Guideline for appeal against regulatory decisions

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MESSAGE FROM THE DIRECTOR GENERAL

The Guideline for Appeal against the regulatory decisions is essential to promote transparency, equal judgment, and good governance in the regulatory system of 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 and exporting 157 countries across the globe. 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).

Bangladesh is now being graduated from Least Developed Country (LDC) to Developing Country (DC) status. The regulatory systems of DGDA are improving toward achieving the WHO Maturity Level 3 in a collaborative approach under the Coalition of Interested Parties (CIP) initiative led by WHO. That achievement will enable Bangladesh promotes better access to quality, safe, effective, and reliable medical products for all. To achieve the goal of WHO maturity level 3, DGDA should ensure transparency in the regulatory system and should make regulatory measures homogenous for all stakeholders/individuals.

Appeal against any legal notice, decree, order, and/or regulatory decision in the case of medical products is the country's legal system and is mandated to obligation. The first version of the guidance for appeal was developed in 2018 and then updated to the second version in 2021. The Drugs and Cosmetics Act 2023 was approved and implemented on 18th September 2023. To align the appellate guidance with the Drugs and Cosmetics Act 2023, the new version is developed.

I hope this guidance will promote transparency of regulatory decisions and ensure equal rights for all individuals and stakeholders toward ensuring quality-assured medical products mitigating potential risks associated with quality assurance and therapeutic efficacy.

I hope all the relevant stakeholders of the Government of Bangladesh will implement this guidance document.

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

Table of Contents

Acknowledgment

The DGDA would like to thank the many individuals who contributed information and ideas for this guidance for Appeal against regulatory decisions. 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.

Abbreviations and Acronyms

Abbreviations		Acronyms
AA	:	Appellate Authority
CIP	:	Coalition of Interested Parties
DGDA	:	Directorate General of Drug Administration
DTL	:	Drug Testing Laboratory
FPP	:	Finished Pharmaceutical Products
GG	:	Good Governance
MoHFW	:	Ministry of Health and Family Welfare
NDCL	:	National Drug Control Laboratory
NRA	:	National Regulatory Authority
PQM+	:	Promoting the Quality of Medicines Plus
SOP	:	Standard Operating Procedure
USAID	:	United States Agency for International Development
USP	:	United States Pharmacopoeia
WHA	:	World Health Assembly
WHO	:	World Health Organization

Definition of Terms

Appeal: According to section (3) of the Drugs and Cosmetics Act 2023 - "Appeal" means case by case and the appeal referred to in Sections 19, 27, and 64 of the Act [1]. An appeal in the context of drug acts involves challenging a decision related to the approval, regulation, or restriction of a particular drug. According to the Code of Civil Procedure, Section 96(1), an appeal shall lie from every decree passed by any Court exercising original jurisdiction to the Court authorized to hear appeals from the decisions of such Court [2].

Appellate Authority: An authority/body/committee having the power to review and decide appeals, as a court/ as a reviewing board/authority known as an appellate authority [3].

Appellate Jurisdiction [4]: Appellate jurisdiction is included under Judicial jurisdiction, in which a superior court tribunal is engaged with the legal power to review/correct, and decides whether legal errors may made in a lower court case;

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[5]. To implement good governance in pharmaceutical regulatory authority and/ or other institutions like manufacturers, marketing authorization holders should have a regulatory framework[6]. 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 [7].

Jurisdiction: Jurisdiction means a legal authority granted to a legal entity for the enactment of justice. Jurisdiction is the constitutional authority of a court to hear and decide case outcomes[8].

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[1] The Drugs and Cosmetics Act 2023, Section-(3); http://bdlaws.minlaw.gov.bd/upload/act/2021-11-17-11-55-47-45.-The-Procurement-Act,-2006.pdf

[2] The code of civil procedure 1908, Section 96(1); http://bdlaws.minlaw.gov.bd/act-86/part-details-85.html#:~:text=96.,the%20decisions%20of%20such%20Court.

[3] Collins Dictionary; https://www.collinsdictionary.com/dictionary/english/appellate#:~:text=having%20the%20power%20or%20authority,decide%20appeals%2C%20as%20a%20court

[4] Britannica definitions; https://www.britannica.com/topic/competence-and-jurisdiction#ref177369

[5] OHCHR and Good Governance; https://www.ohchr.org/en/good-governance

[6] 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

[7] WHO Global Benchmarking Tool (WHO GBT); https://apps.who.int/iris/rest/bitstreams/1346833/retrieve

[8] Britannica; https://www.britannica.com/topic/jurisdiction

Subordination of a Court: For this Code, the District Court is subordinate to the High Court Division, and every Civil Court of a grade inferior to that of a District Court and every Court of Small Causes is subordinate to the High Court Division and District Court[9].

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 for the therapeutic efficacy of medical products [10,11].

[9] Section 3 of The Code of Civil Procedure 1908, http://bdlaws.minlaw.gov.bd/act-86/section-13592.html
[10] 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
[11] Good Governance for Medicines – Model Framework, updated version 2014, https://apps.who.int/iris/bitstream/handle/10665/129495/9789241507516_eng.pdf;sequence=1

Tables, Figures, and Annexes

1. Introduction

The Directorate General of Drug Administration (DGDA) is the sole regulatory authority to ensure quality, safe, and effective medicine for public health protection. To save public health DGDA works to ensure quality, safe, and effective medicines availability and accessibility. DGDA works complying with legislation/ Act, Rules, Ordinances, Policies, Approved Guidelines, SOPs, and work instructions. If any application from stakeholders does not comply, DGDA may request more compliance from the applicant with appropriate reason or may reject/ refuse the application. But if the stakeholder/ applicant may feel confident with their application they may appeal following this guideline.

2. Objective

The Objective of this guideline is to lay down a procedure for appealing against DGDA decisions and handling appeals from stakeholders (manufacturers, importers of pharmaceuticals & medical devices, wholesalers, and retailers).

3. Scope and Responsibilities

This document applies to lodge appeals against DGDA's decision and handles various appeals received from any stakeholders (manufacturers, importers of pharmaceuticals & medical devices, wholesalers, and retailers) to DGDA.

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

4. Legal Provisions for Appeal

4.1 Review or appeal against the suspension order of license and restriction of production[12]:

(1) License of the licensee under section 18 by the Licensing Authority.

In case of temporary suspension and cessation of the production of drugs of the concerned institution, the licensee, within 30 (thirty) working days, may apply to the licensing authority for reconsideration of the said order or file an appeal to the government.

(2) In case of reconsideration or disposal of appeal referred to in subsection (1), the authority concerned shall give its decision after giving an opportunity of hearing to the parties concerned.

(3) The decision rendered by the Licensing Authority or, as the case may be, the Government on disposal of the review or appeal shall be final.

4.2 Review or appeal against orders suspending registration and suspending manufacture and marketing of medicinal products[13]:

1) If the registration of a drug under section 25 is temporarily suspended by the Licensing Authority and the production and marketing of the said drug is suspended, the concerned person or organization shall submit the said order to the Licensing Authority within thirty (30) working days. You can apply for reconsideration or file an appeal with the government.
2) To the parties concerned in the disposal of the review or appeal referred to in subsection (1). The concerned authority will give its decision on the matter after allowing a hearing.
3) The decision rendered by the Licensing Authority or, as the case may be, the Government, at the time of disposal of the review or appeal shall be deemed to be final.

4.3 Appeal[14]:

(1) A person restrained by an order, judgment, or punishment issued by the Drug Court or Chief Judicial Magistrate or Special Magistrate or, as the case may be, the Chief Metropolitan

[12] Section 19, The Drugs and Cosmetics Act 2023
[13] Section 27, The Drugs and Cosmetics Act 2023
[14] Section 64, The Drugs and Cosmetics Act 2023

Magistrate or Special Metropolitan Magistrate may appeal within thirty (30) days to the court specified in the Code of Criminal Procedure 1898 (Act No. V of 1898)[15].

(2) In cases of appeals against penalties imposed by the Mobile Court, the Mobile Court Act, 2009, Section 13 will be followed

5. Appeal Procedure

Appeal is a legal system and follows the procedure according to legislative procedure as described below:

5.1 According to The Drugs and Cosmetics Act 2023, sections 03, 19, 27, and 64, any individual/stakeholder may appeal against the regulatory decision but should be generated within thirty days of the issuance of the regulatory decision/order/decree.

5.2 Until new rules appear against the Drugs and Cosmetics Act 2023, relevant sections of the Bengal Drug Rules 1946 are still under application for legal procedure, related to the appeal systems. According to the Bengal Drug Rules 1946, section 25(d), 44(b), 54(b), 29, 35, 43I, of the (2) a licensee whose license has been suspended or canceled may appeal to the District Judge (session judge)[16].

5.3 Any stakeholder, manufacturer, importer of pharmaceuticals & medical devices, wholesaler, and retailer may appeal against a decision of DGDA. Application of the stakeholders (manufacturers, importers of pharmaceuticals & medical devices, wholesalers, and retailers) for granting or renewal of license, registration of drugs/medical devices, or any other decision under the provisions of the drug act, ordinance, or Rules within a specified period.

5.4 To appeal, stakeholders (manufacturers, importers of pharmaceuticals & medical devices, wholesalers, and retailers) should apply/write to DGDA stating the conditions laid down have been satisfied and should deposit a fee if required.

5.5 The loading of an appeal against of decision by DGDA to reject an application of stakeholders (manufacturers, importers of pharmaceuticals & medical devices, wholesalers, and retailers) shall not change the decision of DGDA unless the case is re-examined and re-inspected based on the compliance submitted by the stakeholders (Manufactures, importers of pharmaceuticals & medical devices, wholesalers and retailers).

[15] The Code of Criminal Procedure 1898 (Act No. V of 1898); http://bdlaws.minlaw.gov.bd/act-75.html
[16] The Bengal Drug Rules 1946;

5.6 An appeal lodged after the specified period (01 month for Drug Appellate Authority) and shall not be considered for registration of product-related issues.

5.7 Necessary communication shall be made to the stakeholders (manufacturers, importers of pharmaceuticals & medical devices, wholesalers, and retailers) once the appeal is considered and the decision is taken on the matter under the provisions of Drug Act, ordinance, Rules, and Policy.

5.8 Stakeholders (Manufacturers, importers of pharmaceuticals & medical devices, wholesalers, and retailers) who are not satisfied with the decision of DGDA may appeal to the Appellate Authority or courts under the provisions of Drug Act, Ordinance, rules, policy, and other relevant Law of the Country.

6. Review and Appeal process flow

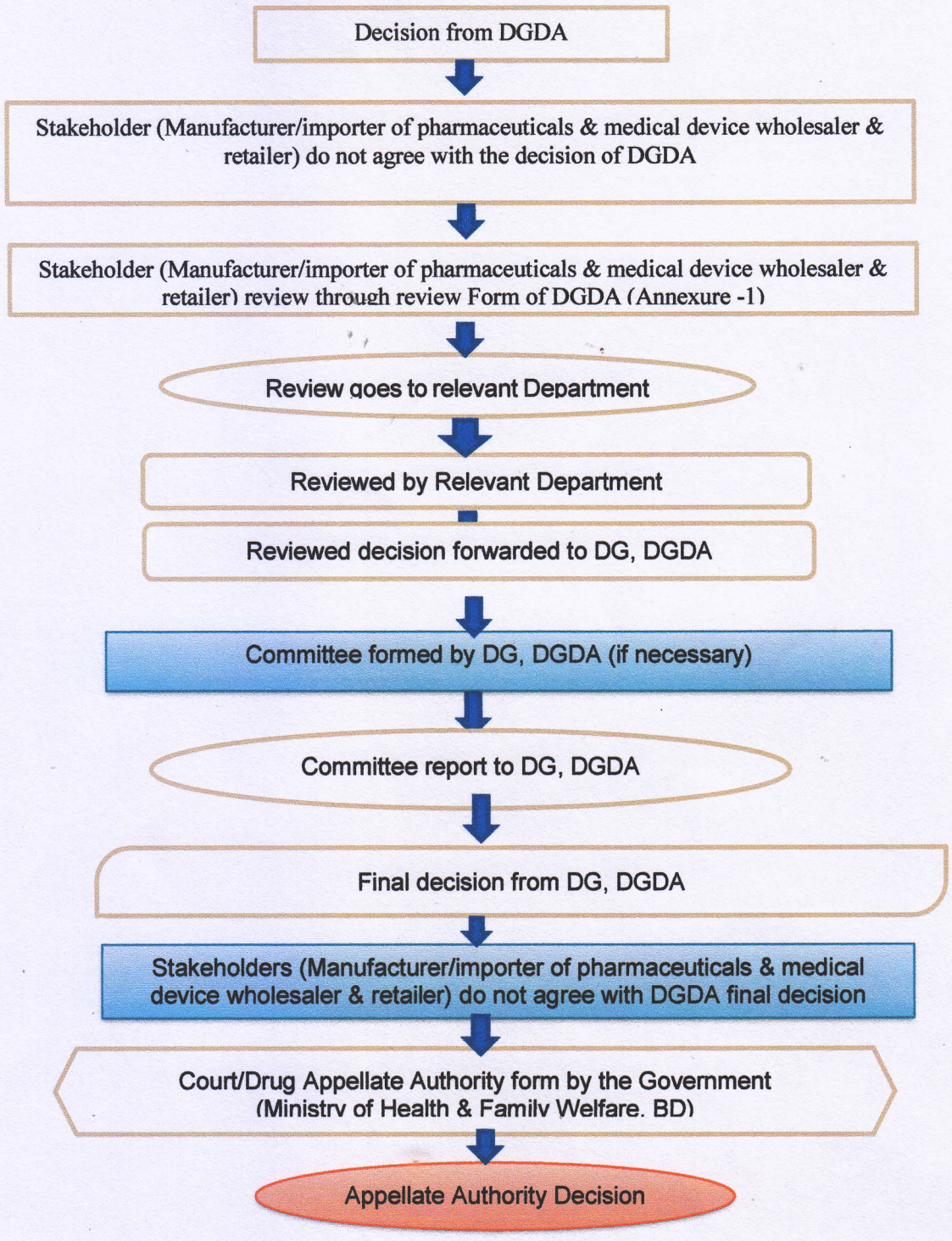

Figure 1: Process flow for Appeal against any regulatory decision

7. Training and dissemination of the guideline

For a transparent regulatory system and good governance, any relevant individual/stakeholder may appeal against the imposed regulatory decision if the confidence is sufficient to prove regulatory justification. To create awareness among the relevant stakeholders, DGDA will organize training, workshops, and seminars for dissemination and making concerns, which will support the successful implementation of the guidance for appeal.

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

Annexure-1: Review or Appeal request form

Reference: Date: /
/

To

Directorate General

Directorate General of Drug Administration (DGDA)

Mohakhali, Dhaka.

Subject: ----------

Sir,

.....
.....
.....
.....
..

Name:----------

Designation:----------

Organization Name:----------

Annexure-2: Appellate Authority

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়
স্বাস্থ্য সেবা বিভাগ
ঔষধ প্রশাসন-১ শাখা
www.hsd.gov.bd

নম্বর: ৪৫.০০.০০০০.১৮২.০৬.০০২.২১.১৩৮

তারিখ: ২৮ আষাঢ় ১৪২৯
১২ জুলাই ২০২২

প্রজ্ঞাপন

স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ের আওতাধীন স্বাস্থ্য সেবা বিভাগের ২৯/১০/২০১৭ খ্রি. তারিখের স্বাপকম/স্বা:সে:বি:/ঔ:প্র:-১/ঔষধ-৪১/২০০৮(অংশ-২)(১১)-১০০ সংখ্যক প্রজ্ঞাপনের অনুবৃত্তিক্রমে ঔষধ নিয়ন্ত্রণ অধ্যাদেশ ১৯৮৪ এর ৬এ(২) ধারা মোতাবেক নিম্নরূপভাবে 'ঔষধ আপীল কর্তৃপক্ষ' পুনর্গঠন করা হলো:

(১)	মাননীয় মন্ত্রী, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়, বাংলাদেশ সচিবালয়, ঢাকা	চেয়ারম্যান
(২)	সিনিয়র সচিব/ সচিব, স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়, ঢাকা	সদস্য
(৩)	মহাপরিচালক, আর্মড ফোর্সেস মেডিকেল কলেজ ও হাসপাতাল, ঢাকা	সদস্য
(৪)	অতিরিক্ত সচিব (ঔষধ প্রশাসন), স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়, ঢাকা	সদস্য
(৫)	প্রফেসর ডাঃ প্রাণ গোপাল দত্ত, নাক কান কলা বিশেষজ্ঞ	সদস্য
(৬)	ডীন, বিভাগীয় প্রধান, ফার্মেসী অনুষদ, ঢাকা বিশ্ববিদ্যালয়, ঢাকা	সদস্য
(৭)	পরিচালক, শিশু ও মাতৃ স্বাস্থ্য ইনস্টিটিউট, মাতুয়াইল, ঢাকা	সদস্য
(৮)	চেয়ারম্যান, Examination কমিটি, বিসিপিএস, মহাখালী, ঢাকা	সদস্য
(৯)	বিভাগীয় প্রধান, মেডিসিন বিভাগ, স্যার সলিমুল্লাহ মেডিকেল কলেজ ও হাসপাতাল, ঢাকা	সদস্য
(১০)	যুগ্মসচিব/ উপসচিব (ঔষধ প্রশাসন), স্বাস্থ্য সেবা বিভাগ, স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়, ঢাকা	সদস্য সচিব

কমিটির কার্যপরিধি:

(ক) 'ঔষধ আপীল কর্তৃপক্ষ' ঔষধ নিয়ন্ত্রণ অধ্যাদেশ ১৯৮৪ এর ৬এ(৩) ধারায় বর্ণিত দায়িত্ব পালন করবে।

(খ) একতৃতীয়াংশ সদস্যর উপস্থিতিতে সভার কোরাম হবে।

(গ) এ বিষয়ে পূর্বে গঠিত "ঔষধ আপীল কর্তৃপক্ষ" বাতিল বলে গণ্য হবে।

(ঘ) কমিটি প্রয়োজনে বিশেষজ্ঞদের সহযোগিতা গ্রহণ/ কো-অপ্ট সদস্য হিসেবে অন্তর্ভুক্ত করতে পারবে।

০২। যথাযথ কর্তৃপক্ষের অনুমোদনক্রমে জনস্বার্থে জারিকৃত এ আদেশ অবিলম্বে কার্যকর হবে।

রাষ্ট্রপতির আদেশক্রমে,

১২-৭-২০২২

মোহাম্মদ মোস্তাফিজুর রহমান
সহকারী সচিব
ফোন: ০২-৫৫১০০৪৪২ (অফিস)
ইমেইল: drugad1@hsd.gov.bd

নম্বর: ৪৫.০০.০০০০.১৮২.০৬.০০২.২১.১৩৮/১(১৭)

তারিখ: ২৮ আষাঢ় ১৪২৯
১২ জুলাই ২০২২