

## **2nd REPORT**

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PROJECT:

### **TA FOR ADVICING ON ESTABLISHMENT OF DRA IN MACEDONIA AND LEGAL ASPECTS OF THE REGULATION ON PRICING POLICY OF PHARMACEUTICALS IN MACEDONIA**

#### **I INTRODUCTION**

The objective of the assignment according to the ToR is to provide TA to the MoH and Drug Bureau, working with national experts in establishing DRA (The Agency for Medicinal Products) and in setting a legal frame for a national pricing policy.

In order to achieve the stated objectives in the ToR preparation work for the 2nd in-country visit, the 2nd in-country visit, and at home work after the 2nd in-country visit performed and aimed at drafting recommendations in line with the legal provisions for formulating and establishing a national DRA as well as defining of legal and technical aspects, prerequisites and preconditions for establishment of the DRA.

This is the 2nd REPORT after 2nd in-country visit

#### **II 2nd IN COUNTRY VISIT**

Preparatory work concerned reviewing experiences gained during the first in-country visit, drafting the Discussion document - Decision on establishing the Agency that was sent to the PEC and the Drug Bureau before the 2nd in-country visit as previously agreed.

The 2nd in-country visit was organized at the end of August/ beginning of September 2009 and was devoted to analyzing the current situation in the Drug Bureau and discussing all legal, practical and organizational steps necessary for facilitation of establishing the Agency.

The following meetings were organized:

- meetings with mag Ilčo Zahariev, Director of the Drug Bureau and his staff
- meeting with prof dr Vladimir Popovski, Deputy Minister of Health, main HSMP coordinator
- meeting with prof dr Zora Uzunoska, the Project Coordinator
- meeting with the PEC
- meeting with asist dr Dimče Zafirov Institute of Pharmacology
- meeting with prof dr Aneta Dimitrovska, Faculty of Pharmacy, Head of the future OMCL
- meeting with mag Katarina Starkovska, Head of Sector for Drug control, Institute for Public Health
- meeting with mag Angelina Bačanović, Head of legal affairs, Ministry of Health
- meeting with Mr Osman Bujani, Minister of Health,

Majority of time was devoted to the Drug Bureau where meetings were organized with director of the Drug Bureau mag Ilčo Zahariev and heads of organizational units:

- mag Vesna Nasteska, head of Drug Registration Sector
- mag Tatjana Petruševska, head of Sector for controlled substances
- mag Lidija Savić, head of Pharmaceutical inspection and in charge for chemical substances
- mag Vera Georgieva, head of department for pharmacovigilance
- mag Maja Evrosimovska, head Sector for medical devices
- mag Merijem Hadžihamza, traditional herbal medicines

The meetings were aimed:

1. to review work of the Drug Bureau in the light of future Agency needs and to underline main concerns and needs and
2. to define and discuss documents needed for proper implementing of the decision of the Law on Medicinal products and Medical devices on establishing the Agency.

#### Ad 1. Review of work of the Drug Bureau

The existing situation in the Drug Bureau reflects the fact that great efforts were expected from a very small team that worked in hardly acceptable working conditions.

The Drug Bureau is a competent authority according to

- the Law on Medicinal products and medical devices
- the Law on Chemicals
- the Law on Control of narcotic drugs and psychotropic substances
- the Law on Precursors
- the Law on fertilization in vitro

There's a long list of activities that are to be performed by the Drug Bureau as the competent authority according to the laws and 61 (!) already prepared and issued by-laws. Some of the procedures are the most demanding in the EU *acquis communautaire* and require specific regulatory knowledge, scientific expertise and directly concern public health.

The Drug Bureau has only 20 employees (including regional inspectors that are dislocated), mostly highly professionally skilled. So small number of employees, despite their enthusiasm, is not in position to perform all the foreseen activities as required by the laws and the by-laws.

Working conditions are hardly acceptable. The available offices are crowded with people who perform different activities, mostly linked to phone conversation or direct contact with stakeholders. Archives are not within the Drug Bureau and are not controlled by the Drug Bureau, although they remain its responsibility. The small number of people and limited resources deprive the Drug Bureau from proper implementing of procedural requirements and educational program obligations for developing internal expertise. This is why the Drug Bureau relies completely on external expertise provided by other institutions.

The above mentioned situation led to the situation that the Drug Bureau adapted legal procedures to the practical capabilities instead of vice versa. The result in practice is that procedures are running on time, but not in line with the laws and the by-laws, so challenges on second instance and challenges before courts are very possible.

Internal expertise is not in position to be developed and to replace partially the external expertise because of the small number of employees and lack of time and resources for educational training programs. The educational program should be in line with EU requirements (e.g. EU obligation for GMP inspectors is 10 training days/year). Trainings that have already been organized were insufficient to ensure compliance with legal requirements and obligatory guidelines, so the level of competences should be substantially improved by investing in certified education.

Documentation on medicinal products, chemicals and other documentation is owned by applicants but is to be stored by the Drug Bureau which is responsible for the proper storing and confidentiality. Since the Drug Bureau has no room to store the documentation, except some recent administrative documents, the main documentation e.g. on quality, safety and efficacy of medicinal products (the basis for main decisions that concern public health) is stored by Institute of Pharmacology, Institute of Public Health and Faculty of Pharmacy. The archive in the Institute of Pharmacology was not available for reviewing during the visit, archive in the Institute of Public Health was moved to another rooms without noticing the Drug Bureau, although the documentation was properly stored. It is necessary to underline that the rooms are not big enough for further storing. Documents in the Faculty of Pharmacy are properly stored.

It raises concern that external experts from the Institute of Pharmacology have not signed obligatory statement on absence of conflict of interest.

Standard Operation Procedures (SOPs) were not available for procedures run by Drug Bureau.

SOPs were not available in the Institute for Pharmacology and Institute of Public Health for procedures that concern assessment of documentation on quality, safety or/and efficacy of medicinal products in the procedure for granting marketing authorizations.

Faculty of Pharmacy has several linked SOPs that traced the assessment procedure properly.

Despite problems with staff and premises, director of the Drug Bureau and his colleagues besides great amount of their regular work, prepared 61 (!?) implementation regulations (by-laws) in a very short period of time. All the by-laws were published in the Official Gazette of the Republic of Macedonia. They also organized very helpful Drug Bureau web site that provided more transparency of their work.

It is necessary to pay attention to compliance of running procedures with the Law on administrative procedures and to discuss non-appropriate legal involvement of MoH as 2nd instance institution into 1st instance decisions that are to be made by the Drug Bureau that could have legal consequences in the case of litigations.

The most outstanding problems in optimizing the Drug Bureau work and transforming it into the Agency for Medicinal products (the Agency), particularly having in mind the need for running the procedures according to the laws, will be:

- to ensure at least (minimum) 60 employees in the Agency

- to ensure adequate premises and equipment (furniture, IT equipment and softwares: special requirement concerns obligatory introduction of e-CTD in 2010 in the EU that is to be followed in a very short period of time)
- to invest in additional regulatory, scientific and practical trainings
- to ensure appropriate archiving of confidential documentation.

Proposals for immediate measures are:

- To invite Ministry of Justice to provide the list of civil servants that passed the exam on State Administration, or to provide individual certificates as well as to ensure that all other employees pass the exam asap.
- Director of the Drug Bureau should authorize all employees that work on state administration procedures for running them and of them (upon his choice) for signing decisions for some of less demanding procedures.
- To ensure that Institute of Pharmacy provides statement of absence of conflict of interest signed by their experts
- To ensure that Drug Bureau takes over all contacts with applicants in writing and runs the procedures properly in line with legal requirements.
- To ensure that 2nd instance institution (MoH) is not involved in decisions that are to be made on 1st instance (see the laws)
- To ensure the review all the archives and to make available a written report on the state of documentation, its traceability and conditions of storing.
- To make efforts to get at least some more staff even before establishing the Agency and ensure, step by step, that all the procedures run in compliance with legislative requirements.
- To make efforts to get some resources even before establishing the Agency for ensuring educational certificated trainings, particularly for inspection.
- Other above discussed lacks of compliance with rules can be solved step by step if appropriate legal basis is ensured for all the procedures that run in practice (e.g. pricing procedure) successfully and that resources meet Institution needs properly.

All the requested documents were made available during the visit. Director of the Agency and Heads of organizational units were available for information and interviews during the whole visit.

Ad 2. Defining and discussing documents needed for proper implementing of the decision of the Law on Medicinal products and Medical devices on establishing the Agency.

The Law on medicinal products and medical devices in the Art. 3 states that the Agency should be established as institution within the State Administration.

The provision implies that the Agency cannot be excepted from the Civil Servant Act.

The nature of processes that are delegated to the Agency imply a high scientific skills of employees, strong international involvements, language skills, requirements for preparing and presenting different regulatory and scientific issues publicly, flexibility of decisions concerning ad hoc meetings, trainings, adopting of job positions to the market needs etc.

The nature of Agency work concerns not only public health but also competitiveness of pharmaceutical industry (it is a part of almost all EU directives and regulations in the pharmaceutical acquis), predictability and stability for other stakeholders, economic operators. This is why they should be in position to be involved in Agency's work, supervision and system through e.g. Management Board

The above described needs will not be properly met if the Agency is not excepted from the Civil Servant Act (Ranging of salaries and job positions, flexibility in decision making, role of a Management Board...)

Since the Law on medicinal products and medical devices should be changed in the segment of drug pricing because of non compliance with EU requirements and because some provisions allow subjective approaches, I strongly recommend introducing changes also in the segment that defines the legal status of the future Agency. The Law on telecommunications could be an excellent example on establishing an independent Agency that is excepted from the Civil Servant Act, flexible and accountable to the Parliament.

Employment Act is to be followed.

Having in mind this possibility, I propose two sets of documents depending on the chosen model.

**A. If the existing legal model of the Agency remains, director of the Agency issues:**

- Rules on Organizational Structure, Job Systemization and Job Description
- Agency Draft Strategic Documents
- Proposal for financing of the Agency

The listed documents were discussed with the Drug Bureau and PEC

# RULES ON ORGANIZATIONAL STRUCTURE, JOB SYSTEMIZATION AND JOB DESCRIPTION

The document is to be issued by director of the Agency and based on the Civil Servant Act

The document could address the following issues

## 1. General provisions

General provisions should refer to the Civil Servant Act

## 2. Agency activities

Agency activities should be listed or referred to the laws, as well as provisions that concern independency, transparency and confidentiality.

## 3. Organizational structure

Organizational structure of the Agency should follow good practices gained in the Drug Bureau. Organizational structure should meet Agency needs. The existing organizational structure of the Drug Bureau is a good starting point having in mind that the number of employees has to reach minimum of 60 people. Different areas of competence are already separated in different organizational units (medicinal products, medical devices, chemicals, controlled substances, inspections), general services/secretariat is to be added and to be divided into: administrative part (main office, archiving, logistics), IT service, financial service and legal service.

Some activities should be formally separated from others e.g.

- marketing authorization procedure and granting from drug pricing
- inspection from licensing (verification can be performed by inspectors within the licensing procedures, but separated from regular inspections)

Sectors should consist of departments, if necessary. Departments can have services or smaller units for some activities, if necessary.

The example is given in the Annex.

Activities for all organizational units have to be described unit by unit.

## 4. Job systemization

Job systemization, ranges/classes of salaries, conditions to be fulfilled concerning requested education level and additional requirements, working experiences etc. have to be prepared according to the Civil Servant Act.

It should be clear that heads of sectors and heads of departments should manage their organizational units, coordinate (vertical/horizontal) work with other organizational units and perform most demanding tasks in the area of their organizational units competences as well as other tasks if requested by director.

Job descriptions on different levels should be described generally.

Job descriptions and obligation for certificate according to the Law on State administration procedure should be stated for all systemized jobs together with the number of foreseen job positions.

Obligation for certificate according to the Law on State administration procedure is to be stated

- job description in cases when (in)appropriate for woman, young persons, handicapped or some other categories of workers

#### 5. Agency management, authorizations

Director's activities are to be listed or referred to the Law on Medicinal Products and Medical Devices.

Director authorizes in writing individuals for performing specific operation procedures for which certificate for running or/deciding is requested according to the Law on State administration procedure.

#### 6. Agency planning and working methods

Agency work should be planned in the annual and long term plans

Agency should report (annual, short term...) on the working results to the MoH

Director has his/her advisory group (deputy director and heads of sectors, heads of departments only if necessary) for solving some interdisciplinary issues.

Director can establish a Project team for performing some specific interdisciplinary projects. Project teams can also involve external experts.

Agency should work on transparent way and should inform stakeholders on any issues concerning publicly available information

Agency should ensure that stakeholders business secrets / documentation are not disclosed and that personal data are protected.

Personnel should sign statements on safety of information and absence of conflict of interest.

#### 7. Working contracts

Working contracts should follow requirements of the Employment Act

## 8. Rights and obligations

Employees have rights and obligations according to the Civil Servant Act and the Employment Act

## 9. Transitional and final decisions

It is necessary to ensure smooth transition from Drug Bureau to the Agency concerning introducing new methods of work and training of new staff.

## AGENCY DRAFT STRATEGIC DOCUMENTS

Irrespective of the legal form of the Agency, it will be necessary to prepare Agency strategic documents, that are:

- Mission,
- Vision
- Strategy - main elements and goals
- Basic elements of Good Regulatory Practice and future Quality system

After the Agency consolidates its work under new legal status, new organizational structure, new number of employees, the next step will be development of the Quality system in compliance with ISO 9000: 2005 standard specifications.

The first Agency strategic documents should be prepared as follows:

### Mission

The Agency mission consists of implementation of the national policy in the field of medicinal products, medical devices, chemicals, controlled substances and precursors with the target of public health protection, following principles of good regulatory practice, where the "good regulatory practice" is interpreted as a quality system guaranteeing the satisfaction of customers of regulatory (administrative and professional) services and observance of the legislation.

### Vision

The Agency should be efficient and autonomous national institution aimed for protection of health in the areas of competence. Quality of Agency work should be comparable with recognized already established agencies in the region and in the EU. The Agency should be an equal partner in communication with other regional and European agencies.

Vision of the Agency is to be adapted concerning details depending on the vision of actual management of the Agency, but basic elements should remain.

### Strategy - main elements and goals

Strategy planning involves quality objectives, short term planning, long term planning, resource management, available resource distribution and risk management.

Director of the Agency is responsible at all Agency levels for definition and documentation of the quality objectives and policy as well for their implementing, monitoring and maintaining.

Director of the Agency has to demonstrate his/her commitment in achieving the Agency objectives and goals by

- following legislative requirements
- following the strategy that arises from Agency mission and vision
- fulfilling national and international commitments of the Agency
- ensuring needed resources (financial, personnel, equipment, premises)
- adequate organizational structure that reflects Agency's needs
- ensuring adequate external and adequate horizontal and vertical internal communication

### Basic elements of Good Regulatory Practice and future Quality system

The Agency should endeavor to carry out its tasks in the most systematic, transparent and efficient ways. This is why a quality system in compliance with the ISO 9000:2005 standard specification should be introduced at an early day and cover all key organizational processes. Basic elements of a quality system should be introduced from the beginning of the Agency work in order to enable high professional level of the e.g. assessment of quality, safety and efficacy of medicinal products, pharmacovigilance, medical devices vigilance and compliance with essential requirements, issuing licenss, inspection and other procedures as well as other undertaking measures aimed at the protection of public health.

The basic elements are:

- Documents for effective planning, implementation and monitoring operations
  - legislation
  - forms
  - Documented Standard Operational Procedures for key operations
  - templates of decrees, certificates, letters, ...

- Quality records, suitably stored: internal and external controls of compliance with basic requirements of quality policy, reporting, corrective measures, list of authorized officers and definition of their authorities, records of trainings
- List of Agency service customers: representatives of the general public, patients, pharmaceutical industry, university institutions, public institutes...
- Customer's satisfaction survey (questionnaire, ...)
- Risk analysis planning: Stating and categorizing risks and ways for eliminating or diminishing it

## PROPOSAL FOR FINANCING OF THE AGENCY

The Founder ensures adequate premises and equipment necessary for functioning of the Agency. The agency manages premises and equipment in accordance with the agreement between the Founder and the Agency.

Financing of the Agency should consist of:

- a. startup fund / initial financing, ensured by the Founder for the starting of Agency activities (XX EUR) as the successor of the Drug Bureau
  - finishing applications that were paid to the state budget
  - expenses linked to establishment of the Agency
  - IT communications
  - premises and equipment linked to a new business model and at least 60 employees
  - additional education
  - expenses linked to a new general services of the Agency (legal, financial, IT, administrative)
  
- b. annual financing according to the annual plan adopted by the Management Board, divided as follows
  - 50% financed from state budget (XX EUR) for activities not financed through fees (pharmacovigilance, hemovigilance, medical devices vigilance, inspections according to the laws: Law on medicinal products and medical devices, Law on chemicals, Law on narcotic substances and precursors, IT Pharmacoinformative Center, drug pricing, international activities, co-operation in preparing legislative documents and guidelines)
  - 50% financed from fees

Income from budget and from fees must be separately evidenced

Donations are to be evidenced separately

**B. If the legal model of the Agency changes following the example of the Agency for telecommunications according to the Law on telecommunications:**

Establishing of the Agency is based on the Law on medicinal products and medical devices. Between issuing the Law and starting the Agency it is necessary prepare to prepare

- Agency Statute
- Rules on Organizational Structure, Job Sistemization and Job Description
- Agency Draft Strategic Documents

All the listed documents were discussed with the Drug Bureau and PEC

## THE AGENCY STATUTE

The Agency Statute should define:

1. General provisions
2. Tasks and activities of the Agency
3. Agency institutions
4. Agency documents
5. Financing of the Agency
6. Relationship with stakeholders
7. Supervision
8. Transitional provisions

Short description:

### 1. General provisions

a. Reasons for establishing the Agency that arise from the Law on medicinal Products and Medical Devices

Agency should be established as a public, non-profit and independent institution excepted from obligation arising from the Civil Servant Act

b. Legal form, name, address, acronym and stamp of the Agency

The Agency should be established as a non-profit independent public institution with competences given by

- the Law on Medicinal Products and Medical Devices
- the Law on Chemicals
- the Law on Control of narcotic drugs and psychotropic substances
- Law on Precursors
- the Law on fertilization in vitro

The Agency should be registered with the Central Register

The Agency has to make decisions within the area of competences professionally and independently from other Governmental or other public legal institution, association or any other legal or physical persons.

For the purpose of performing its tasks, the Agency can engage external local or international experts provided that confidentiality of data and absence of conflict of interest were ensured.

The name of the Agency is the Agency for Medicinal Products

Acronym of the Agency :... (to be defined ) ....

Logo of the Agency: .....(to be defined ) ....

The Agency uses its seal. The seal (to be defined ) ....

Business seat of the Agency is in Skopje

2. Tasks and activities of the Agency

a. according to the Law on Medicinal Products and Medical Devices the competences of the Agency shall include the following:

- issuing manufacturing authorizations for medicinal products;
- issuing manufacturing authorizations for medical devices;
- issuing a wholesale authorizations for wholesaling medicinal products and medical devices;
- issuing retail authorizations for retailing medicinal products and medical devices;

- issuing marketing authorizations for medicinal products, as well as changing and amending and renewing of the authorizations;
- authorizing advertising of medicinal products and medical devices;
- maintaining Register of medicinal products and Register of medical devices in the Republic of Macedonia;
- maintaining Register of manufacturers of medicinal products and Register of manufacturers of medical devices in the Republic of Macedonia;
- maintaining Register of entities for wholesale and Register of entities for retail sale of medicinal products and medical devices in the Republic of Macedonia;
- issuing authorizations and/or notifications for clinical trials of medicinal products;
- issuing authorizations and/or notifications for clinical trials of medical devices;
- issuing import authorizations and export authorizations for medicinal products;
- issuing certificates for compliance with the good practices principles;
- issuing certificates for the needs of export of medicinal products and medical devices;
- establishing and maintaining pharmacovigilance and materiovigilance system;
- establishing and maintaining database;
- inspection of the medicinal products and medical devices;
- inspection of entities for production, wholesale and retailing;
- activities pertaining to assure control of the quality of the medicinal products and medical devices;
- determination of prices of medicinal products;
- collecting and processing statistical data on the sale and consumption of medicinal products and medical devices;
- cooperation with other institutions on promotion of rational use of medicinal products and medical devices;
- integration into international networks of information on medicinal products and medical devices;
- undertaking other activities pertaining to medicinal products or medical devices in accordance with the Law on Medicinal Products and Medical Devices
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- issuing manufacturing authorizations for medical devices;
- issuing a wholesale authorizations for wholesaling medicinal products and medical devices;
- issuing retail authorizations for retailing medicinal products and medical devices;
- issuing marketing authorizations for medicinal products, as well as changing and amending and renewing of the authorizations;
- authorizing advertising of medicinal products and medical devices;
- maintaining Register of medicinal products and Register of medical devices in the Republic of Macedonia;

- maintaining Register of manufacturers of medicinal products and Register of manufacturers of medical devices in the Republic of Macedonia;
- maintaining Register of entities for wholesale and Register of entities for retail sale of medicinal products and medical devices in the Republic of Macedonia;
- issuing authorizations and/or notifications for clinical trials of medicinal products;
- issuing authorizations and/or notifications for clinical trials of medical devices;
- issuing import authorizations and export authorizations for medicinal products;
- issuing certificates for compliance with the good practices principles;
- issuing certificates for the needs of export of medicinal products and medical devices;
- establishing and maintaining farmacovigilance and materiovigilance system;
- establishing and maintaining database;
- inspection of the medicinal products and medical devices;
- inspection of entities for production, wholesale and retailing;
- activities pertaining to assure control of the quality of the medicinal products and medical devices;
- determination of prices of medicinal products;
- collecting and processing statistical data on the sale and consumption of medicinal products and medical devices;
- cooperation with other institutions on promotion of rational use of medicinal products and medical devices;
- integration into international networks of information on medicinal products and medical devices;
- undertaking other activities pertaining to medicinal products or medical devices in accordance with the Law on Medicinal Products and Medical Devices
- cooperation with Ministry of health in preparing legislative documents

b. according to the Law on Chemicals the competences of the Agency shall include the following:

- classification of substances
- licensing (manufacturing, wholesale, retail sale)
- import, export, transit
- inspection

c. according to Law on Control of narcotic drugs and psychotropic substances the competences of the Agency shall include the following:

- import, export, transit

- reporting according to international conventions
- inspection

d. according to the Law on Precursors

- import, export, transit
- reporting according to international conventions
- inspection -

e. according to the Law on in vitro fertilisation the competences of the Agency shall include the following:

- import, export

e. according to this Decision/Statute the competences of the Agency shall include the following:

- publishing (books, journals, bulletins...)
- education (seminars, conference, presentations...)
- involvement in official educational programs (undergraduate, postgraduate studies...)
- IT copying, web services
- data management,
- other regulatory, research/ development and other supporting activities to the main Agency activities in the area of competences

### 3. Agency institutions

Agency institutions are (if more flexible approach accepted)

a. Management Board

b. Director of the Agency

a. Management Board

- ensures that Agency activities are performed in line with public interest
- adopts Agency acts/documents
- adopts working program, financial and staff plans
- adopts annual and other Agency Reports
- proposes changes of Agency activities
- proposes appointing and dismissing of director of the Agency to the Founder
- decides on the use of income over outcome

- proposes director or the Founder any issues from the area of competences
- reviews Agency documents

Agency Management Board has 7 members.

Members of the Management Board are to be appointed by the Founder for 5 years period, once renewable. For example:

- 4 members are appointed upon proposal by Founder
- 2 members representing stakeholders organized in trade associations or chambers appointed upon public call
- 1 member of s stakeholders not organized in trade associations or chambers appointed upon public call

Founder starts the public call, defines the deadline for applications and proposes the Management Board members among proposed candidates who fulfill requested criteria.

Criteria for members of the Management Board are:

- university level of education,
- expert at the area of competence of the Agency
- not employed in the Agency
- having clear records
- not having the status of functionary
- not being employed in profit organizations from the area of competences of the Agency

The Founder appoints members of the Management Board.

The Founder dismisses members of the Management Board:

- on his/her request
- if he/she does not fulfill the requirements
- if he/she becomes functionally incapable for performing the activities
- if he/she acts contrary to requirements of this act, of the Agency acts or acts non-professionally

Members of the Management Board have to be independent, unbiased and keep business secrets.

Members of the Management Board are reimbursed for attendance fees.

Members of the Management Board are responsible for any damage due to infringement of their defined duties.

Members of the Management Board appoint the President of the Management Board and Vice President who chairs the Management Board sessions in the absence of the President.

Management Board decides by simple majority in its sessions that can also be correspondent sessions.

Management Board meets at least twice a year upon invitation by President of the Management Board, Minister or Director of the Agency.

Agenda is enclosed to the Invitation. Session is recorded. Records are to be adopted at the next session.

#### b. Director of the Agency

According to the Art. 4 of the Law on medicinal Products and Medical Devices the Agency shall be managed by a director.

The Director of the Agency shall be appointed and dismissed by the Government of the Republic of Macedonia following the proposal of the Management Board. Director is to be appointed for a 5 year renewable period.

If director's function ceases before the end of the mandate, the Government can appoint person who can perform temporary director without public call procedure, but for not more than 6 month.

The director of the agency shall be a person, who should fulfill general conditions:

- citizen of the Republic of Macedonia,
- clear records,
- language skills,
- not involved in any activities in profitable organizations from the area of Agency competences) and should fulfill special conditions:
  - university degree in the field of pharmacy and
  - at least 5 years of work experience in the field of pharmacy.

Director of the Agency:

- represents the Agency
- organizes and manages the Agency
- issues Agency acts according to the legislation
- proposes business policy and performance
- proposes annual and long term work planning

- proposes annual and long term financial planning
- proposes Agency acts to be adopted by the Management Board
- prepares annual and/or short term reports
- prepares and signs documents necessary for the Agency work
- ensures that Agency performs activities in line with laws, this Decision/Statute, Agency internal documents, national policies in the area of competences,
- appoints Agency Committee members
- performs other activities necessary for functioning of the Agency

Director of the Agency is responsible for damages due to his/her ... or illegal activities

Director of the Agency is responsible to the Agency Management Board and to the Founder.

Director appoints his/her Deputy according to the Agency internal acts.

#### 4. Agency documents

a. The Agency proposes and the Management Board adopts the Rules on organizational structure and systematization of jobs and job descriptions. The Trade union opinion could be consulted before adoption.

b. Strategic Agency documents: Mission, vision and main elements of strategy and goals should be clearly stated. Standard operating procedures should be recorded, list of stakeholders, customer's satisfaction survey act should be elements of the future Quality system and Good Regulatory Practice. Details would depend on individual approach concerning vision and strategy.

c. Other documents necessary for functioning of the Agency, some of them in line with rules used for state administration provided that too rigid approach does not influence functioning of the Agency.

#### 5. Financing of the Agency and necessary premises and equipment

The Founder ensures adequate premises and equipment necessary for functioning of the Agency. The agency manages premises and equipment in accordance with the agreement between the Founder and the Agency.

Financing of the Agency should be as described ad A).

By the end of November, Agency prepares and the Management Board adopts annual plan for the next year that defines tasks and goals in line with national policies as well as ways of implementation.

Financing from state budget is to be approved by December in the calendar year. If a financial plan for the next year is not adopted by the Government by the date, than temporary financing is to be agreed between Founder and the Agency, based on the annual plan for the previous year.

If the approved financial resources are not sufficient for functioning of the Agency, the Management Boards informs the Founder on the issue and presents public health and other concerns.

Agency incomes are to be spent for

- performing Agency tasks
- ensuring resources for adequate functioning of the Agency
- other financing necessary for adequate functioning of the Agency

Surplus (income over outcome) is to be spent for development of the Agency, for rewards for employees or to be given back to the budget.

Agency can take credits if it is in line with adopted annual and long term planning.

Agency is responsible for its responsibilities. The Founder has a subsidiary responsibility if not covered by the Agency.

## 6. Relationship with stakeholders

Relations between the Agency and public (professional and general) must be transparent, correct and aimed to protect public health and public interest.

Information of public interest must be publicly available. At the same time, confidentiality necessary for protecting commercial interest is a priority in relationship with stakeholders.

It is Agency's duty to inform stakeholders properly on its work, tasks, competences. Informing must be in compliance with legislation on availability of classified public information.

State, business or professional secrets must be protected in line with state administration legislation. Employees and external experts must sign statement

on protecting state, business or professional secrets and statement on non-conflict of interest.

Director is responsible for transparent work of the Agency and for issuing internal Agency document on the confidentiality status of documents.

Documentation is handled in line with legislation used for state administration. Legal acts that regulate documentation management for State administration can be expanded to the Agency.

## 7. Supervision

a. Financial supervision is performed by State Financial Revisor

b. Ministry for Justice performs supervision over performing procedures in line with legislation, official hours, work with clients, ensuring transparency.

## 8. Transitional provisions

According to the Law on medicinal Products and Medical Devices, the Agency for medicinal products shall begin to operate starting from 1st of January 2010.

Transitional provisions must foreseen a smooth transition from the Drug Bureau to the Agency

Until the start of operations of the Agency the Bureau for Pharmaceuticals shall continue to perform the activities under the responsibilities of the Agency for Medicinal Products.

Until the start of operations of the Agency for medicinal products, the appeals lodged against the first instance decisions enacted in accordance with this Law shall be resolved by the Minister of health.

## **RULES ON ORGANIZATIONAL STRUCTURE, JOB SYSTEMIZATION AND JOB DESCRIPTION**

The document should be generated in the Agency and partially related to the Civil Servant Act. The scope of the document will depend on the extent of applying the Civil Servant Act to the Agency as public independent institution. The document could address the following issues

#### 1. General provisions

General provisions should list the specific issues that are addressed in the document.

All other issues that are not addressed in the document are to be solved by applying rules used in managing state administration

#### 2. Agency activities

Agency activities described in the Agency Statute should be listed or referred to the laws (as previously described ad A), as well as provisions that concern independency, transparency and confidentiality.

#### 3. Organizational structure

Organizational structure of the Agency should follow good practices gained in the Drug Bureau as previously described ad A.

#### 4. Job systemization

Job systemization concern

- ranges/classes of salaries
- conditions to be fulfilled
- working experiences at the same educational level
- obligation for certificate according to the Law on State administration procedure
- job description in cases when (in)appropriate for woman, young persons, handicapped or some other categories of workers

The Civil Servant Act is to be followed only partially, allowing a wider range of flexibility concerning specific Agency needs

#### 5. Agency management, authorizations, job descriptions

Director's activities are to be listed or referred to the Decision on Establishing the Agency.

Director authorizes in writing individuals for performing specific operation procedures for which certificate for running or/deciding as requested according to the Law on State administration procedure.

Deputy director is to be appointed and dismissed by director. Deputy director activities are to be defined by director.

Heads of sectors and heads of departments should manage their organizational units, coordinate (vertical/horizontal) work with other organizational units and perform most demanding tasks in the area of their organizational units competences as well as other tasks if requested by director.

Job descriptions on different levels should be described generally.

Job descriptions and obligation for certificate according to the Law on State administration procedure should be stated for all systemized jobs together with the number of foreseen job positions.

#### 6. Agency planning and working methods

Agency work is planned in the annual and long term plans adopted by the Management Board and the Founder.

Agency has to report (annual, short term...) on the working results to the Management Board and to the Founder.

Director has his/her advisory group (deputy director and heads of sectors, heads of departments only if necessary) for solving some interdisciplinary issues.

Director can establish a Project team for performing some specific interdisciplinary projects. Project teams can also involve external experts.

Agency should work on transparent way and should inform stakeholders on any issues concerning publicly available information

Agency should ensure that stakeholders business secrets / documentation are not disclosed and that personal data are not disclosed.

Personnel should sign statements on safety of information and absence of conflict of interest.

#### 7. Working contracts

Provisions can follow requirements of the Employment Act

It is particularly important to define that:

Working contract is signed after public call and procedure for choosing candidates. The procedure involves special Committee appointed by director. The Committee follows requirements stated in the public call and other relevant data.

Probatory work is defined by director and is longer for higher positions. After the end of the probatory work the Committee assesses the candidate.

Working hours can be fixed or flexible. Obligatory presence is to be defined as well as duration (30min?) of break. Official hours are to be defined and obligatory presence for some job positions. Work outside of working hours, divided working hours, weekend work or work at home are to be defined.

Duration of cancellation period is to be stated and in accordance with job/salary level

### 8. Rights and obligations

Jobs are valued by salaries and additional payments (working years, mentorship, academic titles, less suitable working hours or conditions, stand by arrangements, special conditions, special efficacy, special achievements, ...). Maximums or ranges are to be defined having in mind salaries for non profitable organizations.

Workers can advance within the job positions according to previously defined ranges and criteria.

Reimbursements, jubilee rewards, retirement rewards, solidarity and other rewards are treated equally as for state administration workers.

Annual leave, maternity/paternity leave, non-reimbursable leave, and educational leave are treated equally as for state administration workers.

Director has a right and obligation to request and ensure additional necessary training for workers. That can be described in detail in the separate act.

Discipline infringements are treated equally as for state administration workers.

Director decides on the workers rights, obligations and responsibilities at the 1st instance. The appeals lodged against the 1st instance decisions shall be resolved in the Administrative Court.

### 9. Transitional and final decisions

it is necessary to ensure smooth transition from Drug Bureau to the Agency

**AGENCY DRAFT STRATEGIC DOCUMENTS**

As described ad item A