Safe Drugs Save Lives

NATIONAL DRUG AUTHORITY

CLIENT CHARTER
FY 2025/26 – 2029/30

JUNE 2025

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STATEMENT FROM SECRETARY

TO THE AUTHORITY

The National Drug Authority is mandated to ensure the availability, at all times, of safe, efficacious, and cost-effective drugs and healthcare products to the people of Uganda, while safeguarding their appropriate use. In fulfillment of this mandate, the Authority continues to strengthen its regulatory systems, enhance service delivery, and uphold the highest standards of public health protection.

This Service Delivery Timelines (SDTs) Charter has been developed as a key instrument to promote transparency, accountability, and efficiency in the provision of regulatory services. It clearly outlines the services offered by the Authority, the standards to be met, and the timelines within which these services will be delivered. The Charter is aligned with national development frameworks, including the National Development Plan IV, and responds to the Government's directive through the Ministry of Public Service requiring all Ministries, Departments, and Agencies to establish and operationalize Client Charters.

The Authority recognizes that effective regulation is best achieved through strong collaboration with stakeholders, including manufacturers, importers, distributors, healthcare providers, researchers, and the general public. This Charter therefore serves as a mutual commitment between the National Drug Authority and its clients. While the Authority commits to delivering timely, efficient, transparent, and professional services, clients are equally expected to fulfill their responsibilities, including submission of complete and accurate information, compliance with regulatory requirements, and timely response to queries.

The Service Delivery Timelines presented in this Charter reflect the Authority's dedication to continuous improvement, adoption of risk-based and evidence-based regulatory approaches, and the use of digital technologies to enhance accessibility and efficiency. These timelines also provide a basis for performance monitoring, evaluation, and accountability, ensuring that the Authority remains responsive to stakeholder needs and emerging public health priorities.

As we implement this Charter, the National Drug Authority reaffirms its commitment to its core values of integrity, collaboration, accountability, responsibility, and excellence. We will continue to strengthen our systems, build institutional capacity, and foster innovation to deliver high-quality regulatory services that protect and promote the health of all Ugandans.

I call upon all stakeholders to utilize this Charter, adhere to the outlined standards, and actively provide feedback to support continuous improvement in our service delivery.

Dr. David Nahamya
Secretary to the Authority

CHAPTER ONE

1.0 INTRODUCTION TO THE SERVICE DELIVERY TIMELINES (NDA SDTs)

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. 198 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.

The SDTs are aligned to NPD IV as a prerequisite for approval and a requirement by the Ministry of Public Service. Every MDA is required to have established Service Delivery Standards, as illustrated in the Ministry of Public Service Client Charter (Objective 1, v: 'Have all MDAs and LGs with approved Client Charters by December 2026').

1.1 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.

1.2 VISION

A globally recognized Authority in drugs and healthcare products regulation

1.3 MISSION

To safeguard public health through effective regulation of drugs and healthcare products.

1.4 CORE VALUES

The core values that guide the delivery of our services are as below;

Table 1: National Drug Authority Core Values

Integrity	The Drug Authority will uphold honest and ethical conduct in every decision, fostering public trust and confidence.
Collaboration	We commit to work together across teams, partners, and stakeholders to achieve common goals, encouraging innovation through shared ideas and trust.
Accountability	We will own our actions, delivering on our promises with transparency an reliability.
Responsibility	We promise to remain steadfast in fulfilling our obligations to the public, advancing research and solutions that transform lives.
Excellence	We promise to strive for the highest standards in our services and outcomes, continually innovating to meet the evolving needs of the health sector.

1.5 NDA STRATEGIC OBJECTIVES

1) To strengthen regulatory frameworks, systems, and enforcement to ensure the safety, efficacy, and quality of drugs and healthcare products while aligning with international, regional, and national standards.
2) To deepen relationships with stakeholders to foster trust and shared accountability.
3) To leverage advanced technologies to automate regulatory processes, enhance data-driven decision-making, and improve service accessibility for all stakeholders.
4) To diversify revenue streams and infrastructure development, invest in staff capacity-building, and foster innovation to enhance operational efficiency, institutional resilience, and financial sustainability.
5) To expand NDA's role in supporting Uganda's public health goals, focusing on equitable access to medicines, enhancing preparedness for emerging health threats, and improving public health outcomes.
6) To enhance antimicrobial resistance (AMR) management through improved stewardship, robust surveillance systems, targeted awareness programs, and strengthened regulations across human, animal, and environmental sectors.

1.6 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, licensed sellers, 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, Saturdays, and Sundays. 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, are regulated as defined in the National Drug Policy and Authority Act Cap. 198.

1.7 SCOPE

The SDTs cover the efficiency of NDA business processes to deliver services for the clients in the regulatory areas.

1.8 RATIONALE

The Service Charter of the National Drug Authority is developed to promote transparency, accountability, and efficiency in the delivery of regulatory services. It provides a clear statement of the Authority's commitment to stakeholders by outlining the services offered, the standards to be met, and the timelines within which services will be delivered. The Charter serves as a practical tool for enhancing stakeholder confidence, guiding compliance with regulatory requirements, and ensuring that services are delivered in a consistent, fair, and responsive manner. It also establishes a basis for performance monitoring and continuous improvement, while providing mechanisms for feedback and redress to address concerns and strengthen service delivery in line with public sector governance principles.

1.9 APPLICATION OF SERVICES STANDARDS

The SDTs apply to internal and external 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.

1.10 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.

CHAPTER TWO:

2.0 COMMITMENTS, RESPONSIBILITIES AND SERVICE DELIVERY PRINCIPLES

2.1 CLIENT'S COMMITMENT

We commit to:

a) Promptly and accurately respond to all requests and correspondence from the National Drug Authority (NDA) regarding product-related matters; and
b) Ensure timely payment of all applicable fees for regulatory services rendered by the National Drug Authority.
c) Raise concerns on the regulated products and services to the Authority timely for effective response / action.
d) Timely and efficient service delivery
e) Clear and accurate information
f) Fair and non-discriminatory treatment
g) Confidential handling of information
h) Feedback and complaint resolution

2.2 CLIENT RESPONSIBILITIES

Clients are expected to:

a) Submit complete and accurate documentation
b) Comply with regulatory requirements
c) Pay prescribed fees on time
d) Respond promptly to NDA queries
e) Adhere to applicable laws and guidelines

2.3 REGULATORS' COMMITMENT TO CLIENTS

We commit to:

a) Continuously improve through feedback and innovation
b) Ensure fairness, integrity, and confidentiality
c) Apply risk-based and evidence-based regulatory decisions
d) Deliver timely, efficient, and professional services.

2.4 SERVICE DELIVERY PRINCIPLES

a) **Transparency:** We provide clear, accurate, and timely information on all our services, including requirements, processes, fees, and timelines, to ensure stakeholders can engage with the Authority with confidence and predictability.
b) **Accountability:** We commit to defined service standards and measurable timelines, and we regularly monitor, report, and take responsibility for our performance in delivering regulatory services.

c) **Integrity:** We uphold the highest standards of professionalism, ethics, and impartiality in all our interactions and decisions, ensuring that our regulatory actions are fair, consistent, and free from undue influence.
d) **Efficiency:** We continuously improve our processes and leverage digital systems to deliver timely, reliable, and cost-effective services without compromising regulatory quality and public safety.
e) **Equity:** We ensure fair, inclusive, and non-discriminatory access to our services for all stakeholders, treating every client with respect and impartiality regardless of background or status.

CHAPTER THREE

3.0 REGULATORY SERVICES

3.1 APPROVED SERVICE DELIVERY TIMELINES (SDTS) FOR FY 2025/26 – 2029/30.

Table 2: Approved Service Delivery Timelines (SDTS) for FY 2025/26 – 2029/30.

Regulatory Area	Service	Minimum Access Time (Working Days)	Service Delivery Point
Clinical Trial Oversight (CTO)	Receipt, screening, and acknowledgment of the initial Clinical Trial Application	10 Days	DPS-Clinical Trials Unit
	Regulatory decision on a Clinical Trial Application	50 Days	DPS-Clinical Trials Unit
	Annual renewal of ongoing trials	20 Days	DPS-Clinical Trials Unit
	Amendment of CT Authorization	20 Days	DPS-Clinical Trials Unit
	Feedback report to a client following a GCP Inspection	45 Days	DPS-Clinical Trials Unit
Regulatory Area	**Service**	**Minimum Access Time (Working Days)**	**Service Delivery Point**
Veterinary Field Trial Oversight and Pharmacovigilance (VFTOP)	Acknowledgment of receipt and screening of a Field Trial Application (FTA)	10 Days	Directorate of Veterinary Services
	Regulatory decision on an FTA	50 Days	Directorate of Veterinary Services
	Feedback report to a client following a GCP Inspection of field trials	45 Days	Directorate of Veterinary Services
	Acknowledgement of receipt of safety report	5 Days	Directorate of Veterinary Services
	Feedback on causality assessment	30 Days	Directorate of Veterinary Services
	Feedback following evaluation of the end of the field trial report	25 Days	Directorate of Veterinary Services

Regulatory Area	Service	Minimum Access Time (Working Days)	Service Delivery Point
Marketing Authorization (MA)	**GENERAL CONSIDERATION**		
	Assessment of application and request for additional information on the application for MA (Human Drugs)	18 months (396 Days)	DPAR-Medicines Unit
	Assessment of application and request for additional information on the application for MA (Veterinary Drugs)	14 months (308 Days)	DPAR-Medicines Unit
	Assessment of application and request for additional information on application for MA (Vaccines)	6 Months (132 Days)	DPAR-Medicines Unit
	Regulatory decision on MA after additional information is received	3 Months (66 Days)	DPAR-Medicines Unit
	SPECIAL CATEGORIES		
	Regulatory decision on MA for domestically manufactured conventional medicines	6 Months (132 Days)	DPAR-Medicines Unit
	Regulatory decision 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)	DPAR-Medicines Unit
	Medical products and technologies granted MA within 66 working days (90 calender days) at both continental and regional level.	3 Months (66 Days)	DPAR-Medicines Unit
	VARIATION AND NOTIFICATION		
	Regulatory decision on minor variation	4 Months (88 Days)	DPAR-Medicines Unit
	Regulatory decision on Major variation (if the application does not require physical verification)	6 Months (132 Days)	DPAR-Medicines Unit

Regulatory Area	Service	Minimum Access Time (Working Days)	Service Delivery Point
	DRUG REGISTER		
	Publication of the drug register	Monthly (5th working day of the month)	DPAR-Medicines Unit
Regulatory Inspection (RI)	GMP Physical inspection after receipt of application – Foreign	180 Days	DIE-GMP Unit
	GMP Report Feedback to Manufacturer after Inspection	45 Days	DIE-GMP Unit
	Feedback after inspection – Domestic	28 Days	DIE-GMP Unit
	Regulatory Decision after CAPA – Foreign	20 Days	DIE-GMP Unit
	Regulatory Decision after CAPA – Domestic (Local Facilities)	17 Days	DIE-GMP Unit
Regulatory Area	**Service**	**Minimum Access Time (Working Days)**	**Service Delivery Point**
Premise Licensing (PL)	Feedback to the applicant on the regulatory decision for pharmacy renewal	40 Days	DIE-Licensing
	Feedback to the applicant on the Regulatory decision for licensing of new Pharmacy applicants	30 Days	DIE-Licensing
Regulatory Area	**Service**	**Minimum Access Time (Working Days)**	**Service Delivery Point**
Market Surveillance and Control (MSC)	Verification of imports (Registered drugs)	3 Days	DIE-Imports and Exports Unit
	Clearance of Imports at Ports of Entry	2 Days	DIE-Imports and Exports Unit
	Regulatory decision on drug promotional materials	10 Days	DPS-Drug Promotions Unit
	Publication of advert of approved promotional materials/advert	Monthly (5th of the following month)	DPS-Drug Promotions Unit

Regulatory Area	Service	Minimum Access Time (Working Days)	Service Delivery Point
Vigilance (PV)	Acknowledgement of receipt of an ADE report	5 Days	DPS-Pharmacovigillance Unit
	Feedback on serious ADE reports	18 Days	DPS-Pharmacovigillance Unit
	Feedback on a serious AEFI report to the Expanded Program for Immunization (EPI)	14 Days	DPS-Pharmacovigillance Unit
Laboratory Testing (LT)	Test results from mandatory testing after sampling (Medicine)-PoE.	48 Days	DLS-Medicnes Unit
	Test results from mandatory testing after sampling (Medical Devices).	25 Days	DLS-Medical Devices Unit
	Test results from client requests after acceptance by the lab (All Products).	45 Days	DLS-Medicines and Medical Devices Unit
	Test results for pre-market samples (Domestic Manufacturers).	60 Days	DLS-Medicnes Unit
	Test results for post-market surveillance (Medicines).	48 Days	DLS-Medicnes Unit
	Test results for post-market surveillance (Medical Devices)	30 Days	DLS-Medical Devices Unit
Regulatory Area	**Service**	**Minimum Access Time (Working Days)**	**Service Delivery Point**
National Regulatory System (NRS)	Issuance of a recall or alert for a substandard or falsified medicine or health care product	8 Days	DIE-PMS Unit
	Acknowledgement of receipt of a product complaint	3 Days	DIE-PMS Unit
	Feedback on a market (process, product, or other) complaint	20 Days	DIE-PMS Unit
	Feedback on the effectiveness of recall after receipt of the recall	15 Days	DIE-PMS Unit

Regulatory Area	Service	Minimum Access Time (Working Days)	Service Delivery Point
	report from the LTR (Local Technical Representative)		
	Feedback on test results from the Lab to the client	5 Days	DIE-PMS Unit
	QUALITY MANAGEMENT SYSTEM		
	Acknowledgment of receipt of a service-related complaint.	2 Days	SA-QMS Department
	Feedback on service-related complaints	21 Days	SA-QMS Department

3.2 INTERPRETATION

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 the National Drug Authority (NDA) requests additional information or clarification from an applicant or client, the processing clock is paused until a response is received. Once the required information is submitted, the clock resumes. As such, the timelines indicated reflect only the duration within which NDA is responsible for executing a given regulatory action

CHAPTER FOUR

4.0 GENERAL SERVICE STANDARDS

4.1 OFFICIAL WORKING HOURS AND ACCESS TO OFFICE PREMISES

i. Our offices shall be open Monday to Friday, 8:00 am to 5:00 pm and closed to the public on weekends and designated public holidays.
ii. Our clients shall be subjected to security checks to access the NDA premises.
iii. Our services can be accessed by visiting our offices during working hours from Monday to Friday or on the website www.nda.or.ug.
iv. Maintaining a safe, secure, and inclusive working environment within the premises of the National Drug Authority.

4.2 CLIENT MANAGEMENT AND COMMUNICATION

i. All our official communications shall be on a standard National Drug Authority letter head.
ii. Responding to written correspondences from clients within the respective service points agreed timelines.
iii. Clients are attended to at our respective service points on a first-come, first-served basis.
iv. The National Drug Authority's website shall be accessible at all times and will be updated daily.
v. All our offices shall be clearly labeled to give proper direction to clients.
vi. All incoming official correspondences shall be addressed through NDA registry and then channed to the respective office for action.

4.3 DRESSCODE AND APPEARANCE

i. Our staff shall wear official identification cards at all times at the work place.
ii. Our officers shall dress decently at all times.

4.4 OTHER STANDARDS

i. We shall process and pay service providers within a month upon completion of the task.
ii. We shall pay salary and pension by the 28th of every month.

CHAPTER FIVE

5.0 FEEDBACK MECHANISM AND COMPLAINTS HANDLING & COMPLIMENTS

5.1 FEEDBACK MECHANISM

Incase of any feedback, you can use any of the following communication channels:

a. Reach out to the National Drug Authority through the Officers at the secretariat located at the Plot 93, Buganda Road , after St. Catherine Hospital and all the nine (9) regional offices as illustrated in the table below.

Table 3: National Drug Authority Feedback Mechanism

Regional Office	Location and Address	Contact
Kampala Extra office	Plot 95, Buganda Rd next to the NDA Tower Kampala	Tel: 0393261548
Central regional office Masaka	Kooki street Masaka Town P.O Box 23096, Kampala	Tel: 0414672734
Northern Region Office	Lira Ato Sebbi Road, Junior Quarters P.O Box 2 Lira	Tel: 0414671032
South Western Region Office-Mbarara	Plot 26, Johnstone Road, Boma (After Boma Primary School). P.O Box 1886 Mbarara, Uganda	Tel: 0414671034
Western Region Office Hoima	GTG Plaza Hoima Plot 7, Rukurato Rd P.O.BOX 192	Tel: 0393255 257
Eastern Region Office Tororo	Plot No: 27 Kwapa Road P.O Box 453, Tororo – Uganda	Tel: 0392004308
South Eastern Regional Office	Plot No. 64 Gokhale Road West Jinja P.O Box 1710 Jinja	Tel: 0434122176
West Nile Region Office- Arua	P. O Box 1034, Arua Plot. 1 MT. Wati Road at Anyafio	Tel : 0414671033
North Eastern Region Office Soroti	Plot 5C and 5D, Hepper Road Senior Quarters Soroti	Tel: 0414662030

b. Write to us using the address given at the end of this Charter,or; Call us on the Toll Free: 0800 101 999, Reception Line: +256 [0]417 788 100, Directorate of Product Safety : +256 [0]417 788 124, Directorate of Inspectorate Services : +256 [0]417 788 129 and Pharmacovigilance : +256 740002070 and +256 740002080.
c. Use available Suggestion boxes after the entrance of the NDA, and at the reception of NDA.
d. National Drug Authority Website www.nda.or.ug or E-mail ndaug@nda.or.ug
e. For any pharmaceutical analysis and quality control inquiries, Please send an email to ndaqc@nda.or.ug.

5.2 COMPLAINTS HANDLING.

Incase of any grievance about our services, utilize the following procedures;-

a) Verbal complaints shall be directed to the Secretary to te Autority, National Drug Authority through the designated phone number and email.

b) Write an appeal to the Secretary to the Autority, National Drug Authority. On receipt of the complaints or appeal,the Authority will: -

i. Acknowledge the appeal within the agreed timelines of receipt including information on the action being taken.

ii. All complaints referred to respective Heads of Departments will be investigated and a response given within within the agreed timelines.

iii. Communicate the decision within within the agreed timelines.

iv. Scan the QR code on the NDA website https://www.nda.or.ug/contact-us/ and send your customer feedback.

CHAPTER SIX

6.0 DISSEMINATION AND IMPLEMENTATION OF THE CLIENT CHARTER.

6.1 DISSEMINATION.

We shall disseminate the client charter through the following channels;

1. It will be uploaded on the National Drug Authority website; www.nda.or.ug for the external stakeholders.
2. It will be shared on email to all the internal stakeholders

6.2 IMPLEMENTATION OF THE CLIENT CHARTER.

We pledge to continue making ourselves accountable for our performance tagged to this Client Charter.

The Drug Authority will monitor implementation of this charter by :-

(i) Report on performance to key clients and key stakeholders. This will help to emphasize transparency and accountability.

6.3 CONTACT

Toll Free: 0800 101 999
Tel: +256 [0]417 788 100
E-mail: ndaug@nda.or.ug
Website: www.nda.or.ug
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