DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Guideline				
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1.0 Purpose:

Directorate General of Drug Administration (DGDA) protects the public health by helping to ensure the quality, safety and efficacy of health care products including active pharmaceutical ingredients, medicines, vaccines, biologicals, medical devices and in-vitro diagnostics for human and animal health care. The purpose of this guideline is to lay down the procedure for complaint by a stakeholder and/ or service recipient and/ or public regarding any service of DGDA and/ or health care products under regulation of DGDA.

2.0 Scope:

This guideline is to supports the implementation of quality systems within DGDA components by clarifying the concept of "customer and/ or stakeholder" of the national regulatory authority DGDA.

This guideline is to adopt correct procedure with respect to complaint by a stakeholder and/ or service recipient and/ or public regarding any service of DGDA and/ or health care products under regulation of DGDA for public health protection.

3.0 Responsibility:

3.1 All staff of DGDA working for regulatory activities.

3.2 Inspector of Drugs and Superintendent of drugs providing regulatory services.

3.3 Assistant Director (AD), Deputy Director (DD) and Director are responsible to establish and control the procedure for handling complaint & customer feedback.

3.4 QA shall conclude the whole process of handling complaint & customer feedback.

3.5 DG, DGDA will direct for further necessary action.

4.0 Definitions/Abbreviations

CAPA	-	Corrective Action & Preventive Action
CFR	-	Code of Federal Regulation
DGDA	-	Directorate General of Drug Administration
DG	-	Director General
ISO	-	International Organization for Standardization
QA	-	Quality Assurance
QMS	-	Quality Management System
SOP	-	Standard Operating Procedure

Definitions:

Customer: A person or organization (internal or external) that receives a product or service anywhere along the product's life cycle [1].

Internal Customer: Internal customers are persons or units within an organization that receive your products, services, or information. Many times you will find your immediate customers to be part of your organization, component, or even unit rather than a party external to DGDA. Internal customers within your own unit may be referred to as "process partners [1]."

External Customers:

Any customers outside of DGDA are called external customers. Many DGDA employees do not interact directly with external customers, but they must know how their work products or services may be related to external customers' requirements downstream in the work process.

The DGDA serves four primary customer groups –

(1) The general public (consumers),

(2) Health professionals,

(3) Other government agencies, and

(4) Pharmaceutical industry.

These four broad categories encompass the populations that DGDA serve and work with most often. DGDA may be involved with other customers such as academia, legal firms, trade associations, or the media. Unlike in some private sector contexts, DGDA's definition of customer does not relate to an exchange of money or a purchase, a buying decision, to define a group as an external customer.

Complain:

Expression of satisfaction/ dissatisfaction made to an organization related to its product or service or the complaints-handling process itself, where a response or resolution is explicitly expected. (ISO 9000:2015).

Customer satisfaction and opinion, comments and expression of interest in a product, a service, or a complaint-handling process (ISO 9000:2015).

Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution (21 CFR 820.3).

5.0 Procedure:

5.1 Any stakeholder/ service recipient/ customer may raise complaint through the standard procedure. The complaint should be in regard to quality, safety and efficacy of supplied medical products in the market and/ or service/ response/ regulatory activities of the national regulatory authority DGDA.

- Complaint may be over phone/ written by mail/ filling up online form of application for raising complaint.
- In-regards to each complaint, responsible officer will provide feedback against complaint according to the SOP: Procedure for complaint Handling and measuring customer satisfaction (NRA-RS-010).
- DGDA will take formal approach for resolution of any complaint, provide final feedback, final solution and keep record.

5.2 Any stakeholder/ service recipient/ customer can report problems about any products/ services that the DGDA regulates.

Products include:

- Human prescription and over-the-counter (OTC) drugs
- Medical devices
- Veterinary products, including foods and drugs for animals
- Biologics, including vaccines, blood and blood components, and tissues for transplantation

Service include:

- Registration of medical products
- Substandard and/ or falsified claim
- Application pending/ hold/ withheld/ cancelled
- License suspension, cancellation, revoke

5.3 Why to Report: Information about problems or unexpected reactions can help the DGDA protect the public health. For instance, if anyone report a problem to the DGDA, could help identify an unknown risk. And the report could help the DGDA to know when to carry out preventive and protective actions, which can include requiring labels to provide new warning information and issuing safety messages to the public. Products also can be

potentially removed from the market. The complaint help DGDA for risk mitigation planning, regulatory decision, policy making, guideline development and update.

5.4 How to issue a complaint:

a) Immediate call to the DGDA complaint management call center number: **16541**

b) Written complaint by using complaint raising form and sending it to DGDA by mail ensuring complete communication information of the issuer oof complaint: Name, Mail address, Phone number, Age, Sex, Area, District, Division, complaint category.

c) After receiving the complaint, DGDA will take responsibility to solve the complaint as earliest as possible, that is within 7 days.

5.4 Standards of complaint management:

5.4.1 The standards described below represent the DGDA's effort to identify the needs and concerns of customers. The standards are based on measured performance attributes—a set of criteria that expresses customer requirements and expectations. Performance attributes are organized into two categories.

(a) Process Attributes:

Internal activity process related characteristics represented by internal operations, such as procedures, policies, and functions.

- **Consistency in policies and procedures** – holding to the same principles or practices across the organization.
- **Convenient feedback mechanisms** – feedback (output that is responsive to input) arrangements that are easy to use or get to.
- **Ease of communication, including follow-up** – any form of communication on a regular basis, where the effectiveness of that communication is enhanced by taking action following that communication.
- **Manages resources well** – careful control and use of resources, human as well as fiscal, to maximize their impact and effectiveness.
- **Problem solving and attempts to remove barriers** – proposed solutions or considerations to resolve something that is an obstruction or prevents progress.

- **Prompt handling of complaints** – immediate or quick management of charges of dissatisfaction.

(b) Quality Attributes:

Image-related characteristics that describe the contact between the customer and the DGDA.

- **Accessibility** – ability or freedom to approach, communicate with, or make use of.
- **Courteousness** – respect or consideration.
- **Flexibility** – capability to adapt to or change requirements.
- **Knowledgeable** – familiarity with or understanding of facts and/or conditions.
- **Listens well** – gives attention and/or careful consideration to what is said.
- **Reliability and Trustworthiness** – dependable, confidence in character, abilities, and truth.
- **Timeliness** – information and/or responses are provided early or on time.

5.4.2 DGDA Customer-interaction Standards

All DGDA Customers should receive:

- Fair, courteous and professional behavior;
- Information that is accurate and current;
- Timely responses to requests;
- Reasonable access to appropriate staff;
- Confidence that efforts are made to assure that regulated products in the marketplace are in compliance with DGDA laws and regulations;
- Two-way communication;
- Opportunities for collaboration and partnerships, as appropriate;
- Participation in the DGDA's decision-making process; and
- Consideration of their opinions and concerns by the agency.
- Consumers should receive accurate and timely health information about regulated products.
- Health Professionals should receive timely information that will assist them in advancing and protecting the public health.

5.4.3 Other Government Agencies should receive:

- Cooperation from the DGDA in maximizing efficient use of resources, eliminating duplication of efforts and carrying out collaborative efforts.
- Technical assistance, training and guidance

5.4.4 Pharmaceutical Industry should receive:

- Harmonized and consistent regulatory procedure
- Timely review of product applications;
- Professional treatment in resolving disputes;
- Fair application of laws and regulations in enforcement activities;
- Fair and consistent inspections and product application reviews; and
- Respect in the agency's performance of duties and responsibilities.

5.5 Complaints are classified in two (02) categories:

5.5.1 Source A–Complaints and/or feedback received internally from staff of DGDA.

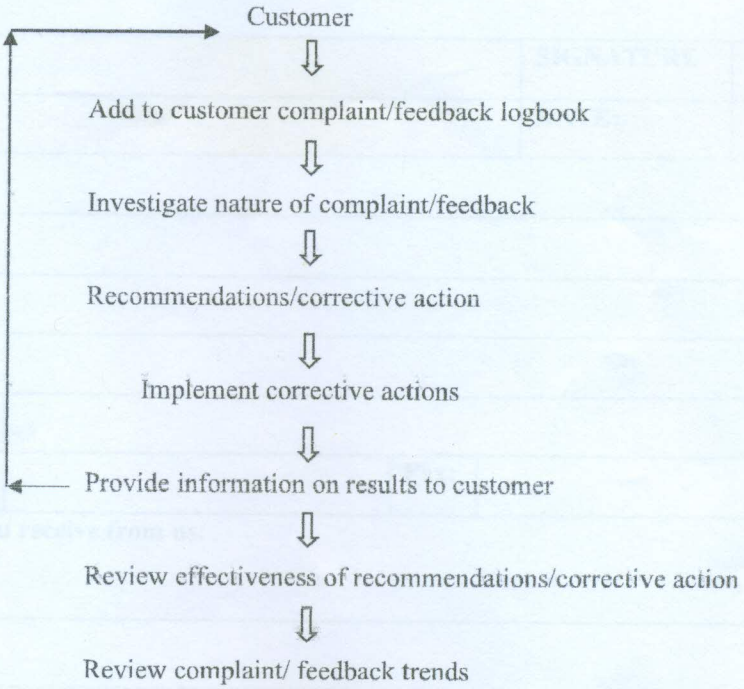
5.5.2 Source B-Complaints and/or feedback received externally from stakeholders and consumers.

5.6 A complaint or customer feedback may be submitted in written format, electronically, by telephone, or in person through the Regulatory Authorities channels of communication mentioned below:

Directorate General of Drug Administration, Bangladesh
Aushad Bhavan, Mohakhali, Dhaka-1212, Bangladesh
Tel: 8802 9880803, 9880864, 9880897, 9880924,
Fax: 8802 9880854,
E-mail: dgda.gov@gmail.com

5.7 After receiving the complaint shall document it on the logbook according to Annex-6.

5.8 **Complaint handling process flow chart:**



5.9 If the complainant requests that their personal data is to be kept confidential, the QA team member that received the complaint is responsible for the confidentiality and the complainant data shall not be filled into the logbook according to Annex-1. In such case the complaint should be marked as "confidential" in the correspondent field. Any communication with the complainant, if necessary, must be done through the QA team member that has the complainant data.

5.10 A complainant is considered anonymous when the personal information of the complainant is not supplied. In such case the form should be marked as "anonymous" in the correspondent field.

5.11 The feedback may be provided in writing or by other means including email, telephone, or through the use of customer/ stakeholder feedback form.

5.12 After receiving the feedback shall document it on the logbook according to Annex-6.

7.0 Customer Feedback form

Dear valued customer/ Stakeholder/ Service recipient

Thank you so much for your complain with our services. As part of our continuous improvement your comments/ complain are so much valuable to us. Your complain / comment helped us for our organizational development.

We are committed to provide continuous service to the people of Bangladesh for public health protection. Considering betterment of public health we are also committed to improve our regulatory standards continuously.

We are very thankful to you.

Please do not hesitate to contact us at Email dgda.gov@gmail.com or fax at +8802 9880854.

YOUR COMPLAIN		**COMPLAIN DATE:**	
Complain Status:	Solved ☐	Hold ☐	Cancelled ☐
Explanation:			

Head of the department
Directorate General of Drug Administration

8.0 Customer complaint and feedback record

Sl No.	Complaint	Complaint Date	Complaint by (Name, Designation, Organization, Email & Phone number)	Complaint Status	Feedback provided by (Name, Designation, Signature & Date)	Feedback date	Remarks

9.0 Revision History

Sl. No	Version No.	Causes for Revision
01	01	Newly prepared guideline for complaint

10.0 Reference:

10.1 Defining the Customer in a Regulatory Agency https://www.fda.gov/downloads/drugs/developmentapprovalprocess/manufacturing/questionsandanswersoncurrentgoodmanufacturingpracticescgmpfordrugs/ucm176384.pdf

10.2 Guidelines for Corrective and Preventive Actions; ISO 17025:2005 guidelines

10.3 WHO Technical Report Series 823.

10.4 Quality management systems requirements for the regulations of medicines and medical devices; Quality Manual.

10.5 Procedure for the preparation, approval and control of Standard Operating Procedures (SOP); SOP Number: NRA-RS-001