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Electronic processing of the drug prescription data

- System Description -

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INTRODUCTION

The USAID funded *e-Gov project* and the Ministry of Health of the Republic of Macedonia are designing and creating a software application, which will introduce a system for electronic processing of the drug prescription data (hereinafter **EPDP**) within the Health sector of the Republic of Macedonia.

The implementation of the new prescription forms will improve the:

- monitoring of the consumption of the drugs;
- monitoring of the EBM (Evidence Based Medicine) guided prescribing.

List of Acronyms:

1. Electronic processing of the drug prescription data – **EPDP**
2. Evidence Based Medicine - **EBM**
3. Ministry of Health - **MoH**
4. Health care institutions - **HCI**
5. Health Insurance Fund - **HIF**
6. General Practitioner - **GP**
7. Republic Institute for Health Care – **RIHC**
8. Personal Identification Number – **EMBG**
9. Tax Identification Number - **TIN**

1. STAKEHOLDERS OF THE SYSTEM

The following users are foreseen to use the EPDP:

1.1 Ministry of Health (MoH) – should provide IT supported registration and updating of the Registry of Health care institutions (HCI) and assign unique identifier for each institution, as a basic data for printing of bar code labels. The Ministry should host and maintain the core system for electronic processing of the drug prescription data.

1.2 Drugs Bureau within the MoH– should provide IT supported registration and updating of the Registry of drugs and assign unique identifier for each registered drug. The Drugs Bureau should provide the bar code labels for the drugs.

1.3 Health Insurance Fund (HIF) – should print the bar code labels for the insured persons, which should consist of the EMBG (Personal identification number) of the insured person and his/her health book number. These labels would be tagged on the first page of the health book of the insured persons. The bar codes should be printed only once - at the moment of issuing the health book. The HIF should also provide the bar code labels for the drugs from the positive list paid by the HIF.

1.4 Pharmacies – should make adjustments to the existing IT systems in order to process the new prescription forms (to enable processing of 3 different types of prescriptions) and install bar code readers for the processing of prescriptions. The software application should also enable preparation of periodic or ad-hock reports that should be sent to the MoH and HIF.

1.5 Chamber of Doctors and Chamber of Dentists – both Chambers should provide IT support for registration and updating of pre-defined data (4.1.3). The Chambers should also generate the Identification numbers for the doctors/dentists, which would be responsible for the printing of their own bar code labels.

2. OVERVIEW OF THE PROCESS

This chapter describes briefly the process defined by the Ministry of Health for the monitoring of the prescription and usage of drugs and is intended as a brief background for better understanding of the environment within which the software shall function.

The Ministry of Health is introducing more stringent rules concerning the way prescription forms shall be completed. Additional and extended requirements will also be introduced regarding for which kind of drugs a prescription will be obligatory.

There will be three **types of prescription forms**:

- **White** – used for drugs, not paid by the HIF, that requires a prescription. Data from this prescription form will not be processed at this stage.
- **Blue** – for drugs that are prescribed by a General Practitioner (GP)¹, paid by the HIF;
- **Green** – for drugs that are recommended and filled in by the (sub)specialist and approved by the GP, paid by the HIF;

Each type of the prescription forms would be consisted of three groups of data:

- **Basic data**, completed by the HCI;
- **Data for prescribing the drug**, completed by the doctor²;
- **Data for issuing the drug**, completed by the pharmacy.

The content of the prescription form would differ depending on the type of the prescription form. One part of the data would be inserted manually, and the other part would be tagged with bar code label.

Legend: √ - contains, ∅ - does not contain, × - included, • - not included³

	Data	Type of prescription form					
		White		Blue		Green	
Basic data	Personal Identification number (EMBG) ⁴	√	•	√	×	√	×
	First and Last name of the patient	√	•	√	•	√	•
	Address of the patient	√	•	√	•	√	•
	Patient's health book number	∅		√	×	√	×
	Participation release ⁵	∅		√	×	√	×
	Code of the Health Care Institution → bar code	∅		√	×	√	×
	Stamp of the Health Care Institution	√	•	√	•	√	•

¹ GP - General Practitioner means chosen doctor by the insuree, in primary health care

² The term doctor includes general practitioner and (sub)specialist

³ Describes the need to be processed electronically or not for the purposes of the reports sent by the pharmacies to the HIF and MoH

⁴ For foreign citizens instead of EMBG, date of birth shall be inserted.

⁵ Yes/No – to circle the appropriate sign from the stated options

Data for prescribing the drug	(Sub)specialist I → bar code	∅	∅	√	×		
	Signature of the (sub)specialist	∅	∅	√	•		
	Date of the recommendation	∅	∅	√	×		
	General Practitioner → bar code	∅	√	×	√	×	
	Facsimile of the GP (doctor) ⁶	√	•	√	•	√	•
	Signature of the GP (doctor) ⁷	√	•	√	•	√	•
	Diagnoses ⁸	√	•	√	×	√	×
	Generic name of the prescribed drug	√	•	√	•	√	•
	Date of prescribing the drug	√	•	√	•	√	•
Data for issuing the drug	Code of the Pharmacy	√	×	√	×	√	×
	Drug issued → bar code	√	×	√	×	√	×
	Quantity	√	×	√	×	√	×
	Code of the pharmacist ⁹	√	×	√	×	√	×
	Date of issuing the drug	√	×	√	×	√	×
	Seal of the Pharmacy	√	•	√	•	√	•

This Table describes the content of each type of prescription form and the need of processing the data within the different types of prescription forms.

The dimensions and form of the bar codes shall enable usage of simple bar code readers.

The prescription forms shall be in an A5 format. Only one package of drugs can be prescribed and issued on one prescription form.

For identification of the data within the new prescription forms three categories of **identifiers** (Identification numbers) would be used:

- Regulated by existing legislation (such as EMBG for the patients);
- Adopted according to the international standards and classification (such as ICD-10 for diagnosis);
- Generated by the software application, as listed:
 - **for health care institutions** – issued by the MoH based on the institution's license;
 - **for doctors and dentists** – issued by the Chamber of Doctors and Dentists respectively generated through the licensing procedure;
 - **for registered drugs** – issued by the Drugs Bureau generated through the drug registration procedure;
 - **for the regional offices of the HIF**– (consisted in the first 3 digits of the Health book number of the insured person). This number would be used for marking of the distribution of drugs prescribed on the blue or green prescription forms.

All of the already existing Identifiers would remain the same and would be used as they are.

⁶ Doctor for white prescription, i.e. general practitioner for blue and green prescription forms

⁷ Doctor for white prescription, i.e. general practitioner for blue and green prescription forms

⁸ The diagnosis in the green prescription form is inserted by the (sub)specialist.

⁹ The code of the pharmacist is defined locally, within the frames of the Pharmacy.

Filling in the white prescription form – the drug is prescribed by any doctor. The basic data for the patient, doctor and HCI would be inserted by the HCI of the doctor that prescribes the drug. All the fields must be filled in and the doctor must state the generic and/or commercial name of the drug.

Filling in the blue prescription form – the drug is prescribed by the GP, who inserts personal bar code, facsimile and signature and writes down the diagnoses and generic and/or commercial name of the drug. The basic data would be inserted in the HCI of the GP where the drug is prescribed. Also, the bar code of this HCI would be tagged to the prescription and would be sealed by the respective HCI. After this, the pharmacist would issue the drug and would tag one of the 2 bar codes tagged to the package of the drug to the prescription, which would mean confirmation that the drug was issued. The pharmacist would also put a stamp in the health book of the patient, where the drug is prescribed and would enter the data within the prescription form for the issuing of the drug.

Filling in the green prescription form – the drug is recommended by the (sub)specialist, who enters: the diagnoses, generic and/or commercial name of the drug, personal bar code, facsimile and signature. The GP, who enters personal bar code, facsimile and signature, should approve this prescription. The basic data of the prescription form would be inserted by the HCI of the GP where the drug is prescribed. Also, the bar code of this HCI would be tagged to the prescription and would be sealed by that HCI. After this, the pharmacist would issue the drug and would tag one of the 2 bar codes tagged to the package of the drug to the prescription, which would mean confirmation that the drug was issued. The pharmacist would also put a stamp on the prescribed drug in the health book of the patient and would enter the data within the prescription form for the issuing of the drug.

For bulk and ambulance therapy, the doctor would prescribe the required quantity. The pharmacist would manually write down the code of the issued drugs and would enter the number of delivered packages in the field “quantity”.

3. ICT INFRASTRUCTURE / TECHNICAL SPECIFICATIONS

Ministry of Health uses the following IT equipment and system software:

- Compaq ML 370 Server
2x36GB HDD Raid 1, 512MB RAM
DDS 3 12/24 GB Backup device
Microsoft Windows 2003 Sever/Microsoft Exchange Server
- PC Server
256MB RAM, 40GB HDD
Microsoft Windows 2003 Domain Controller
- PC Server
256MB RAM, 40GB HDD / 80GB HDD in software mirror mode
Microsoft ISA Server Firewall
- The Microsoft SQL 2000 Server is installed on one of the servers.

The above list defines what is used by the Ministry only. The system for electronic processing of drug prescription data has to be fully compatible with the current ICT platform used by the Ministry of Health.

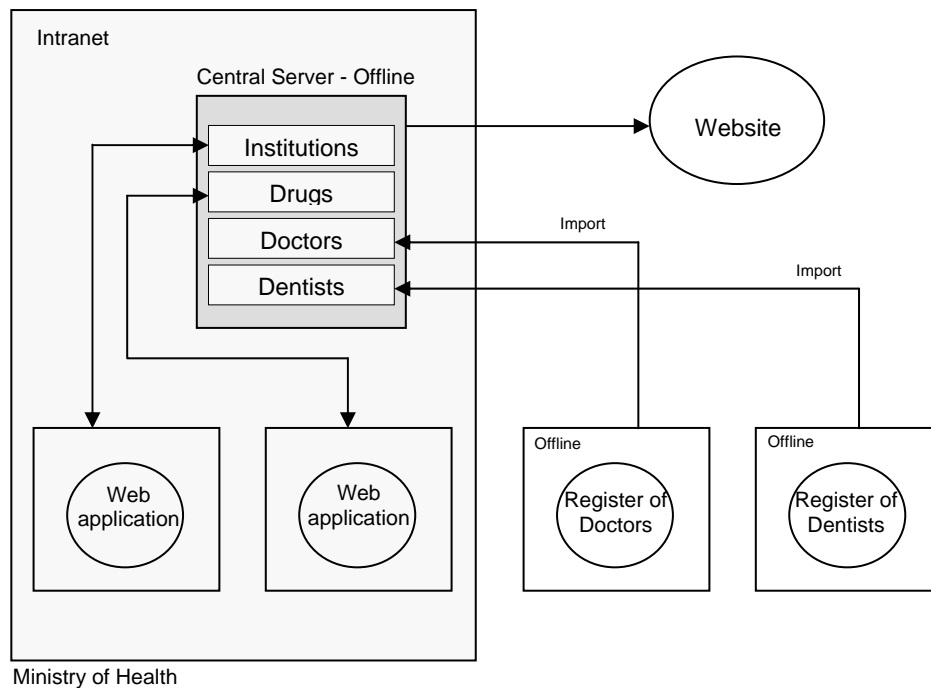
The software application should be able to import data sent from the software applications for maintenance of the registry of Doctors / Dentists installed at the Chamber of Doctors, Chamber of Dentists.

The database should use Unicode representation of the characters to maintain compatibility with the existing data at the stakeholders.

The software developer should import existing data related with the registers of authorized drugs and herbal medicines and the register of Health Care Institutions.

4. SOFTWARE SYSTEM DESCRIPTION

This Chapter describes how the core system shall operate.



The software would be installed on the Central server, located at the Ministry of Health and should be able to import information from the Registers of Doctors and Dentists.

The design of the system for electronic processing of drug prescription data is web based and modular. The following software modules are foreseen for the specific system:

4.1. MODULE 1: Registers

The pre-defined public data of the four Registers should be stored on a central server located at the Ministry of Health and then published on a website for other institutions and the public to use. The Register of HCI and the Register of Drugs (herbal medicines and medical devices) will be maintained locally and the other two registers such as the Register of Doctors and Registry of Dentists should be imported from the data provided by the existing applications from the Chambers of Doctors / Dentists respectively.

4.1.1 Register of Health Care Institutions

This module should be used by the **Ministry of Health** to maintain unique **Register of Health Care Institutions** authorised to provide health care, consisted of the following data:

- Name of the Institution;
- Head of the HCI;
- Number of the Licence for providing health services;

- Date of issuing the Licence;
- Activity and code of the activity; and
- Unique identifier of the Institution/Pharmacy.

The data from this Register should be accessible to the HIF and RIHC.

This Register should be conducted in an electronic form, which means that the MOH should provide IT supported registration and updating of the Registry of Health Care Institutions and assign unique identifier for each institution, as a basic data for the printing of the bar code labels. The identifier would be a 6-digits individual number for each HCI, consisting of 5 digits, +1 control number, generated according to the model $\Sigma\text{mod}11$.

4.1.2 Registers of authorized drugs and herbal medicines.

This module should be used by the **Drugs Bureau** to maintain unique **Registers of authorized drugs and herbal medicines**. These Registries should be accessible to the MoH, HIF, Pharmacies and Republic Institute for Health Care (RIHC). They should be conducted in an electronic form, which means that the Drugs Bureau should provide IT supported registration and updating of the Registers.

1. **Register of drugs** should contain the following data:

- ID Code (identifier) of the drug
- Commercial name of the drug (Cyrillic and Latin alphabet)
- INN (Generic) name of the drug;
- Code of ATC classification;
- Pharmaceutical dosage form;
- Pharmaceutical strength;
- Composition of the drug;
- Packing of the drug;
- Quantity per package;
- Dispensing regime (prescription, for hospital use only, without prescription);
- Drug with specific warnings (psychotropic or opioid effects);
- Dosage regime;
- Drug on Positive list;
- Code of the drug (EAN);
- Manufacturer of the drug (Name, City, State)

The software solution should enable the Drugs Bureau to assign unique identifier for each registered drug. The identifier would be a 6-digit numerical represent of the registered drug, consisted of 5 digits, which would consequently increase for each registered drug (numerical increment with no particular meaning of the digits) +1 control number, generated according to the model $\Sigma\text{mod}11$. For the registered drugs for which the identifier is not generated, the software should generate the identifier. The software should enable assigning of identifiers, i.e. amplification with the appropriate ATC code.

The Bureau should provide the printing and distribution of the bar code labels for the drugs, which should at least contain the ID code of the drug and the number of the batch release certificate.

2. **Register of herbal medicines** should contain the following data:

- ID Code (identifier) of the herbal medicine
- Commercial name of the herbal medicine (Cyrillic and Latin alphabet)
- Code of ATC classification (at later stage);
- Pharmaceutical dosage form;
- Pharmaceutical strength;
- Composition of the herbal medicine
- Packing;
- Quantity per package;
- Dispensing regime;
- Code of the herbal medicine (EAN);
- Manufacturer (Name, City , State)

4.1.3 Register of Doctors and Register of Dentists

This module should enable maintaining of unique **Register of licensed doctors** and unique **Register of licensed dentists**, with pre-defined data, such as:

- ID Code (identifier) of the Doctor/Dentist;
- Name of the doctor/dentist and EMBG;
- Number of the license to work;
- Date of the license;
- Area of work – specialty.

These Registries should be conducted in an electronic form, which means that the both Chambers should provide IT support for registration and updating of the data. The Chambers should also generate the Identification numbers for the doctors/dentists. Each doctor/dentist would have only one unique 6-digit numerical represent, which would remain the same during his/her whole professional engagement. The identifier would be consisted of 5 digits, which would consequently increase for each registered doctor/dentist (numerical increment with no particular meaning of the digits), plus 1 control digit, generated according to the model $\Sigma \text{mod} 11$.

4.2. MODULE 2: Registration

This module should be comprised of various tools for processing of forms for registration of drugs, herbal medicines, import/export licences of drugs and narcotics and registration of Health care institutions. The module is basic module for data collection and the registers are subset of data collected and updated here.

4.2.1 Registration of drugs

This sub-module should enable registration of drugs, comprising the following:

- ID Code (identifier) of the drug
- Commercial name of the drug (Cyrillic and Latin alphabet)
- INN (Generic) name of the drug;
- Code of ATC classification;
- Pharmaceutical dosage form
- Pharmaceutical strength
- Composition of the drug
- Packing of the drug;

- Quantity per package;
- Dispensing regime (prescription, for hospital use only, without prescription);
- Drug with specific warnings (psychotropic or opioid effects);
- Dosage regime;
- Drug on Positive list;
- Code of the drug (EAN);
- Approved price of the drug;
- Manufacturer of the drug (Name, City, State and manufacturing location);
- Marketing authorization holder (Name, City);
- Administrative procedure/number and date of Committee's session;
- Number and date of issuing of marketing authorization;
- Date of validity of marketing authorization;

4.2.2 Registration of herbal medicines¹⁰

This sub-module should enable registration of herbal medicines, comprising the following:

- ID Code (identifier) of the herbal medicine
- Commercial name of the herbal medicine (Cyrillic and Latin alphabet)
- Code of ATC classification;
- Pharmaceutical dosage form;
- Pharmaceutical strength;
- Composition of the herbal medicine;
- Packing;
- Quantity per package;
- Dispensing regime;
- Code of the herbal medicine (EAN);
- Manufacturer (Name, City, State);
- Marketing authorization holder (Name, City);
- Administrative procedure/number and date of Committee's session;
- Number and date of issuing of marketing authorization;
- Date of validity of marketing authorization.

4.2.3 Registration of Domestic Producers

This module should enable registration of the following data:

- ID number of the producer
- Name of the producer
- Description of the production activity (pharmacological, chemical, cosmetics, drugs, etc)
- Location (city)
- Country
- Address
- Status

¹⁰ Herbal medicines = Помошни лековити средства

4.2.4 Registration of Wholesale drug distributors¹¹

This module should enable registration of the following data:

- ID number of the Wholesale drug distributor
- Name of the Wholesale drug distributor
- Location
- Storehouse
- Status
- Contact person
- EMBG of the contact person
- Address
- Activity

4.2.5 Registration of import licenses for drugs

This sub-module should enable the registration of the following data:

- Archive number of the request for approval of drugs;
- Date of the submission of the request;
- Type of the request;
- Applicant;
- Multiple items containing:
 - Name of the Wholesaler
 - Name of the production facilities and country of origin
 - End user
 - Tariff code
 - Quantities
 - Unit price / Total amount
 - Name of the product (this field should be connected with the registration software and should automatically show if this product is previously registered or not)

4.2.6 Registration of Import / export of narcotics, medicines with precursors and chemicals

This sub-module should enable the registration of the following data:

- Archive number of the request for import / export of narcotics, medicines with precursors and chemicals;
- Date of the submission of the request;
- Type of the request;
- Applicant;
- Multiple items containing:
 - Name of the Wholesaler
 - Name of the production facilities and country of origin
 - End user
 - Tariff code
 - Quantities
 - Unit price / Total amount

¹¹ Wholesale drug distributors = Веледрогерии

- Name of the product (this field should be connected with the registration software and should automatically show if this product is previously registered or not)

These data are common for the registration of the 3 different types of above-mentioned medicines.

1. For the registration of the medicines with narcotic drugs, the following additional data should be registered:

- International non propriety name of narcotic drugs
- Total content of active ingredient
- Content of base

2. For the registration of the medicines with precursors, the following additional data should be registered:

- HS code

3. For the registration of the chemicals, the following additional data should be registered:

- Tariff code
- Group of toxicity
- Name of the chemicals

4.2.7. Registration of batch marketing approval

This module should enable registration of the data:

- Archive number of the request for batch marketing approval
- Date of the submission of the request;
- Applicant;
- Multiple Items of the approval containing
 - Batch ID;
 - Name (brand) of the drug;
 - Producer;
 - Pharmaceutical dosage form;
 - Pharmaceutical strength;
 - Quantity of packages per batch (used for printing of labels);

4.2.8. Registration of Health care institutions

This module should enable the registration process of the HCI, which is consisted of the following steps:

1. Request for issuing Licence for providing health care services

This sub-module should be consisted of the following data:

- Type of the HCI: public, private or privatised upon the basis of a rent agreement;
- Number of the request;
- Date of the submitting the request;
- Status of the company that submits the request;

- Type of the request;
- Type of HCI;
- Name of the requesting entity;
- Address of the founder;
- EMBG/TIN of the founder;
- Telephone number;
- Activity (Scope of health services provided);
- HCI name;
- Location of the HCI (including municipality);
- Previous location(s) of the HCI;
- HCI number;
- Appendixes.

After the request is filled in, it would be sent to a special Commission that prepares Minutes on the basis of the analyses conducted within the premises of the requesting entity.

2. Minutes / Report on findings from the commission

This sub-module should enable creation of a special form, which would be consisted of the required elements for foundation of one HCI, such as:

- Number of the Minutes
- Date of the Minutes
- Location of the HCI
- Facility / Premises
- Equipment within the HCI
- Conclusion
- Remarks

3. Licence for providing health care services

This sub-module should enable the registration of the licences issued for providing of health care services and should contain the following fields:

- Number of the previously submitted Request
- Name of the HCI;
- Head of the HCI;
- Number of the Licence for providing health services;
- Date of issuing the Licence;
- Activity and code of the activity (activities);
- Staff members;
- Unique identifier of the Institution/Pharmacy.

The purpose of this module is to keep records of all Licences issued to the HCI.

4.3. MODULE 3: Import of data from the register of Doctors/Dentists

The Chamber of Doctors and the Chamber of Dentists already have their own software application, which allows them to keep electronic Register of licensed Doctors/Dentists. This module should be able to extract public data from their register

and to upload that data to the server located at the Ministry of Health. The updates should be done on regular basis (such as weekly or monthly) or immediately after inserting new record into the database.

The communication between the new system and the existing systems shall be based on the Web services and standard cross-platform languages for data exchange.

4.4. MODULE 4: Identifiers Issuing / Bar codes / labels printing

4.4.1 Identifiers of Health Care Institutions

The software solution should create identifier for the HCI specified in the licence (temporary or final) for providing health care for that institution.

4.4.2 Drugs Labels printing

The software solution should enable the Drugs Bureau to issue and print labels for all drugs that are released¹²:

- For the domestic producers the Bureau would issue labels on the basis of previously received requests for batch marketing approval with a list of drugs, quantity of the drugs and their specification.
- For the drugs with foreign origin the Bureau would issue labels after receiving the request for batch marketing approval with a list of drugs quantity of the drugs and their specification that already have obtained import licence and are imported.

4.4.3 Bar codes of insured person

The software solution should enable the HIF to print bar code labels for the insured persons, which would be consisted of the EMBG of the insured person and his/her health book number. These labels would be tagged on the first page of the health book of the insured persons. These bar codes should be printed only once, at the moment of issuing the health book. For already issued health books the HIF will distribute the bar codes together with the monthly supply of the “blue coupons”.

The HIF will continue to print the labels for the drugs from the positive list.

4.5. MODULE 5: Data analyses and reporting

This module should give statistical data to the Ministry of Health and the Health Insurance Fund about procurement, distribution and usage of the drugs, with specific information regarding the drugs that are on the positive list.

Though the process of data mining, apropos the process of automatically searching for patterns trough large volumes of data collected from the Pharmacies, this module should provide the management of the Ministry of Health and the Health Insurance Fund with simple tools that would give answers to these questions:

- Number of prescriptions issued by individual doctors/specialists per month;

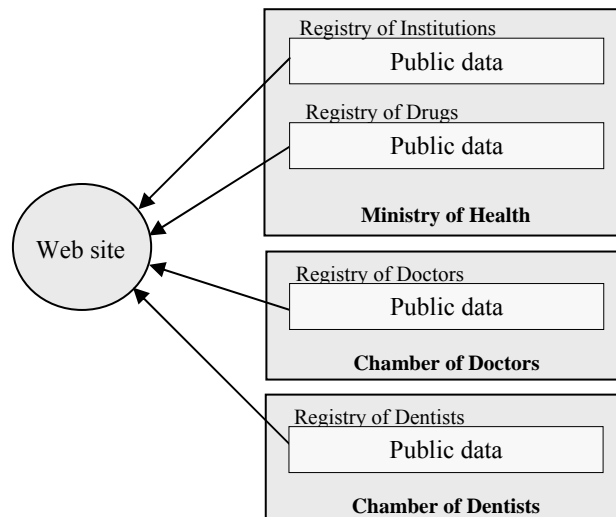
¹² Released = Пуштени во промет

- Average number of prescriptions issued per doctor /specialists per month;
- Number of prescriptions issued by doctors specialists per disease;
- Average number of prescriptions issued by doctors specialists per disease;
- Number of prescriptions issued without participation per months;
- Number of prescriptions issued with participation per months;
- Number of prescriptions issued per drug (top 100 list);
- Amount of issued drugs per month (top 100 list);
- Number of issued prescriptions per doctor and per drug;
- Amount of issued drugs per doctor and per drug.

Additional report will be specified during the development phase.

4.6. MODULE 6: Public website

The public website should contain public data of all registry presented in user friendly fashion with optional import functionality for the other institutions to retrieve them and search trough. The developer is encouraged to define software procedures for automatic website update when the data at the registry is updated.



5. LANGUAGE

Software interface shall be in Macedonian language. For registers on the public website both Macedonian and English language should be used.

6. SECURITY & PRIVACY

Due to the extremely sensitive and confidential data related to the inner workings of the Health care institutions, which is usually classified up to the highest level, a special attention should be paid to the design and the implementation of security and privacy mechanisms. These mechanisms, in addition to being based on stratified and

open standards, should mirror and follow the established and approved government security polices and strategies.

The security modules should have authentication and authorization matrices providing different levels of access, and combining current positions, functions and time limits. This includes, but is not limited to passwords, electronic signatures or digital certificates.

Naturally, the monitoring and record keeping concerning any use of the system by anyone should be on the 24/7 basis, generating a security trail for analysis, review, evaluation, and system checking. The automatic processing of the logs should be subject to searches for access and usage behaviour patterns and consequently semantic reports.

If possible, there should be a single identity representing each user across the whole system and a single-sign in.

6. ARCHIVING, BACK UP AND RECOVERY

A complete subsystem or a module should be devised that will deal with the issues of data archiving, back-up and recovery. The archiving feature should be based on storage mechanisms that would facilitate easy and speedy retrieval of the requested information. The procedures for back-up and recovery should emanate from the well-established and practiced polices of the Government. The back-up should be done in an orderly and periodic manner, both on an internal and external media, with the later being mirrored on dislocated places.