ETHIOPIAN FOOD AND DRUG AUTHORITY

GUIDELINE FOR DRUG INFORMATION SERVICES

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Forward from EFDA

Reliable, timely, and evidence-based drug information (DI) is vital to patient safety, rational medicine use, and regulatory decision-making. In Ethiopia, gaps in access to high-quality DI Services (DIS) contribute to avoidable adverse drug events, and inefficient use of limited health resources. Strengthening DIS is therefore a national priority.

The Ethiopian Food and Drug Authority (EFDA) has prepared this second edition of the DIS guideline to provide a structured, sustainable, and nationally harmonized guidance for delivering high-quality DI across all levels of care. This edition supersedes the 2004 guidance issued by the former Drug Administration and Control Authority and reflects advances in pharmaceutical care, digital health, pharmacovigilance, and public health emergency preparedness.

The guideline targets broad audiences including healthcare professionals, regulatory bodies at national and regional levels, academic and research institutions, the pharmaceutical industry; training institutions, development partners, community health programs, and civil society organizations. By following the standards, tools, and operational procedures contained herein, these groups collectively enable safe, effective, and equitable access to DI.

Recognizing persistent barriers related to access - geographic, infrastructural, linguistic, and technological, this edition promotes the strategic use of digital platforms and innovative technologies to reach both urban centers and remote facilities. Equity is a cross-cutting commitment: DIS outputs must be formatted and delivered in ways that are usable by frontline workers, primary care facilities, and communities with limited connectivity.

EFDA calls on all stakeholders to adopt and institutionalize the standards and procedures described; ensure data reporting and documentation of DI activities; participate in training, quality assurance, and performance monitoring; and provide regular feedback to strengthen future revisions.

We extend sincere appreciation to all experts, organizations, and partners whose dedication and collaboration have made this guideline possible. We believe it will have a lasting impact on patient safety and healthcare delivery in Ethiopia.

Heran Gerba

General Director

Ethiopian Food and Drug Authority

Forward from Ministry of Health

Reliable and timely drug information is vital for safe and effective healthcare. Every decision involving medicines depends on information that is accurate, accessible and based on sound evidence. Ensuring that such information is organised and available to all parts of the health system is central to our efforts to improve patient safety and support high quality clinical care.

This Second Edition of the National Drug Information Services Guideline provides clear national direction for establishing and managing Drug Information Centers and defines the standards required for delivering dependable services across the health system. The revised edition responds to the growing complexity of medicines, the need for early detection of safety concerns and the importance of strong links with pharmacovigilance, antimicrobial stewardship and regulatory information systems. It also aligns with national digital transformation priorities and supports the use of digital tools to expand reliable access to information for both providers and patients. Drug Information Services have not always functioned consistently, and many facilities lacked the resources, tools or technical support needed for effective service delivery. By introducing updated procedures, clarified responsibilities and stronger coordination, this edition aims to ensure that reliable drug information becomes a routine part of clinical and regulatory decision making.

The development of this guideline was made possible through close collaboration involving the Ministry of Health, the Ethiopian Food and Drug Authority, academic institutions and committed professionals. Their expertise ensured that the guideline is practical and aligned with the needs of our health system. We extend our appreciation to all who contributed.

As we implement this guideline, I call upon all health facilities, institutions and professionals to apply this guideline fully. Drug Information Services are not an optional component of care. They are an essential mechanism for protecting patients, guiding clinicians and supporting the responsible use of medicines. Consistent implementation will strengthen safety, improve quality of care and support our national goal of equitable healthcare for all Ethiopians.

Firehiwot Abebe

State Minister

Ministry of Health, Ethiopia

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EFDA extends special thanks to the participants of the consultative and validation workshops including healthcare professionals, regulatory bodies, representatives from academic institutions, industry experts, and international partners, whose valuable insights and feedback were vital in refining this guideline and ensuring its alignment with national and international standards.

We are especially grateful to the members of the Technical Working Group; whose expertise and unwavering commitment were essential throughout the drafting and review processes. Their contributions have shaped a guideline that responds to the needs of diverse healthcare stakeholders, from providers and regulatory bodies to the broader public.

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Abbreviations and Acronyms

ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
ADR:	Adverse Drug Reaction
AMA	African Medical Association
AMRH	African Medicines Regulatory Harmonization
AHFS	American Hospital Formulary system
AMR	Antimicrobial resistance
AI	Artificial Intelligence
BMJ	British Medical Journal
CSO	Civil Society Organizations
CDS:	Clinical Decision Support
CDIC	Community Based Drug Information Center
CHW	Community Health Worker
CD	Consumer Drug Information
CPD	Continuous Professional Development
CQI	Continuous Quality Improvement
CHW	Community Health Workers
DHIS	District Health Information System
DACA	Drug Administration and Control Authority
DTC	Drug and Therapeutics Committee
DI	Drug Information
DIC	Drug Information Center
DIS	Drug Information Service
EWS	Early Warning System
EHR	Electronic Health Records
EMR	Electronic Medical Record
eRIS	Electronic Regulatory Information System
EML	Essential Medicines List
EMA	Ethiopian Medical Association
EFDA	Ethiopian Food and Drug Authority

EPA	Ethiopian Pharmaceutical Association
FDA	Food and Drug Agency
HCP	Health Care professional
HF	Health Facility
HFDIC	Health Facility Based Drug Information Center
HR	Human Resource
HIV	Human Immunodeficiency Virus
IDIC	Industry-based Drug Information Canter
FIP	International Pharmaceutical Federation
KPI	Key Performance Indicator
M&E	Monitoring and Evaluation
MTM	Medication Therapy Management
MOH	Ministry of Health
NDIC	National Drug Information Center
NCD	Non-Communicable Diseases
NGO	Non-Governmental Organization
PIRS	Performance Indicator Reference Sheet
PDIC	Pharmacy Based Drug Information Center
QA	Quality Assurance
RDIC	Regional Drug Information Center
RHB	Regional Health Bureau
SMS	Short Message Service
STG	Standard Treatment Guideline
SOP	Standard Operating Procedure
SF	Substandard and Falsified
SPC	Summary of Product Characteristics
TOR	Terms of Reference
TDM	Therapeutic Drug Monitoring
TB	Tuberculosis
UMC	Uppsala Monitoring Centre
WHO	World Health Organization

Chapter One: Introduction

1.1 Background

Drug information (DI) refers to evaluated, evidence-based, and clinically relevant data about medicines that support health care providers (HCPs), patients, and regulatory bodies in making informed decisions regarding the use of drugs. Drug Information Services (DIS) are structured systems established to ensure the provision of reliable, accurate, and up-to-date drug-related information across all levels of the healthcare system. The ultimate goal of DIS is to promote safe, effective, and rational use of medicines, thereby improving patient safety and clinical decision-making.

In resource-limited settings, consistent access to high-quality DI remains a major challenge. The absence of well-functioning DIS has been linked to increased adverse drug events (ADEs) and higher patient morbidity, particularly in settings with limited healthcare resources and accessibility. DIS helps bridge the gap between rapid advancements in pharmaceutical development and their practical application in clinical settings. By supporting therapeutic decision-making, DIS enables HCPs to navigate complex issues such as drug interactions, ADEs, contraindications, and dosing adjustments.

Global evidence, including meta-analyses, suggests that the establishment of well-structured DIS in health facilities particularly in hospitals and rural areas can reduce ADEs by up to 30%. In Ethiopia's diverse healthcare landscape, where disparities in access to clinical information persist between urban and rural settings, scaling up DIS is critical to ensure equitable, timely, and context-relevant DI delivery. Beyond individual patient care, DIS also plays an instrumental role in addressing broader public health challenges. Common issues such as self-medication, antibiotic misuse, improper storage of medicines, and the unsafe use of herbal and traditional remedies are often exacerbated by low health literacy and a lack of professional guidance. In addition, emerging threats such as vaccine hesitancy and the misuse of over-the-counter medicines, including analgesics and cough suppressants, underscore the urgent need for structured, accessible, and responsive DIS at all levels of the health system. By empowering individuals and communities with accurate information, DIS fosters informed decision-making and supports safer medication practices.

The initial national guideline on the establishment and operation of Drug Information Centers (DICs) was developed by the former Drug Administration and Control Authority (DACA),

now the Ethiopian Food and Drug Authority (EFDA), in 2004. Since then, various institutions have initiated efforts to provide DIS within public health facilities. While the 2004 guideline served as a foundational document for promoting rational medicine use, the evolving healthcare landscape, advances in digital technologies, and global health priorities particularly the threat of antimicrobial resistance (AMR) have necessitated comprehensive revision.

1.2. Rationale for revising the guideline

Since its initial issuance in 2004, the national guideline on DIS has provided a foundational framework for establishing DICs and promoting rational medicine use across Ethiopia. However, over the past two decades, the health system landscape has evolved substantially, and critical limitations have emerged in the structure, functionality, and integration of DICs. These limitations such as the inactivity of most centers, lack of diversified models, and poor alignment with digital innovations have hindered the consistency, reach, and quality of DIS nationwide.

National situational review revealed that many DICs were either inactive or functioned intermittently due to limited institutional ownership, the absence of standard operating procedures (SOPs), and weak capacity for coordination and sustainability. The previous guideline primarily focused on hospital-based DICs and did not accommodate alternative models such as industry-based, pharmacy-based, or standalone community DICs. As a result, service delivery has remained fragmented, especially in rural and underserved areas, where timely and accurate DI is most critical.

In addition, the guideline lacked provisions for integrating digital health solutions, which are now central to Ethiopia's health system modernization efforts. The Digital Ethiopia 2030 Strategy emphasises the need for digitally enabled, evidence-based, and equitable health services. Yet, existing DICs operate in silos, with minimal use of digital platforms for real-time information sharing, data reporting, or early warning surveillance.

Moreover, the absence of harmonized national standards and failure to integrate DISs with global pharmacovigilance and antimicrobial stewardship frameworks have limited the role of DICs in responding to emerging medicine safety threats. This gap is particularly critical given the WHO's 2021 recommendation for countries to strengthen their national DI and pharmacovigilance linkages as part of resilient health systems.

In response to these pressing challenges, the EFDA has initiated the revision of the national DIS guideline. The revised guideline aims to revitalize and standardize all types of DICs by introducing flexible models, tiered coordination structures, and clear institutional mandates. It will incorporate digital platforms to enable real-time DI access and enhance linkage with pharmacovigilance and regulatory data systems. The revised guideline will also strengthen accountability mechanisms, define performance indicators, and foster sustainable partnerships.

Ultimately, this revision aspires to build a responsive, sustainable, and digitally integrated DI system that supports evidence-based decision-making, promotes rational medicine use, and ensures equitable access to reliable DI across all levels of Ethiopia's healthcare system.

1.3. Objectives of the guideline

The objectives of this guideline are to:

1. Establish, revitalize, and ensure the sustainability of DICs at national, regional, facility, and community levels
2. Standardize procedures and protocols for the provision of DIS across all healthcare settings to ensure consistency, quality and regulatory compliance.
3. Ensure timely and equitable access to evaluated, evidence-based DI by leveraging digital solutions, and offline tools suitable for resource-limited contexts.
4. Support capacity building and institutional integration of DIS through structured training, mentorship, and monitoring systems that promote quality improvement and operational excellence

1.4. Scope and applicability of the guideline

This guideline applies to the establishment and operations of DICs at national, regional, institutional (hospital, health center, community pharmacy and pharmaceutical industry) levels. The guideline serves as a foundation for provision of reliable, timely, and evidence-based DI. In addition, this guideline serves to guide academic institutions, inform patients, the public, and advocacy groups by promoting access to comprehensive DI.

Chapter Two: Establishing and Managing DICs

This chapter outlines the processes and requirements for classifying, establishing, operating, and sustaining DICs in Ethiopia. It also discusses the organizational structure and governance of DICs.

2.1. Classification of DICs

DICs in Ethiopia are classified based on their operational scope, target audience, and functional roles within the healthcare system to ensure coordinated, context-relevant, and equitable access to evidence-based DI. This classification enables the establishment of a harmonized national network that supports timely and accurate DI dissemination across all healthcare levels and settings. DICs may be established as:

1. **National DICs (NDICs)**

The NDIC, housed within the EFDA, serves as the central coordinating body for DI services nationwide. It guides policy, coordination, and standardization for the entire DIC network, ensuring alignment with national health strategies and international best practices.

2. **Regional DICs (RDICs)**

Regional DICs, positioned strategically across regions/city administrations to facilitate the implementation of national strategies at the regional level and provide support tailored to local needs within their geographic areas.

3. **Health facility-based DICs (HFDICs)**

Health facility-based DICs, operated within public, private and non-governmental health facilities such as health centers, hospitals and specialty centers to support patient-centered clinical decision-making.

4. **Community-based or Standalone DICs (CDICs)**

Community-based DICs, operated standalone in non-institutional settings to serve the general public, patients, and healthcare providers at the community level.

5. **Industry-based DICs (IDICs)**

Industry-based DICs, operated within pharmaceutical manufacturing industries to provide ethical product-specific DI to healthcare professionals and regulatory bodies.

6. **Pharmacy-based DICs (PDICs)**

Pharmacy-based DICs, operated to provide patient-focused DI to promote safe medicine use in every day practice.

Together, those DICs reach diverse stakeholders and promote rational medicine use throughout the country.

2.2. Core functions and responsibilities of DICs

2.2.1. Core functions of DICs

DICs are integral components of the health system, serving as technical hubs for preparation, evaluation, and dissemination of drug-related information to support evidence-based clinical practice, ensure patient safety, and improve public health outcomes. Their mandates go beyond responding to DI queries, they support a multifaceted set of services that include patient care, professional training, policy formulation, pharmacovigilance, and public education. The following are the core functional domains of DICs.

a) Responding to drug-related queries

DICs serve as a primary resource for addressing inquiries from HCPs, patients, regulatory bodies, and the public. These inquiries may relate to medication selection, medicine use instructions, dosage adjustments, drug interactions, contraindications, ADEs, therapeutic alternatives, and more. DICs ensure all responses are evidence-based, timely, and tailored to the clinical context.

b) Production and dissemination of DI

DICs can produce and disseminate a range of DI outputs, including drug monographs, bulletins, newsletters, alerts, and online updates. These materials support continuous professional development (CPD) and inform clinical decisions.

c) Support clinical services

DICs support clinical decision-making by integrating with clinical pharmacy teams. They provide point-of-care support for Medication Therapy Management (MTM), Therapeutic Drug Monitoring (TDM), and interpretation of laboratory results. DICs also assist in the rational use of antimicrobials and facilitate safe medication practices in both inpatient and outpatient settings.

d) Support to drugs and therapeutics committee (DTC)

DICs serve as a resource center and work closely with the DTC to prepare and revise the institutional drug formulary, facility-specific medicine lists, monographs, treatment guidelines/protocols, standard operating procedures (SOPs), participate in drug utilization and pharmacoeconomic studies, and supporting antimicrobial stewardship initiatives.

e) Support pharmacovigilance

DICs play an important role in pharmacovigilance (PV). They support the prevention, detection, investigation, understanding, and reporting of ADEs including medication errors, allergic reactions, and quality defects and providing timely updates on drug safety, recalls, alerts, and risk–benefit assessments. They also collaborate with national PV programs to ensure rapid communication of drug recalls, alerts, and risk-benefit reassessments.

f) Support public health emergency preparedness

DICs support public health emergency response by providing rapid, evidence-based guidance during emergencies such as drug shortages, disease outbreaks, pandemics, or medicine recalls. Their involvement is essential in evaluating mass drug or vaccine administration campaigns and ensuring preparedness for urgent drug-related risks.

g) Education and training

DICs provide drug related information to patients by creating print and digital educational resources such as posters, brochures and pamphlets. In addition, DICs provide education on drug related information to target audiences through facility health education programs and local mass media.

DICs also serve as academic and professional development platforms. They provide in-service training, facilitate journal clubs and seminars, offer DI-focused workshops, and organize educational sessions for HCPs.

h) Conduct and/or participate in research

DICs engage in research activities to strengthen pharmaceutical services. This includes conducting pharmaco-epidemiological studies, pharmacovigilance research, drug use evaluations, prevention and containment of antimicrobial resistance, assessment of the impact of DIS. Evidence generated is used to inform practices, policies, and national strategy updates.

i) Facilitate networking and collaboration

DICs support horizontal and vertical collaboration across regional, national, and international levels. This includes partnerships with other DICs, regulatory bodies, academic institutions, and international organisations (e.g., WHO). The collaborations enhance resource sharing, referral systems, harmonization of practices, and access to global best practices.

j) Support to drug supply chain management

DICs supports pharmaceutical supply chain management systems by participating in medicine selection, forecasting, and quantification by working closely with supply chain units and DTCs. They review medicine availability, analyse inventory reports (e.g. stockouts, overstocks, expiries), and provide technical input to ensure uninterrupted access to essential medicines at health facilities.

2.2.2. Unique responsibilities by level of DIC

While all DICs share common core functions, their specific responsibilities vary depending on their operational level, institutional setting, and mandate within the national DIS network. Recognizing these unique roles ensures clarity of functions, enhances coordination, promotes an integrated and tiered DI system that can efficiently meet the information needs of diverse stakeholders. The table below outlines the distinct responsibilities assigned to each type of DICs within the Ethiopian healthcare system.

Table 2.1: Unique responsibilities of DICs by type and operational level

Type of DIC	Primary Focus	Key roles and unique responsibilities
National Drug Information Center (NDIC)	Strategic leadership, national coordination, and international alignment	• Develop national guidelines, standards, and SOPs for DIS. • Allocates resources to ensure effective operation of DICs. • Facilitate collaboration among stakeholders such as PV systems and global networks • Lead national training and capacity building programs • Monitor key performance indicators (KPIs) and aggregate reports from RDICs, HFDICs, PDICs, IDICs, and CDICs • Conduct national assessments on DIS activities • Maintains international contacts to receive and disseminate updated DI bulletins and publications. • Host national digital repositories and DI platforms
Regional Drug Information Centers (RDICs)	Regional supervision, adaptation of national guidance,	• Ensure effective implementation of national DI guidelines and standards at regional level • Conduct regional training and capacity building programs. • Receive reports from HFDICs, CDICs, and PDICs, and provide feedback. • Provides technical assistance and support to DICs within the region, • Collaborate with local health authorities (Zonal/Woreda health offices) • Analyse regional DIS data using KPIs. • Issue certificate of competence for community-based DICs.
Health Facility-Based DICs (HF-DICs)	Point-of-care support for clinical teams	• Support clinical decisions, MTM, TDM, and safety issues • Participate in DTC activities such as formulary management • Coordinates with regional DICs for training and updates

Community-Based or Standalone DICs	Community outreach and public education	• Act as a liaison between community and formal health system • Support for community health workers (CHWs) with DI and education.
Industry-Based DICs	Non-promotional product information and regulatory compliance	• Provide ethical, product-specific DI to HCPs and regulatory bodies. • Respond to investigator queries and pharmacovigilance requirements • Ensure separation of DIS from marketing functions
Pharmacy-Based DICs	Frontline medication counselling and public access	• Collaborates with community health initiatives to provide accessible DI • Supports rational drug use and medication adherence at the community level.

2.3. Establishment of DICs

2.3.1. Requirements for the establishment of DICs

A. Human resources for DICs:

- The effectiveness of a DIC depends on the competence and commitment of its personnel while the number and mix of staff working within the DIC shall be based on the complexity of the service they provide.
- Every DIC shall be staffed with qualified personnel whose number and mix reflect the level and complexity of the services provided.
- At a minimum, each DIC shall assign:
  - One full-time DI pharmacist in health center-based or primary-level DICs.
  - Two or more full-time equivalent (FTE) DI pharmacists for hospital-based DICs.
  - One senior pharmacist as DIC Coordinator at regional and national levels.
- The roles and responsibilities of each staff category shall be clearly defined. The DI pharmacist shall manage query responses, reference appraisal, and output validation. The coordinator shall oversee DIC operations, SOP implementation, and quality improvement.
- Support staff (e.g., IT, clerks) may be assigned as needed based on service volume.
- DIC staff shall fulfil the roles described in Table 2.2 below.

Table 2.2: Required Personnel and Key Responsibilities for DICs

Staff	**Minimum qualifications**	**Key responsibilities:**
DIC Coordinator*	A senior pharmacist with leadership skills, preferably with experience in DI management and strategic oversight	● Overseeing the daily operations of the DIC ● Coordinating staffing schedules, ● Monitoring adherence to SOPs, ● Managing internal audits and ensuring that the center meets regulatory compliance requirements. ● Leads quality assurance initiatives, ● Supervises training programs, and is responsible for the continuous evaluation and improvement of the DIS.
DI Pharmacist(s)	A minimum of BPharm degree or PharmD,	● Responding to DI queries, ● Conducting research to provide evidence-based information, ● Peer-reviewing responses, ● Managing pharmacovigilance data, ● Ensuring the accuracy and relevance of information disseminated. ● Engaging in ongoing professional development to update with the latest drug knowledge.

** Facilities with less complex services may assign the DI pharmacist to serve as coordinator. Additional support staff such as IT officers and administrative clerks may be included in higher-level facilities.*

Recommended staffing levels:

The number and skill mix of the personnel assigned to the DIC shall be adequate and appropriate to meet the demands for the service. For hospitals, a minimum of two full-time equivalent (FTE) DI pharmacists is recommended. For non-hospital-based centers, staffing levels should align with the scope and workload, adjusted to meet demand.

Note: In larger centers or during peak demand periods, on-call or rotational support may be available to handle urgent queries, such as ADRs or critical drug interactions.

B. **Physical infrastructure**:

- The center shall be equipped with workstations, shelving, filing systems, internet access, and utilities for printing, scanning, and communication.
- The location of the DIC shall be accessible to DI requestors and, where applicable, the public.
- Each DIC shall be housed in a dedicated and accessible space, with the following minimum DIC room requirement:

Table 2.2: Minimum DIC room area requirements in different types of DICs

Type of DIC	Minimum DIC room area required
• National DIC • Regional DIC • Tertiary Hospital DIC • Standalone DIC	16m²
• General Hospital DIC • Pharmacy Based DIC • Industry Based DIC	12m²
• Primary hospital DIC • Health/speciality center DIC	9m²

C. Technological Resources:

Each DIC shall maintain:

- Computers with reliable internet access;
- Reference management and document processing software;
- Secure email and telephone systems for receiving and responding to queries.

D. Information Resources:

Each DIC shall maintain access to:

- National documents (STGs, formularies, essential medicine lists).
- International tertiary references (e.g., Martindale, Micromedex).
- EFDA-issued bulletins and WHO resources.

E. Training requirements

- All staff shall complete foundational training in DIS operations prior to service initiation.
- Regular CPD is essential to equip staff with up-to-date knowledge. The CPD shall be provided through institutional or national training programs.

F. Financial requirements

- DICs require funding for both capital costs (e.g. equipment, software) and recurrent expenses (e.g. subscriptions, maintenance).to ensure sustainable service provision. This may be covered by the institution through in-kind support, or a dedicated budget allocated according to its governance structure.
- Additional funding may be mobilized from regional bureaus or partners.

2.3.2. Procedures for establishing new DICs

Step 1. Conduct situational and need assessments

- Form a team of key stakeholders, including clinical pharmacists, healthcare providers, hospital administrators, and directors or representatives from EFDA/MoH, to oversee the development and establishment of DICs.
- Assess the demand for DIS within the facility.
- Collect relevant data on DI gaps, sources of drug queries, and current access to evidence-based resources.
- Analyse the data collected to identify the current challenges and opportunities for establishing a DIC.
- Assess the resources available and any barriers that might hinder the establishment or function of the center.

Step 2. Secure resources

- Present need assessment findings to facility management or responsible body. Ensure the DIC has a defined scope and meets requirements outlined in policy guidelines and standards.
- Designate a space for the DIC and equip it with essential tools such as dedicated staff, reference materials, computers, internet access, telecommunication systems, and data storage solutions to support efficient data retrieval and information dissemination.
- Develop operational plans and align with national priorities such as the National AMR Action Plan and National Medicine Policy.

Step 3. Advocacy and orientation

- Conduct advocacy programs within the institution to highlight the importance of DIC.
- Organize orientation sessions to introduce the purpose and benefits of the DIC.

Step 4. Train DIC staff

- Deliver structured DIS training to assigned staff.
- Adopt or adapt national SOPs for DI operations.

Step 5. Establish standard operating procedures (SOPs)

- Adopt/adapt SOPs for the provision of DIS

Step 6. Set up a documentation and follow-up system

- Set up a structured system to log queries, drug alerts, newsletters, responses, and relevant details for quality assurance and reference purposes.

- Develop a follow-up process to evaluate the effectiveness of the provided information and gather feedback from users.

Step 6. Launch the establishment of DIC

- Organize an official launching session (formally announce DIC establishment).
- Disseminate service availability to internal and external stakeholders.
    - Publicize services to clinicians, students, and pharmacy professionals.

2.3.3. Revitalization of non-functional DICs

2.3.3.1 Definition and measurement of functionality

The functional status of a DIC can be systematically measured using eight weighted criteria:

- Availability of essential facilities and a dedicated pharmacist (20%),
- Existence of an approved annual action plan (5%),
- Availability of standard operating procedures (5%),
- Provision of therapeutic and pharmaceutical information using standardized query and response formats (25%),
- Delivery of regular medicine use education to patients and hospital staff (15%),
- Production and dissemination of monthly drug alerts, newsletters, therapy updates, and safety bulletins (20%),
- Preparation of monthly performance reports (10%).

Each criterion is scored individually and compiled into a total performance score, where centers scoring 75% or higher are classified as functional, and those below this threshold are considered non-functional.

2.3.3.2. Steps for revitalization

For those non-functional DICs, revitalizing the service is required through following the following steps:

Step 1: Identify possible causes for non-functionality of DICs

- Conduct staff interviews and surveys to understand their perceptions and experiences with the DIC.
- Examine previous DIS records, performance evaluations, and documentation of queries or complaints.
- Identify any patterns in operational challenges or gaps in service delivery.
- Directly observe the workflow within the DIS, assessing how resources are utilized, how queries are handled, and identifying bottlenecks.

Step 2: Prioritize identified problems

- **Set criteria for prioritization** and prioritize identified causes using the criteria which may include *frequency of occurrence* (how the issue impacts the functioning of the DIS); *severity of impact* (how this issue hinders the DIS's ability to provide accurate, timely information; *feasibility of resolution* (how easily this issue be addressed with available resources or additional support); and *stakeholder concern* (how healthcare providers and staff highly concerned about this issue)
- **Document findings:** record prioritized problems, noting both immediate symptoms and deeper root causes.

Step 3: Prepare action plan for revitalizing the DIC

- Outline activities and resources needed with timelines and milestones: for each issue, outline necessary resources (e.g., budget, technology upgrades, access to online databases, space improvements) and activities (e.g., staff training, management engagement).
- Identify responsible person(s) to address the prioritized problems: assign roles and responsibilities to specific staff members, ensuring accountability for each part of the plan.
- Organize a presentation meeting: present the draft revitalization plan to DTC and/or other key personnel.

Step 4: Implement and monitor the revitalization plan

- Carry out the planned interventions and track implementation progress.

Step 5: Ensure ongoing evaluation

- Regularly conduct training sessions to keep DIS staff updated on best practices, drug databases, and information retrieval techniques.
- Integrate the DIS into routine clinical rounds, meetings, and consultations to ensure it remains a visible and utilized resource.
- **Implement a documentation system:** maintain a systematic process for logging inquiries, tracking responses, and documenting feedback.
- **Conduct regular evaluations**: Establish routine reporting and performance reviews

2.4. Governance and organizational structure of DICs

The governance of DICs operates under a nationally coordinated, tiered structure that ensures strategic alignment, operational accountability, and equitable service delivery across all levels of the healthcare system. The system is anchored in the regulatory oversight of the Ministry of Health (MoH) and the EFDA, who provide overall policy direction, legal mandates, and institutional authority for the functioning of DICs nationwide.

At the center of the network is the NDIC. The NDIC provides technical leadership, develops national guidelines, and supervises the implementation of DIS at all subordinate levels. It maintains direct supervisory authority over RDICs and Federal Hospital DICs, ensuring the enforcement of standards, harmonization of practices, and feedback mechanisms across the country.

RDICs operate under the guidance of the NDIC but work closely with Regional Health Bureaus (RHBs) and Regional Regulatory Bodies (RRBs). They facilitate vertical coordination with lower-tier DICs, including HFDICs, PDICs, and CDICs, while also serving as a technical link between national directives, guidelines and local implementation. RDICs consolidate performance data and reports from these lower-level centers and relay them to the NDIC for national-level review and planning.

Federal Hospital DICs, situated within referral and teaching hospitals, report directly to the NDIC given their advanced technical roles and national service scope. These centers support high-level clinical decision-making and engage in formulary preparation, pharmacoeconomic studies, and medication safety surveillance. Their dual reporting lines - functionally to the NDIC and administratively to their host health institutions position them as key pillars within the national DIS infrastructure.

CDICs, often operated by private, NGOs, CSOs, or community health initiatives, function under the technical supervision of RDICs. While they operate outside formal health facilities, they are expected to align with national DIS standards and contribute to grassroots-level awareness and patient education. Similarly, PDICs report to RDICs and maintain close coordination with nearby HFDICs, especially for referrals and technical updates.

IDICs are maintained by pharmaceutical manufacturers and function independently of the public DIS system. However, they are subject to NDIC oversight for matters primarily related to pharmacovigilance and post-marketing surveillance activities. These centers are required to

share product-specific safety data with NDIC while maintaining clear separation from promotional activities.

This multi-level governance framework facilitates consistent supervision, clear reporting flows, and bidirectional information exchange across the DIS network. It enhances the responsiveness and accountability of the system, allowing DICs at each level to function within a defined regulatory and organizational structure that supports their operational mandate and public health impact.

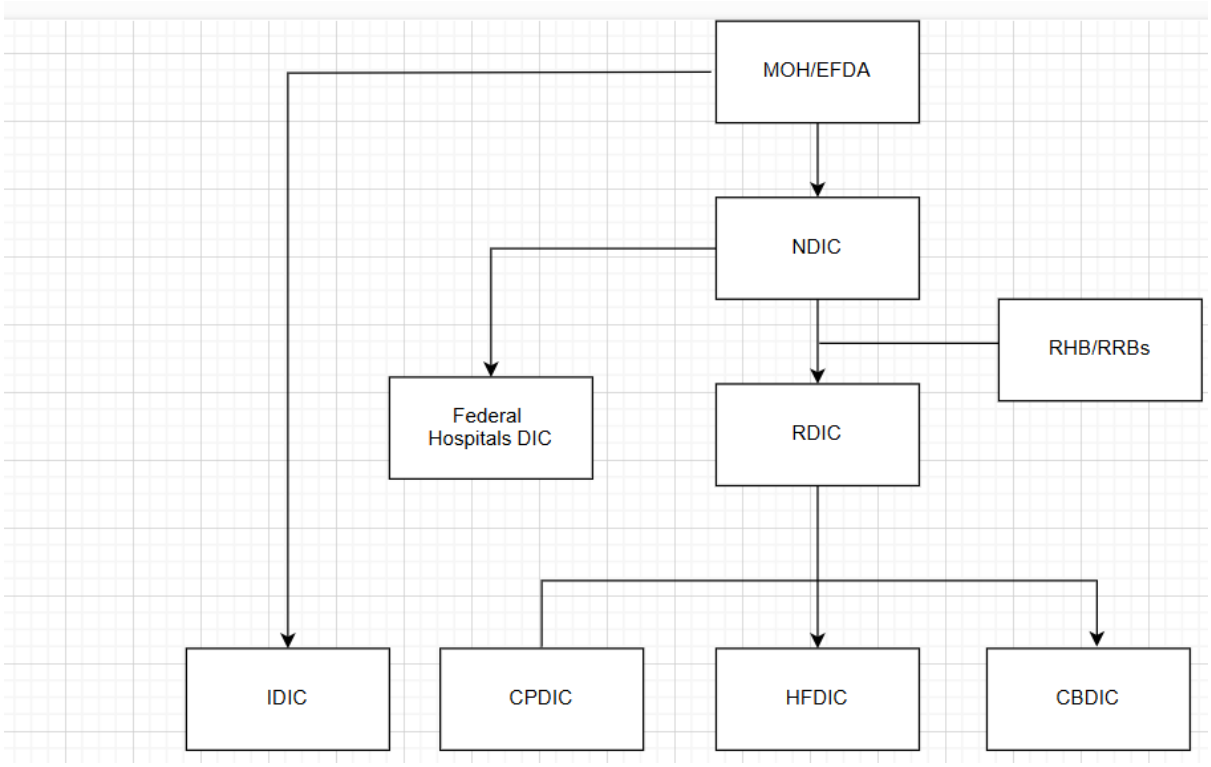

Fig 1: National DIC networking and their hierarchies

2.5. Sustainability

Sustainability is a foundational requirement for the long-term effectiveness and responsiveness of DICs in Ethiopia. It ensures that DIS remains operational, high-quality, and equitably available across all healthcare levels. Sustainable DICs must be institutionally embedded, adequately resourced, digitally equipped, and resilient to external and internal disruptions.

All DICs shall be supported by a defined sustainability plan that is integrated into the institution's routine operations and national health planning frameworks. This plan must include measures to secure stable and predictable financing for personnel, infrastructure, reference materials, and digital platforms. Each DIC shall ensure continuity of service by

assigning trained and retained staff with clear mandates and ongoing professional development opportunities. Workforce sustainability must be supported through structured career development, supportive supervision, and alignment with national health workforce strategies.

In addition to internal capacity, sustainability shall be strengthened through multi-sectoral collaboration with regulatory bodies, academic institutions, HCPs and other stakeholders. These partnerships are essential to maintain resource mobilization, information exchange, and alignment with national priorities such as pharmacovigilance, antimicrobial stewardship, and universal health coverage. Community-based and pharmacy-based DICs in particular must foster local engagement and referral linkages to remain viable and impactful.

Each DIC shall establish mechanisms to routinely assess service demand, operational capacity, query response volumes, and user satisfaction. These performance indicators must inform strategic decisions, guide resource reallocation, and identify areas needing revitalization or technical support. Digital health systems shall be leveraged to enhance adaptability, allowing DICs to update their repositories, disseminate information in real-time, and align with national data exchange systems.

EFDA and RRBs shall ensure that sustainability is assessed during supervisory visits and certification reviews. Revitalized DICs must demonstrate compliance with sustainability criteria before resuming operations. Ultimately, sustainable DICs form the backbone of Ethiopia’s national DIS network to support rational medicine use, promote patient safety, and contribute to national health system resilience.

Chapter Three: Management of DI Queries and Production and Dissemination of DI Outputs

All DI queries shall be handled using a modified systematic approach comprising steps such as securing enquirer demographics, obtaining background, formulating the actual question, searching and appraising information, and documenting the response. This ensures that each query classification is translated into a high-quality response process. Once a DI query is classified and its source materials identified, it shall be addressed through a standardized, stepwise process that ensures technical accuracy, national regulatory alignment, and quality-assured dissemination. This chapter provides standardized guidance for classifying DI queries, identifying reliable and evidence-based information sources for preparing responses, and also production and dissemination of DI.

3.1. Classification of DI queries

3.1.2. National classification framework for DI queries

DI queries vary in complexity, urgency, and clinical context. For uniformity and effective documentation, all DI queries shall be classified into one of the twelve categories listed below.

Table 3.1: Classification of drug information queries

Category	Definition	Illustrative examples
Therapeutic use	Inquiries about indications, off-label use, or comparative efficacy of medicines.	Can methotrexate be used for psoriasis in rural clinics? Compare artemether-lumefantrine vs. artesunate in severe malaria.
Dosage and administration	Information on dose calculation, frequency, route, administration, or adjustment in special conditions.	What is the pediatric dose of cefixime in children under 5? How to adjust enalapril in patients with renal failure? Intramuscular injection technique for ceftriaxone in health centers.
Drug interactions	Questions on drug-drug, drug-food, drug-herb or drug-disease interactions.	Is rifampicin safe with dolutegravir in TB-HIV co-infection? Does iron supplement reduce doxycycline absorption? Interaction between warfarin and herbal tea.
Adverse drug events (ADEs)	Inquiries related to expected or unexpected side effects, medication errors, products defects, and	Does nevirapine cause hepatotoxicity in women? What is the frequency of vomiting with artemether-lumefantrine? Risk of hypoglycemia with glibenclamide.

	management of ADEs.	
Pharmacokinetics & pharmacodynamics	Concerns related to absorption, metabolism, excretion, mechanism, onset, and half-life.	What is the half-life of fluconazole in renal patients? How is metformin metabolized in liver disease? Pharmacodynamics of oxytocin during labor.
Special populations	Use of medicines in children, elderly, pregnant/lactating women, or comorbid conditions.	Can tenofovir be used during pregnancy in Ethiopia? Is artemether-lumefantrine safe for infants under 5 kg? Can atenolol be used in geriatrics with heart failure?
Availability and cost	Information on supply chain availability, and pricing.	Is albendazole 400 mg available through EPSA? Are there cheaper alternatives to pantoprazole for hospitals in Amhara region? Local price variation of insulin 70/30.
Legal and regulatory information	Requests regarding licensing, registration status, scheduling, importation, and classification.	Is tramadol a controlled substance under Ethiopian law? Has hydroxychloroquine been authorized for import? Is herbal cough syrup X registered by EFDA? Is remdesivir approved for COVID-19 in Ethiopia?
Product stability, compatibility, and storage	Questions on proper storage conditions, shelf life, and handling.	How long is ORS stable after reconstitution? Cold chain requirement for oxytocin at health post level. Shelf life of opened insulin pens in ambient temperature.
Quality and safety alerts	Information related to counterfeit products, recalls, or regulatory warnings.	Has EFDA recalled any batches of paracetamol suspension? Are there falsified artesunate tablets circulating in Ethiopia? Is an alert on contaminated cough syrups provided by EFDA?
Formulary and policy compliance	Queries on consistency with national STGs, treatment protocols, national EML, or facility-specific formularies	Is omeprazole approved for use at health centers? Does the HIV STG allow second-line switch to dolutegravir in adolescents? Inclusion of Febuxostat in Ethiopian Medicines formulary.
Contraindications and precautions	Inquiries about conditions where drug	Is metoclopramide contraindicated in pediatric patients under 1 year of age?

	use is inadvisable, requires caution, or poses risk	What precautions should be taken when prescribing clozapine in patients with a history of seizures? Can NSAIDs be used in patients with peptic ulcer disease? Is there a contraindication for using hormonal contraceptives in women with uncontrolled hypertension?

***Note**: For detailed procedures on how DI queries are managed and responded to using the Modified Systematic Approach, refer to **section 3.3.2** below.*

All DICs shall use the national DIS Query-Response Form (Annex 3.1) to record and classify each query. Proper categorization supports performance analysis, quality monitoring, and policy-informed decision-making.

3.1.2. Query prioritization and processing benchmarks

To ensure consistency, timeliness, and clinical relevance in the delivery of DI services, all DICs shall apply national standards for prioritizing and processing incoming queries. This approach supports efficient triage, appropriate resource use, and alignment with national health priorities. All incoming queries shall be classified according to their urgency and clinical impact. The three standard categories are:

- **High priority**: Urgent patient-specific requests requiring immediate input to prevent clinical harm or guide critical decisions (e.g., drug interaction in emergency care, ADRs in surgery, use in pregnancy).
- **Medium priority**: Routine clinical questions that support care delivery but do not pose immediate risk (e.g., dose adjustment in chronic disease, therapy comparisons).
- **Low priority**: Policy, academic, or general interest queries unrelated to immediate patient care (e.g., formulary inclusion, research support, national policy alignment).

Each DIC shall aim to process and respond to DI queries within the following benchmark timeframes, adjusted as needed to local capacity:

Query priority	**Target response time**
High priority	Within 1 to 2 hours
Medium priority	Within 24 hours
Low priority	Within 2 to 3 working days
Research-level or complex queries	Within 5 to 7 working days

DICs shall monitor their performance regularly and document reasons for any significant delays.

When a DIC lacks sufficient capacity or resources to handle a query, it shall promptly escalate the request to other health-facility DIC, regional or national-level DIC using approved communication channels. The referral must be documented in the query log, and the enquirer should be informed of any expected delays.

3.2. Appraisal and selection of DI sources

DI resources vary in structure, content, and level of evidence. All references shall be classified into three standard categories: primary, secondary, and tertiary sources. DICs must select, appraise, and cite sources that meet minimum national standards for reliability, authority, and contextual relevance.

3.2.1. Tertiary sources

Tertiary sources are pre-synthesized materials that consolidate information derived from primary and secondary literature into accessible and comprehensive formats. These sources are typically used as the first point of reference in clinical decision-making and routine DI queries due to their convenience and breadth. The use of tertiary sources must always be based on the credibility of the platform. Applications or websites that are not regulated or peer-reviewed, particularly those with commercial content, should be referenced only when supported by other validated sources. Tertiary sources are divided into six key subcategories, each serving specific operational purposes within DICs.

Table 3.2: Tertiary drug information sources - examples and applications

Types	Illustrative examples	Applications
Drug compendia	AHFS DI (American Society of Health-System Pharmacists), Martindale: The Complete Drug Reference, Lexicomp, Micromedex (IBM Watson), Drug Dex, Stockley's Drug Interactions, Meyler's Side Effects of Drugs, Drugs in Pregnancy and Lactation (Briggs)	Provides drug monographs, pharmacological properties, dosing regimens, adverse effects, contraindications, therapeutic equivalence, and interaction profiles.
Clinical guidelines	Standard Treatment Guidelines (STGs), Clinical Practice Protocols (e.g., Hypertension, Diabetes), National HIV/AIDS and TB Treatment Guidelines, Ethiopian ART Guidelines, WHO Guidelines (HIV, TB, NCDs, COVID-19, malaria), NCCN, NICE, IDSA Guidelines	Offers evidence-based disease management protocols, treatment algorithms, and therapeutic recommendations aligned with national and global standards of care.
Formularies	Ethiopian Essential Medicines List (EML), WHO Model EML, National Medicine Formulary, Institutional Formularies (e.g., Black Lion Specialized Hospital Formulary, SPHMMC Formulary), Regional Formularies (e.g., Addis Ababa Health Bureau Formulary),	Guides selection of medicines based on national priorities, availability, cost-effectiveness, and therapeutic need. Supports rational medicine use and formulary compliance.
Regulatory platforms	EFDA eRIS (Electronic Regulatory Information System), EFDA Controlled Substances List, WHO Global Surveillance and Monitoring System for Substandard and Falsified Medicines, African Medicines Agency (AMA) Platform	Confirms product registration and licensing status, provides safety alerts, recalls, lot-specific warnings, and regulatory classifications (e.g., controlled substances).
Product documentation	Summary of Product Characteristics (SmPC), EFDA-approved Labelling and Inserts, Manufacturer Inserts (e.g., GSK, Cipla, Pfizer), Patient Information Leaflets (PILs), U.S. FDA Prescribing Information, EMA Product Information Leaflets	Details approved indications, dosage, route of administration, reconstitution/stability, adverse effects, and manufacturer-specific instructions.
Digital databases and mobile apps	UpToDate*, Drugs.com*, Epocrates*, Medscape*, DrugBank*, WHO e-Pocket Book of Hospital Care for Children, WHO Essential Medicines App, e-TB Manager (for TB program), mDRA App (for regulatory adverse event classification), Global Drug Reference Online (G-DROP)*	Supports rapid clinical decisions when primary resources are unavailable. Assists with diagnosis, treatment algorithms, drug checking, and medicine information - use with appraisal.

***Note**: Digital applications or websites with commercial content, extra caution should be taken to assess neutrality and evidence transparency, as recommended by the WHO Pharmacovigilance standards and CSHP guidance*

3.2.2. Secondary sources

Secondary sources are indexing and abstracting services that organize, summarize, and provide search access to the body of primary literature. Although they do not generate original research, they serve as essential tools for locating relevant peer-reviewed studies, systematic reviews, and other publications needed to support DI responses. DICs are expected to maintain access to major international secondary sources.

Table 3.3: Illustrative examples of secondary sources

Platform	Description	Scope
PubMed	Indexes biomedical literature from MEDLINE, life science journals, and online books	International (U.S. NLM/NIH)
Cochrane Library	Provides access to systematic reviews and clinical trial data	International (Cochrane)
Embase	Biomedical and pharmacological database with European and global journal indexing	International (Elsevier)
HINARI	Access to health journals for low-income countries, provided by WHO	International (WHO-led)
Scopus	Multidisciplinary citation database covering health, science, and social sciences	International (Elsevier)
Web of Science	Citation indexing and bibliographic database covering peer-reviewed literature	International (Clarivate)
African Index Medicus	Indexes African medical and health literature, including research from SSA	Regional (WHO AFRO)
Ethiopian National Digital Library / National Academic Repository	Institutional theses and Ethiopian health science publications	National (MoE/Universities)
ClinicalTrials.gov	U.S.-based registry of clinical trials worldwide	International (NIH)
Pan African Clinical Trials Registry (PACTR)	Regional clinical trial registry for Africa	Regional (WHO-recognized)
Google Scholar	General academic indexing tool (must be used cautiously and validated)	International
Research4Life - OARE & AGORA	Sister platforms to HINARI for environmental and agricultural research (occasionally relevant)	International (UN/WHO/FAO)

Any study retrieved from a secondary source must be appraised based on methodological quality and relevance before being cited in official responses.

Application: DICs shall use secondary sources in the following scenarios:

- When tertiary references do not address the query adequately.

- When a deeper level of evidence is required to support clinical decision-making or resolve conflicting information.
- For literature reviews, evidence updates, or advisory responses involving emerging treatments, drug safety signals, or off-label uses.
- To supplement responses by identifying recent clinical trials, meta-analyses, pharmacovigilance reports, or health technology assessments.

N**ote**: Responses generated using secondary sources must include critical appraisal of the retrieved articles. Simply citing search results without assessing quality, relevance, and consistency is not acceptable for official DI communication.

3.2.3. Primary sources

Primary sources refer to original, unfiltered research outputs that report first hand clinical, pharmacological, or epidemiological data. These include randomized controlled trials, cohort studies, case-control studies, pharmacovigilance case series, and original articles in peer-reviewed journals. These are essential when addressing new, emerging, or complex questions that are not yet synthesized in tertiary references.

Table 3.4: Illustrative examples of primary sources

Type	Examples	Origin
Peer-Reviewed Clinical Research Journals	*The Lancet*, *New England Journal of Medicine (NEJM)*, *British Medical Journal (BMJ)*, *JAMA*, *Annals of Pharmacotherapy*, *Ethiopian Medical Journal (EMJ)*	International and National
Randomized Controlled Trials (RCTs)	Clinical trial reports published in peer-reviewed journals or trial registries such as ClinicalTrials.gov or Pan African Clinical Trials Registry (PACTR),	Global and Continental
Cohort Studies and Case-Control Studies	Published observational studies in *BMJ Open*, *BMC Public Health*, *Journal of Clinical Epidemiology*	International
Case Reports and Case Series	Reports of rare adverse drug reactions or unique clinical cases in *Case Reports in Medicine*, *BMJ Case Reports*, or *Therapeutics and Clinical Risk Management*	International
Pharmacovigilance Reports	National reports from EFDA Pharmacovigilance Centre, WHO VigiBase case series, UMC signal documents	National, Continental, and Global
Dissertations and Theses (with peer review)	Postgraduate research from Ethiopian universities (e.g., Addis Ababa University, Gondar University, Mekelle University) available in institutional repositories	National

Conference Abstracts (peer-reviewed)	Abstracts from Ethiopian Pharmaceutical Association (EPA) scientific conferences, ISPOR, FIP, or WHO regional summits (with scientific review)	National and International
Official Surveillance Reports	National drug use or ADR surveillance data from EFDA, EPHI, WHO Global Reports, UNAIDS technical surveillance summaries	National and International
Unpublished but Verified Research	Investigator-initiated studies shared with EFDA, hospitals, or universities (must be documented, reviewed, and authenticated)	Institutional and National

Application: When authoritative tertiary references are unavailable or insufficient for a clinical query, DICs may consult and appraise primary sources. DIC staff must ensure the primary source is peer-reviewed, recent, and relevant to the Ethiopian context.

3.2.4. Prioritization of sources

To ensure regulatory alignment, evidence integrity, and national relevance, all DICs shall follow a standardized hierarchy in the selection of DI sources. The priority order is designed to promote the use of locally endorsed, evidence-based, and contextually applicable references before consulting global or un-synthesized sources.

The following order of preference shall apply:

1. **Nationally endorsed sources:** This includes references officially issued or endorsed by the EFDA/MOH, such as the STGs, the EML, national formulary, and EFDA product labelling.
2. **Global and continental guidelines:** Authoritative clinical and regulatory guidance from the WHO, EMA, AMA, and regional harmonization platforms such as the East African Community (EAC).
3. **Up-to-date validated tertiary references:** Peer-reviewed drug compendia, formularies, and reference texts including Martindale, AHFS, Lexicomp, WHO Model Formulary, and similar internationally recognized tertiary sources.
4. **Primary literature:** Original scientific studies such as RCTs, pharmacovigilance case series, observational studies, or surveillance reports. These shall be used only when higher-tier references are unavailable or insufficient.
5. **Secondary sources:** Literature databases and indexing platforms such as PubMed, Cochrane Library, HINARI, and Embase are tools to identify and access relevant primary evidence.

Note: Non-peer-reviewed, unregulated, or commercial sources such as Wikipedia, user-generated blogs, social media content, or commercial (those with ".com" extensions) websites

shall not be used as standalone references for official DIS. In exceptional circumstances, such sources may only be consulted if no alternative exists and the content has been critically appraised and independently verified by the DIC.

3.2.5. Appraisal of information sources

To uphold the quality, reliability, and regulatory compliance of all DI services provided, every DIC shall critically appraise all information sources prior to inclusion in official responses. Appraisal ensures that only credible, current, and contextually relevant sources inform therapeutic and regulatory decisions.

All sources shall be evaluated using the following five standardized appraisal criteria

1. **Authority**: the institutional credibility of the source
2. **Accuracy**: the scientific validity and evidence base
3. **Up-to-date**: the timeliness of the data
4. **Relevance**: the applicability to Ethiopia's clinical and regulatory context
5. **Unbiased**: the absence of commercial or ideological bias

These appraisal domains are harmonized with frameworks from WHO Pharmaceutical Starting Materials Certification Scheme (SMACS), CSHP Guidelines, and EMA reference standards. A source shall only be deemed valid for official use if it satisfies at least four out of the five criteria.

Note: No DI output shall cite or rely on any source that fails to meet this minimum threshold.

Table 3.5: Appraisal criteria for DI sources focus and illustrative examples

Appraisal criterion	Focus of evaluation	Illustrative examples
Relevance	Evaluate whether the source applies to Ethiopia's clinical setting, epidemiological context, health infrastructure, or regulatory environment.	EFDA regulatory documents, Ethiopian EML, national disease protocols, regional formulary data, African region WHO reports, AMA publications relevant to SSA
Authority	Assess whether the source is issued or endorsed by a credible, recognized, and independent institution, regulatory body, or peer-reviewed academic platform.	EFDA, WHO, AMA, U.S. FDA, EMA, NICE (UK), Peer-reviewed journals like NEJM, Lancet, BMJ, Ethiopian Medical Journal
Accuracy	Check whether the content is evidence-based, scientifically valid, internally consistent, and supported by proper citations or cross-referenced data.	National STGs with references, Cochrane systematic reviews, WHO guidelines with references, SPCs with clinical trial backing, validated ADR reports in journals
Timeliness	Determine how recent the information is and whether it reflects current clinical or regulatory practices (preferably within the last 3–5 years).	EFDA product alerts from the past 24 months, WHO Clinical Guidelines, 2022–2025 National STGs, current EML, latest editions of AHFS, Martindale, or Lexicomp
Neutrality	Confirm that the content is free from commercial influence, advertising bias, or ideological distortion.	WHO guidelines, EFDA technical reports, peer-reviewed publications, university-led studies, government-endorsed health bulletins not pharma-sponsored brochures or ads

3.3. Management of reactive DI queries

3.3.1 Reactive DI query handling

- All DI queries shall be managed using the Modified Systematic Approach outlined in Section 3.3.2 and documented using the DI Query-Response Form (Annex 3.1 & 3.2).
- DIC personnel shall respond based on the best available and prioritized sources, applying the appraisal standards detailed in Section 3.2.5.
- Queries shall be answered within the designated time benchmarks as described in Section 3.1.2.

3.3.2. Modified systematic approach for DI query management

All DI queries shall be processed in the following nine (9) standardized steps:

Step 1: Identify and Record the Enquirer

- Record the full name, professional title, institutional affiliation, and contact details of the person making the query. This **e**nsures accountability, enables follow-up, and facilitates tailoring of responses to the enquirer's level of expertise (e.g., prescriber, nurse, pharmacist, policymaker, or patient).

Step 2: Clarify and Define the True Question

- Engage the enquirer to define the precise question, expected use, and clinical or regulatory context.

Vague or ambiguous questions shall not be processed until clarification is obtained.

Step 3: Collect Relevant Background Information

- For clinical queries, obtain all relevant patient details (age, sex, diagnosis, renal/hepatic function, drug history, pregnancy/lactation status, comorbidities).
- For regulatory or product-related queries: collect product name, formulation, manufacturer, and setting of use.
- This step is essential for query types defined in Section 5.1.
- Background information shall be retrieved from verified sources such as medical records, prescribers, or other reliable sources.
- All background information must be documented in the official query-response form.

Step 4: Categorize the Query

- Classify the query according to categories in **Table 5.1** (e.g., therapeutic use, adverse events, dosage, regulatory status).
- Use this classification to guide search scope and depth meaning it supports targeted searching, prioritization, and standardized response metrics.

For queries falling under multiple categories, classify based on the dominant clinical or regulatory intent.

Step 5: Conduct a Systematic Literature Search

1. Conduct a structured literature search beginning with sources prioritized in Section 5.3.
2. If data are insufficient, escalate the query to a higher-level DIC or expert consultant, documenting all efforts.
3. All search strategies and consulted sources must be logged.

Step 6: Appraisal of sources

- Evaluate each consulted source using the five criteria in Section 5.4: relevance, authority, accuracy, timeliness, and neutrality.
- Exclude unverifiable, commercial, or outdated content.
- Record all sources consulted, including negative findings.

Step 7: Formulation and Delivery of Response

- Fill a structured response using the Query Response form (Annex 3.2) and ensure alignment with query prioritization and turnaround time standards in Section 5.5.
- Verbal responses are permitted only for urgent clinical cases and must be followed by brief written documentation within 24 hours.
- Every written response must contain:
    - Summary of query and background
    - Search strategy and resources used
    - Summary of findings
    - Final conclusion and recommendation
    - Fully referenced sources

Turnaround times must follow Section 5.5 response benchmarks.

Step 8: Documentation of the Query and Response

- Every query must be logged using the DIS Query-Response Form.
- Documentation must include:
    - Enquirer details and date/time received
    - Query category and priority level
    - All consulted references
    - Response summary and full text
- DICs must maintain an organized record of all completed forms (electronic or paper-based) for audit and reporting.

Step 9: Follow-Up and Feedback

- Follow up is required for:
    - Clinical queries to verify patient outcome or intervention success
    - Policy/regulatory queries to assess implementation or decisions made
- Feedback methods include:
    - Standard written forms delivered with the responses (see Annex 3.3)
    - Verbal contact via telephone, email or in-person follow-up within 3 days

3.3.3 Adaptations in resource-constrained settings

In facilities or DICs where technical, human, or infrastructural capacity is limited, temporary adaptations to standard DI service procedures are permitted, provided that such deviations are justified, documented, and aligned with national oversight protocols.

These adaptations shall be applied only in exceptional or verified resource-constrained environments, and shall not compromise patient safety, regulatory compliance, or the integrity of DISs.

Table 3.6: Permitted adaptations in resource-constrained settings

Constraint	Permitted Adaptation
No digital access	Use printed copies of STGs, formularies, and tertiary references
Limited human resources	Refer complex queries to higher-level DICs via phone/email
Infrastructure disruption	Use handwritten forms and maintain a physical query-response log
Lack of search tools	Collaborate with universities or regional DICs for literature retrieval

All deviations from standard procedures must be:

- Justified in writing at the time of implementation.
- Documented in the query log or supervisory checklist.
- Flagged during supervisory or regulatory reviews as per the national DIC monitoring protocol.

3.4. Preparation of proactive DI products

Proactive DI products complement query-based services and enable DICs to operate as knowledge hubs and risk communication centers. Hence, this is a national guidance for the structured development, review, approval, and dissemination of proactive DI outputs that are initiated independently of individual queries. All DICs shall regularly produce such outputs to address emerging safety concerns, regulatory updates, clinical needs, and knowledge gaps in the healthcare system.

3.4.1. Typology of DI products

The following DI outputs shall be produced and disseminated by all functional DICs based on public health priority, regulatory need, or professional demand:

Table 3.7: Nationally recognized proactive DI outputs

Type of output	Description	Recommended frequency	Target audience
Drug alerts	Notify urgent risks, adverse events, SF product cases, or new black box warnings	Ad hoc (as needed)	Clinicians, hospitals, pharmacies, regulators, patients
Product recall notices	Announce market withdrawal or regulatory suspension of unsafe/ineffective products	Immediate upon recall	DTCs, pharmacies, health bureaus, wholesalers
Pharmacovigilance bulletins	Compile ongoing safety signals and regulatory actions	Quarterly	All DIC users, EFDA units, academic institutions
Therapeutic update briefs	Summarize new national or global clinical treatment updates	Ad hoc (as needed)	Physicians, pharmacists and other healthcare professionals
Evidence summaries / Rapid reviews	Appraise recent evidence on emerging or controversial therapies	Ad hoc (as needed)	Policy makers, DTCs, senior clinicians
Drug monographs	In-depth review of pharmacological, clinical, and regulatory profile of medicines	Based on priority list	Clinical pharmacists, prescribers, students
Drug class reviews	Review all medicines within a pharmacologic class to guide formulary decisions	As requested	Formulary team, DTCs
Formulary change notices	Inform facilities of additions/deletions to STGs, EML, or institutional formularies	Upon change	Hospitals, pharmacies, procurement staff
Report findings of drug use studies	Summarize prescribing/use patterns, errors	Annual	EFDA, DTCs, stewardship programs
DI consult reports	Disseminate structured responses to priority DI queries of national concern	Ad hoc	Specialists, tertiary hospitals, regulatory officers
Public drug advisories and/or leaflets	Translate medicine information for public understanding	Regularly	General public, patients, caregivers
Infographics and posters	Visually communicate key safety or therapeutic information	Regularly	Outpatient departments, waiting areas, health posts
Patient safety mini-guide/card	Miniaturized quick guides for safe medication use (e.g., antibiotics, teratogens)	Regularly	Patients, health workers in rural settings
Facility-based newsletters	Contextualized updates for institutional practice settings	Quarterly	Health center staff, facility DTC

Clinical decision support briefs	Provide algorithmic guidance for high-risk conditions or medicine selection	As needed	Emergency, ICU, pediatric and maternity units
Seasonal health messaging (e.g., mpox, malaria, influenza)	Issue medicine guidance tied to seasonal disease trends	Seasonal (e.g., every 6 months)	Clinicians, regional programs, health educators

***Note**: Each product must follow approved formats and be documented in the DIC's dissemination register.*

All proactive DI outputs must:

- Be based on credible, nationally prioritized, and evidence-based sources.
- Use clear, non-promotional, and professionally neutral language.
- Comply with EFDA communication protocols for sensitive, public-facing, or regulatory-related content.
- Be reviewed by at least one other DIC staff member before dissemination.
- Carry version numbers, date of issue, and responsible officer for verification.
- Include citations in standardized format (Harvard/Vancouver style as appropriate).

3.4.2. Workflow for development, review, and approval

The production of DI outputs whether reactive or proactive shall follow a standardized, documented workflow to ensure that all information disseminated is accurate, authoritative, timely, and nationally aligned. This workflow supports regulatory compliance, traceability, and continuous quality assurance across all DICs. All DICs shall adhere to the following stepwise production workflow for developing any DI product:

Table 3.8: Workflow for proactive DI product development

Step	Description	Responsible person(s)	Key documentation
1. Topic identification	Identify need for DI product (e.g., guideline update, safety issue, stakeholder request)	DIC Pharmacist; Clinical Team Lead	Topic Proposal Log
2. Prioritization and approval	Determine urgency, relevance, and audience; seek formal approval	DIC Coordinator	Product Approval Form
3. Evidence gathering	Conduct structured search per Section 5.3; appraise sources using Section 5.4 criteria	Assigned DI Pharmacist	Literature Search Log; Appraisal Checklist
4. Draft preparation	Draft content using official template (e.g., drug alert, newsletter)	Primary Drafter; Reviewed by Senior DIC Staff	Draft Document with version control

5. Technical review	Internal peer review by two qualified pharmacists; external expert if needed	Peer Review Panel; External Expert (if needed)	Review Feedback Form; Final Draft Log
6. Final approval	Obtain formal sign-off from DIC Coordinator or Pharmacy Head	DIC Coordinator; Hospital Pharmacy Head	Final Approval Certificate
7. Dissemination preparation	Format product and prepare release tools	DIC Support Staff; Communications Officer	Dissemination Checklist
8. Archiving and Reporting	Archive final version and log dissemination record	Documentation Focal Person	DI Product Register; Document Archive Folder
9. Feedback Collection	Attach feedback tools; analyze comments or suggestions	DIC Pharmacist; Monitoring & Evaluation Officer	Feedback Log and Analysis Summary

3.4.3. Documentation, version control, and archiving requirements

3.4.3.1. Documentation and archiving requirements

All DI products shall comply with national documentation standards, as outlined below.

1. **Use of official templates**
   - All outputs shall be formatted using approved templates.
   - No dissemination is permitted without proper formatting, branding, & disclaimers.
2. **File naming convention**

   Digital filenames shall follow this structure:

   DIC_[ProductionType]_[Topic]_[Version]_[Date].pdf

   Example: DIC_Newsletter_AMR_V1_2025-07-01.pdf
3. **Metadata documentation**

   Each DI product shall be accompanied by a completed metadata sheet containing:
   - Title of the DI product
   - Author(s) and reviewers
   - Production date and version
   - Source list
   - Intended audience
   - Approval authority
   - Dissemination date(s) and channels
4. **Archiving and retention requirements**
   - Soft copies shall be stored in a centralized DIC folder with backup.

- Hard copies shall be filed in chronologic order with distribution logs.
- All records shall be retained for at least five years.
- Each DIC shall maintain a DIS Product Register detailing product type, topic, date, audience, and dissemination method.

5. **Confidentiality and data protection**
   - Any DI output using patient-specific or sensitive regulatory data shall adhere to national data protection laws and confidentiality policies.
   - Personal identifiers shall be redacted in public-facing versions.

3.4.3.2. Version control and coding system

A national versioning and coding system shall apply to all DI outputs to ensure consistency and traceability.

- **Document code format**
  - ***Format***: [DIC Level]- [Product Type]-[Year]-[Serial Number]-[Version]
  - ***Example***: RDIC-Alert-2025-003-V1
    Regional DIC Drug Alert, issued in 2025, third of the year, version 1
- **Version numbering and change history**
  - Major updates: V1.0, V2.0, etc.
  - Minor edits: V1.1, V1.2, etc.
  - All changes must be logged in a version history record.

  Note: Every major revision of a proactive DI product shall receive a new version number (e.g., V1.0, V1.1, V2.0), and the change history shall be documented.
- **Quarterly review and archiving**
  - Every DIC shall conduct a quarterly internal review to verify evidence accuracy, document currency, and version control compliance.
  - Obsolete or outdated versions must be clearly marked as archived and removed from active dissemination platforms.

3.5. Dissemination of drug information services

All DICs shall adhere to a structured dissemination approach to ensure equitable access, regulatory accountability, and measurable impact of DIS.

3.5.1. Principles for dissemination

Dissemination shall be guided by the following national principles:

- **Accessibility**: All DI outputs shall reach their intended audiences in a format, platform, and language that is appropriate to their professional capacity and context whether prescribers, regulatory officers, nurses, patients, or other stakeholders.
- **Timeliness**: DI outputs must be released promptly, particularly during public health emergencies, medicine recalls, emerging safety concerns, or changes in national guidelines.
- **Consistency:** Standardized templates, institutional branding, and approved terminology shall be used to maintain professionalism, credibility, and recognizability across all dissemination materials.
- **Documentation**: Every dissemination activity shall be fully recorded using approved dissemination logbooks and feedback forms to support traceability, audit, and quality improvement.
- **Equity**: Dissemination must prioritize inclusion of public sector facilities, rural and underserved areas, and not focus exclusively on urban or tertiary institutions.

3.5.2. Target audiences and customization approaches

DICs shall direct dissemination efforts toward nationally prioritized audiences, including clinical professionals (e.g., physicians, pharmacists, nurses, midwives, health officers), regulatory personnel (regulatory staff, Regional Health Bureau teams,, procurement officers), public health program managers (e.g., HIV, TB, NCDs, RMNCH), health facility administrators (e.g., hospital directors, pharmacy departments), academic institutions and training centers, professional associations such as the EPA, and community actors including civil society organizations, patient groups, and media platforms. Dissemination shall be tailored to the information needs and access capacity of each audience.

3.5.3. Dissemination channels and platforms

To ensure efficient, equitable, and traceable dissemination of DI, all DICs shall utilize a mix of approved dissemination channels, selected based on the type of DI product, the target audience, and the urgency of the message.

Digital and online platforms are the primary means of dissemination and shall include the EFDA website, the national and regional DIC portals, the eRIS, as well as official mobile applications, SMS alerts, and professional messaging platforms such as Telegram and WhatsApp groups. These platforms are recommended for drug alerts, newsletters, regulatory updates, and urgent clinical advisories. Email listservs targeting prescriber networks, the

National DIS Portal (once operational), and institutional websites also form part of the national digital dissemination system. All content disseminated via social media must be institutionally approved, pre-validated, and archived in line with risk communication protocols.

Print-based channels such as notice boards, circulars, newsletters, and printed brochures shall be used particularly where digital access is constrained. Facilities shall maintain notice boards for displaying drug alerts and safety updates. Printed newsletters and circulars shall be distributed to clinical departments, academic institutions, and rural facilities.

In-person dissemination methods such as clinical rounds, morning sessions, CPD programs, and regulatory inspections shall be leveraged to ensure direct transmission of critical information. DIC staff shall also present DI updates during national or regional review meetings to ensure programmatic alignment.

Mass media and public communication platforms, including radio, television, and approved press releases, shall be reserved for high-priority alerts or wide-scale public awareness campaigns. Dissemination through these channels could be authorized by national DIC and, when applicable, implemented in collaboration with civil society organizations and health extension programs to enhance reach, especially to the general public.

All dissemination activities shall be recorded, monitored, and aligned with national policies and digital health integration efforts.

3.5.4. Review, approval, quality control, and documentation of disseminated products

- Each DIC shall maintain a Dissemination Logbook either in hard copy or electronic format that documents all dissemination activities to ensure traceability and accountability.
- The logbook shall include the date of dissemination, the type of DI product (e.g., bulletin, newsletter, alert, monograph), the intended audience or recipient facility, the dissemination channel used (e.g., print, email, verbal), the number of recipients or facilities reached, confirmation of receipt (if applicable), and any feedback received.
- Standard templates for dissemination logs and feedback tracking tools shall be used, as provided in Annex 3.4 and Annex 3.5 of this guideline.

- All DI products intended for public or institutional dissemination shall be reviewed by at least two qualified DIC staff members and approved by the DIC Coordinator or other authorized pharmacist. No dissemination shall occur without proper review, approval, and entry into the official dissemination log (see Annex 3.4).
- Both soft and hard copies of disseminated DI products shall be retained and archived with clear versioning and authorship metadata, including the date of issue and source references.
- No confidential or sensitive data shall be disseminated without prior written authorization from a designated institutional authority.

3.5.5. Equity and accessibility in dissemination

- All public-facing DI products developed by DICs shall be written in a clear and understandable format suitable for the general population. Technical jargon shall be avoided unless adequately explained.
- Where appropriate, pictorial representations, visual aids, or infographics shall be included to enhance understanding, particularly for populations with limited health literacy.
- DICs shall ensure translation of key public materials into local languages based on the primary languages spoken in the target geographic area.
- Coordination with Health Extension Workers or Community Health Workers is encouraged to support the dissemination of DI materials in underserved areas.

3.5.6. Feedback mechanisms and monitoring of dissemination reach

- DICs shall establish two-way feedback mechanisms to assess the reach, clarity, and utility of disseminated DI products.
- Each disseminated product shall be accompanied by a short feedback form (physical or digital). In cases of verbal dissemination, follow-up communication (via phone or in person) shall be conducted within three working days to gather recipient feedback.
- All feedback shall be documented in the feedback tracking tools as per the standard format provided in Annex 3.5.
- DICs shall summarize feedback and dissemination metrics in their quarterly performance reports. These reports shall include the number and types of products disseminated, dissemination methods and coverage, feedback response rates, satisfaction ratings, and recommendations for improvement.

3.5.7. Integration with national platforms and digital integration

- All DICs shall align dissemination practices with national digital health strategies and regulatory information systems.
- DI bulletins, newsletters, and alerts shall be uploaded to each DIC's internal knowledge repository and shared with the National DIC where relevant.
- Disseminated products shall be planned to align with national health observance campaigns (e.g., AMR Week, World Hepatitis Day) and regulatory policy cycles to ensure strategic relevance and maximum impact.
- DICs shall integrate with national digital platforms such as eRIS, DHIS2, and any planned regulatory dashboards to support automated dissemination, data analytics, and centralized reporting.

Chapter Four: Collaboration and Capacity Building for DIS

4.1. Strategic collaboration and inter-institutional collaboration

4.1.1. National collaboration

Effective delivery of DIS requires robust collaboration between DICs and key national institutions. Strategic partnerships with government health authorities, regulatory bodies, healthcare facilities, academic institutions, professional associations, and pharmaceutical manufacturers are essential to ensure that DICs are well-resourced, technically supported, and institutionally integrated into Ethiopia's health system.

a) Ministry of health and regional health bureaus

1. The MoH and RHBs shall support the establishment, regulation, and integration of DICs into the national health system through the following measures:
   - Joint development of national policies, standard guidelines, and operational procedures in collaboration with EFDA.
   - Inclusion of DICs in key national health programs such as NCDs, infectious diseases, and maternal and child health initiatives.
   - Allocation of funding, infrastructure, digital platforms, and trained personnel to sustain DIC operations.
   - Implementation of structured training and professional development plans to strengthen the capacity of DIC personnel.
   - Facilitation of nationwide dissemination of critical DI, including treatment guideline updates, medicine recalls, and safety alerts.
2. The MoH and RHBs shall collaborate with DICs to monitor and evaluate the quality and reach of DIS at all levels.

b) Healthcare facilities

1. All tertiary hospitals, general hospitals, primary hospitals, specialty centers, health centers, and pharmacy outlets shall establish formal linkages with the nearest DIC or coordinate internally to form an institutional DIC.
2. Health facilities shall ensure:
   - Designation of focal points or units responsible for receiving, processing, and referring DI queries.
   - Use of nationally endorsed tools for query documentation and response tracking.

- Timely feedback and escalation of complex queries to higher-level DICs or national centers.

3. DICs embedded in healthcare facilities shall participate in clinical rounds, in-service training sessions, and quality improvement forums to support evidence-based decision-making.

c) Regulatory bodies

1. EFDA and regional regulatory bodies shall provide authoritative medicine information and serve as the custodians of official regulatory data used by DICs.
2. Specific responsibilities shall include:
   - Regular transmission of updated product registration status, recall notices, safety bulletins, and alerts.
   - Provision of direct access to regulatory information systems (e.g., eRIS, alert databases) for DICs.
   - Technical support to DICs in developing query handling SOPs aligned with EFDA standards.
   - Joint training on regulatory science, risk communication, and evidence appraisal.

d) Pharmaceutical manufacturers

1. DICs may engage with licensed pharmaceutical manufacturers under regulated conditions to:
   - Receive product monographs, safety data sheets, updated package inserts, and educational materials.
   - Report observed ADRs, quality complaints, or efficacy concerns through structured communication channels.
   - Obtain urgent safety information, labelling changes, and recall notices for dissemination to healthcare providers.
2. All communications must comply with EFDA's standards on conflict of interest, transparency, and avoidance of promotional influence.

e) Academic and research institutions

1. DICs shall collaborate with academic and research institutions for:
   - Co-development of training curricula, DI content, and CPD modules.
   - Execution of joint operational research on DI query patterns, medicine safety, and health outcomes.
   - Access to scientific databases, libraries, and student internship placements.

2. Partnerships shall be formalized through memoranda of understanding to support sustained collaboration.

f) Professional associations

1. The EPA, EMA, and other relevant associations shall serve as key partners in:
   - Disseminating DI updates to members through bulletins, newsletters, and CPD events.
   - Co-hosting training programs on rational medicine use and evidence-based prescribing.
   - Participating in the review and co-creation of national DI guidelines and tools.

4.1.2. International collaboration

Strategic collaboration with international health organizations, global regulatory networks, academic institutions, and professional bodies significantly enhances the capacity and quality of DIS. These collaborations enable access to up-to-date global resources, harmonization of practices, capacity building, and participation in international drug safety initiatives.

a) World Health Organization and WHO Collaborating Centres

1. DICs at national and regional levels shall establish institutional linkages with:
   - WHO Collaborating Centres for DI.
   - The Uppsala Monitoring Centre (UMC) and other WHO technical networks.
2. Areas of cooperation shall include:
   - Access to global drug safety databases, including VigiBase.
   - Sharing of safety reports and adverse event signals.
   - Participation in joint training, webinars, and technical working groups on medication safety and risk communication.

b) Global Regulatory Agencies and Networks

1. EFDA and DICs may participate in or engage with:
   - African Medicines Agency (AMA), African Medicines Regulatory Harmonization (AMRH), and regional regulatory platforms (e.g., EAC-MRH, IGAD-MRH).
   - The WHO Collaborative Scheme, European Medicines Agency (EMA), U.S. FDA, and other international authorities for technical benchmarking.
2. Engagement modalities may include:
   - Collaborative safety communications and early warning systems.
   - Co-development of harmonized query-handling protocols and risk communication strategies.

- Subscription or access to internationally validated reference materials and formularies.

c) International Professional Organizations

1. DICs shall pursue partnerships or institutional membership in professional networks such as:
   - The International Pharmaceutical Federation (FIP)
   - The Drug Information Association (DIA)
   - The International Society of Pharmacovigilance (ISoP)
   - International Society of Drug Bulletins (ISDB)
2. These linkages will provide opportunities for:
   - International peer learning and knowledge exchange.
   - Joint research, conference participation, and publication opportunities.
   - Adoption of international standards and innovations in DI practice.

d) Capacity Building and Technical Assistance

1. International collaboration may support DIS through:
   - Joint development of e-learning courses, training-of-trainers (ToT) curricula, and mentorship programs.
   - Technical assistance in establishing or upgrading digital infrastructure and DI databases.
   - Provision of grants, software tools, or infrastructure support to strengthen local DICs.

e) Terms of Engagement

1. All international collaborations shall be governed by:
   - Memoranda of Understanding (MoUs) or institutional agreements.
   - Compliance with Ethiopia's data protection laws and EFDA's regulatory frameworks.
   - Non-commercial terms that ensure objectivity, independence, and neutrality in all DI outputs.

4.1.3. Mechanisms of collaboration

Effective collaboration between DICs and their national and international partners shall be operationalized through structured, transparent, and institutionalized mechanisms. These mechanisms ensure that collaboration efforts are sustained, aligned with national priorities, and result in tangible improvements in DIS delivery.

a) Memoranda of Understanding (MoUs) and Institutional Agreements

1. All formal collaboration between DICs and external entities whether governmental, academic, professional, or international shall be governed by MoUs or legally binding institutional agreements.
2. These agreements shall clearly specify:
   - Roles and responsibilities of each party.
   - Scope of collaboration (e.g., training, data sharing, research, platform integration).
   - Governance structures, timelines, reporting obligations, and exit provisions.

b) Joint Committees and Technical Working Groups

1. DICs shall participate in or co-establish joint technical working groups with key partners (e.g., Ministry of Health, academic institutions, regulatory bodies).
2. These groups shall provide technical oversight, coordinate shared activities, and advise on harmonization of guidelines, query handling protocols, and drug safety communication.
3. Each technical group shall have defined terms of reference and meet regularly to review progress, set priorities, and manage risks.

c) Shared Platforms and Digital Tools

1. DICs shall co-develop or gain authorized access to national or regional shared platforms for:
   - Drug alerts, bulletins, medicine lists and formulary updates.
   - Query submission and response management.
   - Access to international databases and e-libraries.
2. These platforms must:
   - Be compliant with national ICT and data protection policies.
   - Include audit trails, data security protocols, and user access controls.
   - Be interoperable with national health information systems (e.g., eRIS, DHIS2).

d) Collaborative Training and Capacity Building

1. DICs shall institutionalize joint training activities, including:
   - Co-facilitated induction training, CPD, and ToT programs.
   - Joint webinars and workshops hosted by regulatory, academic, or international partners.
   - Mentorship and peer-learning exchanges between higher-level and lower-level DICs.

e) Research and Knowledge Exchange

1. Collaborative research and evidence generation efforts shall be encouraged through:
   - Joint studies on medicine use, safety reporting, and DI service evaluation.
   - Data sharing agreements (DSAs) that protect confidentiality and intellectual property rights.
   - Co-publication and presentation of findings in conferences, journals, and symposia.

f) Coordination through National Forums

1. EFDA shall establish a National DI Coordination Forum comprising representatives from key national stakeholders and DICs.
2. The forum shall:
   - Serve as a platform for planning, alignment, and policy review.
   - Monitor implementation of collaborative activities.
   - Recommend revisions to standards, protocols, and strategic directions for the national DIS framework.

4.2. Workforce development and capacity building for DICs

4.2.1. Guiding principles

The development of a competent and sustainable DI workforce is essential for ensuring the delivery of accurate, timely, and evidence-based services. All training and capacity-building efforts under the national DIS framework shall be guided by the following principles:

1. **Equity**: Training resources shall be distributed to ensure equitable access across all regions, particularly in underserved or rural areas.
2. **Standardization and National Alignment**: Training content and methods shall be harmonized with EFDA regulatory standards, the national CPD framework, and national treatment guidelines.
3. **Competency-Based Learning**: All capacity-building programs must define clear learning outcomes and assess performance against competency benchmarks.
4. **Accreditation and CPD Integration**: Training programs must be recognized under the national CPD system to ensure professional development credit and regulatory compliance.
5. **Blended Learning**: Training shall use diverse methods, including e-learning, in-person workshops, simulation exercises, and on-the-job mentorship.
6. **Contextual Relevance**: Training modules must reflect the regulatory, clinical, and digital landscape of Ethiopia's health system.

7. **Sustainability and Institutional Ownership**: Regional health bureaus, academic institutions, and DICs must co-own training delivery and integrate it into their annual operational plans.
8. **Monitoring and Continuous Improvement**: All training shall include pre- and post-assessment, regular feedback, and post-implementation evaluation for quality assurance.

4.2.2. Induction training

1. All newly deployed DIC personnel shall complete a mandatory Induction Training Program within the first three months of assignment.
2. The training must cover the following standardized modules:
   - Orientation to the National DIS Framework and regulatory requirements.
   - Modified Systematic Approach to DI query handling.
   - Source hierarchy and evidence appraisal.
   - Regulatory, clinical, and digital information handling.
   - Confidentiality, ethics, and professional conduct.
   - Use of national tools (e.g., DIS Query-Response Form, digital platforms).
3. The induction shall be delivered through a blended learning model, comprising:
   - Classroom instruction.
   - Case-based simulations.
   - Supervised practical assignments.
4. Certification of completion must be documented and retained in the staff member's official personnel record.

4.2.3. Continuing Professional Development (CPD) and refresher training

1. All DIC staff shall participate in CPD training annually and in refresher training every two years.
2. Refresher training shall be prioritized for facilities with:
   - Performance concerns (e.g., misclassification, non-compliance).
   - Changes in guidelines or tools (e.g., new version of query forms, updated STGs).
   - Staff transitions or turnover.
3. Refresher training content shall include:
   - Query classification drills.
   - Evidence appraisal updates.
   - Digital platform navigation.

- Regulatory and clinical updates.

4. Refresher completion shall be a requirement for:
   - Renewal of DIC service authorization.
   - Staff promotion or supervisory roles.
   - Eligibility for participation in advanced training or international programs.

4.2.4. Training of Trainers (ToT) and mentorship framework

1. MOH and EFDA shall coordinate the national ToT system to develop a pool of certified trainers across regions.
2. Certified trainers shall:
   - Meet defined eligibility criteria.
   - Complete the national ToT curriculum.
   - Facilitate induction, CPD, and mentorship programs locally.
3. All DICs especially newly established or resource-limited centers shall integrate structured mentorship programs, including:
   - Pairing junior staff with experienced mentors.
   - Using standard mentorship checklists and progress tools.
4. Regional regulatory bodies and academic institutions shall support mentorship delivery and performance tracking.

Chapter Five: Digital and Ethical Foundations of DIS

Modern DIS rely heavily on digital tools and are governed by strict ethical and legal frameworks to ensure safe, equitable, and effective medicine use. This chapter outlines the core digital technologies and ethical standards guiding the delivery of DIS in Ethiopia.

5.1. Integration of digital health technologies into DIS

DICs at all levels shall integrate their services with the following core digital platforms:

a. Electronic systems

- Link DIS tools with electronic health and medical record (EHR/EMR) systems to support personalized DI delivery including drug interactions and dosing guidelines.
- Embed automated clinical decision-support alerts (e.g. duplication, contraindications) to reduce medication errors.
- Use eRIS and regulatory platforms to access product monographs, summary of product characteristics, registered medicine lists and package information and so on.
- Facilitate electronic ADR reporting to national pharmacovigilance centers Use electronic supply and logistics management systems to access availability of medicines.

b. Use of mobile and telecommunication tool (mHealth and Tele-DI)

To expand DIS reach and inclusivity, DIC shall adopt mobile and remote communication technologies appropriate to the Ethiopian context:

Mobile tools:

- Use SMS to quickly disseminate urgent drug alerts and updates.
- Develop or adapt mobile apps with national drug formularies, interaction checkers, and national treatment guidelines.
- Equip health extension workers with basic mobile tools to access basic DI.

Tele-DI services:

- Integrate telemedicine platforms to enable secure remote consultations between providers and DI specialists.
- DICs shall establish Tele-DI services using secure audio-visual platforms to serve remote providers and patients
- Tele-DI should be operated by trained DI DI professionals with clear SOPs on documentation, confidentiality, and follow-up

c. Use of Artificial Intelligence (AI) in DIS

- Use AI to support query categorization, trend analysis of potential ADRs, and real-time response suggestions.
- All AI tools must undergo local validation and operate under human oversight.
- DI personnel must be trained on AI bias, transparency, and accountability.

5.2. Data protection, privacy, and security

- All digital DIS must comply with Ethiopia's data protection laws.
- Patient information must be accessed, stored, and transmitted with documented informed consent.
- Each DIC shall have a documented privacy policy aligned with EFDA standards.
- DICs shall implement the following core cyber security measures:
    - Encrypt all data both at rest and in transit
    - Apply multi-factor authentication and role-based access
    - Regularly update digital systems used for DIS
    - Train staff on cybersecurity awareness and perform background checks on personnel handling sensitive data

5.3. Core ethical principles governing DIS

All DIS personnel shall adhere to the following ethical principles:

Principle	Description
Accuracy and Scientific Rigor	• All DI must be based on the best available evidence, peer-reviewed literature, validated databases, and updated clinical guidelines to ensure reliability and patient safety.
Confidentiality	• Personal and clinical information obtained through queries must be protected in accordance with national data protection laws. • No information may be disclosed without proper consent or legal authorization.
Transparency	• All sources, assumptions, limitations, and potential conflicts of interest must be disclosed when preparing and disseminating DI.
Professional Accountability	• DIC staff must take full responsibility for the quality, consequences, and ethical soundness of the information they provide. This includes adherence to licensing, SOPs, and institutional policies, and national laws.
Justice and Equity	• All users, regardless of location, status, or identity, are entitled to timely and unbiased access to DI.
Autonomy and Respect	• Information must empower clients to make informed decisions, without coercion or commercial influence.

5.4. Ethical practices in routine DIS operations

All routine activities within DICs must comply with applicable legal and ethical standards. The following rules apply:

- DICs reserve the right to decline legally or ethically inappropriate queries, with proper referral or documentation.
- Liability for harm due to erroneous DI may rest with both the institution and the individual DI provider.
- All factual errors must be corrected or retracted promptly, even after dissemination.
- Off-label use must be clearly identified, along with regulatory status and evidence limitations. DI pharmacists must clearly state when a drug's proposed use is off-label and not approved in Ethiopia.
- Institutions may be held accountable for dissemination of harmful or misleading information despite disclaimers.
- The enquirer must be reminded of their legal and ethical obligation to obtain patient consent and apply sound clinical judgment.
- Requests from law enforcement or regulatory bodies must be handled with heightened scrutiny and institutional oversight.
- DI pharmacists may serve as expert witnesses and must adhere to due process while upholding data confidentiality during legal purposes.
- All media requests must be channelled through the institution's public relations or legal office or leadership, per local policy.
- Social media shall be used only to disseminate DI outputs, complying with regulatory guidance and ethical norms. Moreover, DICs must not provide individualized clinical advice or respond to personal queries via social media.
- Patient confidentiality must never be breached; unauthorized disclosure may lead to legal consequences.
- All real or perceived conflicts must be declared and managed through institutional protocols.
- DICs must respect copyright protections when reproducing or distributing third-party content. Use of published material must be cited, and permission obtained if required.
- DICs must not engage in the promotion or advertisement of pharmaceutical products. In addition, endorsements of commercial brands or devices by DICs are prohibited.
- Clear institutional protocols should guide resolution of potential ethical dilemmas.

Chapter Six: Quality Assurance, and Monitoring and Evaluation

This chapter outlines quality assurance measures, and monitoring and evaluation (M&E) frameworks to assess performance of DISs.

6.1. Quality assurance in DIS

Quality assurance (QA) is a foundational pillar of DIS, ensuring that all services delivered by DICs are accurate, reliable, timely, and contextually appropriate. Each DIC regardless of level must implement a structured QA system in line with national standards to maintain professional and public trust. The following QA methods should be used to maintain the quality of the DIS:

a. Standard operating procedures (SOPs)

DICs shall develop, adopt, or adapt comprehensive SOPs for all DIS operations. These SOPs must be context-specific, regularly updated, and used to train staff on consistent service delivery.

Validated source protocols shall be maintained through an Approved Source List (Annex 6.1) and a reliability grading system (High, Moderate, Low reliability).

b. **Information update and dissemination protocols**

Each DIC shall institute rapid and routine update cycles:

- Urgent updates: (e.g., product recalls, safety alerts) must be disseminated within 24 hours using a defined Rapid Update Protocol (see Annex 6.2).
- Routine updates: (e.g., guideline changes) shall be reviewed and integrated monthly.

Designated staff shall monitor EFDA, WHO, FDA, and other credible alerts.

c. Documentation and record-keeping

All queries, sources consulted, and follow-up actions shall be logged as per SOPs. Records should support internal audits and service continuity.

d. Continuous professional development

All DIS staff shall meet minimum qualifications and undergo regular CPD on advanced information retrieval, critical appraisal, information synthesis, and communication.

Institutions shall track CPD using a standardized tool

e. Internal audits and corrective actions

DIS shall conduct internal audits annually to review adherence to SOPs, accuracy, completeness, and timeliness of responses, and use of validated sources and templates. Findings must be summarized (see Annex 6.3: Audit Report Template), and corrective actions implemented and monitored.

f. Peer review and approval of responses

Before dissemination, responses must be reviewed by a peer DI pharmacist or coordinator (whenever applicable). Peer review meetings should be held regularly to identify knowledge gaps and facilitate cross-learning.

g. User feedback mechanisms

DICs shall maintain mechanisms (surveys, suggestion boxes, follow-up calls, or interviews) to routinely assess client satisfaction, relevance, and communication clarity. Feedback shall inform periodic QA revisions.

6.2. Monitoring and evaluation (M&E) of DIS

Monitoring and Evaluation (M&E) provides a systematic approach for tracking the performance, outcomes, and overall impact of DIS at all levels. It ensures transparency, efficiency, and alignment with EFDA's regulatory expectations and national health priorities.

6.2.1. Key performance indicators (KPIs) for DIS

All DICs shall monitor and report on the following KPIs.

Table 6.1: List of KPIs, type and frequency of reporting

S/N	Indicator name	Type of indicator	Means of verification
1	Number of queries received	Output	Query registry Log
2	Proportion of queries responded	Output	Query registry and response Log
3	Proportion of queries responded timely	Output	Timestamped Query log
4	Number of DI materials developed/published	Output	Publication log/copy of materials
5	Documentation completeness rates	Output	Audit report
6	Number of trained DIC personnel	Input	Certificates issued/personal training file/training record
7	User satisfaction rate	outcome	Survey report
8	Proportion of functional DICs	outcome	Survey report

6.2.2. Performance Indicator Reference Sheet (PIRS) for the KPIs of DIS

A Performance Indicator Reference Sheet (PIRS) is a tool that explicitly and clearly defines performance indicators to help understand:

- What is being measured
- How to collect the necessary raw data
- How to process the raw data to derive the indicator's value

- It also helps ensure data quality and consistency.

The elements of PIRS include: indicator name, precise definition, formula, target, interpretation, disaggregation, data source, method of data collection, and reporting frequency.

Table 6.2: PIRS for key performance indicators of DIS

1. Number of queries received	
Indicator name	Number of queries received
Definition	The total count of DI queries formally submitted to the DIC within a specified reporting period.
Formula	Sum of all received queries during the reporting period.
Target	As per the plan
Interpretation	A higher number indicates increased demand for DI services, suggesting greater awareness or reliance on the DIC. A low number might indicate low awareness, lack of perceived need, or accessibility issues.
Disaggregation	By type of query (e.g., dosing, ADR, interaction, availability); by source/requestor profession (e.g., Physician, Nurse, Pharmacist, Patient); by query priority (high, medium, low), means of request (email, verbal…)
Aggregation	Sum queries from individual DICs within the region to generate regional totals. Sum Regional totals to derive a national total.
Data Source	DIC query logbook (manual or electronic).
Method of data collection	Review of the DI query logbook using a standardized abstraction form
Frequency of reporting	Quarterly.
2. Proportion of queries responded	
Indicator name	Proportion of queries responded
Definition	The proportion of all received queries for which a response was provided within the reporting period, out of the total number of queries received.
Formula	(Number of queries responded / Total number of queries received) × 100%
Target	100%
Interpretation	Only a 100% response rate signifies full compliance with expected standards. Any result below 90% indicates suboptimal performance.
Disaggregation	By type of query, by requestor type, means of response

Aggregation	Sum queries responded from individual DICs within the region to generate regional totals. Sum Regional totals to derive a national total.
Data Source	DIC query/response Logbook (manual or electronic)
Method of data Collection	Review of the DI query/response logbook using a standardized abstraction form
Frequency of reporting	Quarterly.
3. Proportion of queries responded timely	
Indicator name	Proportion of queries responded timely
Definition	The percentage of queries for which the final response was delivered to the requestor within the pre-defined target response time
Formula	(Number of Queries Responded Within Target Time / Total Number of Queries Responded) × 100%
Target	100%
Interpretation	Only a 100% response rate signifies full compliance with expected standards. Below 100% but above 85% indicates moderate delay. Any result below 85% indicates suboptimal performance requiring immediate action.
Disaggregation	By type of query, by requestor type, by means of response
Aggregation	Sum timely responses from individual DICs within the region to generate regional totals. Sum Regional totals to derive a national total.
Data Source	DIC query/response logbook with timestamps (Manual or electronic)
Method of data collection	Review of the DI query/response logbook with timestamps using a standardized abstraction form
Frequency of reporting	Quarterly.
4. Number of DI materials developed/published	
Indicator name	Number of DI materials developed/published
Definition	The total number of DI outputs such as drug alerts, newsletters, translated patient leaflets, drug monographs,) formally developed, approved, and published/disseminated by the DIC within a specified reporting period.
Formula	Sum of all formally developed/published DI materials in the reporting period.
Target	As per the plan. However, at least 4 high quality DI materials biannually from each DI output.
Interpretation	Production of 4 and more DI outputs biannually indicates strong performance and implies active engagement in proactive information dissemination and contribution to knowledge translation. 2-3 moderate, and <2 indicates poor performance.

Disaggregation	By type of material, by means of dissemination.
Aggregation	Sum DI materials developed from individual DICs within the region to generate regional totals. Sum Regional totals and National DICs to derive a national total.
Data Source	Admin report, publication log/copy of materials, dissemination records
Method of data collection	Review of admin report, publication log/copy of materials, dissemination records
Frequency of reporting	Bi-annually.
5. Documentation Completeness Rate	
Indicator name	Documentation Completeness Rate
Definition	The percentage of core DIC activities (DI query/responses, production of DI outputs, education and training sessions) that are completely documented according to established SOPs and standards within the reporting period.
Formula	(Number of records with complete documentation / Total number of sample records reviewed) × 100% To calculate documentation completeness rate, use stratified sampling technique across the three core DI activities. Randomly select a defined number of records from each core DI activity within the reporting period. Review each sampled record against SOP standards. If fewer than 50 records exist, review all; for 50–200 records, sample 15–30; for over 200, sample at least 30 per activity.
Target	100%
Interpretation	>90% reflects excellent practice and signifies strong adherence to quality assurance processes; 80-90% acceptable; <80% poor, triggering quality improvement actions
Disaggregation	By type of core activity
Aggregation	Sum completed documents from individual DICs within the region to generate regional totals. Sum Regional totals to derive a national total.
Data Source	DI query/response filled forms/logbook, publication log/copy of DI materials, education/training logs
Method of data collection	Assessment of sampled documentation of core DI activities.
Frequency of reporting	Annually
6. Number of trained DIC personnel	
Indicator	Number of trained DIC personnel
Definition	The total number of DIC personnel who have completed all required initial and ongoing CPD training pertinent to their roles and responsibilities during the reporting period

Formula	Total count of individuals with documented evidence (certificate or training record) of completed DIS-related training
Target	All actively engaged DI personnel
Interpretation	If all actively engaged DI personnel took the required training, it implies a well-invested and competent workforce. In contrast, low numbers indicate training gaps and require immediate intervention.
Disaggregation	By specific training type
Aggregation	Sum trained personnel from individual DICs to generate Regional total. Sum Regional data for National total.
Data Source	Certificates/personal training records
Method of data collection	Review of DIC personnel training records/certificates
Frequency of reporting	Annually

7. User Satisfaction Rate	
Indicator name	User Satisfaction Rate
Definition	The percentage of DIC users who are satisfied with the DIS received during the reporting period. This could be measured via standardized survey tools (refer to Annex 6.4 for a sample).
Formula	(Number of Satisfied Users / Total Number of Users Surveyed) × 100%
Target	>90%
Interpretation	A result of 75% and above indicates the DIC is meeting user expectations, providing relevant information. While, a result <75% requires action to improve service quality and responsiveness.
Disaggregation	By type of requestors (e.g., physician, nurse, patient),
Aggregation	NA
Data Source	User satisfaction survey report
Method of data collection	Survey
Frequency of reporting	Annually

8. Proportion of Functional DICs	
Indicator name	Proportion of Functional DICs
Definition	The percentage of existing DICs that meet all defined functionality criteria
Formula	(Number of DICs Meeting Functionality Criteria / Total Number of Established DICs) × 100%

Target	100% (A health facility DIC is considered functional when 75% of the functionality criteria are fulfilled. (see table 6.3 below)
Interpretation	A high percentage indicates a robust and operational national/regional DIC network. A low percentage highlights poor performance requiring high-level strategic intervention.
Disaggregation	By regions, by type of DIC
Aggregation	NA
Data Sources	DI query/response forms, DI outputs and DIS reporting, site visit reports,
Method of data collection	Observation of DIC room for availability of DIS facilities, SOP, sample query and response forms, sample alerts, newsletters and monographs.
Frequency of reporting	Annually

Table 6.3: DICs functionality criteria

S.n	**Criteria**	**Weight**	**Score**
1.	Availability of required facilities (i.e. room, equipment, furniture, telephone, internet, reference materials) and dedicated pharmacist	20	
2.	Approved annual action plan for the fiscal year	5	
3.	Availability of standard operating procedure	5	
4.	Provides therapeutic and pharmaceutical information using standardized query and responses formats	25	
5.	Organizes medicine use education to patients and general public, and training program to the hospital staff at least monthly (health education programs, community forums)	15	
6.	Prepares and disseminate drug alerts/newsletters, new arrivals, bulletins, therapy updates, monographs, error prone abbreviations, look-alike and sound alike medication at least monthly	20	
7.	Prepare and disseminate performance reports monthly	10	
Total Score			
Functionality of DIC; If $\geq$ 75%, Yes; If < 75%, No.			

Annexes

Annex 3.1: DI query form (Standardized)

Date: _____ Time: _____Enquiry Reference Number: DI-_____

I. Requester Information

- Full Name: _____
- Profession: □ Pharmacist □ Druggist □ Physician □ Nurse □ Health Officer □ Student □ Other: _____
- Facility Name & Address: _____
- Phone No.: _____
- Email: _____
- Fax: _____
- Preferred Response Method: □ Phone □ Email □ Walk-in □ Fax □ Letter □ Other: _____

II. Classification of Request (tick one)

□ Adverse Drug Reaction (ADR) □ Dosage □ Drug Interaction □ Pregnancy/Lactation
□ Storage/Stability □ Identification □ Availability □ Legal/Regulatory □ Therapeutics
□ Other: _____

III. Query Background

- **Type of Request:** □ Patient-specific □ Academic □ Other: _____
- If Patient-specific, fill:
    - Age: _____ Sex: □ M □ F Weight (kg): _____ Diagnosis: _____
    - Current Medications: _____
    - Concurrent Medications: _____
    - Allergies: _____ Other Info: _____

IV. Query/Question:

V. Urgency

- Response Needed In: □ Immediate □ <30 min □ 30–60 min □ Same Day □ Other: _____
- References Requested: □ Yes □ No
- Additional Info Required: □ Yes □ No

Received By (DIS staff): _____
Date: _____ Time: _____ Initials: _____

Annex 3.2: DI response form

To (Name of Inquirer): _____Phone: _____Email: _____

Enquiry Reference No.: DI-_____ Date: _____ Time: _____

Dear [Name],

We acknowledge the receipt of your enquiry on DI regarding [_____]. We are pleased to present the following response:

Question/Query:

Answer/Response:

References Used (with Tier):

1. _____ (Tier ***)***
2. _____ (Tier ***)***
3. _____ (Tier ___)

Additional Information/Recommendations:

Disclaimer: The DIS is designed to support clinical and public health decisions. While every effort is made to ensure accuracy and currency, final responsibility lies with the end user.

Completed By: _____ Date: _____ Initials: _____

Reviewed By (if applicable): _____Date: _____ Initials: _____

Annex 3.3: DI service feedback form

Enquiry Reference No.: DI-_____ **Date of Enquiry:** _____

Dear Enquirer,

We kindly request your feedback to improve our DIS. Your response is voluntary and confidential.

1. Did you receive the information on time? □ Yes □ No
2. Was the presentation of the information clear? □ Yes □ No
3. Did the response meet your needs? □ Yes □ No
4. Was the information used? □ Yes □ No
    1. If yes, what was the outcome?

       _____
    2. If not, why was it not used?

       _____
5. Additional comments or suggestions: _____

Name of Enquirer: _____Phone: _____Email: _____

Feedback Received By: _____ Date: _____ Initials: _____

Action Taken (if any): _____

Annex 3.4: DI dissemination log

Instructions for Use:

The responsible DI pharmacist shall complete this log immediately following each dissemination activity. All fields shall be duly filled. The log shall be retained as part of the DIC's official records and submitted during periodic supervisory or regulatory reviews.

Facility/Institution: _____ Month/Year: _____

Ser. No.	Date Disseminated	DI product Type	Topic / Title	Target Audience	Dissemination Method	Channel Used (e.g., EFDA portal, WhatsApp, circular)	No. of Recipients / Estimated Reach	Approved by	Confirmation of Receipt	Remarks

Annex 3.5: Feedback tracking tool for disseminated DI products

Instructions for Use:

For each DI product disseminated, the DI pharmacist shall enter feedback responses as received through forms, phone calls, or in-person discussions. Usefulness shall be rated on a scale of 1 (Poor) to 5 (Excellent). Follow-up actions, if required, must be documented. Completed feedback logs shall be compiled quarterly for internal evaluation and submitted upon request by regulatory bodies.

Facility/Institution: _____ Month/Year: _____

Ser. No.	DI Product Title	DI Product Type	Date Disseminated	Target Audience	Feedback Method (Form/Phone /In-person)	Feedback Received (Yes/No)	Summary of Feedback	Usefulness Rating (1= Poor, 5= Excellent)	Action Taken / Follow-up	Recorded By

Annex 6.1: DI source validation checklist

Purpose: To ensure that all DI sources used by the DIC are credible, accurate, relevant, and up-to-date, supporting evidence-based responses and resource development.

1. **Scope:** This protocol applies to all primary, secondary, and tertiary sources considered for answering DI queries or inclusion in DIC resources.

2. **Tiered validation approach**

Tier	Description	Validation Process	Frequency
Tier 1: Core Trusted Sources	Established, authoritative sources (e.g., WHO guidelines, UpToDate, peer-reviewed journals indexed in PubMed)	Full checklist validation initially; periodic re-validation annually	Annual or as needed
Tier 2: New / Secondary Sources	New or less familiar sources not previously validated	Complete full checklist validation before any use	At time of first use
Tier 3: Rapid Query Sources	Routine queries citing pre-validated Tier 1 sources	Minimal re-validation; rely on existing validation	Continuous use without re-check

3. Source validation checklist with scoring

For Tier 2 and new sources, complete the following checklist and assign scores as indicated.

3.1 Scoring Scale

Score	Meaning
2	Fully meets the criterion
1	Partially meets / unclear
0	Does not meet the criterion

3.2 Source identification and credibility (Max 12 points)

Criterion	Scoring Guide	Score (0-2)	Notes
Source Type	Primary, secondary, or tertiary identified		
Author Credentials	Qualified experts clearly identified		
Publisher/Organization	Reputable academic, government, or professional body		

Peer Review & Indexing	Peer-reviewed and indexed in major databases		
Timeliness	Published/updated within last 5 years		
Funding Transparency	Funding disclosed and no apparent bias		

3.3 Content Quality (Max 12 points)

Criterion	Scoring Guide	Score (0-2)	Notes
Accuracy	Claims fully supported by evidence		
Objectivity	Balanced content, no undisclosed commercial bias		
Completeness	Information sufficiently comprehensive		
Relevance	Directly relevant to query and local context		
Methodology (if applicable)	Appropriate study design and data analysis		
Clarity and Presentation	Clear, professional language and format		

3.4 Red Flags (Negative Scoring, -2 points each)

Check all that apply; each red flag subtracts 2 points from total score.

- Anonymous or unqualified authors
- Lack of citations or references for key claims
- Excessive advertising or promotional content
- Outdated information for rapidly evolving topics
- Numerous grammars, spelling, or typographical errors
- Unprofessional website or source presentation
- Identified as predatory journal or publisher
- Claims contradict established consensus without strong evidence

4. Validation Process Workflow

4.1. Source Identification: Classify source into Tier 1, 2, or 3.

4.2. Checklist Completion: For Tier 2, complete scoring checklist; for Tier 1, confirm last validation date; Tier 3 relies on existing validations.

4.3. Calculate Total Score:

- Add scores from Sections 3.2 and 3.3 (max 24 points).
- Subtract 2 points for each red flag checked in Section 3.4.

4.4. Assign Reliability Level:

Total Score Range	Reliability Level	Recommended Use
18 to 24 (High)	High Reliability	Use as primary source
10 to 17 (Moderate)	Moderate Reliability	Use with caution; supplement with high reliability sources
Below 10 (Low)	Low Reliability	Avoid as primary source; use only for background if necessary

4.5. Documentation: Record results in the Source Validation Record/Database including:

- Source details (title, authors, publication)
- Scores and reliability rating
- Reviewer name and date
- Notes or concerns

4.6. Decision: Based on reliability level, decide on source use for query response or resource inclusion.

4.7. Periodic Review: Annually re-validate Tier 1 sources and update database.

4.8. Feedback Loop: Staff report concerns or new evidence about sources for reassessment.

4.9. Automation and Tools

- Use bibliographic databases (PubMed, Scopus) to verify indexing and peer-review status quickly.
- Implement electronic forms or software to automate scoring and flag critical issues.
- Explore AI tools for preliminary source credibility screening.

4.10. Integration with DIC Operations

- Embed this protocol in SOPs for query response and resource development.
- Train staff on checklist use and scoring.
- Prioritize rapid access to validated Tier 1 sources for timely responses.
- Document source validation outcomes in query reports when relevant.

4.11. Reviewer Information

Reviewer Name: _____ Date: _____

Annex 6.2. Update schedule template

Purpose: To systematically track and manage the timely review, update, and dissemination of DI, ensuring that all provided information is current and relevant, especially concerning critical safety alerts.

Instructions: DICs should complete this template regularly (e.g., daily for urgent alerts, monthly for routine reviews) to maintain a comprehensive record of information updates.

I. General Update Information

- DIC Name: _____
- Reporting Period: (e.g., July 2025; Q3 2025) _____
- Designated Monitoring Staff: _____

II. Daily Urgent Update Monitoring Log ***(To be completed daily by designated staff for critical alerts)***

Date/Time of Alert	Source of Alert (e.g., EFDA, WHO, FDA, Peer-reviewed Journal)	Type of Alert (e.g., Drug Recall, Safety Warning, New Drug Approval, Major Guideline Change)	Drug/Topic Affected	Action Taken (e.g., Database Updated, Regional DICs Notified, Response Template Revised)	Date/Time of Action Completion	Status (Completed / In Progress / Pending Verification)	Notes / Verification Details

III. Routine Information Review Schedule ***(To be completed monthly/quarterly for regular information categories)***

Information Category / Section (e.g., Dosing Guidelines, Drug Interactions, Adverse Effects, Local Treatment Protocols, Drug Monographs)	Responsible Staff/Team	Last Review Date	Next Scheduled Review Date	Review Outcome (e.g., Updated / No Changes Needed / Pending Review)	Notes (e.g., Specific changes made, sections reviewed)

IV. Major Guideline/Resource Update Tracking ***(For comprehensive resources or national guidelines requiring significant updates)***

Resource Name (e.g., Ethiopian National Formulary, National Essential Medicines List, Clinical Practice Guidelines for TB)	Version/ Year of Last Major Update	Expected Next Major Update (if known)	Nature of Update (e.g., New Edition, Major Revision, Digital Platform Migration)	Internal Impact on DIC (e.g., Requires extensive database overhaul, staff training, new SOPs)	Status of Integration (e.g., Review in Progress / Updates Implemented / Training Scheduled)	Completion Date

V. **Summary and Action Points for Reporting Period**

Total Urgent Updates Processed:

_____

·Total Routine Reviews Completed:

_____

Challenges/Gaps Identified (e.g., delayed alerts, staffing issues):

_____

Action Points for Next Period (to improve timeliness):

_____

Prepared By: _____ Date: _____

Reviewed By: _____ Date: _____

Annex 6.3. Audit report template

Purpose: To provide a standardized format for documenting the findings, observations, recommendations, and corrective actions resulting from internal quality assurance audits of DIS operations. This report supports continuous improvement and accountability.

Instructions: Complete this template after each scheduled or ad-hoc internal audit of a DIC's operations.

I. **Audit Identification**

- Audit Title: [e.g., Q3 2025 DIS Quality Audit]
- Audit ID: [e.g., DIC-AUD-2025-Q3]
- Audited DIC/Service Level: [e.g., National DIC, Addis Ababa Regional DIC, St. Paul's Hospital DIC]
- Audit Period: [Start Date] to [End Date]
- Audit Date(s): [Date(s) of Audit]
- Auditor(s) Name(s): _____
- DIC Coordinator/Manager: _____

II. **Audit Scope and Objectives**

- Scope: [Briefly describe the specific areas/processes audited, e.g., "Review of all DI queries handled in Q3 2025," "Assessment of SOP adherence for new drug monograph development."]
- Objectives: [List the specific goals of the audit, e.g., "To assess accuracy of responses," "To verify compliance with documentation standards."]

III. **Audit Findings**

Summarize observations, both positive findings (strengths) and areas for improvement (non-conformities/observations), categorized by relevant quality parameters (e.g., Accuracy, Timeliness, Completeness, SOP Adherence). Reference specific SOPs or standards where applicable.

Category (e.g., Accuracy, Timeliness, SOP Adherence, Documentation)	Observation/ Finding (Detailed Description)	Evidence/Reference (e.g., Query ID, SOP Section, Date)	Severity (e.g., Major, Minor, Observation)

IV. **Summary of Strengths / Best Practices**

[List key areas where the DIC performed well or demonstrated exemplary practices.]

V. **Recommendations and Corrective Action Plan (CAP)**

For each identified non-conformity or area for improvement, propose specific recommendations and outline the corrective actions to be taken.

Finding ID (from Section III)	Recommendation (What should be done?)	Corrective Action(s) (Specific steps to address the recommendation)	Responsible Person/Team	Target Completion Date	Status (Open / In Progress / Closed)

VI. **Follow-up and Verification**

Date of Follow-up Review: _____

Summary of Follow-up Findings: [Describe whether corrective actions were implemented effectively and if the issue was resolved.] _____

Overall Audit Outcome: [e.g., All findings addressed / Some findings remain open /New issues identified.] _____

VII. **Approval Signatures**

- Prepared By (Auditor): _____ Date: _____
- Reviewed By (DIC Coordinator/Manager): _____ Date: _____
- Approved By (Head of Pharmacy/Relevant Authority): _____ Date: _____

Annex 6.4. User satisfaction survey tool

Purpose: This survey aims to collect your valuable feedback on the quality, usefulness, and impact of the DIS you recently utilized. Your responses will help us continuously improve our services. All responses will be kept confidential and used for quality improvement purposes only.

Instructions: Please tick the appropriate box or provide your comments in the spaces below.

I. User Information (Optional - Helps us understand user demographics)

1. Your Profession:
   - o [ ] Pharmacist
   - o [ ] Physician (Doctor)
   - o [ ] Nurse
   - o [ ] Other (Please specify): _____
2. Type of Facility/Program where you practice:
   - o [ ] Hospital (e.g., General, Referral, Specialized)
   - o [ ] Health Center
   - o [ ] Private Clinic/Pharmacy
   - o [ ] Public Health Program/Ministry of Health
   - o [ ] Academic/Research Institution
   - o [ ] Other (Please specify): _____
3. Which level of DIC did you most recently access?
   - o [ ] National DIC
   - o [ ] Regional DIC
   - o [ ] Facility-level DIC

II. Service Quality Assessment

Please rate your agreement with the following statements regarding the DIS you received:

(Rating Scale: 1 = Strongly Disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly Agree)

Statement	1	2	3	4	5	N/A
1. It was easy to contact the DIC.						
2. I received the response in a timely manner.						
3. The information provided was accurate and correct.						

4. The information was complete and addressed all parts of my question.						
5. The information was clear and easy to understand.						
6. The information was relevant and applicable to my practice/patient in the Ethiopian context.						
7. The information provided was objective and unbiased.						
8. The DIS staff were professional and courteous.						

III. Impact Assessment

1. Did the information you received from the DIS help you in your patient care or clinical decision-making?

- o [ ] Yes
- o [ ] No
- o [ ] Unsure

2. Did the information received lead to a change in your practice (e.g., prescribing, monitoring, counselling)?

- o [ ] Yes, significantly
- o [ ] Yes, slightly
- o [ ] No
- o [ ] Not applicable (e.g., information was for general knowledge)

3. Do you believe the information helped to prevent a potential medication error or adverse drug reaction (ADR)?

- o [ ] Yes
- o [ ] No
- o [ ] Unsure / Not applicable

IV. **Overall Satisfaction & Feedback**

1. Overall, how satisfied are you with the DIS you received?
   - o [ ] Very Dissatisfied
   - o [ ] Dissatisfied
   - o [ ] Neutral
   - o [ ] Satisfied
   - o [ ] Very Satisfied
2. How likely are you to use the DIS again in the future?
   - o [ ] Very Unlikely

- o [ ] Unlikely
- o [ ] Neutral
- o [ ] Likely
- o [ ] Very Likely

3. What did you find most useful or positive about the DIS?

_____

4. Do you have any suggestions for how the DIS can improve its services?

_____

5. Please provide any additional comments or concerns:

_____

Thank you for your valuable time and feedback!