# TCHEALTH

# IMPROVING THE QUALITY AND ACCESSIBILITY OF HEALTHCARE SERVICES PROJECT's CONCEPT DOCUMENT

**Scope and vision of an e-Health Transformation Project**

The ultimate goal of the e-health transformation project is to strengthen public governance over pharmaceutical and medical device market as well as over medical services provided by medical organizations. The governance over market shall lever a baseline for designing more effective healthcare reimbursement system while controlling the total healthcare expenditures associated with drug and medical device. The goal will be achieved by deploying national databases that enable more measurable, accountable, transparent, controlled and competitive market dynamics.

Depending on the Turkey's experience as a model for effective national health reform, a visionary roadmap and segregated the project stages based on priorities identified from the best practices can be defined as shown in Figure 1. The foreseen period of such a project will be to between four to six years as illustrated at Figure-1 with potential budget of 10 to 15 million USD.

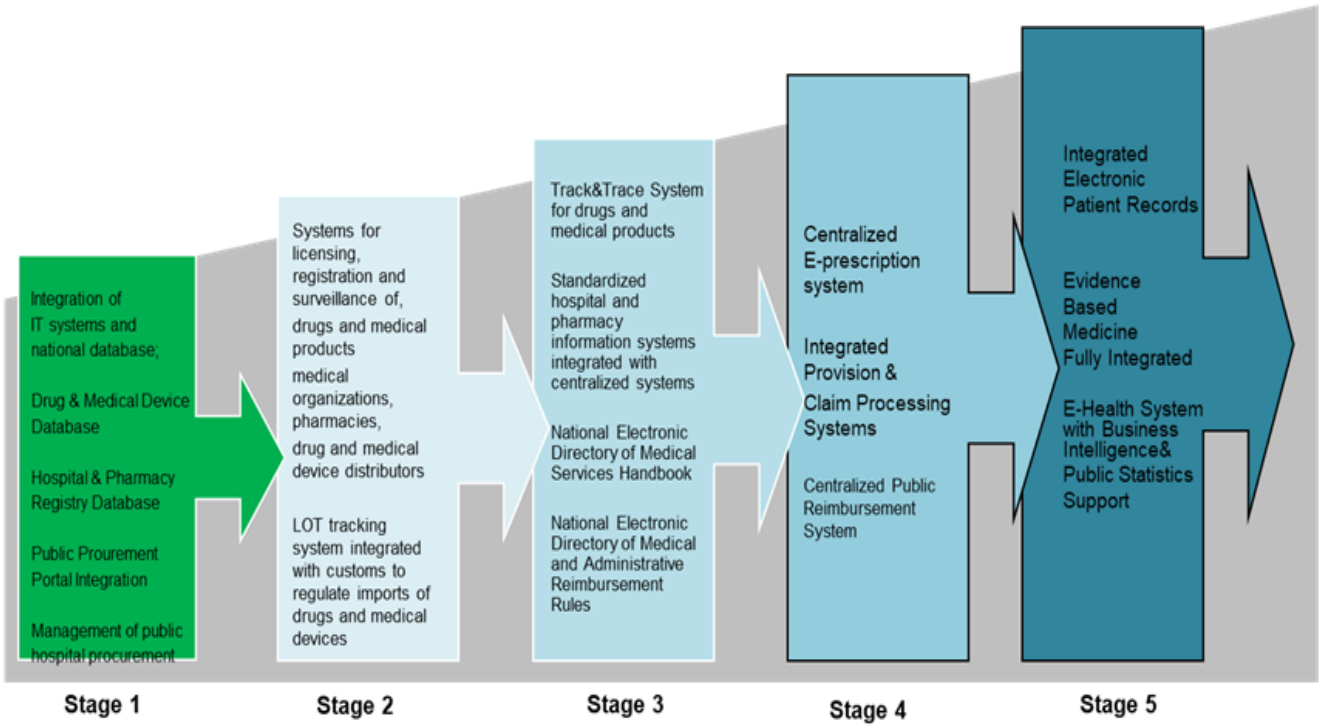


Figure 1. e-Health Transformation Visionary Roadmap

The goal of the e-health transformation project is to strengthen public governance over pharmaceutical and medical device market as well as over medical services provided by medical organizations. The goal will be achieved by deploying a national e-health information systems framework (Figure 2) that enables more measurable, accountable, transparent, controlled and fair health system governance.

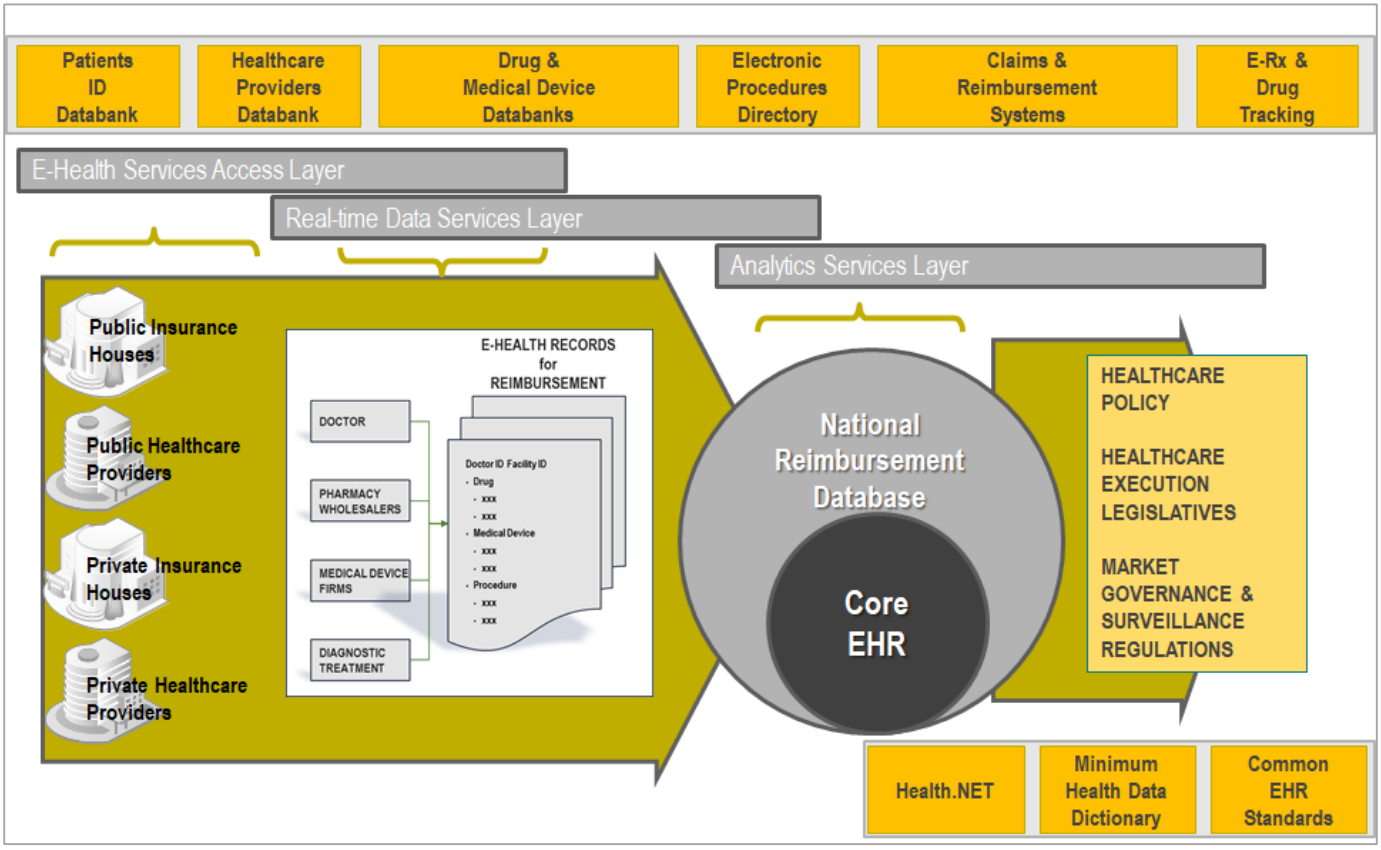


Figure 2. National e-Health Information Systems Framework

The success of the system requires strong commitment from the public authority. Before commencing any project activities, a formal consensus protocol must be signed by the project stakeholders We assume that the stakeholders will include Prime Ministry MOH, MOF, and NHIF. The protocol will include procedures for making necessary amendments to current legislation and publishing official notices for implementing the reform. Such a project could be implemented in two stages with complementary targets tied for each stage.

## Stage 1 : National Drug and Devices Database e trade system

## Stage 1.1. NDDB establishment

The first stage will directly target the establishment of a national **Drug and Medical Devices e-Trade Information System.** (Figure. 3) The major outcomes of the first stage will be:

- Drug and medical device retail prices will decrease due to strong public governance
- Subsequently, effectiveness of national funds spent to drug and medical device expenditures will be improved.
- Standardized and uniquely identified product databases will constitute a common language between stakeholders
- Drug and medical device retail prices will decrease due to increased competition
- The drug transactions will be monitored over pharmacies for better market surveillance

- Citizens will favorably access drug and medical devices with competitive prices thus resulting a positive impact on out-of-pocket healthcare expenses.
- Unscrupulous suppliers will be eliminated from market

The components of the system will include:

- **A centralized Drug and Medical Devices Management Information System**

- Enabling a management of all workflows associated with drug and medical devices in the country from custom clearance to registration, from tracking to market surveillance and up to procurement and reimbursement stages electronically.
- Providing a national records database for drug and medical device suppliers/ distributors
- Providing a national records database for healthcare Service providers (hospitals, physicians, pharmacies)

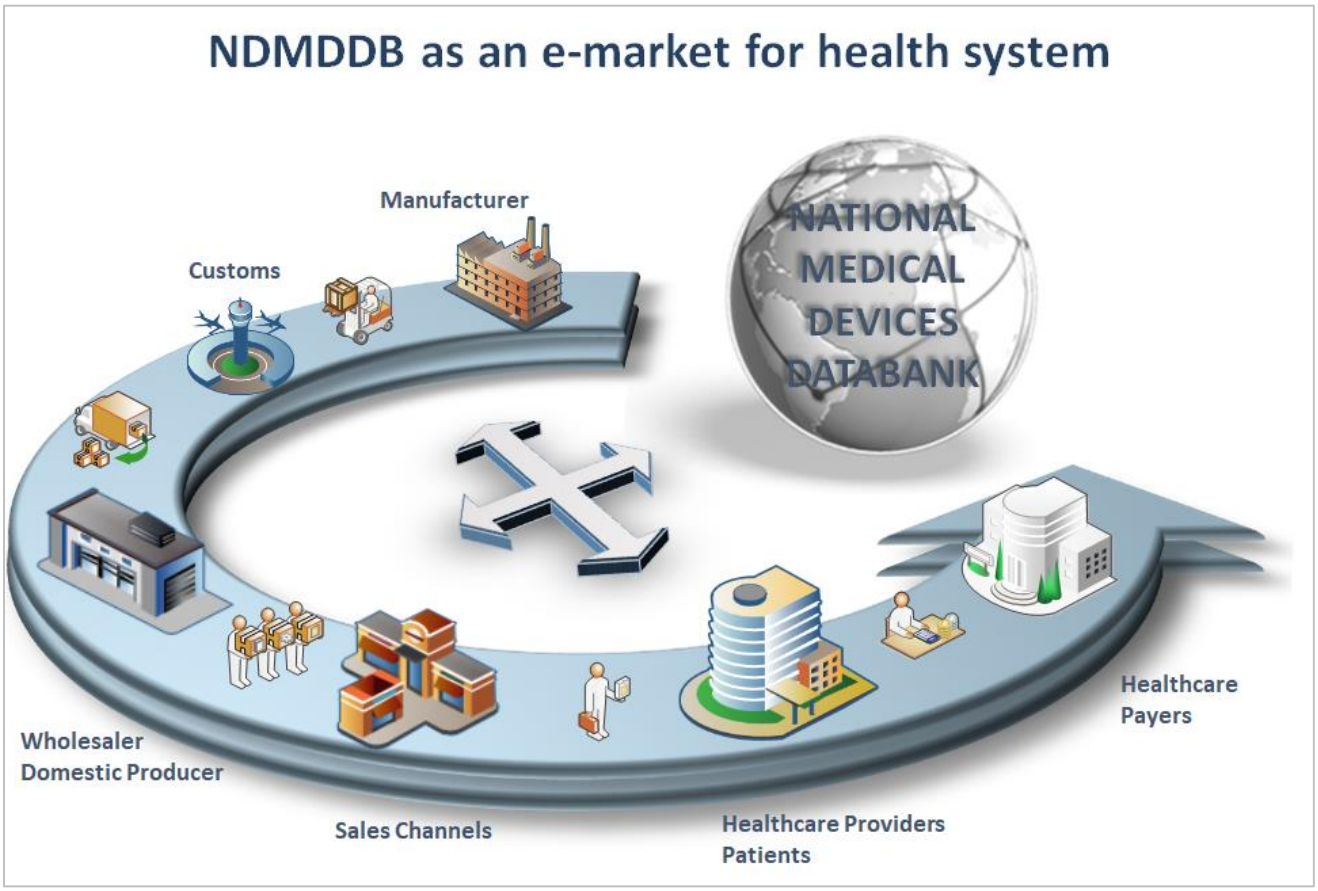


Figure 3. Concept Diagram of Drug and Medical Devices e Trade Information System

## Stage 1.2 A centralized Public Healthcare Drug/Medical e-Procurement Platform

- Enabling infrastructure systems necessary for transparency in the procurement processes of drug and medical device of public healthcare institutions.
- Enabling the collection of procurement data (vendor, prices, and volume) and providing statistical data services to all public healthcare entities for monitoring price levels as an objective negotiation basis with vendors.

- Enabling tracking functions over public procurement for creating transparency and promoting a fair competition among suppliers. (Figure 4)

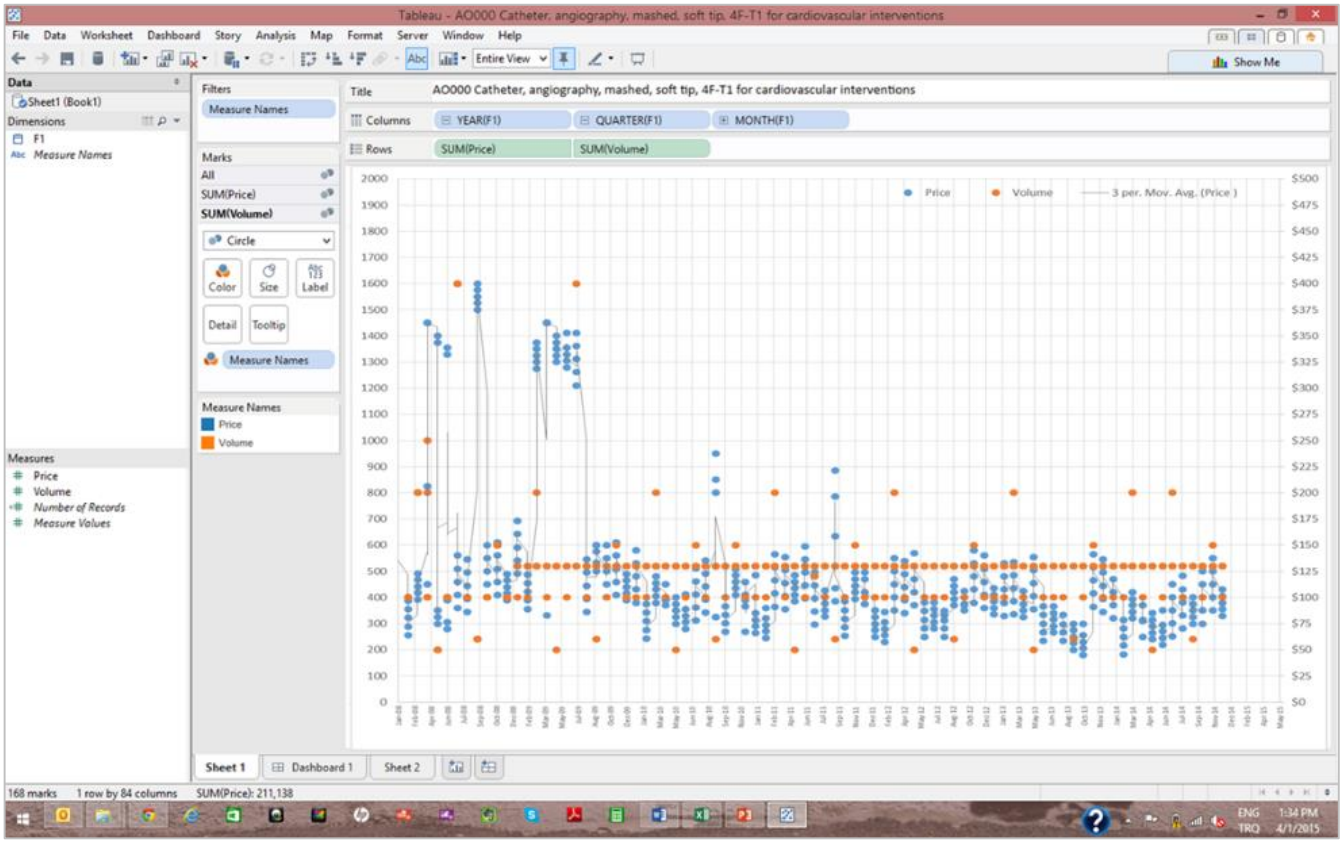

Figure 4. A sample data mining report screenshot illustrating the price/volume fluctuations

## Stage 1.2 Centralized Public Claim Processing System

- Enabling the management of claim and reimbursement activities of public authority (MoH or NHIF) for payments of drugs, orthoses/prosthesis and optics to citizens electronically. (Figure. 5)
- Enabling the management of eligibility of citizens based on their contribution to mandatory social health insurance regime,
- Enabling the management of claim payment to healthcare service providers
- Enabling the design, implementation and monitoring of reimbursement rules based national social insurance policies.
- Enabling the design, implementation and monitoring of services contracts between healthcare service providers and public authority.

## Stage 1.3 Centralized Pharmacy Retail Data Collection System

- Enabling the price and drug transaction data collection from pharmacies for tracking price levels and drug consumption
- Citizens/Doctor portal for accessing best drug price and pharmacy location
- Enables increasing competition in retail pharma. This is accomplished by publishing current prices from pharmacies to a site available to doctors and patients.

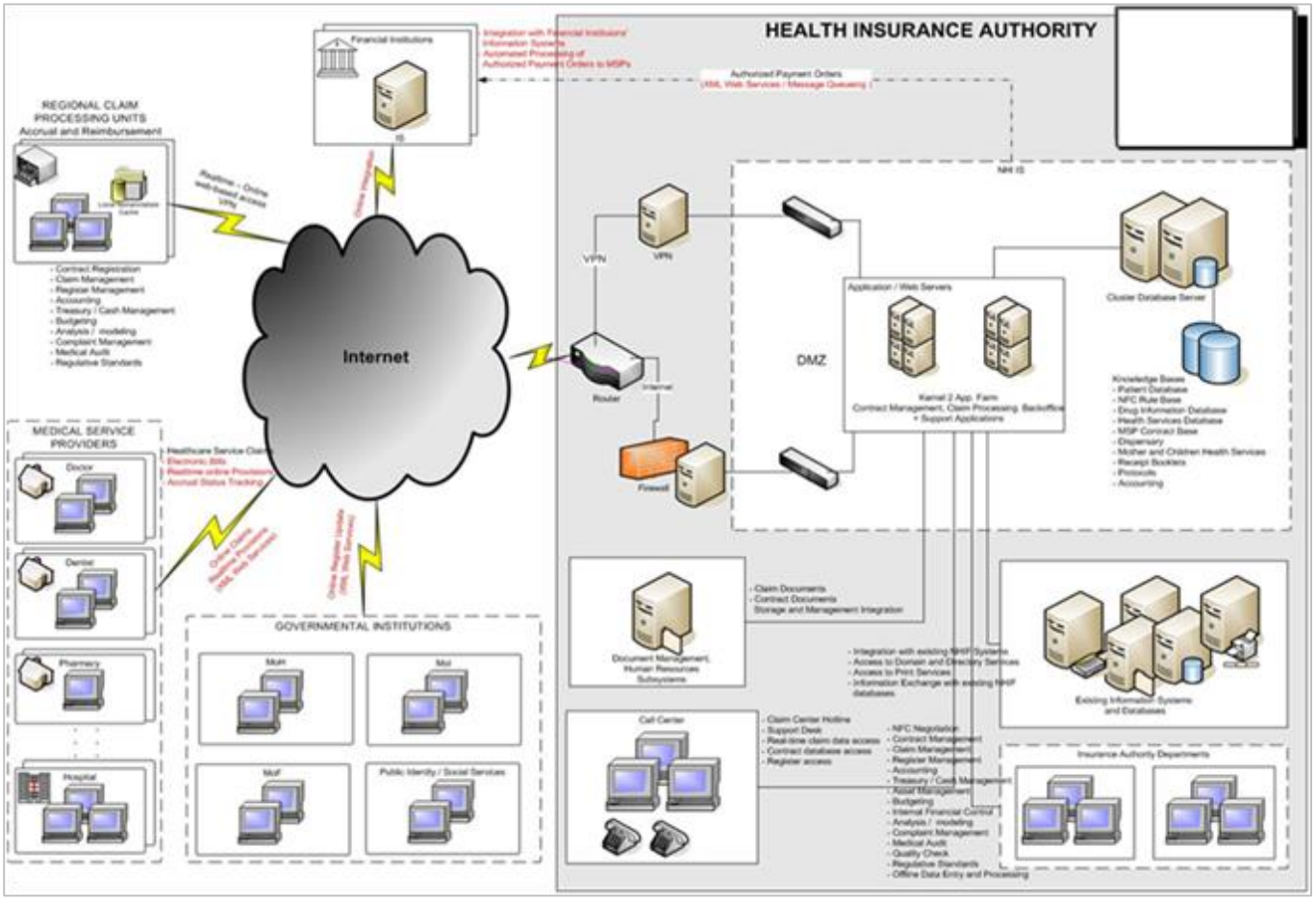


Figure 5. Concept diagram for public reimbursement system

## STAGE 2 - PUBLIC HEALTHCARE REIMBURSEMENT SYSTEM

The second stage will aim to the design a national **Public Healthcare Reimbursement and Budgeting System.** The system will be cover the implementation of infrastructure development of public reimbursement (design of National Electronic Directory of Medical Services Handbook and National Electronic Directory of Medical and Administrative Reimbursement Rules), to establish physicians database and implement e-prescription system. The major outcomes of the second stage will be:

- Total public healthcare expenditures growth will significantly slow due to strong public governance
- The effectiveness of national funds spent to healthcare will be improved while improving quality of service.
- Standardized administrative and medical rules baseline for reimbursement will contribute to more effective control over costs by public healthcare providers.
- Public authorities will be informed about healthcare costs transparently therefore will compare their activities with respect to national benchmarks.
- The healthcare services will be monitored over healthcare providers for better market surveillance.
- Fraud will be significantly decreased.

The components of the system will be defined as:

- **A National Directory of Medical Services Handbook**

- Establishing a national directory of medical services handbook as a common management instrument. The directory includes all relative values of medical services.
- Design of an overall architecture for the health sector and the specific contribution mechanisms; trends in absolute and relative levels of public, private, external, and total health expenditures

- **A National Electronic Directory of Medical and Administrative Reimbursement Rules**

- Establishing a system managing medical and administrative rules to prevent excess utilization and billing of diagnostic procedures as defined in medical services handbook
- Design of explicit rules on patient cost-sharing (e.g. user fees), exemptions for certain population groups or services, and services not covered from prepaid funds

- **A Centralized Public Reimbursement System**

- Establishing a public reimbursement system for payment of healthcare services (Hospitals, Polyclinics, together with the other payment categories such as pharmaceuticals, orthosis, prosthesis and medical supplies) as defined in handbook.
- Design of resource allocation rules, including details of how funds flow differently, in terms of amounts, across geographical locations and health facilities (hospitals, health centers and clinics)
- Design of purchasing arrangements, such as the specific payment mechanisms, the number of purchasers, information systems and governance arrangements for purchasing, and the incentive environment created for providers
- Establishing a unified accounting system to public healthcare providers for collecting cost and transactional data from their activities for supporting their cost control with more transparent and comparative tools.
- Establishing a budgeting system that will reallocate budgets of healthcare organizations from less efficient to more efficient, thus encouraging the provision of quality health care based on their cost performance.
- Design of public financial management rules and systems, including how funds are planned and budgeted, transferred, used, reported on and controlled

- **Centralized e-Prescription System**

- Establishing an e-prescription that will enable the registration, execution and electronic cancellation of prescriptions and maintain a register of all authorized medicines in the country regardless of financing and payment of medication.

**A SAMPLE REQUIREMENTS SET for BASE STAGE I**

**of the CONCEPT can be found in the attachment.**

**FUNCTIONAL REQUIREMENTS**

1.1. General Requirements

1.1.1. The NDDB will have the below functional modules that are supporting the business processes within the contractual scope.

| **Module** | |
|---|---|
| **Key Functions** | **Business process supported** |
| **Account Management** | |
| Controlling access to all modules and functions of NDDB | |
| **Master Data Management** | |
| Providing uniform and consistent set of master data referenced by transactions in all other modules | Master data management<br>• Drug registration office supports master data for drugs and medical products and industry-specific classifications through drug registration process<br>• Center for eHealth maintains master data for medical organizations, doctors, pharmacists, pharmacies, distributors<br>• The registers are also available for public access (anyone can view current drugs registered in the country, current list of pharmacies etc) |
| **Purchasing Management** | |
| • Planning drug purchasing drugs by medical organizations<br>• Preparation of purchasing orders by medical organizations<br>• Preparation of bids by suppliers<br>• Registration of results of purchasing (accepted bids) | • Formulary management<br>• Purchasing planning<br>• Purchase order preparation<br>• Bid preparation by pharmaceutical suppliers<br>• Bid acceptance |
| **Reporting** | |
| Reporting and analysis of transactional data on drug product | Purchasing data analysis |

1.1.2. The NDDB will have external interfaces to external systems summarized below.

| External System | Interface Description |
|---|---|
| Drug registration system (managed by the Drug Registration Office) | Master data for drugs and medical products |
| Government procurement portal (http:/zakupki.gov.kg) | Purchase orders prepared in NDDB |
| | Bids prepared in NDDB |
| | Data on accepted bids and contracts |
| Population register (not in current scope) | Confirmation of patient's identity and status of benefits through a request/response |
| eGovernment services catalog (Tunduk) | Publish NDDB functions in the eGovernment catalog according to specifications from Committee of Information Technologies |

1.2. Account Management

1.2.1. Access control is realized through the use of accounts i.e an entity used for managing access to system functions.
1.2.2. All functions must be called on behalf of an account.
1.2.3. NDDB must provide several types of accounts:
1.2.4. Superuser (system administrator) account to manage all other accounts
1.2.5. System accounts to manage system services and to interact with external systems
1.2.6. User accounts to access business functions. User accounts must be of two types:
- Organization administrator
- Organization user

1.2.7. Anonymous or guest account for access to publicly available functions
1.2.8. Account data (except anonymous) must be sufficient to identify a user and/or organization to which it belongs.
1.2.9. Account functionality must provide login through the following methods:
- authentication through login name and password
- two-step authentication (configurable by user) through login name, password and confirmation via e-mail
- authentication through combination of login name, password and digital certificate, provided by authorized organization.

1.2.10. System administrator must only have access with name, password and digital certificate.
1.2.11. Account rights management must provide for granting and revoking rights to system functions and access to data (Create, Read, Update, and Delete). Standard user profiles (combination of rights) must be configurable.
1.2.12. Access to data must have granularity at user(owner)/group (organization)/others level.
1.2.13. List of rights must be extensible, i.e. the system administrator must be able to add access rights to new functions.
1.2.14. There must be only one administrator account for each organization. A user with this account must be able to create user accounts and manage rights within its own organization.
1.2.15. All changes in accounts and access rights must be logged.

1.3. Master Data Management

1.3.1. General Requirements for Master Data Management

- access to the each of the registers must be restricted by access rights: reading, creating, changing, deleting;
- a user-friendly interface must be provided for viewing/editing registry records;
- registries of organizations (hospitals, pharmacies etc.) must have capability to restrict or allow access to any data field, so that an organization can maintain part of its own record;
- NDDB must provide capability to add new fields to registry records for any type of master data;
- registry records must be uploadable and downloadable to/from external files in eXtensible Markup Language (XML) and Microsoft Excel formats. Access to loading functions shall be regulated through rights management;
- all changes in registries' records must be logged.

1.3.2. Master data management for drugs (Drug registry)

1.3.2.1. NDDB must have a primary product record which is capable enough to uniquely identify each drug (pharmaceutical item).

1.3.2.2. The product record must provide a standard data set capable of storing the structured data.

1.3.2.3. The structured data must contain the groupings according to the international classifications listed, namely:

- International Nonproprietary Names (INN) in English and Russian aligned with official WHO (World Health Organization) INN registry
- Anatomic Therapeutic Chemical Classification (ATC) in English and Russian aligned with WHO (World Health Organization) collaborating center in Norway at http: /www.whocc.no
- New Form Code (NFC) provided by EphMRA (Europian pharmaceutical market research association) (available at http://www.ephmra.org/New-Form-Codes-Classification) in English and Russian
- Drug Dose Measurement Units (WHO-DDMU) provided by Norway WHO (World Health Organization) collaborating center in English and Russian

1.3.2.4. The product record must have the following data at a minimum

- Global Trade Identification Number (GTIN) code of the product
- Trade (Brand) name
- International nonproprietary name
- Classification code from government procurement portal classification
- Anatomic Therapeutic Chemical Classification code
- New Form Code
- Drug form name as stated by the manufacturer
- Standard dosage/strength
- Dosage/strength as stated by the manufacturer
- Drug form unit
- Quantity of drug form units in primary packaging
- Quantity of drug form units in secondary packaging
- Manufacturer
- Country of origin
- Registering organization
- Registration number

- Registration id (license number)
- Essential drug (included in the Ministry of Healthcare list of essential drugs)
- Controlled substance (included in the list of controlled substances)

1.3.2.5. At project acceptance the drug registry must contain records for all drugs officially registered in Country as of acceptance date.

1.3.2.6. Master data entry or changes in master data for drugs must be available in two modes:

- automatic: by downloading drug registration records through interface to drug registration system managed by Drug Registration Office (see interface specification in interface description section)
- manual: direct entry or correction of master data by an authorized user

1.3.2.7. A web service for drug search must be provided. Search must be available by:

- Global Trade Identification Number (GTIN) code of the drug
- free text which fits all or part of international nonproprietary name or synonyms, trade name or class name of anatomic therapeutic chemical class
- similar drug (same anatomic therapeutic chemical class code or international nonproprietary name and same or close drug form)

1.3.3. Master data management for medical products (Product registry)

1.3.3.1. NDDB must have a primary medical product record, which is enough to uniquely identify each medical product item.

1.3.3.2. The product record must provide a standard data set capable of storing the structured data.

1.3.3.3. The structured data must contain the grouping according to Global Medical Device Nomenclature (GMDN) classification. Ministry of Health will provide this international classification.

1.3.3.4. The product record must at a minimum provide the following data

- Global Trade Identification Number (GTIN) code of the product
- Trade (brand) name,
- Generic (product class) name
- Global Medical Device Nomenclature (GMDN) code
- Classification code from government procurement portal classification
- Quantity of units in primary packaging
- Quantity of units in secondary packaging
- Manufacturer
- Country of origin
- Registering organization
- Registration number
- Registration expiration

1.3.3.5. At project acceptance the medical product registry must contain records for all medical products officially registered in Country as of acceptance date.

1.3.3.6. Master data entry or changes in master data for medical products must be available in two modes:

- automatic: by downloading medical product registration records through interface to drug registration system managed by Drug Registration Office (see interface specification in interface description section)
- manual: direct entry or correction of master data by an authorized user

1.3.3.7. A web service for medical product search must be provided. Search must be available by:

- Global Trade Identification Number (GTIN) code
- free text which fits all or part of trade name or Global Medical Device Nomenclature class name
- similar products (by Global Medical Device Nomenclature code)

1.3.4. Master data management for medical organizations (hospital registry)

1.3.4.1. The hospital registry must contain information on all hospitals, policlinics, physician practices, diagnostic centers and other medical institutions in Country, both public and private. The product record must at a minimum provide the following data

- National Unique Identifier
- Name
- Address (-es)
- Organization type, such as hospital, policlinic, diagnostic center etc.
- Ownership (public or private)
- Contact data (phones, emails, etc.)
- Medical specialties
- List of management (general manager and deputies)
- Taxpayer ID
- Practice id (for practice offices that are part of larger medical organizations)
- Organization id from the government procurement portal
- License Number (for private organizations)
- License Dates (for private organizations)

1.3.4.2. The hospital registry must support:

- search of medical organization by name or part of, address, medical specialty
- application for a license or a change in organization data (online)
- printing out the required application forms prefilled with data entered by the organization
- checking application status

1.3.5. Master data management for distributors of drugs and medical products

1.3.5.1. Registry of distributors provides master data for all companies licensed to distribute pharmaceuticals and medical products in Country. At least the following data must be contained in the registry:

- Unique organization id
- Name
- Address(-es)
- Contact data (phones, emails, etc.)
- List of management personnel (general manager and deputies)
- Taxpayer ID
- Organization id from the Government procurement portal
- Contact information
- License Number

- License Dates

1.3.5.2. The distributor registry must support:

- search of distributors by name or part of name
- application for a license or a change in organization data (online)
- printing out the required application forms prefilled with data entered by the organization
- checking application status

1.3.6. Master data management for pharmacies (pharmacy register)

1.3.6.1. Registry of pharmacies provides master data for all companies licensed for retail sales of drugs and medical products in Country. At least the following data must be contained in the registry:

- Unique organization id
- Name
- Owner of pharmacy (foreign key to distributors' registry or data of the business owner)
- Address(-es)
- Contact data (phones, emails, etc.)
- Data for pharmacy manager, business owner or other person legally responsible for its activities
- Taxpayer ID
- Contact information
- License Number
- License Dates

1.3.6.2. The pharmacy registry must support:

- search of pharmacies by name or part of name or location
- application for a license or a change in organization data (online)
- printing out the required application forms prefilled with data entered by the organization
- checking application status

1.4. Purchasing Management

1.4.1. Preparation of purchasing orders by medical organizations

1.4.1.1. A medical organization must be able to maintain its formulary (by International Non-proprietary Name and drug form for drugs and by medical product) in NDDB. The formulary must be built on drug and medical product master data files described in master data management module.

1.4.1.2. A medical organization must be able to maintain its yearly, quarterly and monthly need for drugs and medical products according to the formulary. NDDB must provide an

estimate of the total amount of purchasing in local currency based on stated quantities and statistical information about prices (when it becomes available in NDDB).

1.4.1.3. A medical organization must be able to maintain a set of default data for purchase orders, including:

- default delivery address
- default delivery terms for residents
- default delivery terms for non-residents
- default delivery period (after signing the contract)
- default documents required (such as registration, quality certificate, etc.)
- standard expiration period (from the delivery date)

1.4.1.4. The purchase order must show to the user a sum for each item as well as grand total for all items in the purchase order.

1.4.1.5. A medical organization must be able to create new purchasing order from old purchasing orders (template-based orders).

1.4.1.6. Changes to purchasing order must be prohibited after it is sent via interface to the government purchasing portal.

1.4.1.7. The module must have functionality for consolidation of purchasing orders from several medical organizations into a single purchase order with quantities broken down by item and medical organization.

1.4.1.8. A comfortable user interface for preparation of purchasing order must be provided. That includes a grid presentation of purchase order items (at least 300 items) with scrolling, sorting, filtering and editing.

1.4.1.9. NDDB must provide an overview of purchasing plan status broken down by organization, formulary items, item quantities and amounts by status: planned, ordered, purchased.

1.4.2. Transfer of order to the government procurement portal

1.4.2.1. Done according to the interface (see description below). After the transfer the purchase order must be marked as transferred, after publication of purchase order on the government procurement portal the order must be marked as available for search.

1.4.3. Preparation of bids by suppliers

1.4.3.1. NDDB must provide search of published (transferred to the government procurement portal and published on the portal) purchase orders by matching:

- brand name (through deriving generic name from brand name via master data)
- generic name (International non-proprietary fro drugs or Global Medical Device Nomenclature class name or common name of medical product) against all line items of published orders.

1.4.3.2. Search results must be listed broken down by organization and provide quantities, starting prices and total amounts.

1.4.3.3. To prepare a bid a supplier must be able to select a purchase order and a line item from the purchase order

1.4.3.4. NDDB must provide a list of product codes and names from the master data that fit the line item, and required quantity (in packages) for each code

1.4.3.5. The supplier must be able to select a product that fits the order and enter a quantity

1.4.3.6. The supplier must be able to insert product codes for each line item of the order, or for some line items.

1.4.3.7. After filling the bid, the supplier must be able to confirm it for transfer to the government procurement portal

1.4.3.8. The supplier will enter the prices at the government procurement portal (as they do now).

1.4.4. Transfer of bids to the government procurement portal

1.4.4.1. NDDB sends confirmed bids to the government procurement portal via an interface.

1.4.5. Registration of results of purchasing (accepted bids)

1.4.5.1. The medical organization registers bid selection results at the government procurement portal. After that the portal transfers them to NDDB according to the interface.

1.5. Interfaces

1.5.1. NDDB must provide interface to the web service of drug registration system maintained by the Drug registration office. NDDB regularly (at configurable intervals) polls the drug registration system for new data available since last receiving records from drug registration. The drug registration system either replies that no new data is available or sends records for newly registered drugs and medical products.

1.5.2. NDDB must provide interface to the web service of the government procurement portal to upload drug order specifications and bids and download bid selection results. Data transfer is performed daily (off peak hours).

1.6. Reporting

1.6.1. NDDB reporting module must provide the following set of reports

1.6.1.1. Drug purchasing

Purchasing of drugs in the reporting period in terms of volume (dosage units) and money, broken down by:

- generic name and drug form
- medical organization
- region

1.6.1.2. Medical product purchasing

Purchasing of medical products in the stated period in terms of volume (dosage units) and money, broken down by:

- Global Medical Device Nomenclature code
- medical organization
- region

1.6.1.3. Market share by supplier

Market shares by suppliers in the stated period in terms of volume (dosage units), money and percentage points, broken down by:

- generic name and drug form for drugs or Global Medical Device Nomenclature code for medical products
- supplier
- region

1.6.1.4. Drug prices

Prices of drugs (per dosage unit) (minimal, maximum, average and median) broken down by:

- generic name and drug form
- period
- region

1.6.1.5. Prices of medical products

Prices of medical products (per usage unit) (minimal, maximum, average and median) broken down by:

- Global Medical Device Nomenclature code
- period
- region

1.6.1.6. Unfulfilled demand

Drug shortages (unfilled drug order positions) in quantities broken down by

generic name and drug form

- period
- region

1.6.1.7. Purchasing of antibiotics

Purchase of antimicrobial drugs by medical organizations in quantities broken down by:

- generic name and drug form
- period
- region

1.6.2. NDDB must provide a set of tools to create other reports from the available transactional data

1.6.3. NDDB users must be able to export reports to eXtensible Markup Language, Microsoft Excel and Portable Document Format formats.

1.6.4. The estimated transaction volume is 10 to 20 million transactions per year. Reporting module must provide generation of the above reports no longer than one hour for each on 3-4 years of data.

1.6.5. Access to reports and report groups must be managed through the common access management layer.

1.7. System Administration and Security Management

1.7.1. NDDB must provide for the following management and administration features:

1.7.1.1. NDDB must provide a reliable mechanism to apply changes in functionality from test environment to production environment

- NDDB must provide functionality to roll back to a previous configuration
- Deployment of changes to NDDB functionality must not interrupt the work of NDDB end users

1.7.1.2. NDDB must provide the following tools

- data on number of user sessions (current and historical):
- report on user activities by period, type of activity, user, organization
- generation of trace logs for diagnostics/debugging
- sending configurable notifications of warnings and errors to system administrator email account
- other diagnostic functions that allow to discover, isolate, diagnose and fix the problem

1.7.1.3. NDDB must provide

- regular scheduled backups for database and production code;
- ability to recover database to a point in time in less than two hours;
- backups must not affect the work of logged users (i.e. online backups).

1.7.1.4. NDDB is intended for work 24 hours seven days a week. System maintenance must not interrupt system availability for end users. The projected transaction volume is 10 to 20 million transactions per year. The system must provide comfortable speed to the end users preparing purchase orders and bids (no more than 5 seconds delay on any end user operation).

1.7.1.5. NDDB must utilize the following security mechanisms:

- Database
  Direct access to tables in the database must be prohibited (excluding database administrator), all calls to database from the application server must utilize either views or stored procedures which must apply appropriate access restrictions.
- Application server
  Must utilize https protocol for access by clients. Client sessions must be managed through encrypted session cookies or through JSON Web Tokens (JWT). User authentication is handled with a login and password, a two-step verification via email must be available. All attempts of unauthorized access must be logged.
- Links to external systems
  Interfaces to external systems must be connected through eGovernment network.

CONCEPT NDDB PROJECT ILLUSTRATION