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PARLIAMENT OF THE REPUBLIC OF MACEDONIA

On the base of article 75, paragraphs 1 and 2 from the Constitution of the Republic of Macedonia, President of the Republic of Macedonia and Speaker of the Parliament of the Republic of Macedonia announce:

DECREE FOR PROCLAMATION OF THE LAW ON PUBLIC HEALTH

The Law on Public Health is proclaimed,
that is accepted by the Parliament of the Republic of Macedonia, at the session held
on the 11th of February 2010.

No. 07-717/1

11th February 2010

Skopje

President of the Republic of Macedonia

Gorge Ivanov, s.r.

Speaker of the Parliament of the Republic of Macedonia
Trajko Veljanovski, s.r.

LAW ON PUBLIC HEALTH

I.GENERAL PROVISIONS

Subject matter of the Law

Article 1

This Law shall regulate the implementation of the essential public health functions and tasks, the system of public health, public health emergencies, and the funding of public health activities.

Purpose of the Law

Article 2

The purpose of this Law shall be:

- 1) to preserve and improve the health of the population;
- 2) to enable implementation of the fundamental functions and tasks of the public health through organised measures and activities undertaken by state organs, institutions, units of local self governance and other legal and physical entities in cooperation with health care institutions;
- 3) to improve and strengthen interdepartmental cooperation in the implementation of fundamental functions of public health;
- 4) to improve and strengthen cooperation between competent Ministries and units of local self governance and between the public and private sector and the citizens in

protection and improvement of the health of the population;

5) to provide appropriate response in case of occurrence of public health emergency

6) to provide implementation of international health care regulations;

7) to regulate specific public health issues which are not or not adequately regulated by existing legislation.

Definitions

Article 3

Specific terms used in this Law shall have the following meaning:

1. „Public health” is the science and art of preventing disease, prolonging life and promoting health through the organised efforts of society. Public health analyses and monitors the health status of the population, and tries to improve this health status by influencing the known determinants of health (also known as risk factors) such as environmental and microbiological causes, lifestyle and socio-economic factors;
2. „Essential public health functions,, are a set of fundamental activities that address the determinants of health, protect a population’s health, and treat diseases of public health significance;
3. „Public health emergency” is an occurrence or imminent threat of a situation that can cause wide-spread mortality or serious morbidity from a natural disaster, infectious agent, biological toxin, chemical, physical or nuclear release;
4. „Public health emergency of international concern” is an extraordinary event that may constitute a public health risk to other states through the international spread of disease, and that potentially requires a co-ordinated international response;
5. An “epidemic of a communicable disease” is an increase of cases of a certain communicable disease that according to the time and place of such occurrence overwhelms regular number of cases in the previous period, as for unusual increase of number of the sick with complications or lethal outcome;
6. “Prevention”: is an activity that prevents the occurrence of disease. Action aimed at eradicating, eliminating or minimising the impact of disease and disability;
- 7.” Primary prevention” is a reduction of the occurrence of disease with elimination or minimising the exposure towards the reason to a safe and secure level;
- 8.” Secondary prevention” is a discovery of early changes of the disease in order to undertake activities for prevention of further development of the disease;
9. “Health promotion” is a process of planning and supporting of activities aimed towards improvement of the health status of the population;

10. “Communicable disease” is an illness due to a specific biological agent (bacteria, viruses, parasites, fungus) or its toxic products that can be communicated to humans in a direct or indirect way;
11. A “reference laboratory” is a laboratory that carries out the control of the quality of services performed by other laboratories;
12. The “ National Annual Programme of Public Health” is a standard package of measures and activities provided by the Institute of Public Health of the Republic of Macedonia and Centres of Public Health;
13. “ Screening” is a systematic testing or examination in order to discover individuals with supposed risk of specific disorder, because of further investigation or undertaking of a direct preventive activity;
14. ” Inequalities” represent a disbalance in allocation of the resources or for accessibility of the services between various population groups , regardless of the fact if the differences occurred by the place of residence, or from different national or social background or assets owned and
15. “ International health regulations” is a document adopted by the World Health Assembly by which member countries of the WHO are obliged to take measures in regard to prevention, protection against, control and to provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade, with full respect for the dignity, human rights and fundamental freedoms of persons.

Principles

Article 4

Public health shall be rooted in the following principles:

1. responsibility for the health of the population and the leading role of the state in preservation and improvement of the health of the population;
2. Wide-ranging measures and activities focused on the entire population, and on the socio-economic determinants of health and the most significant risk factors;
3. Multidisciplinary basis and intersectoral cooperation;
4. Comprehensiveness in collection of information by means of qualitative and quantitative methods and;
5. Partnership with the population.

Correlation with other Laws

Article 5

In addition to the provisions of this Law, the provisions in the Laws regulating protection against communicable diseases, food safety, professional safety,

environmental safety as well as other public health issues shall be applied (separate Laws).

Chapter II Public health functions and tasks

Essential public health functions Article 6

(1) The essential public health functions are:

1. Surveillance and assessment of the population's health and well-being.
2. Identification, prediction, investigation and mitigation of health problems and health hazards in the community.
3. Health protection: assessment of the needs and actions required to ensure health protection;
4. Disease prevention: applying interventions for primary and secondary prevention.
5. Health promotion and health education.
6. Development and enforcement of Laws and other regulations that provide health protection, especially through the safety of the food, water, air, work place and the soil;
7. Assuring a competent multidisciplinary public health workforce.
8. Support and carrying out of health-related research.
9. Development and planning of public health policies.
10. Preparedness and management of public health emergencies, including prevention, response and mitigation of consequences.
11. Ensuring intersectoral partnership and community participation to improve health and reduce inequalities.

(2) These Essential Public Health Functions of the paragraph (1) of this Article are the basis for all Public Health activities carried out by all responsible bodies, institutions and other legal and natural entities.

Tasks of public health Article 7

The Republic of Macedonia shall be responsible for public health by means of the following tasks:

1. Providing policy and strategy of public health;
2. Monitoring the health status of the population and identification of health problems in the community;
3. Planning, establishing priorities, passing special programmes and action plans for public health improvement, for screening, as well as passing regulations in this area;
4. Implementation of taxation, economic and other policies that stimulate healthy life styles;
5. Providing conditions for health education and empowerment of the population to take care of their own health;

6. Providing a system of quick response in extraordinary situations (epidemics, physical and chemical accidents, natural disasters, etc).;
7. Development of an integrated and uniform health information system;
8. Development of intersectoral co-operation in solving health problems;
9. Evaluation of effectiveness, quality, accessibility and efficiency of health care services and programmes oriented towards the individual and the population;
10. Ratification of measures for protection of the health of the population within the Laws and regulations;
11. Provision of competence in public health human resources through training and continuing education;
12. Researching new approaches and innovation of measures in solving health problems of the population and
13. creating the conditions for a rational and standardised network of Centres for Public Health.

III. SYSTEM OF PUBLIC HEALTH

Organisation of the system of public health

Article 8

(1) The system of public health that provides conditions for preservation and improvement of the population's health is a network comprised of citizens, families, employers associations, employers, syndicates and employees, health care institutions educational, social, cultural and other institutions, public media, humanitarian, religious, sport and other organisations, associations, health insurance funds, as well as municipalities and state organs, and other associations of citizens and foundations that participate in the implementation of the essential public health functions from Article 6 of this Law.

(2) Ministries competent for the areas of health, education and science, environmental protection and physical planning, culture, traffic, transport and communications, agriculture, economy, labour and social care/ protection and other state organs and organs of the municipalities as stipulated in this and other Laws shall secure and provide essential public health functions.

(3) The Institute of Public Health of Republic of Macedonia and the Centres of Public Health through performance of the duties pursuant to Article 10 and 11 provide implementation of the essential public health functions of the Article 6 of this Law.

Implementation of public health tasks

Article 9

The Ministry of Health, and other ministries competent for the areas of education and science, environmental protection and physical planning, culture, traffic, transport and communications, agriculture, economy, labour and social care/ protection and other state organs and institutions in mutual coordination and cooperation, implement the tasks pursuant to Article 7 of this Law.

Institute of Public Health of the Republic of Macedonia

Article 10

(1) The Institute of Public Health of the Republic of Macedonia (hereinafter: Institute) shall perform the following:

1. Provide expert/professional assistance to the Ministry of Health in the preparation of medium-term and long-term public health plans, including the public health programmes in the area of health protection, health promotion, population screening, and monitoring and control of communicable and non-communicable diseases;
2. Develop and implement professional doctrinal positions in the area of public health;
3. Prepare annual national reports on relevant aspects of the population's health for the needs of the Ministry of Health and propose measures for overcoming of the public health problems ;
4. Prepare standards for the scope of activities, and co-ordinate, monitor and assess the professional operation of the Centres for Public Health;
5. Collect, prepare and analyse and maintain sets of records in accordance with the Law on Records in the health area;
6. Develop and provide programmes for continuous professional development in the field of public health for its own staff, staff of the Centres, and other target groups, in co-operation with the Centres and other educational establishments;
7. Coordinate and monitor implementation of public health activities derived from the National Programme of Public Health together with the Centres;
8. Implement and coordinate public health measures in case of epidemics and other emergencies on the territory of the Republic of Macedonia, in collaboration with other institutions;
9. Participate in international co-operation with peer institutions in the field of public health, and provide health data to international organisations in accordance with the Law;
10. Organise and implement research in the field of public health;
11. Conduct laboratory control of pharmaceuticals and agents;
12. Monitoring and assessment of the risks caused by physical, chemical, biological and radiology agents in the environment, with special emphasis on ionizing radiation and non-ionizing radiation ;
13. Act as a reference laboratory and;
14. Perform other tasks at the request of the Ministry of Health in accordance with the Law.

(2) The activities of paragraph 1 of this Article shall be carried out through analysis, planning and assessment, health promotion, and prevention of diseases, research in the area of public health including mother and child care, communicable and non-communicable diseases, provision of expertise and consultancy and methodology assistance, training and education in the field of public health, assessment of the health risks due to environmental factors, and risk factors related to the behaviour and lifestyle with participation in implementation of public health measures in case of emergencies.

(3)The Institute is to submit an annual report on its activities to the Ministry of Health.

Centres for Public Health

Article 11

(1) The Centres for Public Health (hereinafter: Centre) for the needs of the state and municipalities in which they are founded, shall perform the following tasks;

- 1) Define and prepare medium-term and long-term work plans for the implementation of public health activities, including health promotion, screening of the population, monitoring and control of communicable and non-communicable diseases for the territory under the Centre.
The basis for the annual work plan of each Centre is the National Annual Programme for Public Health;
- 2) Prepare annual evaluation reports on the health of the population, and propose measures for overcoming public health problems for the territory under the Centre;
- 3) Collect, process and analyze records and sets of data stipulated by the Law;
- 4) Monitor, analyse, and evaluate the environmental health and sanitary conditions via risk assessment, as well as propose measures for overcoming public health problems;
- 5) Study and monitor the hygienic and environmental health conditions in regard to the protection of air, foodstuffs and general usage items safety, drinking water, surface water, waste waters and solid waste materials, etc.
- 6) Study the nutrition of the population, as well as the diseases and conditions which emerge as a consequence from improper nutrition, and propose measures for the elimination thereof;
- 7) Microbiological and physicochemical laboratory services, analysis and evaluation of laboratory data, and propose measures for overcoming the public health problems;
- 8) Monitor, analyse, evaluate and implement measures for protection of the population against occurrence of communicable and other diseases, epidemics and other emergencies, and carry out active and passive immunisation.
- 9) Define and implement health education for target groups for the area under the Centre;
- 10) Implement preventive DDD measures of public health interest;
- 11) Draft operational plans for its territory in the framework of the National Strategy for Protection of the Population in case of public health emergencies;
12. Research in the field of public health occurrences and problems and
13. Carry out other public health activities following a request by the Ministry of Health.

(2) Entries of paragraph 1 of this Article shall be carried out by means of analysis, planning, and evaluation; health promotion; disease control and prevention (communicable and non-communicable diseases), including public health emergency preparedness, assessment of the influence of the environment to the health and microbiology and physicochemical analysis.

(3) The Centre, on the basis of an approval obtained by the Ministry of Health, can

carry out certain specialised activities within the scope of activities mentioned in paragraph (1) of this Article.

(4) The Centre is to submit an annual report on the activities to the Ministry of Health.

Criteria for Establishment of Centres

Article 12

(1) Activities pursuant to Article 11 of this Law for the area of one or more municipalities shall be provided and coordinated by the Centres.

(2) The Centre can be established for the area of one or more municipalities with at least 70.000 inhabitants, and for the area of the city of Skopje one Centre is established.

National annual programme for public health

Article 13

(1) The provisions of the Articles 10 and 11, are also implemented by the Institute and the Centre in accordance to the Law on Health Care/Protection and with the National Annual Programme for Public Health (hereinafter: Programme).

(2) The Programme of paragraph (1) of this Article, following a proposal by the Ministry of Health shall be adopted by the Government of Republic of Macedonia.

Quality assurance

Article 14

(1) Quality assurance in performance of activities pursuant to Articles 10 and 11 of this Law in the Institute and the Centres is provided through development and following of agreed professional standards and guidelines, continuing professional development of staff, accreditation of laboratories, and internal control over professional activities.

(2) The Institute and the Centres are themselves responsible for assuring the quality of the services they provide according to jointly developed guidelines. In their annual reports they will describe their efforts and results in this field in the past year and their commitments for the coming year.

(3) The Institute will oversee and assess the activities of the Centres in regard to public health functions according to a jointly developed protocol by the Institute in collaboration with the Centres, on which an approval is given by the Minister of Health.

(4) The Institute will provide reference laboratory services for the laboratories of the Centres according to their needs.

(5) The Institute and the Centres will provide opportunities for continuing professional development to their staff in order to maintain the required level of expertise. The Institute will assist the educational and training activities of the Centres as required.

(6) The laboratories of the Institute and the Centre are accredited in accordance to the Accreditation Regulations.

Collaboration with the state organs
Article 15

(1) In response to the public health needs and emergencies, the Institute and Centres shall provide technical and expert assistance and data delivery and information to the State Sanitary and Health Inspectorate and the Food Directorate, shall submit data and information necessary for ordering measures by the State Sanitary and Health Inspectorate and Food Directorate to natural persons and legal entities, pursuant to this or another Law.

(2) For enforcement of measures stipulated in this or another Law, teams comprised of representatives from the Institute and Centres, and of the State Sanitary and Health Inspectorate and Food Directorate can be formed.

Operation Principles of the Institute and the Centres

Article 16

The Institute and the Centres shall position the delivery of operations stipulated in Article 10 and Article 11 of this Law in the following principles:

- 1) Clearly defined public health purpose;
- 2) Public health procedures based on modern, scientifically sound principles and evidence;
- 3) Well-targeted interventions by involving the optimal number of persons in accordance with public health standards.
- 4) Undertaking intervention which is least restrictive to the rights and interests of individuals in the course of protecting public health;
- 5) Undertaking intervention which will not in an unlawful manner discriminate individuals on the basis of their race, sex, ethnicity, nationality, religious beliefs, assets, sexual orientation, or disability status and
- 6) Respect the dignity of each individual during a public health intervention

IV.COORDINATION AND COOPERATION

National Council for Public Health

Article 17

(1) The Government of Republic of Macedonia shall establish a National Council for Public Health (hereinafter: National Council) as an advisory body dealing with public health issues of shared competency scope of two or more ministries.

(2) The National Council shall study the public health issues and policies, especially safety of the food, water, air and soil, shall prepare opinions, initiatives and/or proposals to submit to the competent authorities for the implementation of this and other Law.

(3) The National Council shall be comprised of a chairman and 14 members representatives from the Ministry of Health, Ministry of Environment and Physical Planning, Ministry of Labour and Social Policy, Ministry of Education and Science, Ministry of Agriculture, Forestry and Water Economy, the Ministry of Local Self-Government, the Institute and independent experts in the area of public health.

(4) In the course of appointment one should consider an equal representation of the entire population in Republic of Macedonia.

(5) The National Council shall be chaired by the Minister of Health.

(6) The National Council shall adopt Rules of Procedure.

Councils for Public Health

Article 18

(1) The Local self-government units in their area shall form Council for Public Health.

(2) By exception of the paragraph (1) of this Article, two or more local self-government units can create Council for Public Health, at which each of the units will be represented by one member.

(3) The Council of paragraph 1 of this Article shall be comprised of 5 members, of which at least 4 shall represent the municipality and one member shall represent the Centre of Public Health within the area of the municipality .

(4) In the cases of the paragraph (2) of this Article total number of members of the council can be higher than 5, depending on the number of municipalities that comprise the same and with odd number of members.

(5) For the area of the city of Skopje, a Council for Public Health of the city of Skopje is established, consisted of 13 members from which one representative of the municipalities included in the structure of the city of Skopje, two members from the Centre for Public Health of the city of Skopje, and three members- independent experts from the public health area.

(6) The Councils for Public Health shall study the public health issues and policies, shall prepare opinions, initiatives and/or proposals to be submitted to the competent organs of the units of the local self-government.

(7) Members of the councils pursuant to paragraphs (2) and (3) of this Article elect a chairman between themselves.

(8) The Council shall adopt rules of procedure for its operation.

Intermunicipal cooperation

Article 19

(1) The units of the local self government can deliver additional activities of interest for public health for their own territory, in cooperation with the Centres for which purpose they have self- generated funds.

(2) The units of the local self government within the inter-municipal cooperation can found a joint working body, committee, coordinative or other expert authority for the purpose of exchange of information, experiences and coordination of the public health cooperation for the territory of their municipality, in accordance with Law.

V. PUBLIC HEALTH EMERGENCIES

Public health emergencies on the state level

Article 20

In case of public health emergencies the Ministry of Health, the Institute and the Centres in cooperation with the other competent authorities and institutions act in accordance with this and other Law.

Public health emergencies of international concern

Article 21

(1) In case of suspected occurrence of public health emergencies of international concern prescribed by the International Health Regulations, the Centre/Centres shall inform the Ministry of Health and the Institute.

(2) The Ministry of Health shall decide if the public health occurrence is of international concern, in accordance with the decision-making assessment instruments stipulated in the International Health Regulations, for which the National Focal Point shall inform the Contact Centre in the World Health Organization according to notification instrument appropriate for such instances, set forth in the International Health Regulations within 24 hours of performed assessment.

National Focal Point

Article 22

The Institute shall be the National Focal Point for the application of the health measures from the International Health Regulations.

Acting in instances of suspicion of a presence of an onboard infectious disease

Article 23

(1) The captain of an aeroplane in an international flight who wants to land at the airport, and who knows or seriously suspects that one or more passengers on board of the aircraft show signs of an infectious disease that may endanger public health, must inform the air traffic controller or the operator at the airport immediately after discovering and before landing.

(2) The air traffic controller must immediately inform the operator of the airport whereas the latter shall inform the responsible person of the medical team of the airport.

(3) The responsible person of the medical team of the airport shall immediately inform the State Sanitary and Health Inspectorate and the Institute.

General declaration of the aircraft and other information

Article 24

(1) Pursuant to a request by the State Sanitary and Health Inspectorate, the captain of the airplane in charge of the international flight shall prepare and submit the Health Part of the Aircraft General Declaration prepared in accordance with the International Health Regulations.

(2) In addition to the Health Part of the paragraph (1) of this Article the State Sanitary

and Health Inspectorate can ask the captain for additional information about the airplane regarding the health situation of the passengers on board.

Entry point Article 25

(1) In case of accepting notification of Article 23 paragraph (1) of this Law, or if suspicion of a potential public health danger on board of an aeroplane has arisen otherwise, the Minister of Transport, after consultation with the Minister of Health, can determine at which airport the aeroplane should land in accordance with the International Health Regulations.

(2) The Minister for Transport following an opinion stated by the Minister of Health shall designate the airport which is to be the entry point for cases pursuant to Article 23 of this Law.

(3) The operator of the airport of paragraph (1) of this Article is obliged to provide the capacities as prescribed by the International Health Regulation.

State Sanitary and Health Inspectorate actions Article 26

(1) In case of Article 23 of this Law, the State Sanitary and Health Inspectorate shall order a list of measures to be applied upon arrival of the airplane in the airport.

(2) In case of a direct threat of an epidemic of an infectious disease, the State Sanitary and Health Inspectorate will decide on measures which must be taken regarding the admission of crew and passengers of the aeroplane.

(3) In cases of paragraphs (1) and (2) of this Article, the captain of the aeroplane will assure that after landing of aircraft, nobody is to enter or exit the aircraft, and no goods will be loaded or unloaded, until permission of the State Sanitary and Health Inspectorate is obtained.

(4) The captain of the aircraft shall, upon request, submit a list with the names, addresses, sex, age and destination of the passengers to the State Sanitary and Health Inspectorate.

Article 27

The State Sanitary and Health Inspectorate can order the operator of the airport:

- 1) to give information to passengers to take measures to prevent infection or contamination of the luggage;
- 2) to assist the Institute or the State Sanitary and Health Inspectorate with the investigation of departing or arriving passengers for the presence of an infectious disease with a risk of serious danger to the public health;
- 3) to carry out technical-hygienic measures for the prevention of contamination, if there is a well-founded risk of contamination;
- 4) to close buildings or sites, or parts thereof, for the control of contamination.

Article 28

The State Sanitary and Health Inspectorate can order the operator of an aircraft:

- 1) to give information to passengers to take measures to prevent infection or contamination of the luggage;
- 2) to carry out technical-hygienic measures on the aircraft and its cargo for the prevention of contamination, if there is a well-founded risk of contamination;
- 3) to check an aircraft and its cargo for the presence of contamination;
- 4) to disinfect an aircraft and its cargo for the control of contamination, including the destruction of vectors.

Road border crossings

Article 29

Designation of the ground border crossings in the aspect of implementation of the health measures shall be regulated in accordance to the International Health Regulations.

Active and passive immunisation and prophylaxis

Article 30

- (1) Active or passive immunisation of persons or the use of prophylaxis in order to obtain an internationally valid certificate as described in the International Health Regulations will be provided according to the Regulations for Protection of the Population from Communicable Diseases.
- (2) The Minister of Health will designate health institutions that can provide active or passive immunisation and chemoprophylaxis of persons that are part of international travel arrangements.

Airport Operators Costs

Article 31

The operators of airports as well as operators of aircrafts shall cover all costs for the implementation of the measures of this Law and the International Health Regulations.

Article 32

The International Health Regulations shall be published on the web page of the Ministry of Health .

VI. SPECIAL PROVISIONS

Traditional and complementary medicine,
tattoo, piercing, permanent makeup, acupuncture and beauty care activities

Article 33

- (1) A legal or natural person can perform activities related to traditional and complementary medicine, activities on the skin (usage of solariums, permanent hair removal and other beauty care activities) or activities by which the skin is punctured (tattoo, piercing, permanent makeup and acupuncture, usage/application of botox, neurosurgical liposuction and laser application) only if a permit by the Ministry of Health is obtained.

- (2) The permit pursuant to paragraph (1) of this Article is issued if the criteria regarding the facilities, equipment and skilled staff are fulfilled .
- (3) It is forbidden to make a tattoo or piercing , except on the earlobe, for persons under the age of 16.
- (4) For persons above the age of 16, and under the age of 18, tattoos and piercing may be applied, only by written consent of the parent or guardian.
- (5) For the persons to whom these services from paragraph (1) of this Article are given, a prior elaboration of possible consequences is compulsory.
- (6) Detailed terms and conditions regarding the facilities, equipment and skilled staff for performance of the activities pursuant to paragraph (1) of this Article shall be prescribed by the Minister of Health.

Revocation of the work permit

Article 34

The work permit pursuant to Article 33 of this Law can be revoked if changes occur as a cause of which significant deviation according to Article 35 of this Law has been performed.

Provision of information on the health effects of cosmetic services

Article 35

The Minister of Health shall prescribe type of information in regard to the health effects by the services and the way of provision of information to the persons that use services pursuant to Article 33 of this Law, and may pose a health risk to the client of the service.

VII. FINANCING OF PUBLIC HEALTH ACTIVITIES

Sources of financing

Article 36

Funds for public health funding shall be secured from the following sources:

- 1) Budget of the Republic of Macedonia;
- 2) budgets of the units of the local self-government;
- 3) self- generated income;
- 4) donations and
- 5) other sources of revenues regulated in another Law.

Allocation of resources from the Budget of Republic of Macedonia

Article 37

- (1) The funding of public health operations of the Institute and Centres shall be carried out under the programme pursuant to Article 13 of this Law.
- (2) The resources required for realization of the programme pursuant to paragraph (1)

of this Article are established on the basis of criteria in regard to the required facilities, equipment and staff for performance of these activities, number of inhabitants, territory, and the area covered by the Institute, or the Centre and volume of activities that need to be implemented in regard to the determined public health needs.

(3) On the basis of criteria from paragraph (2) of this Article the Government of the Republic of Macedonia will establish a resource allocation formula for funding of the public health activities of the Institute and the Centre.

**Control over the earmarked utilization of the resources from the Budget of the
Republic of Macedonia
Article 38**

The Ministry of Health shall control the earmarked utilization of the funds allocated from the Budget of the Republic of Macedonia.

**Self-generated income
Article 39**

- (1) The Institute can generate income by providing services to natural and legal persons, provided such services can not be provided by the Centres.
- (2) The Centres can generate income by providing services to natural and legal persons, within the frames of the activities pursuant to Article 11 of this Law.
- (3) Centres for the services pursuant to paragraph (1) of this Article are determined by the Institute, that is The Centres, and approval is given by the Minister of Health.

**Funds of the units of the local self-government
Article 40**

The funds for funding of additional activities of the public health interest in the area of the units of the local self-government are provided from the budgets of the units of the local self-government.

**Funds from the Health Insurance Fund
Article 41**

In a case when the Institute and the Centres provide diagnostic-laboratory services to individually insured patients according to a referral, the expenses for such services are to be covered by the Health Insurance Fund of the Republic of Macedonia.

**VIII. SUPERVISION
Supervision
Article 42**

- (1) Supervision over the application of the provisions of this Law shall be carried out by the Ministry of Health.
- (2) Inspection supervision over the implementation of the provisions of this Law shall be carried out by the State Sanitary and Health Inspectorate compliant to the Law.

IX. PENAL PROVISIONS

Article 43

(1) Fine in the amount of 1.000 to 1.500 EUR in MKD equivalent value shall be issued for a misdemeanour to a legal person, if:

- 1) does not provide the facilities prescribed by this Law (Article 25 paragraph (3));
- 2) does not act by the order in accordance to the Articles 27 and 28 of this Law
- 3) perform active or passive immunisation of persons or the use of prophylaxis without authorisation (Article 30);
- 4) perform professional activity adversely to Article 33 of this Law and
- 5) make tattoo or piercing, except in the earlobe, to persons under the age of 16 and/or make tattoos on head, neck, wrists or hands, and for genital piercing (boys and girls) and nipple piercing (girls only) to the persons above the age of 16 and under the age of 18 without a written parental or guardian's approval (Article 33 paragraphs (3) and (4)) .

(2) for the misdemeanour pursuant to paragraph (1) of this Article, a fine in amount from 500 to 800 Euro in MKD equivalent value shall be issued to the responsible person within the legal entity.

Article 44

A fine in amount of 500 to 800 Euro in MKD equivalent value shall be issued for the misdemeanour to the natural person, if:

- 1) does not act in accordance with Article 23 of this Law;
- 2) does not prepare and submit the Health Part of the Aircraft General Declaration prepared in accordance with the International Health Regulations or does not submit additional information regarding the health situation of the passengers on board on request of the State Sanitary and Health Inspectorate (Article 24);.
- (3) allow the entrance or exit of the aircraft, and/or goods to be loaded or unloaded, until permission of the State Sanitary and Health Inspectorate is obtained.
- 4) perform professional activity adversely to Article 33 of this Law and
- 5) make tattoo or piercing, except in the earlobe, to persons under the age of 16 and/or make tattoos on head, neck, wrists or hands, and for genital piercing (boys and girls) and nipple piercing (girls only) to the persons above the age of 16 and under the age of 18 without a written parental or guardian's approval (Article 33 paragraphs (3) and (4)) .

Article 45

The competent authority for handing down of the penal provisions pursuant to Article 43 and 44 of this Law is the competent Court.

Article 46

Before submission of request for misdemeanour procedure, for the misdemeanours stated within this Law, The Ministry of Health initiate out of the court procedure, in accordance with the Law on Misdemeanours .

X. TRANSITIONAL AND FINAL PROVISIONS

Article 47

On the day of entering into force of this Law, the Institute of the PHI Health Home Skopje-Skopje from the part of the working unit- The Institute for Mother and Child

Care take on the employees that perform public health activities and tasks, movable and immovable property and other assets.

Article 48

Bylaws as foreseen with this Law shall be passed within a one year time limit counting from the day of entering into force of this Law.

Article 49

Existing legal and natural persons that perform activities pursuant to Article 33 paragraph (1) of this Law will harmonise their operations with the provisions of this Law in a time limit of 18 months starting from the day of entering into force of this Law.

Article 50

With the day of entering into force of this Law cease to exist provisions pursuant to Article 110 paragraphs 2 and 3 of the Law on Health Care/Protection (“ Official Gazette of Republic of Macedonia” number 38/91, 46/93, 55/95, 10/2004, 84/2005, 111/2005, 65/2006, 5/2007, 77/2008 and 67/2009).

Article 51

This Law shall enter into force on the eight day following the publication in the “Official Gazette of Republic of Macedonia”, and provision pursuant to Article 13 of this Law in regard to the programme will start with their implementation from 1st of January 2011.