ASEAN Guidelines on GMP for Traditional Medicines & Health Supplements (TM/HS)

CHAPTER 9 – COMPLAINTS AND PRODUCT RECALLS

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OUTLINE

- Definition
- Principle
- Product Complaints
  - Case Study
- Product Recalls
- Complaints on Adverse Product Reaction (APR)

DEFINITION

- **Complaints**

When a customer or any other party (internal or external) has **reported a product defect or adverse event** with any of the company's marketed products.

- **Recall**

A procedure of retrieval or withdrawal of products known or suspected to be defective, promptly and effectively, from the market

PRINCIPLE

All complaints and other information concerning potentially defective products must be kept and reviewed according to written procedures. In order to provide for all contingencies, a system shall be designed to recall, if necessary, promptly and effectively products known or suspected to be defective from the market.

PRODUCT COMPLAINTS

The importance of handling complaints and recall appropriately:

- Identifying and addressing the root cause of complaints will help to prevent the recurring of complaints
- Reviewing trends of complaints can help to tackle systemic issues before it got worse. A decreasing trend of complaints also shows customer satisfaction or trust in the product/service
- Appropriately handled complaints can help to retain or get more customers and ensure customer satisfaction
- If there are serious quality problems and there are potential harm to consumer, product recall shall be considered.

PRODUCT COMPLAINTS

Clause 9.1 - Product complaints are usually concerned with the quality of the product such as its physical properties, or condition of its packaging. Complaints (internal or external) could be made to the manufacturer, verbally or in writing by consumers, distributors or the NRA.

PRODUCT COMPLAINTS

Source of Complaints

Internal and External	Verbal and Written
Internal : complaint can be from Production,Quality Control, Warehouse and Marketing Division	**Verbal :** complaints received by oral and must be doccumented by appointed person
External : complaint can be from customers, doctors, paramedics, clinics, hospitals, pharmacys, drugstores, supermarkets and NRA	**Written :** complaints received in writing (e.g.: mail, letter, etc).

PRODUCT COMPLAINTS

Examples of complaints:

- Colour, smell or taste of products – *possible deterioration of products*
- Wrong label or wrong products – *possible mix up*
- Less products found container – *possible leaking or production issues*
- Adverse reaction after consuming product – *presence of possible allergens or prohibited substances*
- Slow delivery, products were wet when it was received – *delivery issues*

Special attention should be paid to complaints concerning quality of the product and adverse reaction.

PRODUCT COMPLAINTS

Example of complaints :

Subject	Description	Non conformance
Physical properties	Colour, smell or taste of products	possible deterioration of products
Product	• Less products found container • Contamination with toxic substances and microbial spoilage	possible leaking or production issues contamination issues
	Adverse reaction after consuming product*	presence of possible allergens or prohibited substances
Packaging	• Wrong label, missing label, wrong products, leakage • Damage of packing	possible mix up and contamination
Delivery	Slow delivery or products were wet when it was received	delivery issues

***Complaints concerning adverse reaction shall be dealt with in accordance with Clause 9.24**

PRODUCT COMPLAINTS

All complaints shall be investigated and evaluated.

- Written procedures (*Clauses 5.43.7, 9.2 and 9.4*) describing the handling of all written and verbal complaints regarding the product shall be established and followed. Such procedures shall include provisions for review by the Quality Control unit.

- A written record of each complaint (including verbal complaints) shall be recorded and filed.

  – Two recording forms should be established - Complaint Register and Complaint Record Form. To facilitate tracking, each complaint case should be assigned with a unique number.

PRODUCT COMPLAINTS

- Clause 9.3 - A person shall be designated responsible for handling the complaints.

- Clause 9.4 - There shall be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint concerning a possible product defect.

- *Clause 9.5 - Any complaint concerning a product defect shall be recorded with all the original details and thoroughly investigated. The person responsible for Quality Control shall be part of the team.*

PRODUCT COMPLAINTS

- Head of Quality Assurance / Quality Control shall be involved (Clauses 2.3.10, 9.2, 9.3 and 9.5)

- All actions taken:
  - including investigation to find the root cause, checking of retention samples and batch related documents
  - the eventual decision made (accept or reject refund, replacement or recall)] shall also be recorded.

- Conduct investigation:

Review of relevant documents (such as batch manufacturing record, QC test records and reports, retention samples) of the concerned batches including before and after the complaint batch.

PRODUCT COMPLAINTS

- *Clause 9.6 - Special attention shall be given in establishing whether the product which is the subject of a complaint, genuine or is a counterfeit product.*

- All investigations, root cause and action taken shall be recorded. Complaint could be on
  - products manufactured by legitimate company or
  - on a counterfeit product,

PRODUCT COMPLAINTS

- There must be a way to differentiate the genuine from counterfeit.

- Ways to prevent counterfeit include but not limited to:
  - unique identification of/on product itself,
  - unique packaging and labelling,
  - unique batch numbering system, etc.

PRODUCT COMPLAINTS

- *Clause 9.7 - If a product defect is discovered or suspected in a batch, consideration shall be given to check other batches in order to determine whether they are also affected. In particular, other batches which may contain reworks of the defective batch shall be investigated.*

- A product defect could be an isolated incident or could point to a BIGGER systemic issues, therefore there is a need to check other batches to see whether they are also affected.

- If other batches are also affected then need to address systemic issues [e.g. substandard materials were used, contamination (either from human, environment or equipment), undesirable production operation (out-of-spec or deviation was not reported, rework to salvage product that didn't meet original specification), poor storage of materials and/or products].

PRODUCT COMPLAINTS

- *Clause 9.8 - All decisions and measures taken as a result of a complaint shall be recorded and referenced to the corresponding batch records.*

- As mentioned earlier, all investigations, root cause and action taken shall be recorded by cross-referencing to corresponding batch records.

- Also sometimes customer may request to return a product due to various reasons (e.g. short expiry date or other reasons), assessment should be made to determine whether goods are returned due to (or can potentially lead to) product quality issues, the case should be handled as a complaint after proper evaluation.

PRODUCT COMPLAINTS

- *Clause 9.9 - Complaint records shall be reviewed regularly for any indication of specific or recurring problems requiring attention and possibly the recall of marketed products.*

- *Clause 9.10 - For recurring problem, a trending shall be established in order to identify the possible systemic defects.*

- *Clause 9.11 - The NRA shall be informed if a manufacturer is considering action following possibly faulty manufacture, product deterioration, or any other serious quality problems with a product.*

- *Clause 9.12 - The NRA and the complainant shall be furnished with a summary of the action taken.*

PRODUCT COMPLAINTS

- Regular review of complaint records to identify recurring problems (Clauses 1.5, 9.9 and 9.10), recurring problems shows there is a systemic issue.

- Inform National Regulatory Authoirty (NRA) regarding serious quality problems that has potential harm to consumer

PRODUCT COMPLAINTS

- If there are serious quality problems and there are potential harm to consumer, product recall shall be considered. The company shall also inform the National Regulatory Authority (NRA) of the action taken or to be taken and furnish both the NRA and complainant with a summary report.

- Complaints related documentation include:
  - Sample Procedure on Handling of Complaints. (Refer to Annex 1)
  - Sample Complaint Register. (Refer to Annex 2)
  - Sample Complaint Record Form. (Refer to Annex 3)

CASE STUDY

- A consumer bought 2 bottles of product manufactured by your company. He/she is supposed to take 1 tablet each day, but by day 28 he/she found that there are no more tablets left in the bottle. He/she opened the other bottle to count the tablets and found that there are only 28 instead of 30 tablets as indicated on the label on the bottle. He/she then called and lodged a complaint with your sales department.

- Use the sample complaint record form,

1. Record how would you handle such complaint
2. What are the things you will evaluate as part of the investigation
3. What could be the possible root cause
4. What are the action(s) to be taken

PRODUCT RECALLS

- Clause 9.13 - Responsibility and procedures for recall of the product shall be established by the manufacturer to facilitate the recall of a batch from any link of the distribution chain when this becomes necessary.

- Clause 9.14 - The recall procedures shall take into account the degree and level of recall which in line with the NRA requirement.

- There must be a procedure (*Clauses 5.43.7, 9.13, 9.14, 9.15 and 9.17).*
- The procedure shall describe the degree and level of recall in accordance to NRA requirement.

PRODUCT RECALLS

- Recalls could be initiated:

(a) By Company (Voluntary Recalls)

As a result of defective reports from various sources such as manufacturers, wholesalers, retailers, medical practitioners, hospital and retail pharmacists, end-users and members of the public.

All recalls triggered by the company voluntarily shall be reported to the NRA.

(b) By NRA (Mandatory Recalls)

As a result of adverse drug reaction monitoring, product quality surveillance or defective reports from reputable sources.

PRODUCT RECALLS

Example on Classification of Recall

- A recall will be classified depending on the potential hazard of the defective product.
- 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 are contamination with toxic substances and products with major labelling errors.

PRODUCT RECALLS

- 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 labelling errors or products which fail to meet product specification or pharmacopoeia standards but are likely to cause minimal hazard to users.

PRODUCT RECALLS

- **Example on Level of Recall**
  - There can be a few levels of recall. Each recall will be assigned the appropriate level of recall depending on the nature of defect, the distribution networks of the product and the extent of distribution.
  - <u>Recall to Wholesale level includes</u>

    All parties involved in wholesale sale and may include wholesalers and retail pharmacies

PRODUCT RECALLS

- Recall to Retail level includes
  - All pharmacies and other retail outlets eg. health food stores, supermarkets
  - Healthcare practitioners' establishments
  - Nursing homes and other related institutions
  - Clinical trial centres
  - Wholesale level
- Recall to Consumer level includes
  - Patients
  - Other consumers
  - Wholesale and retail levels

PRODUCT RECALLS

- Clause 9.15 - Any action taken to recall a product suspected or known to be defective or hazardous, shall be done immediately and in accordance with a pre-determined plan. The procedures to be followed shall be specified in writing and made known to all that may be concerned.

- Clause 9.16 - A person shall be designated as responsible for execution and co-ordination of recalls and shall be supported by sufficient staff to handle all the aspects of the recalls with the appropriate degree of urgency. This responsible person shall normally be independent of the sales and NRA requirements.

PRODUCT RECALLS

- Recall shall be handled immediately and in accordance to procedure and **NRA requirement**.

- Must designate a person responsible for execution and co-ordination of recalls and this person shall not be from the sales/marketing department and the person liaising with NRA e.g. preferable person is Head of Quality Unit (QA/QC) or regulatory affair personnel.

- Sufficient staff must be given to provide support (e.g. to carry out investigations, to generate distribution records, to contact customer and consumers, to retrieve products back from the market, to securely store products in warehouse and retrieved from market, to generate recall reports, to liaise with NRA, etc)

PRODUCT RECALLS

- In the event that a recall is deemed necessary, the company also has to:
  1. Cease all sales of defective products immediately
  2. Quarantine all defective stocks
  3. Inform all affected wholesalers / distributors / retailers to do likewise first through verbal communication and followed by recall letter or when there is a risk of significant hazard to consumers and the distribution has been extensive,
  4. The Company responsible shall consider employing all possible mass communication media available including newspaper, radio and television broadcast to disseminate the recall information to the consumers.

PRODUCT RECALLS

- Clause 9.18 - Recall operation shall be capable of being initiated immediately and at any time.

- Clause 9.19 - All NRA of all countries to which products may have been distributed shall be informed immediately if products are intended to be recalled because they are, or are suspected of being defective.

- Clause 9.20 - The distribution records shall be readily available to the person(s) responsible for recalls, and shall contain sufficient information on distributor / importer / retailer / wholesalers and directly supplied customers (with latest and valid addresses, contact number including mobile phone, phone and/or fax numbers inside and outside working hours, batches and amounts delivered), including those for exported products.

PRODUCT RECALLS

- All distribution records (including those exported) shall be maintained and able to be generated immediately (*Clause 5.42*) so that the recall operation can be executed with highest importance and urgency.
- All NRAs where products are exported to shall be notified immediately.
- Recall team should be facilitated with approriate communication system.

PRODUCT RECALLS

- Clause 9.21 - Recalled products shall be identified, recorded and stored separately in a secure area while awaiting a decision on their fate.
- Clause 9.22 - The progress of the recall process shall be recorded and a final report issued, including reconciliation between the delivered and recovered quantities of the products.
- There shall be designated and secured area for storage of recalled products (*Clauses 3.24, 3.26 and 9.21*).
- A final report which include reconciliation of products and destruction of recalled products, shall be established.

PRODUCT RECALLS

- Clause 9.17 - There shall be established written procedures, regularly checked and updated when necessary, in order to organise any recall activity.

- Clause 9.23 - The effectiveness of the arrangements for recalls shall be evaluated regularly.

PRODUCT RECALLS

Regularly evaluate the initiation of recall (i.e. the procedure is regularly checked to assess the effectiveness (how fast to generate distribution records, generate recall report, etc) and the procedure shall be updated if it was found ineffective.)

Product Recalls related documentation include:

- Sample Procedure on Product Recalls. (Refer to Annex 4)
- Product Recall Record Form. (Refer to Annex 5)

COMPLAINTS ON ADVERSE PRODUCT REACTIONS

•Clause 9.24 - Unexpected adverse product reactions resulting from the use of the product must be thoroughly investigated and documented. Reports of serious unexpected adverse reactions shall be immediately forwarded to the NRA.

Adverse Product Reaction is defined as:

- an allergic or any other untoward reaction, toxic reaction, fatal or near fatal reaction etc, which are unintended and occurred after consuming a product

COMPLAINTS ON ADVERSE PRODUCT REACTIONS

- Adverse product reactions shall be thoroughly investigated and documented and reported to NRA accordingly following respective national regulation .
- Written procedure for handling adverse products reaction should be available

REFERENCE

1. ASEAN Guidelines on Good Manufacturing Practices for Traditional Medicines.
2. ASEAN Guidelines on Good Manufacturing Practices for Health Supplements.

THANK YOU!

ONE VISION, ONE IDENTITY, ONE COMMUNITY