**The contribution of the Ministry of Health for the Subcommittee "The internal market and Competition" Brussels, 5 March 2015.**

***Mental Health (March 2014 – February 2015)***

Taking into account all the developments regarding mental health legal framework, from the entry into force of the Law 44/2012 “On Mental Health”, on June of 2012, and the approval of the Operational Plan for Mental Health Services Development in Albania, 2013-2022, at the beginning of the last year, the work for 2014 has been focused mainly on monitoring the implementation of the legal framework and the development of regional plans for the implementation of the above mentioned national action plan.

All this process has been coordinated by the National Committee for Mental Health, chaired by the Deputy Minister of Health. This committee, as an intersectorial consultative body to the Minister of Health, is implementing an ambition agenda, by organizing meetings in regions where the mental health services are located. The on-site meetings and visits are aiming to provide to the members of the committee with a concrete and direct perception of the mental health services, the background, the capacities and the eventual needs and gaps.

Actually, were organized four meetings in Tirana (May 2014; December 2014), Korça (June 2014), Elbasan (November 2014), also in Tirana, on 30 October 2014 was attended the first meeting of the Coordinating Group for the Implementation of the National Mental Health Action Plan at regional level (appointed by Order of the Deputy Minister No. 371, dated 03.09.2014). The outcomes of this meetings has been very fruitful, by underlying the provision in the next year budget, the establishment of one supported home for 12 persons (6 women and 6 men) in the district of Korça.

Meanwhile the experts from Ministry of Health, Ministry of Social Welfare and Youth, Ministry of Justice, World Health Organization, Ombudsman, State Policy, and other relevant actors dealing with mental health, are evaluating the local/regional possibilities on human and infrastructure resources for establishment of elements of the integrated mental health services system (acute mental health inpatient services in regional hospitals, community mental health centres, etc.), aiming the closure of the two psychiatric hospitals. To support this activity the Minister of Health has proposed to the Minister of Social Welfare and Youth to both establish an inetersectorial working group who will analyze and propose the ways to address the chronic residents’ issues, specifically those with mental retardation, which from years are accommodated in both two psychiatric hospitals of the country. This co-order is planned to be signed within February 2015, and will be co-chaired by the relevant Deputy Ministers of Health and Social Welfare and Youth.

As regards to mental health legal framework, during this period (March 2014 – February 2015), on 12 November 2014, has been adopted the Council of Ministers Order No.762, on “Organization and provision of mental health care for people who are in residential care institutions”, according to the article 18, paragraph 2 of Law No.44/2012 "On Mental Health". Meanwhile on 19 November of 2014, has been adopted the Order of the Minister of Health No.504, for “One addition and change in the order of the Minister of Health, No.386, date 17 June of 2013 "On the establishment of the medical commissions for direction in KMCAP for patients with mental health disorders”, amended, in implementation of Article 19, paragraph 5 and Article 20, paragraph 4 of Law No.44/2012 "On Mental Health".

***E-health (March 2014 – February 2015)***

1. **The EHR Project.** The agreement of export credit (the Austrian soft loan) for the contract between AME International GmbH and the Ministry of Health of Albania to establish the National Health Electronic Record (EHR) is ratified on 03.07.2014.

**Status:** The project has started

The Ministry of Health in collaboration with some of its institutions of dependency has started creating some projects in the field of computerization of the health system.

1. **The e-prescription project:** is initiated by the Ministry of Health in collaboration with the Social Insurance Fund. E-prescription system will enable more efficient management of medical drugs. Through this project, the hard copy recipes will be eliminated and the prescriptions can be accessed online from the parties involved in this process:
* doctors
* patients
* pharmacists

**Status:** From January 2015, the project has started its pilot implementation in the District of Durres.

1. **Inventory of biomedical equipment.** Currently at the National Centre of Biomedical Engineering operates a system that manages data equipment in 10 hospitals. The aim is to include all health units, hospitals or centres, with data on the equipment they dispose and their working status.

**Status**: In progress

1. **Health Facility Inventory List** is initiated by the Ministry of Health. This project aims to have complex information for any health centre or hospital, the building, laboratories, equipment and personnel working near them. All the data collected will be placed in a data centre at the Ministry of Health.

**Status:** The project is in the final stage of implementation

1. **The Track & Trace** project is initiated by the Ministry of Health in collaboration with the National Centre of Drug Control. This project aims to:
* Ensure reliable supply of medical drugs to patients
* Prevent forgery, fraud, smuggling and illegal sale of medical drugs
* Setting up the system with barcode for tracking medication
* Support for the rational use of medical drugs and getting data to monitor

medicaments market

**Status:** In progress for the creation of the ToR

1. For the creation of e-health components such as **Hospital Management System**, the Ministry of Health is negotiating with the World Bank for a comprehensive credit where the e-health component is an integral part of the negotiation package.

***Progress on implementation of the operational Measures for the Roma and Egyptians. (March 2014 – February 2015)***

* In February 2014, the Ministry of Health has supported the proposal of the Vodafone Albania Foundation for the inclusion of Roma Community to the project for basic health control, through the use of telemedicine medical techniques. They report once a year, and monitoring carried out jointly with the Ministry of Youth and Social Welfare and the Public Health Institute.
* In the framework of drafting the New Action Plan for the Integration of Roma and Egyptians 2015-2020, as part of the Policy Document on Social Inclusion, lead by Ministry of Social Welfare and Youth, the Ministry of Health has taken its commitment to develop specific measures, in cooperation with civil society, to address the health problems of Roma and Egyptians community, and to build sustainable integration by providing equal access to health care services. **Strategic goal in the healthcare field is to ensure *accessible, affordable and equitable healthcare* to Roma and Egyptians.**

Status: In progress.

***Blood Transfusion and Transplants (March 2014 – February 2015)***

This project is funded by the IPA Adriatic Cross-border Cooperation Program”. The period of implementation is March 2011-February 2014. The following outputs have been achieved:

* Software for management of voluntary blood donors;
* Development of European common promotional campaigns aiming at increasing the number of ethical blood donors and raising the awareness on blood safety issues among potential donors and current donors;
* Recommendation book for policymaker in management of blood donors;
* Ethical chart for voluntary blood donors;
* Memorandum of Understanding between network partners.

Another project that was implemented in this field is the project for the prevention of infection transmission through safer blood and components, which was funded by Italian Albanian debt for development. The objectives of the projects are:

* Sufficient blood through more voluntary non-remunerated donations;
* Safer blood through improvement of testing;
* Correct use of transfusion in the clinical side.

The period of implementation is June 2013 June 2015. The implementation of the project activities are s in process. Until February 2015 the following outputs have been achieved:

* 1. Promotion activities are in process.
	2. Testing of blood donors for Virus of hepatic B and C. this activity has finished
	3. Preparing the protocols, guidelines and pocket book for clinical use of blood is in process.

***Medical devices (March 2014- February 2015)***

The Law 89/2014 “For Medical Devices” was approved by Albanian Parliament.

The law enables partially approximation of the three European directives:

Directive 93/42/EEC of 14 June 1993 for Medical Devices,

Directive 98/79/EEC of 27 October 1998 "On the diagnostic medical devices in vitro"

Directive 90/385/EEC dated 20 June 1990.

The law regulates the circulation of medical devices in Albanian market and will improve the safety for the patients and users.

The law defines and enables the regulation of:

Drugs and Medical Devices Agency for registration, inspection, and adverse event report.

The registration of medical devices and registration of persons responsible for putting medical devices in the market.

The essential technical requirements that medical devices, in vitro medical devices and implantable medical devices must meet.

Conformity assessment procedures for medical devices, authorization criteria for conformity assessment bodies for medical devices, documentary requirements needed to be submitted to the competent authorities before putting on the market and / or using of medical devices,

Vigilance system and market surveillance procedures.

Within deadlines previewed by the law, the sub laws (CMD, Orders of Minister) will be prepared.

***Increasing institutional capacities and new investments in Health sector. (March* *2014-February 2015).***

There are prepared the costing 10 packages of the the most important diseases of the heart and kidneys, enabling contracting and financing of the patients in private hospitals.

• Start-up of Check-up for ages 40-65 years old

• Repayment of obligations created last years at the level of 90%

• VAT is removed for medication and medical materials.

• It doubled funding for treatment with chemiotherapy in the Oncologic Service.

• A CT scanner for Trauma Hospital was purchased.

• 2 mobile mammography were purchased.

• It was conducted for the first time after 25 years disinfection of wetland areas of the country.

• Significant intervention in the infrastructure of some hospitals as:

- New Building in Vlora Psychiatric Hospital.

- Completion of the civil works and conversion of the former Sanatorium in an University Hospital Center

- Civil works at the pathology service at Koco Gliozheni Maternity.

- Reconstruction and complete furniture and equipment for the Neurology Service at the University Hospital Center.

 - Purchasing of a medical helicopter.

* Purchasing of autoambulances.

- Purchase of 2 angiography equipment for TUHC and Hospital of Shkoder.

- Purchasing of a Magnetic Resonance for Trauma University Hospital.

- Purchase of a set of modern medical devices for cardiac surgery service at University Hospital Center.

- Purchase of a incubators for the Maternities of Tirana.

***Cancer (March 2014- February 2015)***

*Cancer registry.*

Decision of council of Ministers 327 28/05/1914 on data reporting from public and private health service providers covers the cancer registry among other health registries.

June 2014 –One day Workshop with national and international experts on population based cancer registry. Ministry of Health (MoH), Institute of Public Health (IPH), Hospital University Center (HUC) and experts from Italy and Slovenia. Supported by IAEA. A draft regulation of the Population based cancer registry is prepared.

*Training for cancer screening and cancer awareness*

April-September 2014 - Finalisation of primary health care professionals training on breast cancer early detection. 10 more 2-days accredited training courses organized in Tirana Lushnje, Lezhe, Ballsh, Korce, Bilisht and Corovode with around 300 professionals trained. IPH-THUC with support from IAEA

November 2014 - A new accredited 4-day training on cancer screening programme management is organised by IPH in collaboration with Italian experts from Cancer Screening Center of Regione Piedmonte. 40 public health specialists from Tirana and all regions were trained. Course was supported by UNFPA.

*Cancer screening workshops and conferences.*

May 2014- international workshop on cancer screening in Albania with participation of experts from IARC Lyon. MoH-IPH-UHC supported by IAEA.

May 2014 – International cancer conference Academy of Sciences, UHC, IPH, MoH with international experts from EU countries and Western Balkan countries.

February 2015 – workshop on short term cervical screening plans IPH-UHC-MoH with support from UNFPA. Plans for 2015-2016 which include preparation of guidelines and standards and training of professionals were agreed upon

.

*Breast cancer screening campaign.*

October 2014 order of Minister of Health 407 27 /09/2014 on organising a campaign for breast cancer screening 2 new mobile mammography units were procured and started to work in Tirana by 30 th of October 2014 and in other towns of Albanian by 15th January 2015.

During the campaign 8500 mammograms were carried out in all Albania (a similar number is performed during all year in the country)

A large number of awareness raising activities were organised during October 2014 in Tirana, and other regions of Albania (conference with prime minister Participation, March, marathon, public information, social media and mass media activities etc.

***Drug prevention (March 2014- February 2015)***

June-October 2014. For the first time a general population survey was carried out and the preliminary report was prepared. A representative sample of Albanian population (15-65 years old) was reached at their homes by trained interviewers. IPH provided technical support. The project was supported by EMCDDA in Lisbon.

November 2014- February 2015. A survey on problematic drug users is underway. The aim is to estimate the size of problematic drug users in population and gather other data on these group, by using respondent driven and capture-recapture techniques. The activities are carried out by IPH, UHC and Aksion Plus. The project is supported by UNODC.

November 2014. The second Drugs National report is finalised by a group of experts from IPH, UHC and Ministry of Interior.

November 2014. An international conference on internet based drug control services was organised in Tirana with participation from EU experts and representative of south Eastern Europe. The conference was supported by TAIEX

Decision of council of Ministers 327 28/05/1914 on data reporting from public and private health service providers covers the drug related service utilisation among other health registries.

***Tobacco (March 2014 – February 2015)***

As regards legislative developments, in the field of tobacco control, during March 2014 - March 2015, the following activities were carried out:

* The Albanian National Assembly, on the proposal of the Council of Ministers, adopted amendments. Legislative changes to the existing law, No. 76/2014, No 8652, dated 30.07.2014 “On Amendments and Additions to the Law No. 9636, dated 06.11.2006 “On protection of health from tobacco products”, aiming prevention of smoking in indoor public environments. The changes were enacted on 23 August 2014.

According to the amendments, smoking has been completely banned in workplaces ; health institutions (except for patients of mental health institutions) ; educational establishments ; public transport facilities, including taxis ; indoor shopping malls, bars, restaurants, discos and night clubs; cultural and sports facilities; shared areas of private homes’ buildings; and enclosed areas of any other public facilities. Fines are applied, for the first time, to the client violating the non-smoking rule. In the case of the owners of premises, the fines were increased by 6 times (from 50,000 to 300,000 Albanian Lek).

As an additional new requirement of the Act, the Albanian Radio and Television will have to broadcast 90 minutes of anti-tobacco information each month.

* The tax reform, increasing the tobacco excise.

 In January 2015 had risen cigarettes excise 90 lek per pack 110 lek per pack

* Training of health personnel in schools of Tirana, focusing on young people and their relationship with smoking. The training curriculum is part of the curriculum prepared by health promotion specialists of IPH, under the support of the MoH and WHO. Trainings continued until the end of 2014. Until now there are trained 90 school doctors, covering as well health promotion specialists from other districts.
* Training workshop for health professionals.

 “The Alcohol, Smoking and Screening Test (ASSIST) and brief intervention, manuals, for use in primary care”. 75 Family doctors from policlinics of country participated in it.

* Organization of the World Day “No Tobacco“, where meetings and conversations with students of public health on tobacco control policies, took place.
* According the methodology recommended by WHO, the sector of tobacco control in IPH, has given assistance for smoking cessation on more than 25 persons, and on 15 persons for alcohol consuming.

***Approximation of Albanian legislation with EU Acquis (March 2014 – February 2015)***

Ministry of Health for the period March 2014 February 2015 in the field of approximation of national legislation with the EU Acquis has been approximation with the following directives;

Directive 90/269/EEC. DCM no. 523 of 6.8.2014 “On the approval of the Regulation “On the minimum health and safety requirements regarding for the manual handling of loads and for repiling points 15.1-15.10 of Annex V of the DCM no. 312, dated 5.5.2010 “On the approval of regulation for security at the construction area.

Directive 2004/37/EC. DCM no. 520 of 6.8.2014 “On the approval of the Regulation “On the minimum health and safety requirements regarding the exposure of workers to the risk related to exposure to carcinogens or mutagens at work”

Directive 98/24/EC, DCM no. 522 of 6.8.2014 “On the approval of the Regulation “On the minimum health and safety requirements regarding the exposure of workers to the risk related to chemical agents at work”

Directive 2000/54/EC, DCM no. 550 of 27.08.2014 “On the approval of the Regulation “On the minimum health and safety requirements regarding the exposure of workers to the risk related to exposure to biological agents at work”

Directive **2003/10/EC** of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise); (Seventeenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

Celex no: **2003l0010.**

Directive 90/270/EEC, DCM no. 521 of 6.8.2014 “On the approval of the Regulation “On the minimum health and safety requirements for work with display screen equipment”.

Directive 2002/44/EC, DCM no. 842 of 12.2014 “On the approval of the Regulation “On the minimum health and safety requirements regarding the exposure of workers to the risk arising from vibration”

Directive 2013/35/EU, DCM no. 843 of 12.2014 “On the approval of the Regulation “On the minimum health and safety requirements regarding the exposure of workers to the risks arising from nonionizing fields”

Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 On the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation) (19th individual Directive within the meaning of Art. 16(1) of Directive 89/391/EEC) (OJ L 114, 27.4.2006, p. 38), DCM no. 844 of 12.2014 “On the approval of the Regulation “On the minimum health and safety requirements regarding the exposure of workers to risks arising from artificial optical radiation”

***Communicable Diseases (March 2014- February 2015)***

Order of Minister of Health Nr. 463 Date. 29.10.2014 on, “Draft National Guide And Protocols On Prevention transmission of infectious agents from mother to child "

***Improving quality and access to healthcare services for all - Reform of the primary healthcare system and sustainability.***

• In accordance of the program of the Government to establish a periodic inspection program Nationals 40-65 years age group, based on DCM. 185, dated 2.04.2014 "On determining the manner of implementation of Basic Medical Control for citizens ages 40-65 years", in 2014 and preparatory work was done in 2015 has been the implementation of the above program.
There are about 900 thousand Albanians citizen who are invited, once a year to appear in the health center location and make basic health control, which is offered free to any citizen, whether or not insured for health care .

The program includes:
a) Assessment, counseling, treatment, and follow the life style factors;
b) measurement, assessment, counseling, referral and prosecution of physiological parameters;
c) measurement, assessment, counseling, treatment, referral and prosecution of biochemical parameters.
This Is the first step major and concrete towards universal coverage.

In each of the 415 health centers, basic control will be offered through five mobile units, which will be available to people who live far from the health center, and especially, to remote areas, where unlike the usual procedure where anyone could make basic control during birth, control will be provided in the period 1 May to 30 September of each year. Is drafted and adopted legal and regulatory framework, has been drafted the medical protocol of control, has been drafted Manual of training. Are trained trainers and medical staff and nurses, is selected private entrepreneur charged for the initial investment and logistics realized daily for a period of 10 years, has launched a public information program.

• Removal of VAT on health care services and medicines. In force since 1 April 2014. Removal of VAT 20% for all implantable medical devices, including cardiology, dentistry, orthopedics, etc. It reconfirming in July with the new law of VAT.

• Expanding the list of reimbursable drugs to 56 new drugs.

• Investments are realized and realized in primary health care, including:

Reconstruction of the specialties Polyclinic No. 2 in Tirana;
New health center in Divjake;
Health centers in Koplik
Health Center in Rrogozhinë;
Health center in the municipality Anes se Malit (Shkodra);

Approval of Law No. 138/2014 "On palliative care in the Republic of Albania", which provides the organization of services, the training of professionals in this field and provides access to medicines and social support for terminally patients.
Pilot testing of electronic prescription in Durres.
Replacing of health care card with health card, enabling a reduction of administrative load for the medical staff and computerization of health information.

Based on the Government's program (2013-2017) for health that aims to provide universal coverage for health care for all Albanians resident, where no individual is left without health care because it does not have the necessary financial means; increasing the role of public health and prevention programs and health promotion, Order No. 510 dated 21 11.2014 Minister of Health changed the forecast of the second phase (2014-2016) of providing contraceptives to target only the most vulnerable groups of the population for public health services, the implementation of the National Strategic Document "for providing contraception for 2012-2016 Order stipulates that the estimated period of implementation of the strategy (2015-2016) all contraceptives used in the public sector will be provided free to all populations in need, as was done during the first phase.

Focused campaign

Pursuit of reported cases (October, November)
Systematic analysis of the description of the list of reimbursable drugs in 2014
Continuous surveillance of hospital services
Surveillance and security of continuous supply with drugs
New rules of the way maintenance of apparatus in for public hospitals

Anti-corruption monitoring in the hospital service

From October 2014 the Ministry of Health has launched a service monitoring process across the territory hospital and outpatient care service in several major cities of the country.

During the monitoring process being tested four target groups of 150 services of 42 hospitals in the country: a) hospitalized patients who receive service; b) patients who are hospitalized through the Emergency Service; c) doctors in hospitals; d) hospital nurse But also interviewed doctors, nurses and patients to outpatient care services in Tirana Interviews conducted with different techniques, patients are interviewed face to face on the basis of a semi-structured questionnaire, while doctors and nurses meet individually a structured questionnaire
During the period October-December 2014 were interviewed about 250 doctors (from 1244 hospital care doctors) and 600 nurses (from 4253 nurses hospital care) in most hospitals in the country.

Also, in cooperation with technical and financial support of the World Bank, the Ministry of Health has begun implementing a project on measuring patient satisfaction through their interaction with SMS This project is being implemented in hospital and ambulatory service: University Hospital Center "Mother Teresa" in Tirana as well as regional hospitals and specialty clinics in Shkodra, Vlora, Elbasan, Korca and Durres.

***Progress in addressing health inequalities, in particular access of vulnerable groups to primary health care and access to health care in rural areas.***

In October with an Order No. 407, dated 24.09.2014 of the Minister of Health was organized campaigns of breast cancer screening for women over 50 years age group During this period was abolished payment of examination fee mammography, as well as requests to pass through the referral system
Victims of trafficking are considered economically inactive persons, therefore the payment of contributions is covered by the state or other lawful sources

Law No. 141/2014 On some nr.10383 the Law dated 24.02.2011 '' on compulsory health care in the Republic of Albania ', change the following is added:

In Article 5 point '' ë '' - victims of trafficking according identifying structures made by the Interior Ministry.
Article 29/1 contract with health service providers abroad
Adopted on 23.10.2014.

Throughout 2013 and 2014, the MoH with the support of the international Migration (IOM) through the project 24 months "Strengthening Albania's Efforts Towards an Effective and Sustainable response to trafficking in persons", organized two training sessions a day on May 8, 2013 (Tirana ) and 23 April 2014 (Shkodra), with around 40 representatives of health services by the 12 counties These training consisted of information on legal and institutional framework for human trafficking, the standard procedures of operation and the position of the MoH and health services in the implementation of SOPs,

Initial identification of a VMT, within the territory of the Republic of Albania;
Reference Case respective regional structures trafficking;
Providing health care to the needs of prioritizing emergencies and providing ongoing support;
Help for rehabilitation and reintegration
MOH is in the process of redefining the roles and responsibilities of specialists Services psychosocial and mental health, within DRSH-governmental sectors, roles that will be in focus and VT / VMT, among other vulnerable groups.

In April 2014, in collaboration with Gender Alliance for Development Center, under the project "Support of the Swedish Government to the Ministry of Interior / Albanian State Police Community Policing, funded by SIDA and implemented by SIPU International, conducted training the topic "How to respond to domestic violence" under the law for measures against domestic violence ", with representatives from MoH and institutions responsible for coordinating the response of domestic violence, with a special focus on police officers Albanian state

We all DFS (Directory Foreign Service) are reassigned persons who collaborate responsible for case management when requested by the child protection units in the municipality
Also recently been sent to all public health departments in the districts letter for updating the Order of the Minister no. 230, dt.25.05.2012, to resend the names of the persons responsible for child protection issues, as well as periodic reporting on MOH related cases treated by the health sector.

Safety and Health at Work

During June 2014, with the assistance of the ILO, in the framework of IPA 2010, is working to prepare the draft Decision transposing Council Directive 92/85 EEC "on the introduction of measures to encourage the improvement of safety and health at work for pregnant workers and workers who have recently given birth or are breastfeeding ", which set minimum standards and measures to be taken

In all collective labor agreements at branch-profession stored in MMSR are legal references relevant to the protection of pregnant women and breastfeeding mothers

Decision no. 762, dated 11.12.2014 "On the organization and provision of mental health care services in residential social care institutions"

The DCM no. 762, dated 11.12.2014 "On the organization and provision of mental health care services in residential social care institutions"
Ministry of Health during 2014 has supported the proposal of Vodafone Albania Foundation, the Roma community involved in the project of the association to control or early basic health through the use of telemedicine medical techniques For this reason has made available to this national initiative location map of the Roma community and health centers that are closer to them Vodafone Foundation Reporting becomes once a year, and monitoring carried out jointly with the Ministry of Social Welfare and Youth and Public Health Institute. The Ministry of Health has supported the project implemented by Save the Children in the period August 2013 - July 2014 "9 + 3 Healthy Maternity" The project involved the Roma women in the area and Shkoza , which trained 86 women from weekly information sessions regarding access to health services 61 pregnant women were identified and benefited while pregnant (4 regular checks, support medications, supplements,) and 25 recently married women (future mother) benefited from the project, while 12 women were supported to obtain a health card.

Vaccination is a service provided free of charge to the entire population, including Roma and Egyptian children Nurses make vaccines, going door to door to identify children and to provide those vaccines Migration of Roma and Egyptian families and lack of education makes them vulnerable to every year, the Institute of Public Health makes screening areas where they live Roma and Egyptian families to identify children vaccinated. During 2014, IPH initiative to cover more than 95% of every community and working to adjust all related documents with them, to include in this way Roma and Egyptians Often, nurses make vaccines, cooperate with social workers or mediators to improve communication with the community and to vaccinate more children Romans and Egyptians once. Also, IPH has piloted immunization information system in Shkodra and Lezha is now working and to Malësia e Madhe, including children vaccinated. All Roma and Egyptian children vaccinated free even when they do not have papers, but IPH identifying them.

**MEDICINAL PRODUCTS FOR HUMAN USE**

Reporting period: February 2014 – February 2015

In the **field of medicinal products for human use** (drugs), have been approved the below mentioned acts:

1. Council of Ministers Decision no.53, of February 5th, 2014 "On designation of manufacturing and trading margins of drugs”;
2. Council of Ministers Decision no. 135, of March 12th, 2014 “On approval of the list of drugs reimbursed by the Compulsory Insurance Health Care Fund and their price’s coverage size”;
3. Order of Minister of Health no. 116, of March 21th, 2014 “On establishment of the working group on monitoring of drugs that circulate within the Republic of Albania”;
4. Mutual Guideline between the Ministry of Health and the Ministry of Finance no. 119, of March 25th, 2014 “On some changes in the Guideline no. 2, of January 15th, 2013 ”On the production, codification, stamping, distributing procedures and monitoring of the control’s stamps of drugs”, amended;
5. Council of Ministers Decision no. 235 of April 23th, 2014 “On an addenda in the Council of Ministers Decision no. 135, of March 12th, 2014 “On approval of the list of drugs reimbursed by the Compulsory Insurance Health Care Fund and their price’s coverage size”;
6. Order of Minister of Health no. 248, of June 16th, 2014 “On establishment of the working group for preparing the draft-acts with regard to implementation of the Law no.105/2014, of July 31th, 2014 “On drugs and pharmaceutical service”;
7. Law no. 105/2014 of July 31th, 2014 “On drugs and pharmaceutical service”, partly harmonized with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use, amended and Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
8. Council of Ministers Decision no. 645 of October 1st, 2014 “On establishment and functioning manner of Drug Pricing Commission”;
9. Minister of Health Regulation no. prot. 6090, of October 23th, 2014 “On methodology of defining drugs prices and their manner of declaration’s administration in the Republic of Albania, based on Council of Ministers Decision no. 645 of October 1st, 2014”;
10. Order of Minister of Health no. 524, of November 26th, 2014 “On establishment of the working group on reviewing the Drugs Reimbursement List”.

In the **field of medicinal products for human use** (drugs), currently is being working on the fulfillment with sublegal acts of the Law no. 105/2014 of July 31th, 2014 “On drugs and pharmaceutical service”. Specifically, have been submitted to be approved in the Council of Ministers, the following sublegal acts:

1. “On designation of manufacturing and trading margins of drugs”;
2. “On defining the rules for granting the authorization of Minister of Health for importing of drugs without marketing authorization”.

In the **field of cosmetic products**, has not been progresses. The draft – Law, prepared by the working group, assisted by the selected expert from TAIEX (during November 2012), has not yet entered into force. This draft – Law has been prepared in harmonization with the **Regulation (EC) No 1223/2009** of the European Parliament and of the Council of 30 November 2009 on cosmetic products.