Central Administration of Inspection on Pharmaceutical Institutions
General Administration of Market Control

Guideline

GUIDELINES ON

RECALL & RAPID ALERT SYSTEM

For Medicinal Products

Year 2025

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1. Introduction

A recall is an action taken to withdraw/remove a drug from distribution or use including corrective actions for which deficiencies in quality, efficacy or safety have been reported. Quality-related defective products include substandard, adulterated or counterfeit medicinal product. Recalls regarding safety and efficacy include serious adverse reactions and death. The recalls also include medicinal products prohibited under the Pharmacy Profession Law, as well as products whose licenses have been suspended / revoked. The recall applies to all pharmaceuticals, including medicines, biological preparations, cosmetics, and medical supplies.

The rapid alert system is the actions taken in the event of warnings, the urgency and seriousness of which does not allow any delay in the alert. An assessment should be made of the severity of the defect and its potential to cause harm to the patient.

2. Background

According to the law 151 for year 2019 law establishing the Egyptian drug authority EDA's objective is to regulate, implement and supervise the quality, efficacy, and safety of medical products. EDA regulate and supervise the production and circulation of medical products and devices and raw materials stipulated under this law, and verify its quality, efficacy, and safety within and outside the republic in the context of regulating Egyptian products and its representation aboard. EDA Set the rules and procedures that regulate the processes of import, export, registration, pricing, circulation, supervision and inspection of medical products and devices subject to this law and raw materials used in its manufacture, through coordination with relevant entities and in accordance with international standards.

3. Scope

This guideline applies to all reports of defective product quality and all safety and efficacy incidents reported and received for all medications including vaccines and biologics. This guideline is followed by licensees (manufacturers, importers, agents, distributors, retailers) and recall can be voluntary or statutory. This guideline can be applied by other agencies in the event that urgent action is needed to protect public health or animal health. This guideline will assist in the adoption of the stepwise actions to be followed in the recall strategy also help in assessing recall at each level and compliance with the time frame.

This guideline is mainly applied on the distributed and marketed batches and incase of the non-conformity of batches that has not been marketed no need for the issuing of recall.

4. Definitions

- **Recall:** Removal of marketed products for reasons of lack of quality, safety, or efficacy, including labeling that is against the law.
- **Batch (es) recall:** The process of removing the selected lot(s) from a product that is found to be defective and poses health risks to consumers if left in the market.
- **Batch:** A specific amount of material produced in a process or series of processes that is expected to be homogeneous within certain limits.
- **Customer:** Any person, institution or entity that purchases / receives goods from the company for storage, distribution and sale.
- **Substandard medical products**: also called ‘out of specification’ refer to authorized medical products that fail to meet either their quality standards, or their specifications or both.
- **Falsified medical products:** are products that deliberately or fraudulently misrepresent their identity, composition or source.

- **Voluntary Recall:** Recall initiated by a Licensee as a result of an abnormal observation in the quality of any product during a periodic (internal/external) review or investigation of a market complaint or any other failure.
- **Statutory Recall:** A recall directed by drug control authorities after verification that a product is in violation of the laws
- **Recall letter**: a document issued by the EDA stating the withdrawal of marketed products as a result of lack of quality, safety, or efficacy, including labeling that is against the law directed to all the relevant stakeholders as well as the public.
- **Alert notice letter**: a document issued by the EDA stating the alerting of the entire rapid alert contact list of the presence of counterfeited product as well as the public.
- **Public awareness letter**: Notification issued by the regulatory body and published on the EDA website notifying the public of incidence of the possible presence of SF product marketed.
- **Rapid alert contact list:** it is contact list of the entire stakeholders and other relevant organizations Contact details include telephone and fax numbers, electronic mail address, who should be notified in case of the presence of SF product.
- **Rapid alert system:** procedures done by EDA for rapid notification of the licensee, manufacturers, the entire stakeholders, other relevant organizations and the public in case of issuance of recall letter/rapid alert notice letter for substandard/falsified respectively that could affect the public health
- **The entire amount of the non-conforming product**: the product that has been detected in the market and still available at the time of recall letter issuance at the supply through evaluating the effectiveness of the recall according to the data of the distributed quantities by the licensee or manufacturers of the recalled product, the quantities that has not been distributed by the licensee,

manufacturers, the quantities that has not been distributed by the entire stakeholders and the quantities distributed by the entire stakeholders.

- **Cytotoxic waste:** waste containing substances with genotoxic properties (i.e., highly hazardous substances that are, mutagenic, teratogenic or carcinogenic), such as cytotoxic drugs used in cancer treatment and their metabolites
- **Infectious waste:** refers to all types of waste that contains pathogenic (disease-causing) microorganisms, for example live attenuated vaccine.
- **Non-hazardous or general waste:** waste that does not pose any particular biological, chemical, radioactive or physical hazard.
- **pharmaceutical waste are**:

· all expired pharmaceuticals;
· all unsealed syrups or eye drops (expired or unexpired);
· all cold chain damaged unexpired pharmaceuticals that should have been stored in a cold chain but were not (for example: insulin, polypeptide hormones, gamma globulins and vaccines);
· all bulk or loose tablets and capsules. If unexpired these should only be used when the container is still sealed, properly labelled or still within the original unbroken blister packs;
· all unsealed tubes of creams, ointments, etc. (expired or unexpired);
. all recalled and SF products.

5. RECALL ACTION CLASSIFICATION

Recall classification assigned to a particular product recall that indicates the relative degree of health hazard by country regulatory authorities.

Class I: A dangerous or defective product that can cause serious health problems or lead to death.

For instance:

- Microbial contamination of sterile injectable or ophthalmic product
- Correct product but wrong strength, with serious medical consequences
- Chemical contamination with serious medical consequences

Class II: A product that may cause a temporary health problem or pose a minor threat of a serious nature.

For instance:

- Mislabeling, e.g., wrong or missing text or figures
- Missing or incorrect information (leaflets or inserts)

Class III: A product that is not likely to cause a health problem but violates labeling or manufacturing laws and guidelines.

6. LEVELS OF RECALL ACTION

The level (or depth) of product/lotion recall should be determined based on the redemption classification and the level to which it was distributed.

There are three levels of recovery:

Consumer or user level:

Individual consumers, patients, doctors and hospitals.

Retail level:

Call to the level immediately preceding the consumer or user level. It includes pharmacies and hospital pharmacies.

Distributor level:

All levels of distribution between manufacturer and retailer.

All invocations must be executed from

Class I to distributor, retail and consumer levels. In such cases, public advertising should be done using media, electronic, newspapers, television, and radio etc., In addition to obligating the distribution companies to print the recalled item on their sales invoices.

Class II to distributor and retail levels.

Class III to distributor levels.

7. Phases of Recall

The Recall Action Process involves the following phases of activity

- An initiation phase when problem identification, risk assessment, the decision on whether to recall, and the planning for the recall action occurs.
- An implementation phase when the recall action notice is issued by the sponsor and the requested recall action is undertaken.
- A review phase when monitoring and review of the effectiveness of the recall action is undertaken by the sponsor with oversight by authority.

8. Product defect reporting

- Market authorization Holders, product registrants, manufacturers, and importers of medicinal products, in addition to the distributors of the whole supply chain and the pharmacies, are obliged to report to EDA any defect in a medicinal product within the scope of their authorization that could result in a recall or abnormal restriction in supply (like suspension of manufacturing).
- If a batch or batches of affected products have been imported into the Egyptian market, MAH is required to report any alerts related to product defects or enforcement taken in this regard.

- Product defect that affects the product's safety, quality, and efficacy include possibly faulty manufacture, product deterioration, detection of falsified medicines, or any other serious quality problems with a product.
- Market authorization Holders and suppliers should have systems and procedures in place to investigate, review, and report the product defects to EDA, and if necessary, to promptly recall affected products. These defects might include quality defects on APIs used as starting materials.
- It is the responsibility of the company to undertake the actions taken by EDA including recall. In case of any batch(es) or product recall, it is normally the responsibility of the company to implement, follow up, and notify concerned authorities, the supply chain, and customers. If the recalled batch(es) or product is exported by the MAH, it is required to notify the importing entity of the recall and provide proof of receipt to EDA.

8.1 Classification of product defect

A defect is classified according to the potential impact on public health and the risks posed to the product's intended user.

The product defect can be classified into:

critical quality defects are defects that are potentially life-threatening or could cause serious risk to health.

Moderate-risk quality defects are defects that could cause illness or mistreatment with potentially non-serious medical consequences but are not classified as critical.

Low-risk quality defects are defects that are not likely to pose a significant hazard to health.

8.2 Information to be included in the initial product defect reports

The initial report of product defects should contain as much details as available, but reporting should not be delayed due to the time needed to gather the full information.

The minimum information required for the submission of an initial report of product defect is:

1- Product information (e.g., name, strength, and dosage form)
2- Description of defect.
3- Number of the product(s) or batch(es) affected and the total number of packs.
4- Date of occurrence.
5- The expiry date of affected batch(es).
6- Date of last distribution of the affected batch(es) to the market.
7- Full details of focal point to contact in case of more information inquiries.

8.3 timeframes for the initial quality defect reporting

Critical defects should be reported within two working days while medium and low-risk quality defects should be reported within 15 calendar days.
For critical defects that pose a risk to the public, prompt measures must be taken to minimize the risk (including market actions) even if they must be taken during non-working hours.

8.4 The follow-up investigation and risk assessment report

Following the initial report, the MAH is needed to submit the investigation report, health hazard assessment, and corrective and preventive actions (CAPA) plan to EDA.
The follow-up investigation and risk assessment report should include the following (but not limited to):

1- A more detailed description of the defect.
2- The root cause analysis of the defect.
3- Detailed information about how the defect was detected, the exact date of occurrence, and the pharmaceutical institute where the product was collected (if applied).
4- Evaluation of samples of the defective product and clear comparison between it and the retained sample of the same batch.
5- Local and Overseas distribution records of affected batches.
6- Indicate whether the product was supplied to the UPA or under tender

contract or pending tender consideration.

7- Review of previous complaints, quality defect reports, and relevant

8- information for any indication of recurring problems; whether other similar defects had occurred locally or globally.

9- Health hazard assessment on the potential short-term and long-term consequences of the defect to intended users.

9. Initiation of recall

Any batch of the product that does not meet the specified quality standards must be withdrawn from the market. The recall can be of two types: Voluntary recall and statutory recall.

9.1 Voluntary recall

The manufacturer or importer of a medicinal product shall provide the Authority with request for recall including the following: -

(a) product name and generic name, dosage form, strength, batch or lot number, pack size, the name and address of the manufacturer, manufacturing date and expiry date of the recalled product;

(b) The reason for the recall, the nature of the defectiveness or possible defectiveness, the date on and circumstances under which the defects or possible defects were discovered;

(c) The distribution list of the product batch(es) to be recalled containing :

1-quantities produced or imported

2- date on which distribution of the product began.

3- List of customers to whom product was distributed with the dates of distribution for each.

(d) The manufacturer or importer of a medicinal product should provide the EDA with the plan of recall and the timeframe for the recall that is proportional to the class of recall

(e) The manufacturer or importer of a medicinal product shall submit to the EDA

an investigation report detailing causes of the defect and corrective and preventive actions undertaken.

EDA will publish the voluntary recall on the website to notify the public after the voluntary recall request risk assessment.

The manufacturer or importer of a medicinal product shall submit to the EDA a weekly progress report of recall and the final report after completion of a recall which includes reconciliation between delivered and recovered quantities of the product

In case of the manufacturer or importer non-compliance with the plan of recall EDA will mandate statutory recall and regulatory decision will be taken if needed.

9.2 Statutory recall:

A statutory recall may be initiated in response to a direction or authorization by the drug authority in one or more of the cases as follows:

1. If it is found that the batch or batches do not comply with the regulatory specifications during the post-marketing surveillance study
2. If it is found that the batch is defective during the investigation of the market complaint.
3. During any random conformity and validity investigation if there is a negative quality impact on the lot already analyzed (e.g., potential for contamination, mixing, deterioration, etc.).
4. If there is any unusual observation during the visual inspection of the retention samples which indicates an effect on the quality of the product after investigation.
5. If the post-marketing monitoring reports or the pharmacovigilance reports indicate the presence of serious safety risks associated with the product.
6. To recall the drug product / batch that is in violation of laws such as non-standard quality

7. Withdrawal of prohibited drugs.
8. in case that there are promotional materials that are in violation of the law or there is an error in the internal bulletins
9-Issuance of instructions from international bodies

When evaluation of a reported issue concerning a medicinal product indicates that a recall action may be necessary the classification and level of recall action is determined following discussion between the different departments within the EDA and will involve an assessment of the health hazard presented by the product.

The level of recall action will generally reflect the safety risk and distribution pattern of the product.

9.2.1 Factors affecting the statutory recall

In case of detecting non conformity for product there should be factors that should be taken in consideration before the initiation of recall action, and more investigation should be done to emphasis that the findings have been monitored is not affected by other external factors and to determine the necessity of recalling of the product according to risk assessment.

A. Risk assessment

The risk assessment includes consideration of the following factors:

The nature, extent and urgency of possible public health risk

- The likelihood of the issue occurring
- The ability of the consumer, healthcare professional or caregiver to discover/identify the issue should it occurs.
- Whether the product complies with the approved specifications.
- The availability of an alternative product, or the risk associated with not providing treatment if an alternative product is not available.
- Risk of not receiving the correct medication.

- Long-term risk as well as immediate risk.
- In the case of suspicion of defective vaccines (cross contamination with a virus), risk of distorting the analysis in national programs against certain viral diseases.

Further professional assessment of the risk from the product should involve discussion with the manufacturer or importer and include consideration of: Any other reports which may be related;

- The distribution of the batch (e.g., restricted to known hospitals, widespread through wholesalers).
- Date of first distribution and last distribution.
- any remaining stock with the manufacturer or importer.
- Probability that other batches are affected in the same way, and their distribution.
- If a recall is being considered extremely important issues to consider include:
- possibility of an out-of-stock situation.
- availability of alternative products.
- Clinical effect of a disruption in supply.

B. On-site inspection

On routine investigation or upon complaint unusual observation has been detected and thus a recall action is taken in consideration, some points should be stated in the onsite inspection to help in taking the decision of recall action.

The storage condition should be mentioned to exclude incorrect storage as the cause of the suspected defect.

Visual inspection is a must and identify if the defect is visible and a full description of the defect should be described.

it should be stated was the defect identified in a new previously unopened container or had the container previously been used to exclude user errors such as product mix-ups and so other unopened containers of the same batch available could be checked.

If the product is used with a medical device because in some cases the device could be the cause of the incident

Authority should contact the manufacturer or importer for providing an original pack for the suspected product to make a comparison between the original and suspected pack

C. Previous history.

Previous report of the manufacturing or importing site should be made included and any comment on general GMP compliance and what related products manufactured or imported.

On-site inspection may be required to assess batch records of the product concerned, plant records and records of other batches or products which could also be affected.

Samples may be taken of the batch concerned, related batches and related starting materials. When considering taking material from the company's retained samples, consideration must be given to the quantity available and all tests which may be required for further investigations.

10. Rapid Alert System

This procedure covers the transmission of information when urgent action is required to protect public or health by means of a rapid alert relating to the recall or withdrawal of medicinal products, which have quality defects or which are falsified, the aim of the Rapid Alert System is to transmit those alerts whose urgency and seriousness cannot permit any delay in transmission.

10.1 Criteria for Rapid Alert notification

The urgency of the removal of defective medicinal products can be classified to: -
Class I defects are potentially life threatening. A rapid alert notification must be sent to all contacts of the rapid alert notification list irrespective of whether or not the batch was exported to that country. Transmission of a Class I rapid alert must be within 24 hours, with a maximum of 48 hours of the recall letter issuance.
The notification shall be sent stating the severity of the defect, using the fastest mode of communication which may include email, telephone, fax, SMS etc. to the entire supply chain.
EDA can offer guidance to the recalling firm so that the product will be promptly removed or corrected
Alert notification can be in multiple forms including press releases, telephone calls, telegrams, telefaxes, mailgrams, or first-class letters.
Alert notification should be brief and to the point; clearly identify the product(s) such as the product name, size, brand name, serial numbers(s), potency, dosage, type, model, and batch number
Alert notification should be sent in the most expeditious manner and commensurate with the hazard of the product being recalled, and, where appropriate, sent with proof of receipt (e.g., by certified mail).
The licensee/representative of licensee where the product is marketed shall inform the concerned regulatory authority where the product batch (es) in question was distributed immediately after the decision of recall has been taken. Further actions on recall will be undertaken according to class of recall.

Class II defects could cause illness or mistreatment, but are not Class I. A rapid alert notification should be sent to all contacts of the rapid alert notification list as it might be difficult to know where a batch has been distributed. If the product distribution is known, the notification should be only sent to the contacts concerned. Whenever feasible, transmission of a Class II rapid alert should be transmitted within 72 hours.

Class III defects May not pose a significant hazard to health, but notification of the entire stakeholders should be done within 5 days of the recall letter issuance.

For the falsified product that an alert notice letter or public awareness letter has been issued a rapid alert notification should be sent to all contacts of the rapid alert notification list within 24 hours, with a maximum of 72 hours of the issuance.

The contact list for rapid alert notifications shall be used for the transmission of notification falling in the scope of this procedure and the GMP non-compliance procedure; these messages should clearly identify the subject and whether they are for information or action.

All procedures should be documented and maintained up to date.
The rapid alert Contact lists for officials and companies should be maintained up-to-date and should be verified at intervals (e.g., a rolling program of annual checks of company contacts, possibly as part of GMP inspections).
All staff who could be involved in receiving a report of a suspected defective product or handling a Rapid Alert should be trained in the relevant procedures and have access to a copy of the CA s and report forms wherever they needed.

10.2 Criteria for recall letter/rapid alert notice publication

Upon the issuance of the recall letter or the alert notice letter by the EDA, the publication on the EDA website should be done according to the category of risk involved this is done based on the category of risk involved:
Class I recall: publication is made within 24 hours, with a maximum of 48 hours.
Class II recall: publication is made within 72 hours.
Class III recall: publication is notified within 5 days.
Alert notice letter/ public awareness letter: publication is made within 24 hours, with a maximum of 72 hours.

10.3. Intervals for efficient recall system

This is done based on the category of risk involved
Class I recall: the recall process is executed with a maximum of 14 days.
Class II recall: the recall process is executed with a maximum of 21 days.
Class III recall: the recall process is executed with a maximum of 30 days.

The EDA reserves the right to determine the maximum time for recall depending on the urgency and health risk involved.

11. Implementation of recall

11.1 Stepwise Recall Procedure:

Once the product / batch or batches to be recalled by the authority have been identified, the company that owns the product or the agent of the product must be informed immediately. The authority will form a committee from the competent departments in order to ascertain the extent of the commitment of all parties to the success of the recall process and review the extent to which the time plan is followed based on the recall category and determine any Weaknesses in the process, whether by communicating with the company that owns the product or the importing agent, as well as distribution companies and public and private pharmacies, and following up on the detailed steps in the recall process. Accordingly, a file is opened by the formed committee specifying all the information related to the process.

The company that owns the product or the agent of the recalled product must inform the Authority of the distribution of the product / batch as soon as it is notified of the recall.

The company that owns the product or the agent of the recalled product must review the information related to the defective product / batch or batches, enter the details in the “Recall Record” and assign a unique recall reference number that represents the serial number of the month and year in which the recall began.

Within 24 hours of the decision taken to retrieve the product / batch or batches, the company that owns the product or the agent of the product that has been recalled or the head of quality in charge must inform the distribution company or the store by the fastest communication method which may include email, phone, fax, SMS etc. To stop the further distribution of the preparation and to reserve the quantities they have, depending on the severity of the defect that must be mentioned

The Product/Batch withdrawal notice sent by the company that owns the product, the agent for the recalled product, or the responsible head of quality to the distributor.

After completing these steps, the company that owns the product must provide the Authority with copies of the notice of product withdrawal explaining the seriousness of the defect and warning of the reservation of quantities at the distributors and the withdrawal of the product from the market for each of the distributors indicated in the distribution statement.

The Distributor shall immediately check the distribution history to identify the customers and warehouses in which the respective product/runs have been distributed and send copies of the recall notice to them for further necessary action.

The head of the main store or the head of the sales sector must ensure that the circulation of the product has been stopped by reviewing the register and at the same time keeping the available stock.

All branches must send Return Notes with merchandise (if any) to the main store. All returned stocks must be sent to storage warehouses.

The head of the main store or the head of the sales sector ensure that he sends a periodic report to the owner of the product or the agent for the product with the stock available to them and the returns received from the branches.

Head of Main Store or Head of Sales segment should reconcile the stocks of recalled materials against the total quantity of materials received and fill in "Product Summary Report / Batch Recall".

The copy is sent to the owner of the product or the agent for the product with the stock they have, and the returns received from the branches for review, taking the necessary action and preparing for receiving the recalled quantities. The copy is sent to the competent department of the Egyptian Drug Authority based on the nature of the recalled product in the quantities to be returned to the companies that own the product or the agent of the product, the receipt of the owner of the product or the agent of the returns is monitored.

The recall of the product / lot depending on the recall category must be completed within the specified time.

12. Review phase

12.1 Follow-up procedures for products returned by the drug authority

The inspectors of the EDA make an inventory of all quantities returned from the distribution companies to the company that owns the product.

An inventory is made of all the quantities in the stores of the company that owns the product, and it is matched with the quantities returned from the distribution companies.

The stock of returned products must be placed under 'quarantine' and stored separately under lock and key in a secure area until a decision is made by EDA inspectors

A final report is made by the drug authority explaining all the observations on the recall process, identifying strengths and weaknesses, and determining any corrective measures for the process, if any.

There are factors that help in evaluating the recall as:

1-The date of production of the batch and the time period from its production until the publication of the publication

2- Likewise, the recalled product or batch is specific to the local market or hospitals

3- Product consumption rate

4- Quantities in the possession of the owner of the product or agent and in distribution companies and warehouses, as well as the quantities that were distributed to pharmacies when the recall publication was issued Summoning class and summoning level.

A date must be set for the destruction of all the quantities recalled by the owner of the product or the importer, no later than three months from the date of issuance of the recall letter or the voluntary recall request, unless a justification is submitted to the authority and been approved.

12.2 Follow-up procedures for the returned products by the owner of the product

12.2.1 In case of class II

The follow-up procedure consists of checking the effectiveness of the recall, investigating the cause of the recall and remedial actions taken to prevent recurrence of the defect.

The Licensee / Licensee's Representative / Head of Quality Assurance shall monitor the recall of the product / lot to determine whether the recall is proceeding satisfactorily.

The stock of returned products must be placed under 'quarantine' and stored separately under lock and key in a secure area until a further decision is made.

Where required, the Head of Quality Assurance at the manufacturing site must perform a physical examination of the recalled merchandise and collect samples of the returned merchandise for investigation to determine the root cause of a product quality defect.

Investigation of recovered lot(s) shall be conducted in accordance with Licensee's SOP, "Investigation of Non-Conformity" to identify the root cause of failure and initiate corrective and preventive actions Impact assessment shall be conducted on other runs of the product concerned and extended to runs of other product(s), where applicable.

If the reason for recall proves to be a quality issue associated with any of the raw materials used, then traceability of that material in all products/runs must be determined through records to identify the batches/products in which the specified materials were used.

12.2.2 In the case of first class I recall.

Monitor relevant data, i.e., material, plant and lot number in each of them

Determine traceability of raw materials in different formulations and their functions.

List all raw materials with batch numbers and quantities used in those batches.

List all products with batch numbers and related quantities used in those batches.

Calculate the total quantity by adding up the individual quantities used in different products/batches.

Monitor the movement of materials to get a complete stock overview for that particular material in the factory and extract information about the total quantity received and the stock quantity.

The balance, if any, should be checked against the actual physical stock available. A plan must be made to make a random drawing based on this data to verify the effectiveness and safety of products or processes.

The decision to withdraw any affected batches, if necessary, should be made after evaluating the quality of the product.

Based on the results of the investigation, the Head of Quality Assurance / authorized representative shall instruct the distributor / marketing company in order to appropriately dispose of the batch(s) of returned merchandise in accordance with the regulations.

13. Appeals:

the licensee or manufacturers has the right to submit technical appeal directly to the head of CA of Inspection on Pharmaceutical Institutions accompanied with all technical justifications within fourteen days of the recall issuance.

these appeals then directed to the relevant decision to investigate and prepare a detailed report about the issue in question, accompanied with all related documents to be viewed by the head of CA of Inspection on Pharmaceutical Institutions for final decision.

Unsatisfied applicants may only resort to Grievance committee, all other appeals shall be deemed as previously resolved, except for those admitted accompanied by new technical documents.

Grievance shall be submitted not later than sixty days from the date of the recall issuance, which will be submitted to the Grievance committee.

a ruling on the grievance shall be rendered within sixty days from the grievance submission.

14. Disposal

Recalled medical product should be destructed not more than three months of recall letter issuance unless request from the product licensee is submitted to the EDA to postpone the disposal for instance in case of appeals and should be approved by EDA, the destruction of the SF products is mandatory to prevent the reentrance of these products to the supply chain and thus a unit related to the Market control administration has been developed for the recall follow-up and

disposal of all unwanted medical products.

14.1 The following procedures will be applied on the safe disposal of SF products as well as:

a- Batches for which non-conformity reports have been issued by EDA and the whole batch is sealed in the factory and the company wants to destruct them upon its own request.

b- Batches for which non-conformity reports have been issued internally by the company and the company wants to destruct them upon its own request.

c- Defected batches after a detailed report carried out by the inspector to find out the cause and make sure of it.

d- Batches that the technical committee of the EDA issued a decision of disposal

e- Batches that the supreme inspection Committee issued a decision of disposal

f- SF medical products that the competent judicial authorities issued a decision of disposal

g- Batches for which a decision of disposal has been issued by international organizations warnings (WHO - EMA- ...)

h- Pilot batches, clinical trial and R&D batches.

This guideline provides recommendation for safe disposal of unusable unwanted Medical Product; Unwanted, Expired pharmaceutical product, medical device, Biological, cosmetics and Kits

The best environmental choice for Medical Product disposal is high temperature incineration with adequate flue gas cleanup. However, this is not only method that can be used to achieve adequate disposal.

15. procedures of safe disposal

A series of steps need to be taken when disposing of unwanted pharmaceuticals, and these are briefly summarized below.

15.1 Request

The licensee, warehouse, pharmacy, hospital or organizations with pharmaceutical programs decide when action needs to be initiated, because of an accumulation of unwanted pharmaceuticals which are unfit for human consumption and for veterinary treatment, will follow the following procedures:

A request for the disposal of damaged or expired medical product by the product owner or the manufacturer or the agent of importation or the scientific office in case of promotional samples fulfilling the following documents.

1- Letter approved and stamped by the company addressed to EDA (Central administration of Inspection on Pharmaceutical Institutions) requesting the disposal of the products clarified in the product list attached to it and showing the place of disposal and the method of disposal Email of the service requester.

2- product list showing the products to be destructed and reasons of disposal request and in case of more than one reason it will be determined a in the product list by linking the products and the reason of their disposal that should contain the following items:

a-Name of product (s)(including pharmaceutical finished products or raw materials)
b-Batch/ Batches no. c-Expiration dates d-Quantities of each batch
e-The weight of the products to be destructed

3-The recent official approval by the Ministry of Environment for the place of disposal should be submitted

4-Notification letter stating the person in charge of the company to deliver and receive the papers and attend the execution process

5-Written pledge that these products not pending submission to the prosecution

15.2 Decision

The approval and sanctioning of disposal of pharmaceuticals is done after revising all these documents within 5 working days and respond will be sent to the service requester email or informing the contact person stating the case of the request as follow :

1- incase all documents submitted meets the EDA criteria the service requester will be informed to decide the date of disposal of the products within 14 days of the informing email otherwise the request will be cancelled

2- incase of missing documents the service requester will be informed by all the documents needed to be submitted within 5 working days otherwise the request will be cancelled and upon submission these documents will be revised within 2 working days for final decision and if these documents meets the EDA criteria the service requester will be informed to decide the date of disposal of the products within 14 days of the informing email otherwise the request will be cancelled

3- incase of needed reports from other administration for instance in pilot batch disposal the service requester will be informed with the case, the relevant administration will be contacted to submit the report needed within 5 working days to inform the service requester.

4- incase of the request refusal a full detail of the reason of refusal will be sent to the service requester and another request can be submitted after corrective actions is done

15.3 Planning

Planning, in terms of human resources, professional time, space, equipment, material and available disposal options will be required. This is essential before practical steps can be taken to start disposal. To obtain a rough estimate of the volume of materials to be sorted, it is recommended that measurements are made using a tape measure, and conversion from volume of material to weight is made using a density figure of 0.2 metric tons/cubic meter, which Is mandatory to be submitted by the request provider

15.4 Forming work teams

EDA will identify the auditors who will take over as technical members to participate in the committee formed by the service requester to supervise the destruction and informs the applicant. The size of each team, and the ratio of experts to workers, will be determined by the volume and composition of the stockpiles, and working conditions at the site. The work teams could be including:
-Quality assurance representative (in case of the applicant is the manufacturer)
-Warehouse representative
-Responsible pharmacist
-Financial department representative
-Security representative

15.5 Sorting

The objective of sorting is to separate the pharmaceuticals into separate categories for which different disposal methods are required. EDA auditors shall go to the warehouse where the products are kept to supervise and follow up the work of the committee formed by the service requester to carry out the disposal process to ensure the type and quantity of products to be destructed and the expiration date compared with the list approved to be destructed and then all these inventory items sealed whether in a separate warehouse or in the trucks for transportation by the auditor's seal.

15.6 Disposal

the EDA auditors shall go the day after to the execution site to supervise the disposal process and ensure the safety of the seals and to follow up on the disposal process of all the products that have been released. The disposal shall be carried out in accordance to method and place mentioned in the notification letter

In the case that the EDA Auditors observed any lack of safety of the seals or the existence of any change in the type or quantity of products to be destructed or change the method of disposal, auditor will stop disposal process and write report and justification from the applicant should be admitted within 24 hours.

15.7 For Destruction of IMP and Surplus Human Samples

The applicant should notify administration of protocols and studies follow up at general administration of clinical trials- Bio-Inn upon planning for IMP or surplus human samples' destruction (Figure 1) by submitting all required documents to the e-mail (bio.ct@edaegypt.gov.eg)

- The required documents are:
  - The IMP accountability and reason for destruction,
  - The records of IMP quantities and batches that will be destructed,
  - The Ministry of Environment accreditation certificate for the vendor or the site at which the destruction will take place (in case of IMP and/or human samples destruction)
  - The contract with the vendor at which the destruction will take place (in case of IMP and/or human samples destruction)
- The administration of protocols and studies follow up send this document to the Central Administration for Inspection on Pharmaceutical Institutions as a request for planning of destruction. The Central Administration for Inspection on Pharmaceutical Institutions will contact the applicant for the arrangement of the destruction process in the presence of one of EDA's inspectors.
- After completion of the destruction process, the applicant is required to send the destruction minutes via e-mail (bio.ct@edaegypt.gov.eg).

16. Disposal methods.

16.1 Landfill

To landfill means to place waste directly into a land disposal site without prior treatment or preparation. Landfill is the oldest and the most widely practiced method of disposing of solid waste. Three types are recognized.

A) Open uncontrolled non-engineered dump
which is not used approved by EDA for safe disposal of any medical product due to pollution, with the risk of drinking water contamination in the worst cases and also subjecting to scavenging.

B) Engineered landfill Such a landfill has some features to protect from loss of

chemicals into the aquifer. Direct deposit of pharmaceuticals is second best to discharging immobilized pharmaceutical waste into such a landfill.

C) Highly engineered sanitary landfill

An appropriate landfill consists of an evacuated pit isolated from watercourses.

16.2 Waste immobilization: encapsulation

It involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum.

16.3 Waste immobilization: inertization

It is a variant of encapsulation which transform the pharmaceutical product into homogenous paste, The paste is then transported in the liquid state by concrete mixer truck to a landfill and decanted into the normal urban waste.

16.4 Sewer

Some liquid pharmaceuticals, e.g. syrups and intravenous (IV) fluids, can be diluted with water and flushed into the sewers in small quantities over a period of time without serious public health or environmental affect.

15.5 Burning in open containers

This method is not approved by EDA , as toxic pollutants may be released into the air.

16.6 Medium temperature incineration

two–chamber incinerator that operates at the minimum temperature of 850°C, with a combustion retention time of at least two seconds in the second chamber.

16.7 High temperature incineration

furnaces that operate at temperatures well in excess of 850°C, have long combustion retention times and disperse exhaust gases via tall chimneys, often to high altitudes.

These furnaces existing in industrial plants Industries which use high temperature technology, such as cement kilns13, coal fired thermal power stations or foundries.

16.8 Chemical decomposition

which is chemical inactivation of the unwanted medical product

17.Recommended disposal methods according to the dosage form and product nature.

17.1 Antineoplastic

Antineoplastic should be segregated from other pharmaceuticals and kept separately in clearly marked containers.
first option: High temperature incineration
Second option: Waste immobilization: encapsulation
Antineoplastic drugs/waste should never be disposed of in a landfill or disposed in sewer or watercourses or even use medium temperature incineration

17.2 Anti-infective drugs

first option: High temperature incineration
Second option: Waste immobilization: encapsulation or Inertization
Liquid anti-infective drugs may be diluted in water, left for two weeks and disposed to the sewer.
Anti-infective drugs should not be discarded in an untreated form.

17.3 Disinfectants

In general disinfectants do not have an expiry date. If possible, disinfectants should be used, for example for toilet cleaning in hospitals. Some disinfectants with strong bactericidal and antiviral activity, such as Lysol (50% cresylic acid), may have an expiry date. If this date has passed, the material can still be used for general disinfection purposes at an appropriate dilution decided by a pharmacist, or disposed of in a chemical waste disposal facility or a cement kiln.
Large quantities of disinfectants must not be flushed into the sewer, as they may kill the bacteria in a sewage works and so stop the biological treatment of the sewage. Similarly, large quantities should not be put into watercourses since the disinfectants will damage aquatic life. Small quantities of diluted disinfectant may be disposed of by discharge to a sewer.

17.4 Pesticides

they are not disposed and should be shipped out of the country.

17.5 Solids, semi-solids and powders

Small quantities of solid and semi-solid pharmaceuticals, can be disposed of directly in an Engineered landfill with large volumes of municipal solid waste, if no other suitable method is available.

Large quantities of solid and semi-solid pharmaceuticals are best destroyed by high temperature incineration. Medium temperature incineration is however widely practiced for solid form pharmaceuticals, provided that the pharmaceuticals are “diluted” in large quantities of municipal waste. the use of the encapsulation method represents an acceptable, but not always feasible, method of disposal for large quantities of pharmaceuticals.

17.6 liquid pharmaceuticals (except controlled drugs, antineoplastic or anti-infective drugs)

they may be diluted and flushed into a sewer. If there are no sewers or there is no functioning sewage treatment plant, liquid pharmaceuticals can be first diluted with large volumes of water and poured into large watercourses, providing they are immediately dispersed and diluted by the flowing river water. Liquid pharmaceutical waste may be disposed of using the cement encapsulation procedure, high temperature incineration or in cement kilns.

17.7 Ampoules

These can be crushed on a hard impermeable surface (e.g. concrete) or in a metal drum or bucket using a stout block of wood or a hammer. The crushed glass should be swept up, placed in a container suitable for sharp objects, sealed and disposed of in a landfill. The liquids released from the ampoules should be diluted and disposed of as described above.

Ampoules should not be burnt or incinerated as they will explode, possibly causing injury to operators and damage to the furnace or incinerator. Melted glass will also clog up the grate of a furnace or incinerator if the operating temperature is above the melting point of glass.

NB: Ampoules of antineoplastic or anti-infective drugs must not be crushed and the liquid discharged to sewers. They should be treated using the encapsulation or inertization disposal methods described above.

17.8 Aerosol canisters

Disposable aerosol canisters and inhalers should not be burnt or incinerated, as high temperatures may cause them to explode, possibly causing injury to operators and/or damage to the furnace or incinerator.

Provided they do not contain poisonous substances they should be disposed of in a landfill, dispersed among municipal solid wastes.

18. References:

1. Law No. 151 for Year 2019 for establishing Egyptian drug authority.
2. The Pharmacy Practice Law 127/1955
3. Ministerial decree 540/2007
4. EDA Chairman Decree No. 146/2022
5. The WHO TRS for GMP Guidelines.
6. EMA/572454/2014 Rev 17 Compliance and Inspection
7. USFDA documents on recall.
8. WHO Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies.
9. Management of wastes from immunization campaign activities.
10. safe Management of wastes from Health care activities (WHO, 1999)
11. EDA Chairman Decree No. 420/2021
12. Ministerial decree 104/2003
13. الدليل الإرشادى الخاص بوزارة البيئة بشأن إدارة نفايات الرعاية الصحية في مصر

19. Abbreviation:

EDA	Egyptian Drug Authority
CIP	Central Administration of Inspection on Pharmaceutical Institutions
GMP	Good manufacturing practice
SOP	Standard Operating Procedure
CA	Central Administration
WHO	World Health Organization
EMA	European Medicines Agency
R&D	research and development