled product back from the market, the pharmacies, hospitals, distributors or any other outlets as stated in the distribution record.
- 4.9 All recalled goods collected from the market shall be clearly identified and stored in the designated secure area while awaiting Management's decision or *National Regulatory Authority's* instruction on their fate.
- 4.10 The progress of the recall process should be recorded and a final report issued, including a reconciliation between the delivered and recovered quantities of the products.
- 4.11 The records should be filed in the Recall file kept by the Admin or QC Department.
- 4.12 Mock recall shall be carried out on a yearly basis to assess the effectiveness recall system put in place. Any gaps found in the system during the mock recall shall be appropriately addressed so that operation can be activated immediately and promptly during an actual recall.

## 5.0 Reference to other documents

- 5.1 Product Recall Form (*FORM-XXX*)

## 6.0 END OF DOCUMENT

### REVISION HISTORY

Rev No:	Document Change Number:	Author	Effective Date	Remarks of Revision
001	<i>XXX</i>	<i>YYY</i>	<i>DD-MMM-YYYY</i>	New Document.

### APPROVAL

Prepared by: \_\_\_\_\_ Signature/Date: \_\_\_\_\_

<b>STANDARD OPERATING PROCEDURE</b>		
Title <b>Product Recalls</b>		
<b>SOP No.:</b> <i>XXX</i>	<b>Revision No.:</b> <b>001</b>	<b>Effective Date</b> <i>DD-MMM-YYYY</i>

Approved by: \_\_\_\_\_

Signature/Date: \_\_\_\_\_