national health authority

Ministry of Health and Family Welfare
Government of India

सत्यमेव जयते

Consultation Paper on Drug Registry

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Written Comments on the Consultation Paper are invited from all the stakeholders by 11:59 pm of May 1, 2022. Comments are to be preferably provided electronically on the NDHM website via form available at https://abdm.gov.in/home/Publications. The comments may also be sent on the email ID abdm@nha.gov.in

Acronyms and Abbreviations

API	Application Programming Interface
EMR	Electronic Medical Records
HFR	Health Facility Registry
HPR	Healthcare Professionals Registry
HIMS	Hospital Information Management System
NDHB	National Digital Health Blueprint
NDHE	National Digital Health Ecosystem
ABDM	Ayushman Bharat Digital Mission
NHA	National Health Authority
NHP	National Health Policy
UHI	Unified Health Interface
CDSCO	Central Drugs Standard Control Organization
AYUSH	Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy
IPC	Indian Pharmacopoeia Commission
NPPA	National Pharmaceutical Pricing Authority
C-DAC	Centre for Development of Advanced Computing
NRCeS	National Release Centre for EHR Standards
SNOMED CT	Systematized Nomenclature of Medicine - Clinical Terms
UDC	Unique Drug Code
GTIN	Global Trade Item Number
DIAT	Drug Information Authoring Tool

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Executive Summary

Ayushman Bharat Digital Mission (ABDM) has been launched to create a national digital health ecosystem that supports universal health coverage in an efficient, accessible, inclusive, affordable, timely, and safe manner. ABDM envisions open, interoperable, standards-based digital systems, and ensures the security, confidentiality, and privacy of health-related personal information.

Registries are one of the core building blocks of the ABDM which if standardized would help in enabling interoperability of healthcare data. These registries shall be designed with strong data governance mechanisms, adhering to the principles of verifiability, accessibility, and identity management.

One of the critical components of these registries is the Drug registry, which is envisioned to be a single, up to date, recognized registry of all the drugs. It is being conceptualized as the primary source of information for all other databases and lists and facilitates the exchange of standardized data across all systems of medicine, from allopathy to Ayurveda.

A central database of the approved drugs sold in the market will serve multiple benefits including free availability of verified information for all drugs, simplified regulatory flows, smoother supply chain management, streamlined insurance claim processing, innovations in clinical decisions, disease management and assurance models.

Initially, the goal is to comprehensively capture relevant & accurate details of all drugs sold in India. Over time, the drug registry is envisaged to help smoothen the inventory flow throughout the drug supply chain, improving the quality and patient trust and ultimately enabling patient-centric digitization by ensuring machine readability of prescribed drugs.

This document covers the strategic and technical design associated with the Drug Registry. The potential sources of input data, self-certification, verification, and data distribution flow have been proposed in the document to ensure the creation of a single nationally recognized source of truth for data on drugs that is trusted, digitally enabled, and widely adopted by the healthcare ecosystem stakeholders. We look forward to feedback and support from the ecosystem partners to enable the design and adoption of a Drug registry in India.

Chapter 1

Introduction and Background

1.1 Objectives

1.1.1. This document has been published to invite stakeholder comments and consultation on the strategic and functional fundamentals of the Drug Registry. Drug Registry is envisioned to be a nationally recognized registry of all the drugs across various systems of medicines that are sold in the Indian market.

1.1.2. In this document, an attempt has been made to frame and contextualize the issues for consultation and provide adequate context for the public to weigh in with their comments. A wide range of policy, strategic and technical matters are covered, some of which may depend upon the interpretation of the law. The information given is not intended to be an exhaustive account of statutory requirements and should not be regarded as a complete or authoritative statement of law. The approaches discussed henceforth are ideas and not decisions. The final decision shall be taken after considering suggestions and feedback received to this paper. Implementation, including necessary course correction in the pilot, shall be done after that.

1.1.3. Multiple sources have been consulted to draft this consultation paper and the information presented herein. However, NHA understands that there might still be gaps with respect to practical implementation. Hence, the desired outcome from this process of consultation is clear feedback and answers to the questions posed at the end of each chapter. Additionally, stakeholders are welcome to raise any other issues they deem critical for the development of such a platform.

1.2 Evolution of ABDM

1.2.1. The National Health Policy (NHP), published in 2017, had the following goal - ³7KH attainment of the highest possible level of health and wellbeing for all at all ages, through a preventive and promotive health care orientation in all developmental policies, and universal access to good quality health care services without anyone having to face ILQDQFLDO KDUGVKLS DV D FRQVHTXHQFH ´

1.2.2. A key tenet of the NHP was the adoption of digital technologies in the healthcare ecosystem. To realize this goal, the Ministry of Health and Family Welfare constituted a committee headed by Shri J. Satyanarayana to develop an implementation framework for the National Health Stack. This committee produced the National Digital Health

Blueprint (NDHB) , laying out the building blocks and an action plan to implement digital health comprehensively and holistically.

1.2.3. To define the rationale, scope, and implementation arrangements of the framework of the digital healthcare ecosystem laid out in NDHB, Ayushman Bharat Digital Mission (ABDM) , was then launched, with the following vision:

³7R FUHDWH D QDWLRQDO GLJLWDO KHDOWK HFRV\VWHP V efficient, accessible, inclusive, affordable, timely and safe manner, that provides a wide range of data, information and infrastructure services, duly leveraging open, interoperable, standards-based digital systems, and ensures the security, confidentiality and privacy of health-related personal LQIRUPDWLRQ ´

1.3 Building Blocks of ABDM

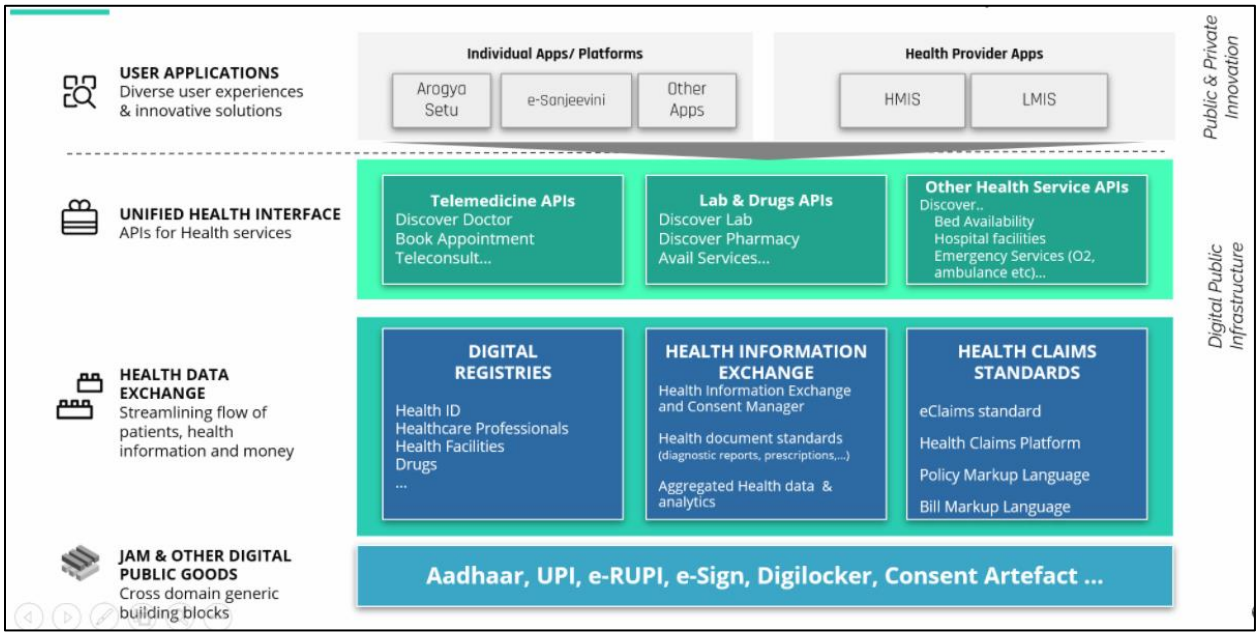


Figure 1: ABDM Architecture

1.3.1. The National Digital Health Blueprint (NDHB) outlined NH\ EXLOGLQJ EORFNV IR Digital Health Ecosystemafter detailed discussions with stakeholders and research on existing systems. Detailed information on each of these building blocks can be read in the official NDHB strategy document.

1.3.2. Registries have been envisioned as core building blocks. Registries are securerepositories of data of various types (on health facilities, healthcare professionals, etc.) that users

(individuals or organizations) may voluntarily enroll in. These registries shall be designed with strong data governance mechanisms, adhering to the principles of verifiability, accessibility, and identity management. In their respective domains, these registries are designed to emerge as nationally recognized and accepted databases.

The data registries will be considered successful if they are adopted by ecosystem stakeholders across the private and public sectors as sources of truth. These registries will only achieve this vision if trust and verifiability of their data are paramount in the design. Further, to drive adoption, these registries must be interoperable with other ABDM building blocks.

1.3.3. One of the main objectives of the National Digital Health Blueprint (NDHB) is to establish national and regional registries to create a single source of truth for pharmacies. The creation of such a standardized drug registry is essential for the attainment of the other objectives of the NDHB for instance, the use of Clinical Decision Support Systems by health practitioners. Drug registries also form an integral part of the building blocks in the NDHB to ensure identification and interoperability.

1.3.4. In the initial pilot phase, the following registries were launched by ABDM in the 6 Union Territories:

1. ABHA: ABHA is an acronym for Ayushman Bharat Health Account. It was earlier known as Health ID. It is important to standardize the process of identification of an individual patient across healthcare providers. Therefore, every patient who wishes to have their health records available digitally must start by creating an ABHA. Each ABHA will be linked to a µ K H D O W K G D W D F R Q V H Q W P D Q D J H U ¶ D X V H U ¶ V F R Q V H Q W D O O R Z W K H P W R P D Q D J H W K H S ecosystem. Multiple health data consent managers are likely to be available for patients to choose from, developed by both public and private players. ABHA will be designed to not require a physical card. Healthcare providers will be able to rapidly lookup ABHA by searching on the ID, alias, mobile, or Aadhaar number. The ABHA can be presented in e-card format(s) and issued to patients who need them. The ABHA card will also include a QR code that can be scanned to enable seamless patient registration at health facilities.

2. Healthcare Professionals Registry (HPR):Healthcare Professionals Registry, referred to as Health Workforce Registry in the NDHB, is the master data of information on doctors, nurses, paramedical staff, ASHAs and many other healthcare S U R I H V V L R Q D O V ¶ F D G U H V $ % ' 0 L Y H G R S L Q J W K H a phased manner.

3. Health Facility Registry (HFR): The Health Facility Registry will consist of one record and a unique identifier for each healthcare facility in the country ±hospitals,

clinics, diagnostic centers, etc. across all systems of medicine and covering both public and private health facilities. The initial version of HFR was launched as a part of the ABDM pilot in August 2020.

1.4 Scope of the consultation paper

2.5.1 This paper only focuses on the Drug Registry within the National Digital Health Ecosystem 1'+(,W GHVFULEHV 1+$¶V FXUUHQW WKLQNLQJ UHODWHG WR Drug Registry, the process for its creation and potential benefits to various ecosystem stakeholders. Each section has specific open questions where feedback from stakeholders is sought.

2.5.2 The paper consists of five chapters. Chapter 1 provides the background information and introduction to ABDM; Chapter 2 aims to create a framework for analysis by setting the current context of drug registry in India, analyzing selected international case studies and deriving key learnings for drug registry creation in India; Chapter 3 outlines some of the stakeholders to be considered in the design and build of drug registry and provide an initial assessment for the value proposition for each; Chapter 4 introduces the guiding principles for drug registry and DIAT tool; Chapter 5 outlines the process for the creation of drug registry in detail including the role of various stakeholders, and provides detailed information on Drug Registry data and proposed data standards and codes.

2.5.3 The Ayushman Bharat Digital Mission (ABDM) plans to develop the Drug Registry building block as a public good. Inputs from all are sought through this consultation paper to ensure Drug Registry is beneficial to all parties.

1.5 Feedback received from Internal Stakeholders

Internal stakeholder feedback session on Consultation Paper for proposed Drug Registry (DR) held on 18th January 2022. Inputs/ suggestions on fundamental aspects related to Drug Registry were discussed, and suggestions were requested from the stakeholders. The paper has been updated based on the feedback/suggestions received from various internal Stakeholders.

1.6 How to provide Comments on the consultati on paper

Comments and feedback can be uploaded on the link provided at https://abdm.gov.in/home/Publications or can be emailed to abdm@nha.gov.in WLOO VW 0D\¶

Chapter 2

Setting the context for Drug Registry

2.1 Current pharma landscape in India

2.5.1 On the regulatory front, the Drugs & Cosmetics Act, 1940 and Rules, 1945 have entrusted various responsibilities to central & state regulators for the regulation of drugs & cosmetics. Under the Drug and Cosmetics Act, the regulation of the manufacture, sale and distribution of Drugs is primarily the concern of the State authorities while the Central Authorities are responsible for approval of New Drugs, Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs, coordination of the activities of State Drug Control Organizations and providing expert advice with a view of bringing about the uniformity in the enforcement of the Drugs and Cosmetics Act.

2.5.2 As different authorities have different responsibilities and collect data at different times of the product lifecycle, the data is present in different forms with multiple regulatory authorities, which in turn leads to a lack of a central database on the approved drugs sold in the market. The lack of visibility creates certain challenges for multiple stakeholders in the healthcare ecosystem.

2.5.3 Currently, medical IT systems use their master database of drugs, their constituents, and codes to identify individual drugs. This leads to problems in the interoperation of medical records and information between the systems. The lack of a single source of truth for medical drugs, generics and substances adds to the problem.

2.5.4 Despite regulatory checks and balances on drug approvals, there is infiltration in the movement of drugs from pharmaceutical manufacturers to the patient. This infiltration can lead to the consumption of counterfeit/unapproved drugs, which can be harmful to the patient and the drug brand owner. Moreover, the lack of a common identifier throughout the supply chain causes ordering and inventory management issues leading to wastage of drugs due to expiry and returns. The movement of drugs through the supply chain can be smoother and more transparent if a common code is used by all the players.

2.5.5 Multiple discussions have been conducted with CDSCO to understand the current landscape including approval flow, potential areas for improvement and Drug registry enabled solution themes.

Various Regulatory Frameworks in Indian Pharmaceutical Industry are listed in Appendix III.

2.2 The vision of Drug Registry

2.5.1 To achieve the vision of Ayushman Bharat Digital Mission it is important that the healthcare data across all the building blocks to be standardized and interoperable. Drug registry is, therefore, the key building block to ensure this standardization of healthcare data. The Drug Registry is proposed to be a single, up-to-date repository of all the drugs present in the domestic market. It is the primary source of information for all other databases and lists and facilitates the exchange of standardized data across all systems of medicine, from allopathy to Ayurveda. Every drug entry in the registry is proposed to have a unique drug code and information corresponding to a comprehensive list of data attributes defined across clinical, regulatory and supply chain domains. Moreover, any new drugs that come into the Indian market are also proposed to be added to the registry.

2.5.2 It is envisioned that every ecosystem stakeholder uses the same drug code for communication regarding drugs ensuring no scope of confusion and incorrect drug supply or administration. This would reduce the number of errors in understanding and the dispensing of drugs, thus reducing errors in inpatient healthcare. The drug registry will also enable the implementation of digital healthcare by allowing machine readability, which can then augment e-prescription, telemedicine, e-pharmacy, etc.

2.5.3 Initially, the goal is to comprehensively capture relevant & accurate details of all drugs sold in India. Over time, the drug registry is envisaged to help smoothen the inventory flow throughout the drug supply chain, improving the quality and patient trust and ultimately enabling patient-centric digitization (e.g., Clinical Decision Support System, telemedicine, etc.) by ensuring machine readability of prescribed drugs.

2.3 Existing efforts in India on drug registries

While designing an approach for the drug registry best suited to India, a study of existing drug registries in the country and their design was conducted. The following are key observations on the current Indian landscape of drug registries that will influence the functional and technical design of the platform.

- Need for a National Source of Truth: A comprehensive set of verified data on all the approved drugs marketed in the country would enable a more efficient regulatory process. Moreover, given the regulatory landscape of drugs at the central and state level in India, there is a need to create an official source that captures all the clinical and regulatory information about the drugs in the country.
- Universal Identifiers for drugs: A unique identifier that is recognized by any authority or entire healthcare ecosystem for auditing, monitoring, prescribing, and dispensing a drug to the general public

- Diverse Systems of Medicine: The prevalence of both allopathic and traditional systems of medicine further compounds the problem. This level of diversity in drug modeling, specialization, governance, and regulatory mechanisms across systems of medicines present several challenges in creating a common platform. A well-defined system is needed in the future that can meet the requirements of such a diverse system.

To summarize, there is a need for a nationally recognized source of truth for data on the drug in India that is trusted, digitally enabled, and widely adopted by healthcare ecosystem stakeholders. The Drug Registry under ABDM aims to solve this problem.

2.4 Key learnings from international models

To build a holistic, comprehensive, and ecosystem-friendly platform, an analysis of national drug registries being implemented across the world is imperative. Detailed assessment of models in Canada, Israel, Turkey, Sweden, and the United States has been included in Appendix II. Key learnings from these models are as follows:

- Participation of regulatory bodies: All data entered in the registry needs to be verified and completed for it to serve as one comprehensive source of information on all drugs. While the regulatory bodies are entrusted with the task of creating of national drug registry in other countries, in the Indian context, it is proposed that drug information already approved by the regulatory bodies or self-certified by the manufacturers would be imported to the drug registry. Later, newer drugs can be added to keep the registry updated.
- Scope of benefits: A comprehensive drug registry can be significant in enabling clinical, regulatory and supply chain benefits such as EMR linkages, e-prescription, regulatory compliance, and track and trace system, among others. While other countries have designed their national drug registry to achieve their tailored outcome V D Q G K D Y H Q ¶ W H [S O R U potential benefits, the drug registry under ABDM can aim to build a single comprehensive registry that provides all the benefits.

- Focus on citizen-facing platforms: To impart the benefits of the registry to citizens of the country, the countries have placed a high focus on building citizen-facing platforms that allow them to validate the authenticity and safety of the prescribed drug before consumption. Similar platforms need to be built for drug registries to ensure that the benefits of the registry reach every citizen.

- Regulatory levers for adoption: The adoption of a national drug registry in global countries have been achieved by mandating the use of standard codes generated as part of drug registry in drug packaging, national insurance claim reimbursement and others. There may be a need

to explore similar levers to ensure the participation of ecosystem stakeholders in building and adopting the drug registry.

2.5 Questions for consultation

2.5.1 As discussed in Section 2.2, are there other international case studies or best practices that should be studied to inform the design of the Drug Registry?

- Which best practices should be adopted from these international models?
- How do we tailor these best practices for the Indian context?

2.5.2 Countries like Sweden have included preferential consumables such as ostomy products and foods for special nutrition for children under 16 years of age in the drug registry. Should there be the inclusion of preferential consumables or any other category in the drug registry? Please give reasons for the same.

Chapter 3

Ecosystem adoption

3.1. Potential Benefits for Stakeholders

The Drug Registry aims to create a nationally recognized source of truth for information on various systems of medicine in the country. The creation of a drug registry will require participation from multiple stakeholders, and in turn, these participants stand to benefit from the drug registry over time. In addition to registry participants, various other healthcare ecosystem participants will benefit from the creation of the Drug Registry and other business applications that will be built upon the Drug Registry.

The benefits from Drug Registry are expected to be realized over time as the scope and scale of the information captured in the registry expand with the participation of key stakeholders. In the near term, Drug Registry will bring the following ecosystem benefits ±

The potential value proposition of drug registry is envisaged across two buckets:

1. Direct value-add: Benefits to the stakeholders by virtue of the creation of a reliable source of truth for information all licensed drugs

S. No	Stakeholder	Near-term benefits (not exhaustive)
Direct value-add / Primary use-cases		
1.	Patients	X Reliable, nationally recognized single source of truth on the clinical and regulatory data of licensed drugs.
2.	Regulatory bodies	X The Drug Registry will provide a single view of licensed drugs in the market which will enable ease of conducting regulatory activities.

2. Enabling use-cases: Benefits to the stakeholders from the adoption of drug registry to build solutions that can be built leveraging the drug registry

S. No	Stakeholder	Near-term benefits (not exhaustive)
Enabling / Secondary use-cases		
1.	Pharma companies and authorities	X The pharma authorities can build separate solutions leveraging Drug Registry as the base master database to track prices and availability of all drugs including the National List of Essential Medicines (NLEM) against their unique codes.

2.	Healthcare providers	X The prescription and other medical records may contain the standard drug terminologies as in Drug Registry. This will enable healthcare providers to provide better follow-up treatment to patients based on individual drug responses to previously consumed drugs by removing any ambiguity in order/prescription. Brand substitution using their generics will add to the ease of ordering.
3.	Health tech	X Private health-tech ventures rely on the existence of robust datasets to develop and scale their products. Drug registry can offer a reliable source of truth for e-pharmacies, digital solution providers such as HMIS / EMR systems, inventory management systems, etc., and simplify information exchange between different stakeholders.

Following are potential long-term direct benefits for various stakeholders:

S. No	Stakeholder	Long-term benefits (not exhaustive)
Direct Value -add		Primary use cases
1.	Patients	X Drug Registry will store information about every saleable unit of drugs that are dispensed to the patient via authorized points. All the data is verified by an appropriate pharmaceutical company or regulatory body. This drives trust and assures the patient of the quality of the drug.
2.	Pharma companies and authorities	X Central availability of information about licensed drugs will enable system checks on the entry of spurious drugs in the supply chain. This ensures no counterfeits are being consumed by the patients and prevents harmful effects due to such drugs.

Following are potential long-term enabling use-cases for various stakeholders:

S. No	Stakeholder	Long-term benefits (not exhaustive)
Enabling / Secondary use-cases		
1.	Healthcare providers	X Standardized drug information in longitudinal health records of patients/individuals will enable healthcare providers to provide better care to patients
2.	Pharmaceutical companies, other pharma	X All the drugs will have a unique identifier recognized by an authority that will serve as a common communication identifier among all the supply chain players. This will enable

	supply chain players	smooth movement of drugs and synergistic inventory management across supply chain players. X Drug registry will reduce revenue leakages for pharmaceutical companies due to the presence of spurious drugs in the market, expiry of drugs, etc. X The usage of unique codes will ensure that there are minimal errors in dispensing drugs.
3.	Other pharma authorities, policymakers / Government	X Over time, Drug Registry will present an accurate picture of the supply of drugs in the country as it will emerge as a source of truth. Such a registry may be used by administrators to ensure that the availability of drugs is in line with strategic health policy goals and emergency response needs. X Aggregated and anonymized EMR data including drug prescriptions may be used by policymakers to track disease incidence, drug consumption, which in turn will enable population health management, informed policy decisions, etc.
4.	Insurers	X Machine-readable EMR with unique drug codes will enable auto-adjudication of claims, in turn, introducing operational efficiencies for both insurers and third-party administrators X Reduced claim processing cost and verifiable prescription records (contains Health Professional ID, drug codes, etc.) may trigger innovation in insurance, especially OPD coverage
5.	Health tech	X Trigger innovation in healthcare delivery with availability of targeted clinical knowledge, patient information and other health information backed by international terminology standards such as SNOMED CT

3.2. Potential risks

7R HQVXUH WKDW WKH 'UXJ 5HJLVWU\ LV VXFFHVVIXOO\ DG
the potential risks that may result from the creation of the Drug Registry and need to be addressed.

1. Self-substitution by patients: The availability of clinical information of all the drugs in one place will empower citizens with increased knowledge about drugs and their effects. This may promote self-substitution among them without consulting a doctor, which potentially may result in many challenges such as delay in diagnosis of chronic disease, adverse drug reactions in patients, etc.

   Risk mitigation- Only licensed pharmacies and doctors should change any brand/generic based on medical compatibility and clinical goal for the patient. Drug dispensation points like pharmacies should discourage substitution by the patient. It is also proposed that drugs requiring a prescription or having any adverse effect may have a warning indicator when viewed in the drug registry.

2. Ensure quality of drugs: In India, currently, there is a need for defined standards to ensure the quality of all drugs. Inconsistency in the quality of drugs across manufacturers may pose a challenge in the complete substitutability of drugs.

   Risk mitigation- Empower state FDAs to ensure consistency in the quality of drugs across manufacturers by having strong drug efficacy review mechanisms in place. Availability of a master database showing all brands, generics, their substances, etc. will assist state FDAs to take consistent regulatory decisions.

3. Data Privacy and Security: Due to a large amount of data to be made available on the Registry and exchange of data with other platforms, there may be a risk of breach of sensitive information.

   Risk Mitigation: It is proposed to have a strong data privacy and security architecture, data governance mechanism with supportive policies that will ensure that any information is not exposed and misused. Moreover, the principle of minimalism is proposed to be followed to avoid capturing any irrelevant sensitive data.

3.3. Questions for consultation

3.3.1. In addition to potential benefits/risks discussed in Chapter 3, please suggest any other stakeholder(s) for consideration of benefits and risks. Please provide any additional

benefits/risks that would be relevant for various stakeholders to participate in Drug Registry.

3.3.2. For the risks mentioned in section 3.2 and the ones provided as an answer to the question above, please provide details on possible mitigating measures that may be taken to minimize the impact of said risks.

Chapter 4

Drug Registry in Depth

4.1. Key guiding principles

The following are the key fundamentals guiding the development and implementation of the Drug Registry:

- Unique Drug Code: Generated for verified drugs to serve as common communication identifiers and ensure duplicate entries are not created.

- One-stop platform: All the drugs from all the systems of medicine listed on one platform covering multiple attributes that enable clinical and regulatory benefits for unique drug codes. However, to begin with, the drug registry is proposed to have allopathic prescription medicines and later expand to include other systems of medicine.

- Verified data: All the drug details in the registry are either verified by drug regulators in the country or self-certified by the manufacturer. Moreover, the coding body will check for completeness and correctness of data against other known sources of similar information.

- Accountability and Data Provenance: A verification trail for all changes made to entries in the registry.

- Easily accessible: Accessible to multiple stakeholders through various avenues such as drug registry web portal, external APIs, CSV format, etc. However, to ensure that registry, IT system is not overloaded, some form of rate control may be applied.

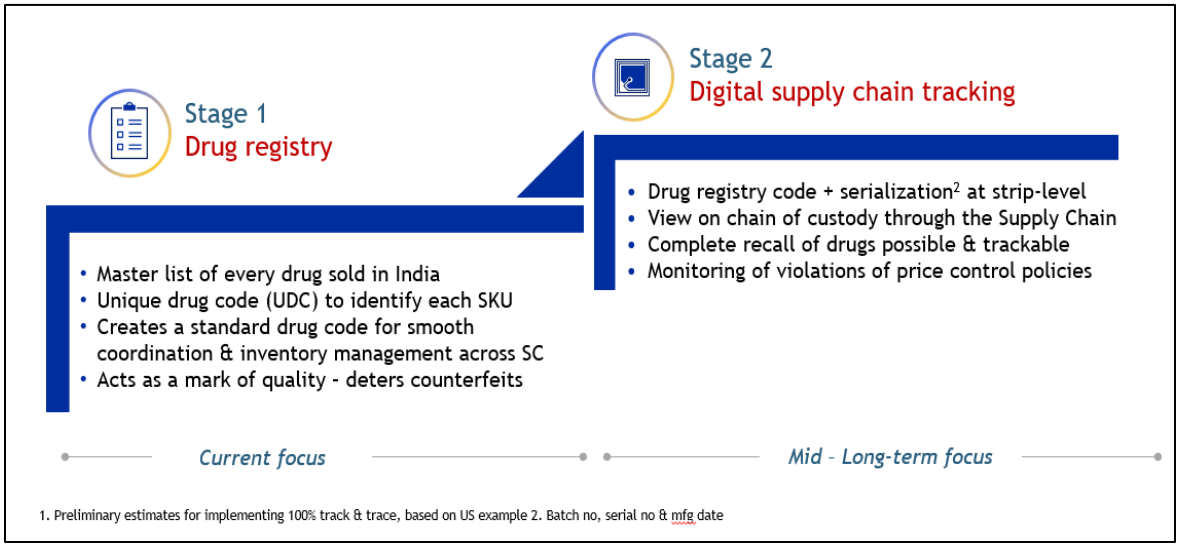
- Interoperable and Scalable: Interoperable with other building blocks of the ABDM and able to scale vertically and horizontally as the need arises.

- Link to other databases: Maintain reference to any existing or future government-owned drug repositories such as SUGAM (CDSCO) to ensure a continuous exchange of data that benefits all systems.

- Public Database: Accessible to any user/company searching for drug information across the world. It is a shared database, regularly updated by multiple stakeholders

4.2. Drug Registry

The drug registry platform is proposed to be a centralized repository of all the drugs which are approved and are available in the Indian Market. A two-stage process is envisioned for building the drug registry, initial focus will be on creating a master database of drugs in India.



Drug registry platform is proposed to utilize the output of the Drug Information Authoring Tool (DIAT) developed by C-DAC Pune. DIAT tool will facilitate the import/ upload of drug information from various data sources i.e., CDSCO, State Drug controlling organizations, Manufacturers, and other data providers. Uploaded data will go through a cleansing and certification process (in the case of hospitals, pharmacies, etc.). The Common Drug Codes for India (CDCI), as an output of the DIAT tool, is proposed to be imported to the centralized Drug Registry database and will be published through the drug registry portal. The Drug Registry platform will also provide API integration with various other government and private entities for the utilization of drug registry data.

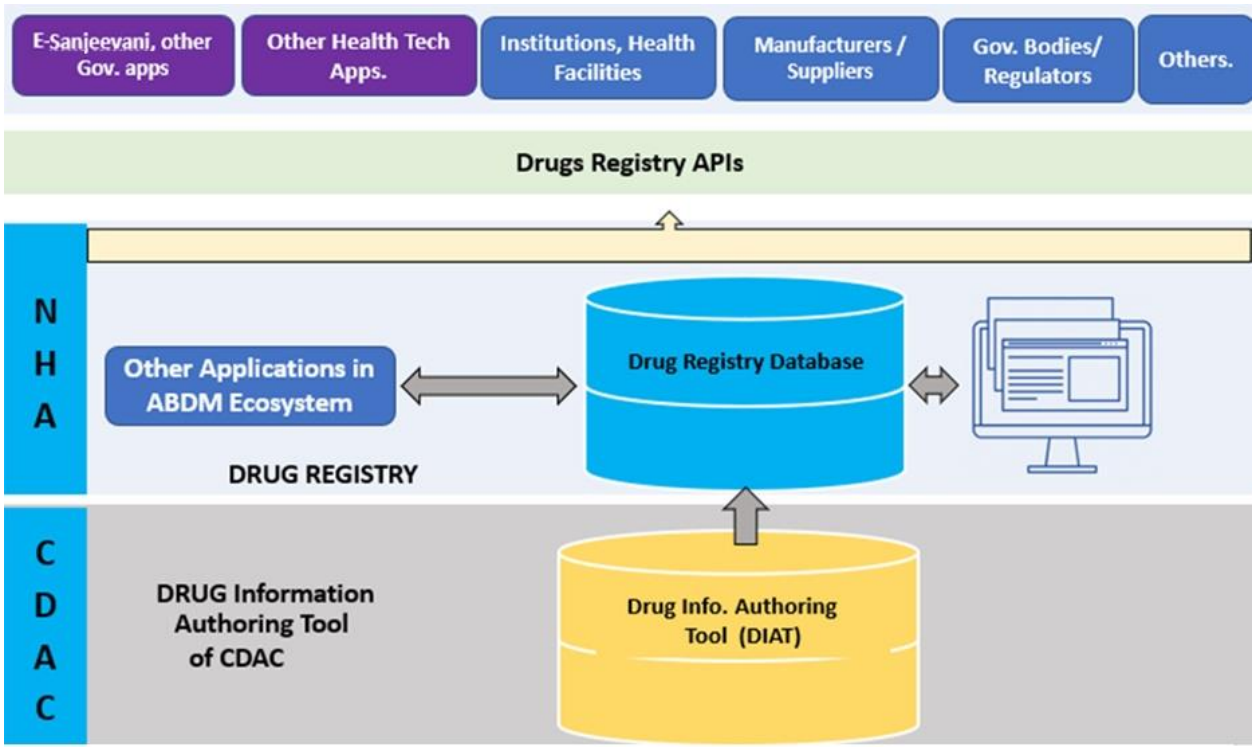


Figure 2: Different layers of Drug Registry Platform

4.3. Drug Information Authoring Tool (DIAT)

The Drug Information Authoring Tool (DIAT) is a web-based application developed by C-DAC, Pune to help in the creation and curation of drug information and build the corpus for creating Common Drug Codes for India (CDCI) distributed by National Resource Centre for EHR Standards (NRCeS). DIAT web application is a secured platform for users (doctors/organizations, suppliers/manufacturers, regulatory bodies, and other relevant sources) to add drug and associated details. It includes workflow for reviewing and authoring the drug contents for completeness and correctness.

DIAT has role-based user access and privileges for different stakeholders including drug manufacturers, regulatory bodies, hospitals, other organizations, etc. The tool provides a facility to stakeholders to feed data manually, through APIs or pre-specified import format depending on the user. This provides automatic mapping to existing global SNOMED CT clinical vocabulary codes for pharmaceutical and biological products, substances, clinical drugs, etc. The tool also provides the unique numeric identifier from SNOMED ID namespace as Unique Drug Code (UDC) to all the drugs and its detail entries include substances, generics, brands, package details, dose forms, route of administration, product name and manufacturer. The output of this tool is Common Drug Codes for India (CDCI) which will be imported to the drug registry. This will allow drug codes, as an extension, to be usable in any system that already incorporates SNOMED CT terminology. Systems not using SNOMED CT

terminology (e.g., a pharmacy POS system) will still be able to directly use the codes as a numerical ID and consume/produce an interoperable record from say, an e-prescription system.

4.4. Questions for Consultation

4.4.1 As discussed in 4.2, is this the right conceptual framework to build Drug Registry? Are there other potential models or approaches that can be considered? Please provide details

4.4.2 As discussed in 4.3, is the proposed model for data entry appropriate? Are there other modes of data entry to be considered? Please provide details.

Chapter 5

Data Management in Drug Registry

5.1 Creating Drug Registry

The key central driver for stakeholders willingly adopting and integrating the Drug Registry is hinged on ensuring that the data available in the directory is updated, accurate and complete. Due to the criticality of ensuring that data in the Drug Registry is complete and correct with respect to the approval given by the regulator(s), it is envisioned that the drug information be self-certified by the manufacturer / suppliers or health facility .

The below diagram outlines the process by which a drug record can be created and verified at a high level. The individual elements of this process are expanded upon in greater detail below.

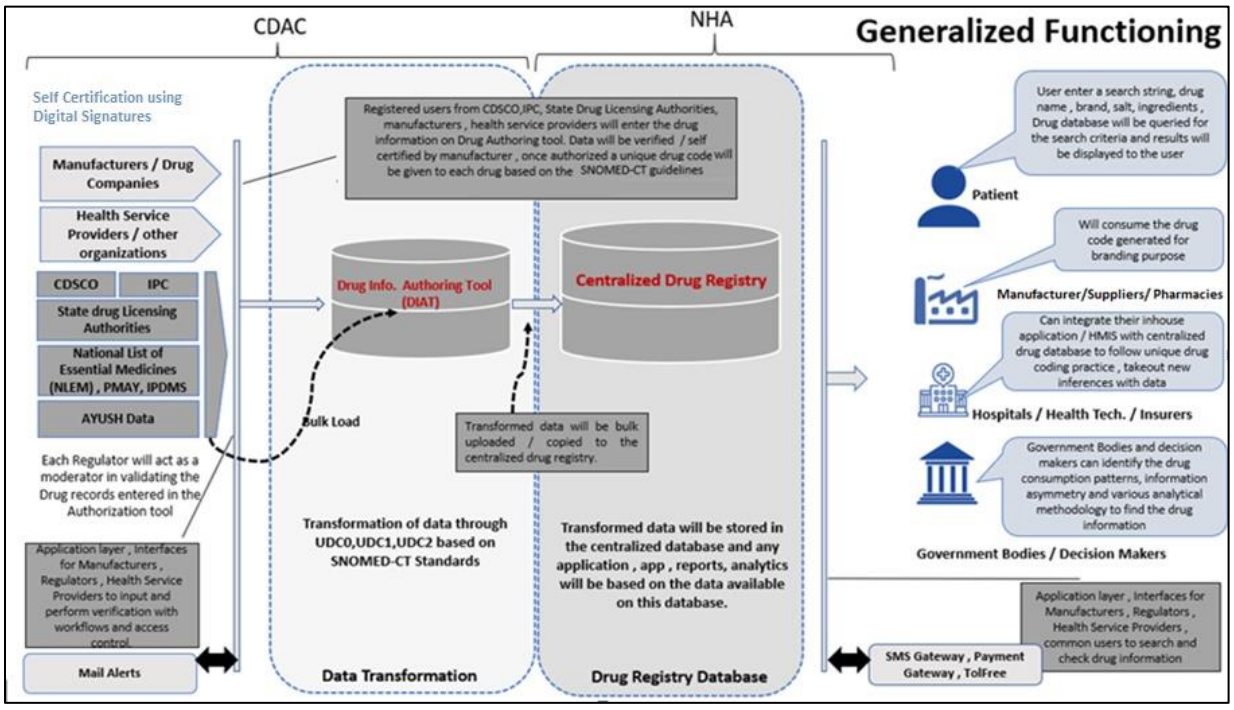


Figure 3: Generalized functioning of Drug Registry

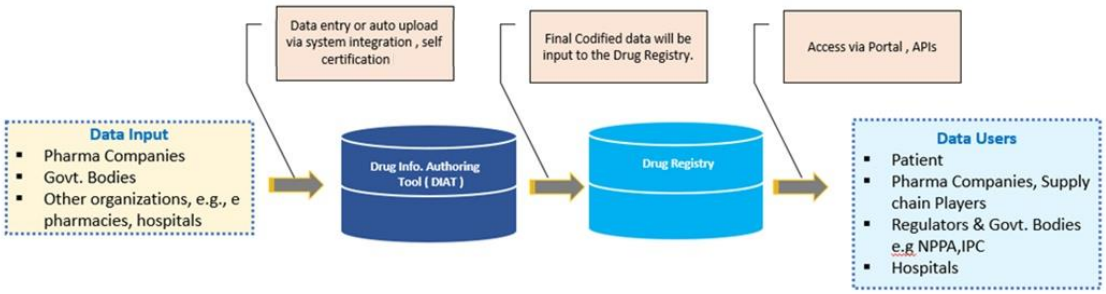


Figure 4: Process for creation of Drug Registry

Data input: In the current absence of any single source of digital drug information, multiple data sources will be utilized to populate data into the Drug Registry. As the pharmaceutical companies are primary sources of the information of drugs marketed by them, it is imperative to design an approach that allows them to input their drug information into the Drug Registry. It is proposed that the Drug Registry platform will leverage the DIAT for uploading and codification of the drug data. DIAT will enable pharmaceutical companies along with other stakeholders to import, review and self-certify data in the system by various means provided in the DIAT system. In the initial phase, drug information available through different sources that have curated such information (e.g., Government programs, public/private hospitals, e-Pharma, etc.) will be populated and managed, while manufacturers are on-boarded. In later phases, digital systems available with regulators will be linked for automatic pulling of information through API integration or bulk import.

Data Certification: ' X U L Q J W K H L Q W H U Q D O F R Q V X O W D W L R Q Z L W K suggested that since all the drugs have already gone through a detailed approval process controlled by the state and central drug controlling organizations, drug manufacturers / importers/ suppliers may self-certify the information related to the drug manufactured by them for correctness and completeness in DIAT. The drug data uploading user will receive a notification to self-certify the newly added/pending drugs of their organization before publishing the drug information. Any change in the provided drug information should be updated in DIAT and re-self-certified. All changes in already published information due to regulatory action and received through regulator/regulatory digital systems will be enforced and will not require any re-certification. This process will ensure that verified drug information will be available in the drug registry.

Drug manufacturers/suppliers or health facilities providing false /incorrect or manipulated drug information or self-certifying such information will be liable for prosecution as per the provisions of the laws/rules.

5.2 Drug Registry data

Drug Registry data refers to the information or data attributes that are included in Drug Registry for each drug sold in the Indian market. These attributes include both necessary information that is required to uniquely identify a saleable unit of the drug in the market and additional attributes that will further enable clinical and regulatory benefits. The data published through the drug registry is proposed to be as per the public data definition defined in section 4.2.2.

5.2.1 Drug attributes

The drug data will be captured at three different levels and each level will have a unique drug code to enable multiple use cases. The following table summarizes the data attributes that will be captured at each level ±

S. No.	Level	Description	Data attributes
1	Generic (contains the same chemical substance as a drug that was originally protected by chemical patents. Allowed for sale after the patents on the original drugs expire.	This captures clinical modeling of drugs that can be used to manufacture branded or generic drugs that will yield the same therapeutic effect	‡ Composition Details (Strength, Unit, Substance Name) ‡ Route of Administration ‡ Dose Form ‡ Anatomical Therapeutic Chemical (ATC) Classification ‡ Additional information incl. Drug-drug interactions, Drug usage, Contraindications, therapeutic category, prescription mandate, Adverse Drug Reactions (ADRs) and Schedule of drugs
2	Branded drug	This captures the information of all branded drugs manufactured/marketed in India by any pharmaceutical company	‡ Brand Name ‡ Manufacturer Name ‡ License Number ‡ License Status ‡ Generic Name ‡ Additional details incl. National List of Essential Medicines (NLEM) status, Drug Price Control Order (DPCO) status, Type - Over

			the Counter (OTC) v/s Prescription and drug release mechanism
3	Saleable Unit (Serialization)	This identifies individual saleable units at the primary, secondary, or tertiary packaging level	‡ GTIN ‡ Serial Number ‡ Batch / Lot Number ‡ Expiry date

5.2.2 Public data

A predefined set of data attributes of a drug shall be mandatorily displayed for public view. This includes the following data fields:

- Composition Details (Strength, Unit, Substance Name)
- Route of Administration
- Dose Form
- Brand Name
- Manufacturer Name
- License Status
- Package Details (Size, Unit, and Form)
- Schedule of Drugs
- Classification of Drugs

7KH GHILQLWLRQ RI µSXEOLF GDWD¶ PD\ EH FKDQJHG IURP WLPH WR WLPH EDVHG RQ WKH PRGLILFDWLRQ RI fields in the Drug Registry.

5.2.3 Drug Data Specifications

Drug data specifications allow for each data attribute in Drug Registry to be defined and formatted for data entry so that the information collected and stored in the registry is standardized and consistent across all drug entries.

For each attribute, the following specifications will be present while providing drug data in the technical platform (details present in Annexure I).

1) Data Rules: Each attribute will have a list of conditions applied to it. This may include:
   - Number of characters
   - Type of string: Use of letters, numbers, and symbols
   - Language (including when to use symbols and accents)

2) Mandatory or Optional: Some data fields are mandatory for the unique identification of drugs - these are marked as mandatory. Other additional information may be optional for the drug, depending on the case.

The entire list of fields proposed to be included in the Drug registry along with their specification has been attached with this consultation paper as Annexure I.

5.3 Data standards and codes

Drug Registry aims to follow international standards from among the minimum set of standards in a large number of areas as recommended in the National Digital Health Blueprint. However, the standards must align with the following guiding principles for their adoption in Drug Registry ±

1. Interoperability: Standard and encoded terminology to document patient information within Electronic Health Record (EHR) and communicate with other systems using a common language.

2. Comprehensive coverage: Wide range of data attributes and a number of drugs should be covered to reduce any cross-terminology mapping efforts.

3. Local customization: In addition to international standards, the standards must allow customizations to address any country-specific requirements.

4. Open availability: The international standards must be openly available to all member countries for use with regular updates in accordance with any new regulatory requirements, additions, etc.

5. Wide acceptance: The international standards must have high adoption among global countries to enable the global exchange of information as and when required.

For the Drug registry, SNOMED CT meets the above-defined criteria among the international standard terminologies and codes for medicinal information. Whereas, to enable track and trace systems, GTIN is proposed for serialization of each saleable unit of drug.

S. No.	Level	Proposed international standard	Reference in Drug Registry
1	Generic	x SNOMED CT International Edition x Common Drug Codes for India (CDCI) SNOMED CT Extension	Unique Drug Code (UDC) 0

2	Branded drug	x Common Drug Codes for India (CDCI) SNOMED CT Extension	Unique Drug Code (UDC) 1
3	Saleable Unit	x GTIN	Unique Drug Code (UDC) 2

5.4 Drug Codes integrated with SNOMED CT

SNOMED CT is a structured clinical vocabulary that covers a wide range of topical areas such as problems, diagnosis, organisms, pharmaceutical descriptions, and anatomic areas, and is used within different EHR systems in over 80 countries.

India is a member of SNOMED International represented by MoHFW, Govt. of India. MoHFW has made SNOMED CT freely available for use in India. NRCeS set up by MoHFW at C-DAC Pune supports the adoption of SNOMED CT in the country. Being the notified National Release Centre for SNOMED CT, NRCeS has its own allocated SNOMED CT identifier Namespace from the standard body and that is used to provide any country-specific codes for concepts in local extensions. NHA is working in close collaboration with NRCeS, C-DAC Pune to adopt SNOMED CT in Drug Registry.

NRCeS has developed Common Drug Codes for India (CDCI) as National Extension to SNOMED CT to fulfil the requirement of standardized capturing of medicines and drug information in clinical systems. The CDCI is distributed in two different formats for ease of use and adoption:

- CDCI [Terminology Integrated Package]
- CDCI [Flat Files Package]

The CDCI along with SNOMED CT International Edition currently covers generic and branded medicines from various national programs including

- National List of Essential Medicines (NLEM) 2015
- Pradhan Mantri Jan-Aushadhi Yojana
- Affordable Medicines and Reliable Implants for Treatment (AMRIT) program
- Medicines referred in Telemedicine Practice Guidelines
- HIV Drug list referred by National AIDS Control Organisation (NACO)
- COVID-19 drug list referred in Clinical Management Protocol: COVID-19 by MoHFW

CDCI uses the same concepts ID and naming scheme as used in the SNOMED CT International Release along with the editorial guidelines for change management. While SNOMED CT provides several drug items as part of their release, the CDCI adds several other items specific to India including brands, manufacturers, etc.

SNOMED CT has been adopted as a clinical terminology standard in India. It is also a recommended primary terminology standard in EHR Standards for India-2016 and the National Digital Health Blueprint (NDHB) by MoHFW, Govt. of India. SNOMED CT covers a large number of substances (active ingredients) and medicinal products (generics). It also facilitates the expansion of terminology for local and national requirements. The development of standardized drugs based on SNOMED CT norms ensures the applications that are already using SNOMED CT for clinical data coding, need not develop or implement a new infrastructure for handling drug codes. This will help the system developers in adopting and implementing a single clinical standard to standardize health data.

After careful analysis of different parameters such as interoperability, coverage, local customization, open availability, ease of implementation and wider acceptance extending SNOMED CT to also include drug codes and made available to all clinical and non-clinical systems as was found fastest, reliable, and easier to roll-out for the purpose.

5.5 GTIN

Global Trade Item Number (GTIN) is an internationally recognized code to identify trade items uniquely across the globe. GTINs are proposed in Drug Registry for all pharmaceutical drugs such that they can be scanned throughout the supply chain to ensure smoother inventory management. The primary, secondary and/or tertiary packaging will be encoded with barcode linked unique ID to identify drug details such as medicate name, dose, route of administration name, etc. captured in Drug Registry.

5.6 Data up-keeping and update in Drug Registry

A time-to-time update and up-keeping of drug information are crucial if there is any change in drug information. Manufacturer / suppliers or health facility have to update the drug details when there is any change in drug information or regulatory direction/action regarding the drug.

The below table shows the action performed for different activities by users ±

Sr. No.	Activity	Action
1.	Change in ± x Drug name x Composition Details (Strength, Unit, Substance Name) x Route of Administration x Dose Form	New entry
2.	Change in ± x Therapeutic role	A new version of the same entry

	x Indication x Contraindications x Drug usage x Interactions with Drugs x Schedule of drugs x Package details	
3.	Retiring, withdrawal, suspension of drug	A new version of the same entry with the change of status

5.7 Self-Certification

Drug manufacturers/ suppliers or health facilities are proposed to self-certify the drug information entered by them by digitally signing the undertaking on the correctness of the information supplied by them. Certification process has to be completed during the submission of drug information in the drug registry, without which, they will not be able to enter any drug information.

Drug manufacturers/suppliers or health facility, providing false /incorrect or manipulated drug information will be liable for prosecution as per the applicable law.

5.8 Identified data sources

On the regulatory front, the Drugs & Cosmetics Act 1940, and rules 1945 have entrusted various responsibilities to central & state regulators for the regulation of drugs & cosmetics. Under the Drug and Cosmetics Act, the regulation of the manufacture, sale and distribution of Drugs is primarily the concern of the State authorities while the Central Authorities are responsible for approval of New Drugs, Clinical Trials in the country, laying down the standards for Drugs, control over the quality of imported Drugs, coordination of the activities of State Drug Control Organizations and providing expert advice with a view of bringing about the uniformity in the enforcement of the Drugs and Cosmetics Act.

Since different authorities have different responsibilities and collect data at different times of the product lifecycle, there currently exists no nationally recognized source of truth for data on drugs in India that is trusted, digitally enabled, and widely adopted by healthcare ecosystem stakeholders. Thus, there is a need to refer to multiple sources to ensure a comprehensive and up-to-date drug registry. The following are the data sources that have been identified to populate the drug registry via DIAT ±

1. SUGAM Portal

CDSCO has launched SUGAM (www.cdscoonline.gov.in), an e-Governance system, to discharge various functions performed by CDSCO under the Drugs and Cosmetics Acts, 1940. The software system is an online web portal where applicants can apply for NOCs, licenses, registration certificates, permissions & approvals. Further, MoHFW has inserted Rule 84AB in Drug and Cosmetic Rules, 1945 that requires all the licensees to register with portal SUGAM and upload information pertaining to the licenses granted for manufacture for sale or distribution of drugs.

The integration with the SUGAM portal will be a vital step towards building a drug registry. The integration will ensure the up keeping of all data attributes of licensed drugs into the drug registry. Further, any updates in terms of change of licensing status, manufacturer information, brand name, etc. in the SUGAM Portal will also be reflected in the drug registry.

2. State Drug Control Organizations

Since the regulation of the manufacture, sales and distribution of drugs is a primary responsibility of the State authorities, all the drug details corresponding to a branded drug will lie with individual state authorities. The contribution of data of all licensed branded drugs by state authorities will be a vital step in populating a drug registry. All the State Drug Control Organizations may contribute their respective drug database to NHA. These databases can then be migrated to a pre-specified import format and uploaded to DIAT via bulk import functionality.

3. Indian Pharmacopoeia Commission (IPC)

Indian Pharmacopoeia publishes Indian Pharmacopoeia (IP) and National Formulary of India (NFI) at regular intervals for improving the quality of medicine in India and promoting rational use of generic medicines respectively. The publications contain details of monographs of therapeutics and administrative and regulatory information pertaining to the prescribing and dispensing of drugs. IPC may contribute these publications to NHA which will then be uploaded against the respective clinical and regulatory information attributes in Drug Registry.

4. Other Data sources – Jan Aushadhi (PMBJP), NLEM, AMRIT & IPDMS databases

These data sources may be taken as a reference for the removal of any duplicate information or missing data or any new drug data in the future.

Integrated Pharmaceutical Database Management System (IPDMS) of National Pharmaceutical Pricing Authority (NPPA) is used in fixation & price revision in respect to scheduled drugs, price fixation in respect of new drugs, monitoring the production and availability of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulations, and monitoring the prices of non-scheduled formulations.

Jan Aushadhi (PMBJP) list of medicines contains information on drugs sold through various Jan Aushadhi Kendra across India. The list may be used as a reference for generics available in the Indian Market.

The National List of Essential Medicines (NLEM) is one of the key instruments in the balanced healthcare delivery system of a country which inter alia includes accessible, affordable quality medicine at all the primary, secondary, tertiary levels of healthcare.

Affordable Medicines and Reliable Implants for Treatment (AMRIT) programme aims to reduce the expenditure incurred by patients on the treatment of cancer and heart diseases. The AMRIT list provides cancer and cardiovascular drugs and cardiac implants at very affordable prices.

5. Pharmaceutical companies or drug manufacturers

The pharmaceutical companies are the primary owners of all the information on the branded drugs and their stock-keeping units (SKUs) manufactured by them. The DIAT enables pharmaceutical companies to register into the tool and enter all the details of their drug brands and their SKUs.

6. Other organizations

Various organizations, for instance, hospitals, e-pharmacies maintain their drug database for purposes such as prescription, dispensing, etc. The drug registry will invite data contributions from these organizations for the initial population of the drug registry. The interested organizations will be required to submit data to National Health Authority in a pre-specified format. The data then will be uploaded to DIAT via bulk import functionality. As the data is coming from unregulated sources, certification by manufacturers or verification by the regulator will be required to publish the data in the drug registry.

5.9 Distribution of data

The Drug Registry shall be made accessible to the general public along with ecosystem stakeholders such as regulators, consumers, tech solution providers, hospitals, pharmacies, pharmaceutical companies, etc. The access can be provided via either external APIs to link drug databases with tech solutions (HMIS, EMR, Inventory Management System, etc.) or a public web portal for open access to information in the drug registry. Data consumers can create separate layers based on the data provided by the drug registry to take out any new inference as per their requirements.

The details of external APIs and public web portals are yet to be defined in detail. NHA may release a separate consultation paper to seek comments on the design of the same.

5.10 Questions for consultation

5.10.1 Are there any other drug data attributes that should be covered under Drug Registry? If yes, please provide the list and mention the description and example of the attribute.

5.10.2 Are there any alternate drug terminology standards and codes that should be considered for adoption in Drug Registry? If yes, please provide details and reasons to choose them over currently proposed standards.

5.10.3 As discussed in 5.5, are the proposed up-keeping and update approach is appropriate? Is there any other approach that need to consider?

5.10.4 As discussed in 5.6, is there any other user type that should be provided access to Drug Information Authoring Tool? Are there any other functionalities that should be provided in Drug Information Authoring Tool? Please provide details.

5.10.5 Are there any other data sources that can be referred to populate data in Drug Registry? If yes, please provide details.

5.10.6 As discussed in 5.6, are the proposed modes and conditions for data certification appropriate? Are there any other rules, regulations, or operational challenges that should be considered? Please provide details.

5.10.7 As discussed in 5.6, apart from regulatory bodies (CDSCO, State Licensing Authorities), are there any other bodies that should be considered for conducting data verification? Please provide details.

5.10.8 Are there any other modes of data distribution that should be considered to provide access to the Drug Registry? If yes, please provide details.

5.10.9 It has been proposed to populate the drug registry primarily based on self certification. What are the possible risks for this approach and what could be some mitigation strategies in relation to the self-certification approach? Are there any other modes of populating the drug registry that should be considered? if yes, provide details.

5.10.10 Should there be timely updates and certification of the drug by the manufacturer, or one-time verification is sufficient? please suggest an SOP in this regard.

5.10.11 Should certification of drug be a periodic process or onetime certification is sufficient? please suggest SOP in this regard.

5.10.12 Should Certification be carried out every time any change is made in the drug information, or it should be self-certified for the subsequent changes? please suggest a SOP in this regard.

Appendix I: List of Questions

This appendix summaries all the questions for consultation raised in this consultation paper for ready reference

Chapter 2

1. As discussed in Section 2.2, are there other international case studies or best practices that should be studied to inform the design of the Drug Registry?
    1. Which best practices should be adopted from these international models?
    2. How do we tailor these best practices for the Indian context?

2. Countries like Sweden have included preferential consumables such as ostomy products and foods for special nutrition for children under 16 years of age in the drug registry. Should there be the inclusion of preferential consumables or any other category in the drug registry? Please give reasons for the same.

Chapter 3

1. In addition to potential benefits/risks discussed in Chapter 3, please suggest any other stakeholder(s) for consideration of benefits and risks. Please provide any additional benefits/risks that would be relevant for various stakeholders to participate in Drug Registry.

2. For the risks mentioned in section 3.2 and the ones provided as an answer to the question above, please provide details on possible mitigating measures that may be taken to minimize the impact of said risks.

Chapter 4

1. As discussed in 4.2, is this the right conceptual framework to build Drug Registry? Are there other potential models or approaches that can be considered? Please provide details.

2. As discussed in 4.3, is the proposed model for data entry appropriate? Are there other modes of data entry to be considered? Please provide details.

Chapter 5

1. Are there any other drug data attributes that should be covered under Drug Registry? If yes, please provide the list and mention the description and example of the attribute.

2. Are there any alternate drug terminology standards and codes that should be considered for adoption in Drug Registry? If yes, please provide details and reasons to choose them over currently proposed standards.

3. As discussed in 5.5, are the proposed up-keeping and update approach is appropriate? Is there any other approach that need to consider?

4. As discussed in 5.6, is there any other user type that should be provided access to Drug Information Authoring Tool? Are there any other functionalities that should be provided in Drug Information Authoring Tool? Please provide details.

5. Are there any other data sources that can be referred to populate data in Drug Registry? If yes, please provide details.

6. As discussed in 5.6, are the proposed modes and conditions for data certification appropriate? Are there any other rules, regulations, or operational challenges that should be considered? Please provide details.

7. As discussed in 5.6, apart from regulatory bodies (CDSCO, State Licensing Authorities), are there any other bodies that should be considered for conducting data verification? Please provide details.

8. Are there any other modes of data distribution that should be considered to provide access to the Drug Registry? If yes, please provide details.

9. It has been proposed to populate the drug registry primarily based on self certification. What are the possible risks for this approach and what could be some mitigation strategies in relation to the self-certification approach? Are there any other modes of populating the drug registry that should be considered? if yes, provide details.

10. Should there be timely updates and certification of the drug by the manufacturer, or one-time verification is sufficient? please suggest SOP in this regard.

11. Should certification of drug be a periodic process or onetime certification is sufficient? please suggest SOP in this regard.

12. Should Certification be carried out every time any change is made in the drug information, or it should be self-certified for the subsequent changes? please suggest SOP in this regard.

Appendix II:

2.1 Canada: Drug Product Database

1. Health Canada has the authority and responsibility to authorize drugs for sale in Canada. It evaluates the safety, efficacy, and quality of drugs, and provides an authorization for sale in Canada. After the review, the drug is issued a Notice of Compliance (NOC) as well as a Drug Identification Number (DIN) which permits the sponsor to market the drug in Canada and indicates the drug's official approval in Canada.

2. Intending to increase transparency and accessibility of data, Health Canada maintains the Drug Product Database (DPD) which contains product-specific information on all drug products approved for use in Canada, including human pharmaceutical and biological drugs, veterinary drugs, and disinfectant products. The database covers approximately 23,000 drug products that companies have notified Health Canada as being marketed. +HDOWK &DQDGD¶V 'UXJ ,GHQWLILFDWLRQ 1XPEHUV ',1 labels of prescriptions and over-the-counter drug products.

3. The Drug Product Database is available on the Health Canada Internet Website in the form of several data sets. The users can search the Drug Product Database for drug information including DIN, product name, active ingredients, strength, pharmaceutical form, and route of administration. The database can also be integrated into healthcare information systems in Canada, allowing systems to use the DPD as the basis of their system to provide the most trusted and authoritative drug information to clinicians and support them through every stage of the decision process, increasing safety and accuracy through better-informed patient care.

Further reading link(s):

1. https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html
2. https://www.re3data.org/repository/r3d100012754

2.2 Israel: Israeli Drug Registry

1. The regulatory authority entrusted with pharmaceuticals in Israel is the Ministry of Health (MoH) Pharmaceutical Administration which consists of several bodies under its umbrella to conduct the associated activities. An application to register a medicinal product in Israel must be filed with the MoH Drug Registration Department (Pharmaceutical Division) and this is the national body responsible for maintaining the national drug registry system.

2. The application to list a medical preparation in the Israeli Drug Registry must contain data proving the safety, efficacy, and quality of the preparation. Pharmaceutical Division evaluates drugs for registration, in cooperation with the medical substance standards and auditing institute and publishes the drug into the drug registry upon verification.

3. To increase the transparency and competition among pharmaceuticals and provide information for consumers to enable them to make wiser decisions regarding choice of drug type, price, and purchase, the MoH has created a website for the Israeli Drug Registry.

4. The Israeli Drug Registry website consists of all commercial pharmaceutical products and the terms of registration, including the commercial name, the manufacturer, the active LQJUHGLHQWV GRVH LQGLFDWLRQV WKHUDSHXWLF FODVV packaging and an updated medication price. It includes additional information items such as information regarding gluten-free medications. The website is updated every month and is widely used by patients, health care professionals and the general public. Future development is aimed at addressing the issue of generic substitution, information regarding optional actions (such as medication grinding), as well as images of all registered drugs.

Further reading link(s):

1. https://pubmed.ncbi.nlm.nih.gov/15270477/
2. https://www.hspm.org/countries/israel25062012/livinghit.aspx?Section=5.6%20Pharmaceutical%20care&Type=Section
3. https://israeldrugs.health.gov.il/#!/byDrug
4. https://www.gov.il/en/service/israeli-drug-index

2.3 Turkey: Ilaç Takip Sistemi (ITS)

1. Affiliated with the Ministry of Health in 2012, the Turkish Medicines and Medical Devices Agency (TITCK) is the governmental regulatory authority responsible for the regulation, evaluation, inspection, control and monitoring of human medicinal products in Turkey. In 2012, Turkey became the first country in the world to implement a full track and trace system to secure its domestic pharmaceutical supply chain. This project was financed and managed by WKH 7ø7&.

2. The main drivers for implementing the pharmaceutical track and trace system in Turkey centered on the elimination of reimbursement fraud and the prevention of falsified medicine in the regulated supply chain. Before the introduction of the pharmaceutical track and trace system, quality assurance of medical products was mainly based on market surveillance and inspections. This largely reactive system was time and resource intensive.

3. The implementation of the pharmaceutical track and trace system in Turkey (i.e., Ilaç Takip Sistemi (ITS)) took place in 2 phases. The phase 1 system corresponded to a point-of-dispense check system that validates medicine packages at the points where they are dispensed to patients (e.g., pharmacy or hospital) with the code assigned during the manufacturing process. This system allows for verifying the authenticity of the product, but not for tracking

4. the product throughout the supply chain. Phase 2, implemented in 2012, corresponded to full track and trace that cross-checks movements of a product between each actor within the domestic regulated supply chain.

5. The pharmaceutical track and trace system in Turkey was a successful implementation both in terms of industry adoption and realization of intended outcomes. The system, currently used by 40,000 active stakeholders and tracks over 10 billion drug units with a response time of fewer than 0.2 seconds, enabled a clean regulated supply chain, minimized reimbursement fraud, and facilitated fast market recalls. A mobile application of ITS was launched in 2014 that allows citizens to scan the DataMatrix code of products. Citizens can immediately check the legitimacy of the product and obtain additional information, such as the expiry date, price and recall status.

Further reading link(s):
1. https://www.its.gov.tr/
2. https://its.technarts.com/events.php?Id=172&lang=en

2.4 Sweden: The prescribed drug register

1. The Prescribed Drug Register was established in July 2005 and is maintained by the Swedish National Board of Health and Welfare. It contains data on all prescribed drugs dispensed at pharmacies in Sweden. The drug register is regulated in the Ordinance (2005: 363) on drug registers at the National Board of Health and Welfare and in the Act (1996: 1156) on prescription registers. These regulate what information may be in the register as well as the e-health authority's obligation to provide information to it. The Prescribed Drug Register is a health data register and is also regulated in the Health Data Register Act (1998: 543).

2. The purpose of the Prescribed Drug Register is to increase patient safety in the field of medicines. The register is used by researchers, journalists, investigators within county councils and authorities as well as by representatives from the pharmaceutical industry. Increased knowledge about the effects and safety of different drugs can in the long run be beneficial for each patient.

3. The Prescribed Drug Register contains all medicines that are collected against prescriptions at pharmacies, but also information on collected preferential consumables, such as ostomy products and foods for special nutrition for children under 16 years of age. The number of entries in the register is just over 100 million per year.

4. The register contains information about the patient (gender, age, place of registration), the product (e.g., ATC code, drug name, strength, pack size), the prescription (for example, the prescribed quantity, the date of the prescription and the date when the goods were picked up), costs (county council cost and deductible), characteristics of the workplace where the prescription took place (for example, business orientation) and what profession and specialist training the prescriber has.

6. All data in the drug register comes from the E-health authority. All retailers that sell medicines have an obligation to report sales information to the E-health authority. In addition, pharmacies must provide additional information to the E-health authority when a prescribed medicine is dispensed. The e-health authority, in turn, submits information on prescription dispensations to the National Board of Health and Welfare.

Further reading link(s):

1. https://www.socialstyrelsen.se/en/statistics-and-data/registers/register-information/the-swedish-prescribed-drug-register/
2. https://pubmed.ncbi.nlm.nih.gov/16897791/

2.5 The United States of America: NDC Directory & DSCSA track and trace

1. The United States Food and Drug Administration (FDA) is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs. For this purpose, a comprehensive list of drug products needs to be maintained that supports a variety of compliance activities and health initiatives at the FDA including recalls of dangerous or tainted drugs, bioterrorism response, drug importation and barcoding of drug products.

2. The Drug Listing Act of 1972 requires drug firms to list with FDA prescription drug products manufactured, prepared, propagated, compounded, or processed by them for commercial distribution. The drug products are then uniquely identified and reported using a three-segment number, called the National Drug Code (NDC). FDA publishes the listed NDC numbers in the NDC Directory which is updated daily. However, the accuracy of the listing data is the responsibility of the company submitting the information to the FDA. This drug product listing process and lack of oversight contribute to deficiencies in the Directory.

3. NDC is widely used in the healthcare industry in the US for unique identification in prescribing, dispensing, reimbursement, safety, clinical management, supply chain management, and pharmaceutical manufacturing and labeling systems. However, National 'UXJ &RGH LQ VWDQGDORQH IRUPDW GRHVQ¶W SURWHFW FRQVXPHU¶V H[SRVXUH WR FRXQWHUIHLW FRQWDPLQDWH

4. For this purpose, FDA introduced Drug Supply Chain Security Act (DSCSA) in November 2013 to build an electronic, interoperable system to identify and trace certain prescription drugs over 10 years. As part of the DSCSA, manufacturers, and re-packagers are required to put a product identifier on drug packages. This includes the product's national drug code (NDC), serial number, lot number and expiration date on each package in human- and machine-readable form.

5. The DSCSA aims to accomplish at least 3 goals by the Year 2023. First, the system should allow for verification of the legitimacy of a drug product down to the package level. This leads to the second proposed accomplishment of this act: illegitimate products in the drug supply chain should be easily detectable. Finally, the system should aid in a more successful drug recall situation.

Further reading link(s):

1. https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory
2. https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

Appendix III: Regulatory Framework in the Indian Pharmaceutical Industry

Sr. No.	Name ofthe Act / Regulation / Law
1.	'UXJV &RQWUROOHU *HQHUDO RI ,QGLD 3'& Ministry of Health and Family Welfare
2.	Drugs and Cosmetics Act, 1940
3.	Drugs Rules, 1945
4.	Drug Prices Control Order, 1995
5.	Central Drug Standards and Control Organization (CDSCO)
6.	