Safe Drugs Save Lives

NATIONAL DRUG AUTHORITY

Approved Service Delivery Timelines (SDTs) FY 2023-2024 and FY 2024-2025

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1.0 INTRODUCTION TO THE SERVICE DELIVERY TIMELINES (NDA SDTs)

1.1 NATIONAL DRUG AUTHORITY BACKGROUND

The National Drug Authority (NDA) was established in 1993 by the National Drug Policy and Authority Statute which in 2000 became the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda (2000 Edition). The Act established a National Drug Policy and National Drug Authority to ensure the availability, at all times, of essential, efficacious, and cost-effective drugs to the entire population of Uganda as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.

1.2 MANDATE

To ensure the availability, at all times, of essential, efficacious, and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.

1.3 VISION

A world-class drug regulatory Agency.

1.4 MISSION

To protect and promote human and animal health through the effective regulation of drugs and healthcare products.

1.6 NDA STRATEGIC OBJECTIVES

1) To improve the regulatory efficiency and effectiveness that ensure safe, efficacious, and quality drugs and health products
2) To streamline the legal and regulatory framework for the operational effectiveness of NDA.
3) To increase stakeholder awareness, engagement, and collaboration to support NDA regulatory functions.
4) To improve NDA's institutional capacity to effectively and efficiently implement its functions.

1.7 QUALITY POLICY STATEMENT

The Drug Authority is committed to providing the highest standard of drug regulatory service to all customers.

Timely and reliable service, compliance to all applicable statutory and regulatory requirements, and meeting customer requirements underlie all our effort in ensuring quality, safety and efficacy of all drugs and healthcare products used in Uganda. This is done through comprehensive pre- and post-marketing activities for the regulation of drugs and healthcare products.

We are committed to implementing a quality management system that complies with ISO 9001:2015 and WHO guideline on the Implementation of Quality Management Systems for National Regulatory Authorities, TRS 1025 2020, Annex 13 for the entire NDA; WHO Good Practices for Pharmaceutical Quality Control Laboratories, TRS 957 2010 for the testing of drugs; ISO/IEC 17025:2017 for testing healthcare products; ISO 13485:2016 for medical devices and PIC/S 002 for pharmaceutical inspectorates.

Quality objectives, processes, systems and procedures that support this quality policy are established and reviewed periodically for continuing suitability. Quality is the responsibility of all employees and the Drug Authority commits adequate financial, physical, technological resources, and a workforce that is trained, motivated, facilitated and empowered to implement, maintain and continually improve the quality management system to achieve set objectives.

1.8 APPLICATION OF SERVICES STANDARDS

The SDTs apply to external clients and stakeholders who utilize National Drug Authority services. It provides for standards of service delivery expected by clients and what the Authority anticipates from its clients.

1.8.1 DEFINITION OF TERMS

Per this tool, the following terms and phrases are defined as follows:

1) SERVICE DELIVERY

Service delivery refers to a relationship between policymakers, service providers, and consumers of those services, and encompasses both services and their supporting systems. Service delivery is a mechanism used by an organization to meet the needs and aspirations of the people it is meant to serve.

2) CLIENTS

This means product manufacturers, healthcare providers, researchers, distributors, processors, wholesalers, retailers, a group, or individuals interested in or affected by services offered by the National Drug Authority. They also include government and private institutions as well as consumers and the general public;

3) STAKEHOLDER

This means an individual, institution, or organization that in one way or another is related to or affected by the National Drug Authority services.

4) WORKING DAYS

This means days from Monday to Friday except public holidays, Saturday and Sunday. The days highlighted in the delivery of services do not mean calendar days but working days.

5) REGULATED PRODUCTS

This means medicines including human and veterinary medicines, Surgical instruments, diagnostics, and herbal medicines regulated as defined in the National Drug Policy and Authority Act Cap.206.

6) CLIENTS COMMITMENT

a) Timely and accurately respond to the National Drug Authority requests regarding products; and
b) Timely payment of fees for regulatory services provided by the National Drug Authority.

7) REGULATORS COMMITMENT TO CLIENTS

The Authority aims to provide quality services to our clients. We will fulfill this by operating within the service standards as highlighted in the table below.

2.0 APPROVED SERVICE DELIVERY TIMELINE (SDTS) FOR FY(S) 2023-2025.

REGULATORY AREA	ACTION	TIMELINE (WORKING DAYS)
Clinical Trial (CT) Oversight	Receipt, screening, and acknowledgment of a Clinical Trial Application (new, renewals, and amendment)	10 Days
	Regulatory decision on a Clinical Trial Application	50 Days
	Annual renewal of ongoing trials	20 Days
	Amendment of CT Authorization	20 Days
	Feedback report to a client following a GCP Inspection	45 Days
REGULATORY AREA	**ACTION**	**TIMELINE (WORKING DAYS)**
Veterinary Field Trial Oversight and Pharmacovigilance	Acknowledgment of receipt and screening of a Field Trial Application (FTA)	10 Days
	Regulatory decision on a FTA	50 Days
	Feedback report to a client following a GCP Inspection of field trials	45 Days
	Acknowledgement of receipt of safety report	5 Days
	Feedback on causality assessment	30 Days
REGULATORY AREA	**ACTION**	**TIMELINE (WORKING DAYS)**
Marketing Authorization (MA)	**GENERAL CONSIDERATION**	
	Assessment of application and request for additional information on application for MA (Human Drugs)	18 months (396 Days)
	Assessment of application and request for additional information on application for MA (Veterinary Drugs)	12 months (264 Days)
	Assessment of application and request for additional information on	6 Months (132 Days)

REGULATORY AREA	ACTION	TIMELINE (WORKING DAYS)
	application for MA (Vaccines, Anti-cancer medicines, and other vital (medicines)	
	Assessment of application and request for additional information on application for MA (Herbal medicines-Imported)	6 Months (132 Days)
	Regulatory decision on MA after additional information is received	3 Months (66 Days)
	SPECIAL CATEGORIES	
	Regulatory decision on MA for domestically manufactured products (Herbal, Conventional)	6 Months (132 Days)
	Regulatory decisions on products already authorized for marketing by Stringent Regulatory Authorities, WHO Prequalified products, and those approved under Article 58 of EU regulations	6 Months (132 Days)
	VARIATION AND NOTIFICATION	
	Regulatory decision on minor variation	4 Months (88 Days)
	Regulatory decision on Major variation (if the application does not require physical verification)	6 Months (132 Days)
	Regulatory decision on Annual or Immediate notification change	3.6 Months and 2 weeks (80 Days)
	DRUG REGISTER	
	Publication of drug register	Monthly (5th working day of the month)
REGULATORY AREA	**ACTION**	**TIMELINE (WORKING DAYS)**
Regulatory Inspection	GMP Physical inspection after receipt of application – Foreign	180 Days
	GMP Report Feedback to Manufacturer after Inspection	45 Days
	Feedback after inspection – Domestic	28 Days
	Regulatory Decision after CAPA – Foreign	20 Days
	Regulatory Decision after CAPA – Domestic (Local Facilities)	17 Days

REGULATORY AREA	ACTION	TIMELINE (WORKING DAYS)
REGULATORY AREA	**ACTION**	**TIMELINE (WORKING DAYS)**
Premise Licensing	Feedback to the applicant on the regulatory decision for pharmacy renewal	40 Days
	Feedback to the applicant on Regulatory decision for licensing of new Pharmacy applicants	30 Days
REGULATORY AREA	**ACTION**	**TIMELINE (WORKING DAYS)**
Market Surveillance and Control	Verification of imports (Registered drugs)	2 Days
	Clearance of Imports at Ports of Entry	2 Days
	Verification of imports (un-registered drugs)	10 Days
	Regulatory decision on drug promotional materials	10 Days
	Publication of the database of approved promotional materials/advert	Monthly (5th of the month)
REGULATORY AREA	**ACTION**	**TIMELINE (WORKING DAYS)**
Vigilance	Acknowledgement of receipt of an ADE report (email/letter)	5 Days
	Feedback on serious ADE reports	18 Days
	Feedback on a serious AEFI reports to the expanded program for Immunization (EPI)	14 Days
Laboratory testing	Test results from mandatory testing after sampling (Medicine)-PoE.	48 Days
	Test results from mandatory testing after sampling (Medical Devices).	25 Days
	Test results from client requests after acceptance by the lab (All Products).	45 Days
	Test results for pre-market samples (Domestic Manufacturers).	60 Days
	Test results for Public Health Products (LLINs, Face Masks, Hand Sanitizers, and other) samples.	45days

REGULATORY AREA	ACTION	TIMELINE (WORKING DAYS)
	Test results for post-market surveillance (Medicines).	48 Days
REGULATORY AREA	**ACTION**	**TIMELINE (WORKING DAYS)**
National Regulatory System	Issuance of recall or alert for a substandard or falsified medicine or health care product	14 Days
	Acknowledgement of receipt of a product complaint	5 Days
	Feedback on a market (process, product, other) complaint	20 Days
	Feedback on the effectiveness of recall after receipt of the recall report from the LTR (Local Technical Representative)	10 Days
	Feedback on test results from the Lab to the client	5 Days
Support to Regulatory areas.	**QUALITY MANAGEMENT SYSTEM**	
	Acknowledgment of receipt of a service-related complaint.	2 Days
	Feedback on service-related complaints	21 Days

Notes

A. All days stated are working days.
B. All timelines are counted from day zero which is the date of the application, service request, or notification at NDA. For electronic submissions, it is assumed that the date submitted is the date received.

C. When a request is made to an applicant or client for additional information or clarification, the NDA clock stops counting until the client's response is received. The timelines presented therefore only represent the total time NDA has to undertake on a particular action.

NDA MANAGEMENT.

David Nahamya
SECRETARY TO THE AUTHORITY