

Managing Drug Supply in the Public Sector in Republic of Kosovo

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Abstract

Kosovo is the newest country in Europe. After the armed conflict in 1999, the United Nations administration was installed. Kosovo declared independence in February 2008. Since the post war period, Kosovo, jointly with the international administration gradually built the healthcare institutions. Since declaring independence in 2008, competences were transferred from the international institutions to the local, Kosovo institutions. In 1999, the WHO took the role of the Ministry of Health. In 2000 the Department for Health and Social Welfare was established, preceding the establishment of the Ministry of Health in 2003. Pharmaceutical Department was responsible for managing the supply of drugs and medical material from Essential Drug List for the three levels of the Health Care Institutions. Health Financing Agency is the executive Agency under the authority of the Ministry of Health, predecessor of the Kosovo public Health Insurance Fund. Department for Pharmaceutical Services within the Health Financing Agency is working together with other stakeholders on pharmaceutical reform and drug reimbursement scheme.

KEYWORDS: Kosovo, drugs, supply, public health institutions, pharmaceutical sector reform.

Introduction

- The Republic of Kosovo has an area of 10,908 km² and 1,804,944 inhabitants;
- Of the total population, 28% are under age 15 and half of the population is aged younger than 28.2 years. The average age of the population is 30.2 years;
- The average life expectancy in Kosovo in 2011 was estimated to be 76.7 years. For males 74.1 years and for females 79.4 years;
- Kosovo is characterized with higher medium degree of the average birth rate. The average ratio for the period 2006-2011 of the birth rate was 17.9 ‰, with an average annual increase of 0.5 ‰. This value was 16.3 ‰ in 2006 and 19.8 ‰ in 2011. Number of births in 2015 was 24,594 (births occurred only in Kosovo);
- Although mortality rate from all causes has continued to decline in the European Region, the rate of mortality in Kosovo for 2006-2011 showed a slight growth trend whereas in 2014 from data reported by KAS it was at 4.4 ‰;
- The rate of perinatal mortality for 2015 was 12.13 ‰ (for new-borns weighing \geq 500 g or \geq 22 weeks of gestation) showing thus a significant decrease compared to 2000, when perinatal mortality rate was 29.1 ‰; in 2012 it was 17.34 ‰, in 2013 it was 16.26 ‰, and in 2014 it was 11.99 ‰;
- Kosovo is one of the poorest countries in Europe with Gross Domestic Product (GDP) of € 3,084 per capita, or 257 euros per month Economic growth in 2014 was 1.2%, while overall poverty in 2014 was 29.2%, whereas extreme poverty is

- 8.2% (KAS 2014). Real growth rate of GDP for 2013 compared to 2012 was 3.2%, according to estimates of Macroeconomics Unit in the Ministry of Finance;
- Analysis of the health status of the population show that the morbidity rate in Kosovo is lower by a total of 422 cases per 100,000 inhabitants in 2011, compared to the EU with 663 cases per 100,000 inhabitants;
 - The health sector in Kosovo is financed mainly from income tax, taxes and co-payments, while direct private payment is very high and covers about 40% of the medical costs. The budget allocated by the government for health for 2015 was a total of € 163,760,703. The total share of the health budget in the Kosovo budget is 9.73, and 2.79% of GDP, which provided € 90.72 per citizen per year. Total budget for drugs and medical consumables from the essential list of drug was € 21,670,496;
 - According to the survey with citizens, 86% of patients are paying for medicines, 59.5% for co-payments, 33.4% have paid for medical materials;
 - Taking into account total public spending, private and private pocket spending on health, in 2013 the value will reach € 135 per person or 4.5% of GDP, which is lower compared to the EU and to all countries of the region; EU in 2010 spent € 2,171 per capita;
 - In 2013, Kosovo had 2,767 doctors and 7,016 nurses employed in public health institutions. In private health institutions are employed a total of 3,472 employees, of which 1,806 are doctors and 1,666 nurses;

Building health/pharmaceutical Institutions

Since the post-war period, Kosovo with the help of the international community has begun to gradually build up its governing institutions. Immediately after the war, the United Nations Administration was established in Kosovo. Initially, departments were co-governed by a local and international representative. The Department of Health and Social Welfare was established in 2000 through UNMIK Regulation 2000/10.

Department for Health and Social Welfare

The duties of the Department of Health were as follows:

2.1 The Department may make policy recommendations to the Interim Administrative Council through the Deputy Special Representative of the Secretary-General for Civil Administration concerning, inter alia:

- (a) An overall strategy for the development of non-discriminatory, efficient, transparent and accountable health care and social welfare in Kosovo, respectful of human dignity, and addressing the needs of vulnerable groups and other persons within the population who may be at risk;
- (b) The infrastructure relating to health and social welfare including, but not limited to, hospitals, medical clinics, and institutions for children, aged persons and persons with disabilities;

(c) The regulatory framework for health care and social welfare, including the setting of standards to be maintained, and the preparation of regulations; and

(d) Prevention, monitoring and control of health and social problems.

2.2 The Department shall:

(a) Implement the strategy and policies for the development and provision of health care and social welfare, within the framework of the Kosovo Consolidated Budget;

(b) Co-ordinate with other Administrative Departments on matters pertaining to health and social welfare;

(c) Monitor the health and social welfare situation, and implement appropriate measures as required;

(d) Oversee adherence to standards, including, where appropriate, conducting inspections and other services, for which fees may be charged;

(e) Develop infrastructure and human resources to meet the health and social welfare needs of the population;

(f) Regulate and monitor pharmaceuticals, medical supplies and equipment, and radioactive material related to medical uses;

(g) Co-ordinate activities of international and governmental agencies and non-governmental organizations in order to promote the coherent development and implementation of health and social welfare policies;

(h) Encourage community participation and the development of community initiatives and activities related to health care and social welfare;

(i) Develop and implement a system of social insurance;

(j) Provide financial assistance, to the extent possible, to families and individuals in need;

(k) Design and implement a fully-operational management information system so that all decisions, policies and processes in the health and social welfare sector rest upon a sound and up-to-date basis of accurate data; and

(l) Perform such functions as are ancillary to those set out above in this section and are assigned to the Department by the Deputy Special Representative of the Secretary-General for Civil Administration.

Kosovo Drug Regulatory Agency

In 2000 with the administrative Instruction 200/7 the Kosovo Drug Regulatory Agency (KDRA) was established with the following terms of reference:

1. Receive, verify and record applications for licences to import drugs, other pharmaceutical products, medical equipment and radioactive material related to medical uses;
2. Receive. Verify and record applications for licensing pharmaceutical wholesale and retail premises;
3. Issue licenses for import goods referred to in paragraph I.2. above and for establishing pharmaceutical wholesale and retail premises according to criteria approved by the Department of Health and Social Welfare;
4. Assess and approve applications for the import of donated pharmaceuticals.
5. Maintain a register of premises licensed to operate as wholesalers or retailers and of their responsible managers;
6. Collect license fees according to laid down accounting procedures, including the provision of receipts;
7. Inspect premises that apply to be or have been licensed in accordance with this Administrative Instruction;
8. Establish their suitability for licensing:
 - a. Ensure compliance with the applicable regulations;
 - b. Inspect goods intended for import in case of dispute or deviation from details
9. specified in the import license:
10. Support technically customs officials when necessary
11. Advice technically the Department of Health and Social Welfare in matters related
12. to the regulation and licensing of products referred to in paragraph I.2.

II. The Department of Health and Social Welfare will be the final authority on matters pertaining to the issuance of licenses for the import, distribution and sale of products referred to in paragraph I.2.

Kosovo Drug Regulatory Agency has been transformed into the Kosovo Medicines Agency in 2003 through the Law on Medicinal Products 26/2003.

Ministry of Health

The Ministry of Health as a Provisional Institution of Self Government was established in 2001 by the UNMIK Regulation no. 2001/9 of 15 May 2001, "On the Constitutional Framework for Provisional Self-Government in Kosovo".

In Annex VI of UNMIK Regulation no. 2002/5 on the establishment of the Ministry of Health, the competences of this ministry were defined.

In the organizational chart of the Ministry of Health, within the Department of Health Services, a Pharmaceutical Division has been in charge of organizing the supply of medicines and medical consumables from the essential list of drugs to the health institutions of all three levels of health care. In 2005, with the Administrative Instruction 11/2005, the Pharmaceutical Division was transformed into a Pharmaceutical Department. Pharmaceutical Department has three divisions:

- Division for Supply,
- Division for Monitoring,
- Pharmaceutical Policy Division.

The role and duties of the Pharmaceutical Department expanded as follows:

1. Management of Department Staff, consultation in operational and decision making issues.
2. DF defines, implements, monitors and manages the pharmaceutical policy in Kosova.
3. Manages the Budget of Pharmaceutical Department.
4. Creation of a consistent strategy for supply of health structures of three health levels with medicines, expendable materials. Vaccines and hemo-dialysis products from the Essential List,
5. Coordination of different donations for medicines and medical equipments across the different health structures in conformity with the applicable laws.
6. Cooperate and coordinate activities with AKPM. Other departments and divisions inside the Ministry of Health itself.
7. Provision of good pharmaceutical services will include Warehouse management, distribution and dispersion of pharmaceutical products.
8. Preparation and securing the needs and specifications for pharmaceutical products in such a manner that the purchased products have ensured a high quality and a better access to patient.
9. Preparation of administrative directions within the department competences.
10. Initiating the creation of a strategy for financing system in pharmaceutical Sector.
11. Supervision of tender documents preparation for supply with pharmaceutical products and realization of the tender process in cooperation with the department.
12. Revision and compilation of the essential list for all health care levels.
13. Designing of standard forms for prescription, evidence and order of pharmaceutical products for health structures.
14. Research and creation of pharmaceutical policies for more consistent pharmaceutical system in Kosova.
15. Preparation of operational researches for monitoring the availability, access and use of essential medicines in public health sector.
16. Preparation of weekly, quarterly and annual reports for Permanent Secretary,

In 2006, the Administrative Instruction 19/2006 entered into force. With this Administrative Instruction the dispersion of drugs from the Essential List was transferred from the former public pharmacies to the Main Family Medicine Centers managed by the municipalities. This has happened in the context of the decentralization process ongoing in Kosovo. The dispersion of the essential list drugs continues in the same way at present.

In 2007 Administrative Instruction 11-2007 regulating the Storage, Distribution and Dispersion of Essential Drug List entered into force.

Drug management cycle

The pharmaceutical management cycle includes four basic functions: selection, procurement, distribution and the rational use of drugs.

Selection of medicines

- Essential Drug List in Kosova was first introduced in 1999, immediately after the war.
- In 1999 the first Essential Drug List for primary health care was introduced. This list largely was based on international experiences developed by WHO.
- In 2000, the Essential Drug List of primary and secondary health care was drafted.
- In 2001, with the initiative of the Department of Health And Social welfare Essential Drug List was revised;
- In 2004, the first definition of the Essential Drug List was given in Kosovo's Health Law:
Essential Drug List: the list of medical products and sanitary medical consumables purchased by the Kosovo Consolidated Budget to meet the needs in all levels of health care.

Section 24 of Health Law describes the obligations of the Ministry of Health regarding the fulfillment of this list as follows:

Section 24

24.1. Drugs from the Essential Drug List are provided in the public and private health institutions having contractual relations with the Health Insurance Fund from section 57.1.c.

24.2. The essential drug list is determined by the Health Insurance Fund on the proposal of the Ministry of Health;

24.3. At all levels of the health care the drugs has to be prescribed by the generic names;

24.4. Drugs from the essential drug list shall be delivered only through medical prescriptions issued by the doctor of family health service.

24.5. Only pharmacist shall give prescribed drugs;

24.6. Issues related to the narcotics, psychotropic substances are regulated in the special Law for Medicinal Products and Medical Equipment;

24.7. Issues related to blood derivates and human plasma are regulated in the Law for Medical Products and Medical Equipment.

- Essential Drug List is revised biannually. At 2004 Cytostatic and immunosuppressant drugs were added to the Essential Drug List.
- At 2013 based on the WHO guidelines the "VEN" (Vital, Essential and Non Essential) System of classification for drugs and medical supplies was introduced.

Procurement

- In 1999, the supply of healthcare institutions of Kosovo was based on donations of medicines from different donors;
- In 2000 the procurement of essential medicines for primary health care has been done by the Pharmaciens sans Frontiers (PSF) while the supply of the secondary health care was handled by donors responsible for each Hospital of Kosovo including Clinical Center through direct Procurement.
- In 2001 procurement of medicines was handled from the Department of Health and Social Welfare and UNMIK for the three levels of the healthcare including hemodialysis products through the Open procurement procedure.
- In 2003 procurement of drugs was managed from United Nations Office Project Service contracted by UNMIK through the direct and open procurement procedure.
- Since the establishment of the Ministry of Health in 2003 and the entry into force of the first Law on Procurement 2003/17, procurement of the medicines, medical consumables and hemodialysis products in Kosovo was carried out by the Procurement Department within the Ministry of Health.
- Even today, Kosovo has a centralized procurement for drug and medical consumables from the Essential Drug List. The Ministry of Health contracts on behalf of all the health institutions of Kosovo.

Distribution

- Pharmaciens sans Frontiers were responsible for the distribution of Essential Drug List in Kosovo right after 1999;
- In 2001 this role has been transferred to the Pharmaceutical Corporation of Kosovo until 2008.
- After 2008 until present drug distribution is a contracted service. The contractor is the Ministry of Health

Health Financing Agency

Health Financing Agency is the executive Agency under the authority of the Ministry of Health, predecessor of the Kosovo Public Health Insurance Fund, that on behalf of the state realizes the rights, obligations, responsibilities, and authorizations regarding contracting and buying of the healthcare services from healthcare institutions in all forms of ownership, as well as pooling all financial means of the Fund for this purpose, until the establishment of Fund by this Law.

Duties and responsibilities of the Health Financing Agency are determined by Law no. 04/L-125 on Health and the Law no.04/L-249 on Health Insurance,

Within the organizational chart of the Agency of Health Financing, the Department for Pharmaceutical Services has two divisions:

- Division for planning management and analysis of the Drug Supply,
- Division of pricing and reimbursement of medicines

The Department for Pharmaceutical Services is now working on creating policies and guidelines for the drug management once the Health Insurance Fund is operationalized.

The establishment of the health insurance fund will completely reform healthcare and pharmaceutical system in Kosovo. It will change the entire drug management cycle starting with drug selection, distribution and procurement. The health insurance fund is expected to become functional next year.

Conclusions

As can be seen from the presented results, Kosovo with the help of international organizations has successfully managed the emergency situation. The legal framework and the health Institutions were built gradually. In parallel with this, executive competences were transferred from the international organisation to the local institutions.

The drug management cycle related to selection distribution and dispersion of drugs was established properly. No concrete initiative has been taken to develop policies and guidelines for the rational use of medicines. This remains a challenge for the healthcare institutions.

Establishment of the Health Insurance Fund together with the harmonization of the legislation with the EU are now the biggest challenges that the health system is facing in our country now. Creating a new health insurance structure in Kosovo will start a new challenging phase of healthcare system reform.

Acknowledgements

The authors would like to acknowledge the Ministry of Health of Kosovo and Kosovo Medicines Agency for the access provided to the official documents and access to Ministry of Health archives.

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