Guidelines for Management of Complaints

Directorate General of Drug Administration
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MESSAGE FROM THE DIRECTOR GENERAL

The Directorate General of Drug Administration (DGDA) is the national regulatory authority (NRA) of Bangladesh for the regulation of drugs and cosmetics for successful therapeutic outcomes and better public health in accordance with the Drugs and Cosmetics Act, 2023. The DGDA is stepping up towards achieving WHO Maturity Level 3 at least through harmonization and benchmarking of its regulatory practice at global standards. According to the requirements of the sub-indicator RS01.09 of the WHO Global Benchmarking Tool (GBT), DGDA developed the guidelines for the Issuance, Handling, and Management of Complaints.

The guidelines are essential to promote compliance, transparency, stakeholder satisfaction, equal judgment, and good governance in the regulatory system of the Directorate General of Drug Administration (DGDA).

In 1974, the Directorate of Drug Administration (DDA) was established and in 2010 the directorate was promoted to the Directorate General of Drug Administration (DGDA). Before 1982, Bangladesh was an import-based country for meeting the demand for medical products for public health protection. However, after the development and implementation of the Drug (Control) Ordinance 1982 and the first National Drug Policy 1982, Bangladesh made tremendous progress and created exemplary footsteps for being self-sufficient with local production and supply of medical products to meet local demand. Now, Bangladesh is meeting 98% of the local demand for medicines through its local production. The local production promoted access to medical products for all towards achieving Universal Health Coverage (UHC), and meeting target 3 for the Sustainable Development Goal (SDG).

DGDA is responsible to handle and manage any received complaint related to relevant products and services. The DGDA follows the government-prescribed online platform for Grievance management, which is known as the Grievance Redress System (GRS). Any stakeholder or individual can issue a complaint against a product or service and DGDA is mandated to resolve the complaint. The Guideline will ensure better compliance with the system for complaint management.

I am highly pleased to acknowledge the continuous support of the USAID-funded Promoting the Quality of Medicines Plus (PQM+) Program led by the United States Pharmacopoeia (USP) for the development of guidance, dissemination, and concern for better compliance toward achieving WHO Maturity Level 3 by DGDA.

I hope all the departments of the DGDA, relevant stakeholders, and relevant individuals will use this guideline for handling and management of any complaints related to products and services.

Major General Mohammad Yousuf
Director General, Directorate General of Drug Administration

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The DGDA would like to thank the many individuals who contributed information and ideas for this guidance for management of complaints regarding medical products and relevant services. Especial thanks to the USAID-funded Promoting the Quality of Medicines Plus (PQM+) Program for making direction through external audit to update the guidance document and dissemination widely for making common concerns among stakeholders and/or other relevant individuals.

DGDA is grateful to the involved relevant development partners for continuous support under the Coalition of Interested Parties (CIP) initiatives.

Specific gratitude to the WHO for providing guidance through a review of compliance against the requirement in the WHO Global Benchmarking Tool (GBT) regarding harmonization and benchmarking of regulatory systems of DGDA, as well as improving transparency through good governance and regulatory decision-making.

DGDA is highly pleased to acknowledge the contribution of WHO for continuous support throughout the development and update of this guideline. Implementation of this guideline will promote understanding and confidence of stakeholders for regulatory activities, compliance, and better quality assurance of medical products.

Abbreviations and Acronyms

Abbreviations		Acronyms
CAPA	:	Corrective Action & Preventive Action
CFR	:	Code of Federal Regulation
CIP	:	Coalition of Interested Parties
DGDA	:	Directorate General of Drug Administration
DGHS	:	Directorate General of Health Services
FPP	:	Finished Pharmaceutical Products
GG	:	Good Governance
GRS	:	Grievance Redress System
ICH	:	International Council for Harmonization
ISO	:	International Organization for Standardization
MoHFW	:	Ministry of Health and Family Welfare
NDCL	:	National Drug Control Laboratory
NRA	:	National Regulatory Authority
PQM+	:	Promoting the Quality of Medicines Plus
QA	:	Quality Assurance
QMS	:	Quality Management System
SOP	:	Standard Operating Procedure
USAID	:	United States Agency for International Development
USP	:	United States Pharmacopoeia
WHO	:	World Health Organization

Definition of Terms

Customer: A person or organization (internal or external) that receives a product or service anywhere along with the product's life cycle throughout the supply chain[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 Customer: 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 several primary customer groups –

(1) The General Public (Consumers),
(2) Health professionals,
(3) Other relevant agencies (Government, Non-Government, Private), and
(4) Pharmaceutical Industry
(5) Retail and wholesale pharmacy
(6) Pharmaceutical Storage and Depots (Public/ Private/ Non-Government)

These broad categories encompass the populations that DGDA serves and works 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.

Complaint: Expression of 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).

According to the 21 Code of Federal Regulations (CFR) 820.3(b) of the US-FDA – "Any informed issue from any individual/ stakeholder in a form of written, electronic, or verbal communication to allege any deficiency relating to identity, quality, safety, efficacy, durability, reliability, and/or performance of medical products will be treated as a Complaint.

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

Good Governance: The way of measuring performance, how a public institution conducts public relations and manages resources, and guarantees the reservation of human rights in a system essentially free from any abuse, conflict, and corruption and with due regard for the implementation of rules of law, act, or ordinance[1].

To implement good governance in pharmaceutical regulatory authority and/ or other institutions like manufacturers, marketing authorization holders should have a regulatory framework[2]. Good governance includes (a) the exercise of the country's system for economic, political, and administrative authority at all levels, (b) the exercising institutions and traditions, (c) the procedure of responsible authority/organizations, (d) Policies to achieve desired outcomes [3].

Grievance: A grievance is one type of a complaint, which may be formal, and may be filed with safety and reliability concern about work, service, and other professional issue. A grievance can be or can't be justified.

Transparency: Transparency is the approach and effective exercise of ensuring integrity avoiding any potential conflict of interest by an organization/individual toward promoting reliance and recognition of a system. Lack of transparency diminishes trust, reliance, and recognition of the therapeutic efficacy of medical products [4,5].

[1] OHCHR and Good Governance; https://www.ohchr.org/en/good-governance
[2] WHO Expert Committee on Specifications for Pharmaceutical Preparations; fifty-fifth report, Annex-11: Good regulatory practices in the regulation of medical products; https://www.wto.org/english/tratop_e/trips_e/techsymp_290621/gaspar_pres2.pdf
[3] WHO Global Benchmarking Tool (WHO GBT); https://apps.who.int/iris/rest/bitstreams/1346833/retrieve
[4] Framework for Good Governance in the public pharmaceutical sector, Ministry of Health-Malaysia; https://www.pharmacy.gov.my/v2/sites/default/files/articles-upload/ggm_0.pdf
[5] Good Governance for Medicines – Model Framework, updated version 2014, https://apps.who.int/iris/bitstream/handle/10665/129495/9789241507516_eng.pdf;sequence=1

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1. Introduction

Directorate General of Drug Administration (DGDA) protects public health by helping to ensure the quality, safety, and efficacy of healthcare products including active pharmaceutical ingredients, medicines, vaccines, biologicals, cosmetics, alternative medicines, medical devices, and in-vitro diagnostics for human and animal healthcare. 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 the regulation of DGDA.

2. Objective

The Objective of this guideline is to lay down a procedure for –

- Issuance of external complaints against medical products and services
- Issuance of internal complaints like grievances related to governance
- Management of Complaints for the betterment of public health
- Ensuring quality, safety, and efficacy of medical products

3. Scope and Responsibilities

This guideline is to support the implementation of quality systems within the departments of the Directorate General of Drug Administration (DGDA) by clarifying the concept of "customer and/ or stakeholder, and/or internal departments/systems" of the DGDA as the national regulatory authority (NRA) for medical products.

The complaints may be internal or external related products or services. Products-related complaints will be handled by the Department of Market Surveillance and Control (MC) and/or Vigilance (VL). If the complaints related to quality of product, the complaints will be handled by the MC department, and if the complaints are related to the safety and efficacy issue of the product, the VL department will handle the issue for better resolution and compliance. And, all service-related complaints will be handled by the National Regulatory Systems (RS) department under the leadership of the Director General of DGDA. If necessary, DG, DGDA may involve responsible persons from other departments of DGDA like Registration and Marketing Authorization (MA), Licensing (LI), Regulatory Inspection (RI), Laboratory Access and Testing (LT), Clinical Trial Oversight (CT), and/or NRA Lot Release (LR) for resolution of the issued complaint in an appropriate way.

This guideline is to adopt the correct procedure with respect to complaints by stakeholders, and/ or service recipients, and/ or internal departments, and/or the public regarding any service of DGDA or stakeholders and/ or health care products under the regulation of DGDA for public health protection.

The DGDA is responsible for amending, revising, updating, and controlling this guideline. DGDA publishes this guideline to follow the complaint issuance by stakeholders (manufacturers, importers of pharmaceuticals & medical devices, wholesalers, and retailers) and management procedure by the DGDA.

4. Legal Provisions for Complaints

4.1 Investigation of Complaints[6]:

According to the section 58 of the Drugs and Cosmetics Act, 2023-

(1) Without prejudice to the generality of section 61, an employee or Inspector authorized by the Director General within the prescribed manner and time limit, may investigate any complaint mentioned in column (3) of the Schedule as an investigating officer.

(2) During the investigation of any complaint under this Act, the investigating officer may exercise the same powers as the officer in charge of the police station in accordance with the provisions of the Code of Criminal Procedure.

(3) During the investigation under sub-section (1) of section 58, the investigating officer may, if necessary, seek the assistance of any other agency or authority including the law enforcement agency and if such assistance is sought, the law enforcement agency and such agency or such authority shall be bound to render the assistance required.

5. Complaints Procedure

Complaint is a system to ensure legal rights for the public and stakeholders according to legislative procedure as described below:

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

[6] Section 58, The Drugs and Cosmetics Act, 2023

- Complaint should be raised in a documented way - written by mail/ filling up online form/ direct submission of written complaint.
- With regard to each complaint, the responsible officer will provide feedback against the complaint according to the SOP: Procedure for Complaint Handling and Measuring Customer Satisfaction (NRA-RS-010).
- DGDA will take a formal approach for the resolution of any complaint, provide final feedback, and a final solution, and keep the record.

5.2 Any stakeholder/ service recipient/ customer can report dissatisfaction and complain through DGDA website (www.dgda.gov.bd) or by using Grievance Redress Systems (GRS) about any services provided by the DGDA. The Portal for Grievance Redress System is: https://www.grs.gov.bd/

5.3 Any service recipient/ stakeholder can issue dissatisfaction or provide opinion about the government service and the promised service of the underwriters/agencies, service delivery methods and the quality of services or products through this GRS portal https://www.grs.gov.bd/. After submitting the complaint, the latest status of complaint remedies may be communicated through SMS or e-mail. The Complainant stakeholder can also know about updated information by logging in. However, if the complaint is filed anonymously, the complainant will not get any further information about the complaint.

5.4 Product and service-related complaints can be submitted directly through the DGDA website portal https://info.dgda.gov.bd/complaint

Products include:

- Active Pharmaceutical Ingredients (API)
- Human prescription and over-the-counter (OTC) drugs
- Medical devices
- In-vitro Diagnostics
- Veterinary medical products, including foods and drugs for animals
- Biologics, including vaccines, blood and blood components, and tissues for transplantation
- Cosmetics
- Alternative medical products including Ayurvedic, Unani, Homeopathic, and/or Biochemic
- Dietary Supplements

Services include:

- Registration of medical products
- Adverse drug reaction or incompatibility of medical products
- Substandard and/ or falsified claim
- Price of medical products
- Application pending/held/ withheld/canceled
- License suspension, cancellation, revoke

5.5 Why to Report: Information about problems or unexpected reactions can help the DGDA protect public health. For instance, if anyone reports a problem to the DGDA, it could help identify an unknown risk. 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 helps DGDA with risk mitigation planning, regulatory decisions, policy making, guideline development, and updates.

5.6 How to issue a complaint:

a) Complaint through the online GRS platform: https://www.grs.gov.bd/

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

c) Written complaint on the paper as an application/letter

d) Complaint over the phone in some special cases

e) Complaint using the complaint box

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

5.7 Standards of Complaints Management:

5.5.1 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.

5.5.2 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 public health.

5.5.3 Other Government Agencies should receive:

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

5.5.4 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 for the agency's performance of duties and responsibilities.

5.8 Complaints are classified into two categories:

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

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

5.9 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
Complain Portal: https://info.dgda.gov.bd/complaint

5.10 After receiving the complaint, it should be recorded in the logbook according to the Customer Complaint and Feedback Record Log (Annex-4 of the SOP NRA-RS-010; Procedure for Complaint Handling and Measuring Customer Satisfaction).

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 form "Customer Complaint Form (NRA-RS-010/F01-01)" following the SOP of DGDA (NRA-RS-010). 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 QMS team member who has the complainant's data.

5.11 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.

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

5.13 After receiving the feedback shall document it on the logbook according to Customer Complaint and Feedback Record Log (Annex-4 of the SOP NRA-RS-010; Procedure for Complaint Handling and Measuring Customer Satisfaction).

6. Complaint Handling Process Flow

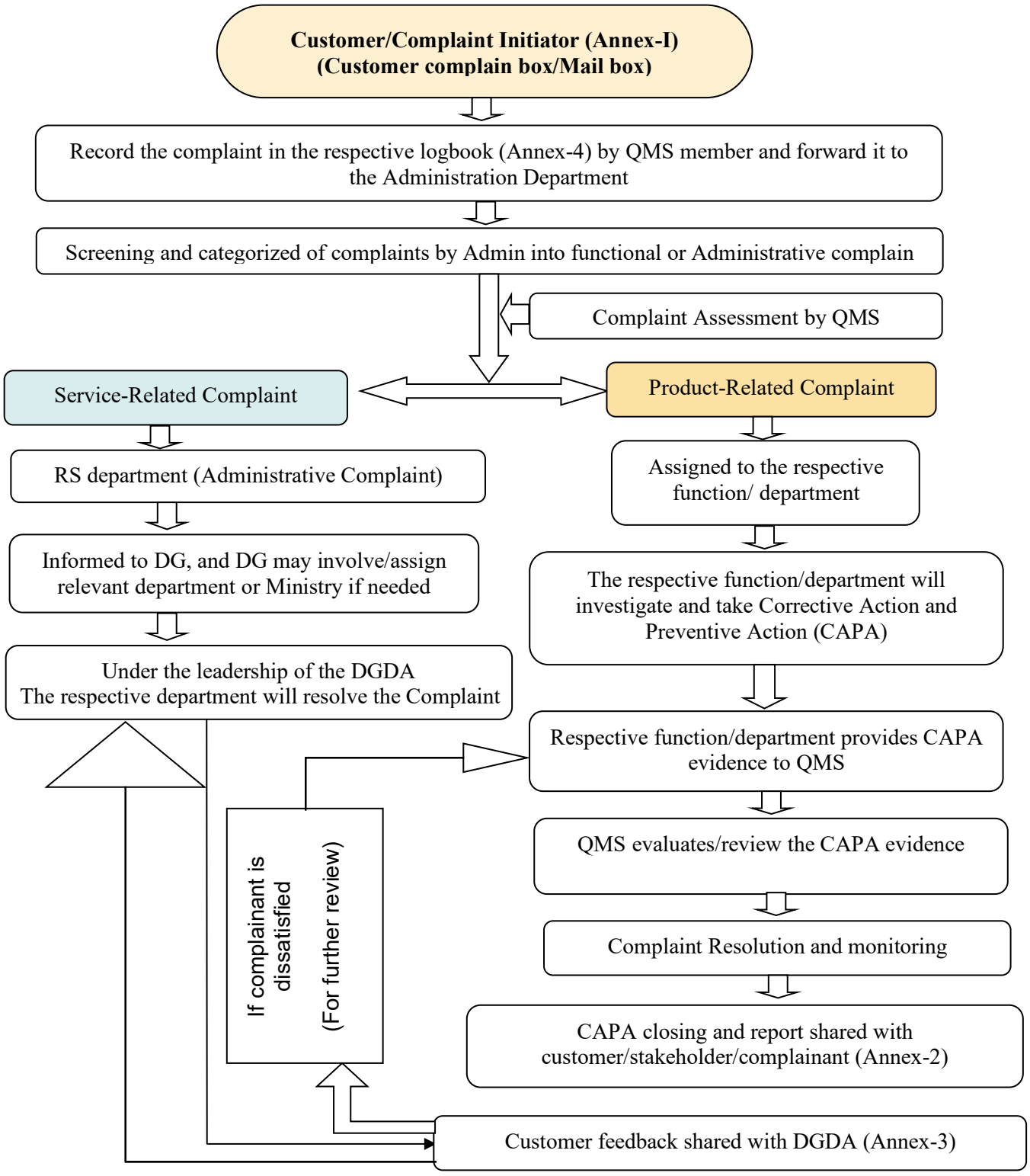

Figure 1: Process flow for complaint handling

7. Training and dissemination of the guideline

For a transparent regulatory system and good governance, any relevant individual/stakeholder may complain about any issues with regulation related to the quality, safety, and efficacy of medical products. To create awareness among the relevant stakeholders and relevant public community DGDA will organize training, workshops, and seminars for dissemination and making concerns, that will support the successful implementation of the complaint guidelines.

The National Regulatory System (RS) department will be liable for the wide dissemination of the guidelines and for conducting training for relevant stakeholders/individuals to make concerns about complaint systems.

8. Revision History

Sl. No	Version No.	Causes for Revision
01	01	Newly prepared guidelines for complaint
02	02	Update of involvement of different departments of the DGDA Update of the process flow and communication for complaint handling

9. References

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

10. Forms as Annexure of this Guideline

Annexure-1: Complaint issuance form

NAME		**SIGNATURE**	
DESIGNATION		**DATE:**	
Organization			
Country			
Present Address:			
Permanent Address:			
E-Mail Address:			
Phone:		**Fax:**	
Which services did you receive from us:			

Complaint Category						
Accessibility	Reliability	Timeliness	Fair	Policy & Procedure	Professionalism of DGDA Person	Communication
☐	☐	☐	☐	☐	☐	☐

Detail about the complaint *(If needed use additional pages)*

Annexure-2: Customer Feedback Form

Dear valued customer/ Stakeholder/ Service recipient

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

We are committed to provide continuous service to the people of Bangladesh for public health protection. Considering the betterment of public health we are also committed to improving 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

Annexure-3: 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