Pharmaceutical Pricing and Reimbursement Information

ALBANIA 2009

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PPRI

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ALBANIA

Pharma Profile

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Executive Summary

BACKGROUND

The health system in Albania involves a number of structures, organisations and stakeholders. In the following years the pursuit of integration in the European Union and NATO represents the main challenges at international level for Albania. So, this process will have a major influence in the health system as well and will involve great efforts to make it commensurate with European standards.

The Ministry of Health, MOH (Ministria e Shëndetësisë, MSH) remains the major founder and provider of health care services in Albania. Although it has been partially reorganised, MOH continues to assume the leading role in most areas of health care and it devotes most of its effort to health care administration, rather than to policy and planning. Health directorates are organised in a hospital directorate and a Primary Health Care (PHC) directorate. When the 12 regional prefectures were created in 1993, some administrative authority was shifted to those prefectures from the centre. The local government authorities of all 315 rural communes now own their PHC facilities and are those responsible for PHC.

In Tirana prefecture, which includes two districts, a decentralisation initiative stronger than that of districts has been piloted since 2000. Tirana Regional Health Authority (Autoriteti Shëndetësor Rajonal i Tiranës / ASHR/ TRHA) is responsible for planning and managing primary health care services and public health programs. Hospital care in Albania remains highly centralized and depends on the Ministry of Health budget and management.

In 1995, the Health Insurance Institute (Instituti i Sigurimeve Shëndetësore, ISKSH/HII) was created in the framework of one of the major reforms planned to be undertaken for transforming the health care system into a split purchaser-provider contract model. As a corresponding national statutory fund and purchasing authority, HII was granted autonomy as a quasi-governmental body. HII is formally accountable only to the Parliament. The Albanian health insurance system is a Bismarck-type social insurance system. Health insurance system was established and arranged by law No. 7870, dated 13.10.1994 “For health Insurances in the Republic of Albania” and it has been amended during 1995, 2002 and 2004. Currently, HII is working to reformulate the regulation framework in order it may become adapted to an enlarging and sophisticated private health sector. Reforms being undertaken within HII intend its transformation into the sole buyer of all health services offered by the public sector.

HII features a limited scheme that has been introduced in stages. Premiums have been kept low and with different rates for different income groups. HII has purchased a restricted package of health services and pharmaceuticals. HII enrolment varies among different population groups. The majority of the unemployed people including children and women who work at home and the elderly are automatically covered by the state budget. In 1995, HII covered only PHC physician salaries and essential pharmaceuticals whereas nowadays the medicines list has been extended with new innovative medicines covering around 95% of all the diagnosis. The main part of HII expenditures goes to primary health care financing (47%) and pharmaceutical reimbursement (40%).

Albanian health services are funded through a mix of taxation and statutory insurance. The Ministry of Finance is the major source of funds as it allocates more than 79% of HII funds. According to 2007 estimations, Albania spent 43.8 billion Lek / € 356 Mio. in the health sector and per capita expenditure of Lek 13,983 / € 114 occured. The total expenditure on health is 5.9 percent of the Gross Domestic Product (GDP). Public sources account for 34 percent, private sources for 62 percent of health care financing and international donors for the remaining 4 percent. The largest source of financing comes from households and represents 60 percent of total expenditures. In terms of expenditures, private pharmacies are the major provider of health services.

PHARMACEUTICAL SYSTEM

One of the major areas in the Health sector is pharmaceuticals and it is one of the critical areas for the success of health interventions in primary and hospital care. The organisation of the pharmaceutical service in Albania is arranged based upon Law No. 9233, dated 25.11.2004 "On pharmaceuticals and pharmaceutical services", which was drafted on basis of the previous abrogated law No. 7815, dated 20.04.1994.

This law provides regulations on pharmaceuticals output, import, export and trading, quality control and inspection of all activities relating to medicaments used by the people in the Republic of Albania.

The Ministry of Health (MOH) is the responsible institution for drafting legal acts and by-laws in the pharmaceuticals field. MOH and HII are the key actors who decide on the reimbursement of pharmaceuticals. The Pharmaceutical Pricing and Reimbursement Department (Departamenti i Çmimeve dhe Rimbursimit të Barnave/ DÇRB/) of HII in collaboration with the Drugs Pricing Commission in the MOH (Komisioni i Çmimit të Barnave/ KÇB/) drafts the list of medicines, that are reimbursed by HII, the so-called Positive List. The final draft of the Positive List is approved by the Commission for the Drugs' List (Komisioni i Listës se Barnave/ KLB) which is headed by the Minister of Health.

One of the most important actors in the pharmaceutical market authorisation is the National Center for Drugs Control (Qendra Kombëtare e Kontrollit të Barnave QKKB). This institution is a specialized body for the medicaments analysis, registration, control and inspection of pharmaceutical activities.

Pharmaceutical industry in Albania is not too much developed. There are only three national manufacturers that produce very limited sorts of drugs: Profarma, Euromedica and Radofarma. The importing companies play the most important role in the pharmaceutical market. Big international companies such as Novartis, Glaxo, Janssen-Cilag, Hofman La Roche, Richter Gedeon, Krka, Lek etc. play an important role in the pharmaceutical market in Albania.

There are two main distribution channels in Albania. Direct delivery of pharmaceuticals by wholesalers is applied for in-patients service (the hospitals' pharmacies), via procurement procedures and tenders. In case of out-patient service, pharmaceuticals are provided only by pharmacies.

In 2006, pharmaceutical expenditures in Albania were estimated at around 2.65 percent of GDP. Public expenditures on pharmaceuticals during 2006 amounted to Lek 23,690 mio. / € 193 mio., while public health expenditures in % of total expenditures were 9.15%. In 2007, expendi-

tures of HII for reimbursed drugs amounted to LEK 3.5 billion / € 28.5 million. In 2008, HII expenditures for reimbursed drugs were increased to around Lek 4.2 billion/ € 34 million.

PRICING

A system of free pricing for all pharmaceuticals at manufacturer level is in place. All the pharmaceutical companies that are drugs importers or producers may set the prices of the drugs upon their own free will. Concerning Over-the-counter pharmaceuticals (OTC) and hospital pharmaceuticals there is no specific pricing policy applied. The prices of reimbursed pharmaceuticals are negotiable only in case of expensive drugs. Negotiations are held by the Pricing Drugs Commission (KÇB) at the manufacturer level.

Retail mark ups (wholesale and retail margins) are regulated annually by the Council of Ministers Decisions and according to the proposal put forth by the Prices Commission after negotiations with local and foreign producers or their representatives and holders of the registration certificate.

Different levels of margins are applied for reimbursable and non-reimbursable pharmaceuticals (cf. section 3.5). The wholesale mark up is a linear add-on of 18% on top of the manufacturer price for non-reimbursable pharmaceuticals and of usually 12% for reimbursables. However, selected, often expensive, reimbursable POM are subject to a different wholesale mark up.

The pharmacy mark up is a linear add-on of 33% on the pharmacy purchasing price for non-reimbursable pharmaceuticals and of usually 29% for reimbursables. Also in this case, selected, reimbursable POM[1] are subject to a different pharmacy mark up.

The current Albanian distribution mark ups are high compared to other countries and - as they are linear percentage add-ons - they create an incentive to distribute higher priced pharmaceuticals. The introduction of reduced mark ups for selected expensive reimbursed pharmaceuticals (covering about 20% of the products on the positive list) was a first step to overcome this situation.

The standard value added tax (VAT) rate for all products is 20% and 0% for all pharmaceuticals.

Being that cost containment provides a support for the review, development and implementation of policies which define the funding and overall allocation of resources to health services, HII is trying to improve the insurance mechanisms in order to contain cost.

REIMBURSEMENT

MOH (MSH) and HII (ISKSH) are responsible for pharmaceuticals reimbursement for all the drugs included in the positive list, for some categories of patients. The Reimbursement Department (Departamenti i Rimbursimit/DR/RD) at HII in collaboration with Pharmaceutical Directorate in MSH (Drejtoria Farmaceutike/DF) prepares the proper information on all the drugs (reimbursed and non-reimbursed pharmaceuticals) on an annual basis. This information concerns pharmaceuticals prices and reimbursement policy. The Drugs Reimbursement List Commission

[1] The same for which also a different wholesale mark up is applicable.

(Komisioni i Listës së Barnave te Rimbursuara/KLBR) headed by the Minister of Health decides on the list.

There is a positive list, which contains a restricted number of pharmaceuticals compared with the total number of drugs on the market. Prices of reimbursed drugs are negotiable at the manufacturer level whereas prices of pharmaceuticals not included in the positive list are not negotiable. Prices of non-reimbursed drugs are set on free bases and are subject to statutory mark-ups. Drugs included in the positive list are selected according to the following criteria: product specific criterion, disease criterion and economic criterion.

Under the HII there is 100% reimbursement of prescription drugs for children 0-12 months, people with severe disabilities, military veterans, old age pensioners, as well as patients with cancer, tuberculosis, multiple sclerosis, anaemia caused by chronic kidney failure, major thalassemia and kidney transplantation. The patient's categorisation happens according to law No. 7870, dated 13.19.1994, on Health Insurances, which was amended by Law No. 9368, dated 7.04.2005.

There is partial reimbursement ranging between 50% and 100% of prescription costs, dependent on the therapeutic class of the product for employees and voluntarily insured those with mild and moderate disabilities, social welfare recipients, children aged one year and over, students, expectant and new mothers and soldiers.

The levels of reimbursement were last approved by the Council of Ministers decision in February 2007. The reimbursement rate is calculated using a reference price which represents the lowest retail price of a generic drug (= the lowest CIF (Cost, Insurance and Freight) price + wholesale mark up + retail mark up). Moreover, military veterans can be prescribed any branded product (i.e. a registered drug, regardless of its reimbursement status).

The positive list is applied only for out-patient health care, because the in-patient health system (hospital services) is not encompassed yet in the reimbursement scheme. The hospital services are covered by the special governmental budget.

Pharmaceuticals in the positive list are classified according to Anatomic Therapeutic Chemical Classification (ATC-5 level). Since 1995 when the first list of pharmaceuticals reimbursement was drafted, the number of medicines has been increased continuously. There are currently 362 medicines on the reimbursement list (that came into force on 1 April 2007) and some can only be prescribed under specific conditions or following approval from a specialist.

Patients treated at public polyclinics and healthcare centres, which require a pharmaceutical product, receive a prescription and get the drugs from a private pharmacy. Private pharmacies procure products from private wholesalers. If the patient is insured (covered by HII), the pharmacy will be partially or fully reimbursed for the price of the medicine. The patient pays the remainder out-of-pocket.

RATIONAL USE OF PHARMACEUTICALS

Treatment protocols for reimbursable medicines are defined by special commissions created by HII in cooperation with the University of Medicine, Department of Pharmacology and services heads at Tirana University Hospital Centre (QSU). Concerning other drugs, treatment protocols

are defined by commissions created by the Ministry of Health in cooperation with University of Medicine, Department of Pharmacology and QSU service heads.

The marketing of pharmaceuticals is regulated in Law. No. 9323 on pharmaceuticals and pharmaceutical service, that was amended in 2004. Advertisement of Over-the-counter (OTC) products is permitted in all electronic and written media.

Albania spends 45 percent of its total health expenditures and 68% of out of the pocket expenditures on drugs. Pharmaceutical expenditures is a major area of the health sector that needs to be better managed and regulated if health care expenditure growth shall stay in the budgetary limits. The high level of expenditures on pharmaceuticals is likely due to the lack of rules and regulations controlling this major sector and lack of a significant policy for using generic drugs as substitutes for expensive products with the same active ingredient.

Hence to effectively contain overall health care expenditures, Albania is trying to implement policies intending to improve the efficiency by which pharmaceuticals are imported, distributed and sold in the country and improve its management and oversight of this sector.

CURRENT CHALLENGES AND FUTURE DEVELOPMENTS

Concerning health care system the current and future challenges are: Increasing the capacity to manage services and facilities in an efficient way; increasing access to effective health services; improving health system financing; improving health system governance.

As far as HII is concerned its major challenge is to become the sole purchaser of health services offered by the public sector and preparation of an affordable and predetermined profitable package for pharmaceuticals, in line with HII funds.

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List of abbreviations

ASHR/RHA	Autoriteti Shëndetësor Rajonal/Regional Health Authority
ATC	Anatomic Therapeutic Chemical classification
BMG	Austrian Ministry of Health
CEFTA	Central European Trade Agreement
CIF	Cost, Insurance and Freight
DÇRB/DPRD	Departamenti i Çmimeve dhe Rimbursimit të Barnave/ Drugs Pricing and Reimbursement Department
DF/PD	Drejtoria Farmaceutike/ Pharmaceutical Department
DG SANCO	Health and Consumer protection Directorate General
DIAS	Department of Informatics and Statistics Analyses
DRSSH/DHCI	Drejtoria Rajonale e Kujdesit Shëndetësor/Regional Directorate of Health Care Insurance
ECHR	European Convention of Human Rights
EFPIA	European Federation of Pharmaceutical Industry Association
FTA-s	Free Trade Agreement
GDP	Gross Domestic Product
GGE	General Government Expenditure
GP	General Practitioner
HE	Health Expenditure
HiT	Health systems in Transition
HOM	Hospital-Only Medicine
INSTAT	Instituti i Statistikave/ Institute of Statistics
ISKSH/HII	Instituti i Kujdesit Shëndetësor/Health Insurance Institute
KÇB/DPC	Komisioni i Çmimit të Barnave/Drugs Pricing Commission
KHLB/CDLD	Komisioni i Hartimit të Listës së Barnave/Commission of Drugs List Drafting
KM/CM	Këshilli i Ministrave/Council of Ministers
KP/PA	Kuvendi Populllor/People's Assembly

KSK/NSC	Komisioni i Sigurimit Kombëtar/National Security Commission
LSMS	Living Standards Measurement Study
MOF	Ministria e Financave/Ministry of Finance
Mio.	Million
MSH/MOH	Ministria e Shëndetësisë/ Ministry of Health
NCU	National Currency Unit
NHS	National Health Service
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development
OPP	Out-of-Pocket Payment
OTC	Over-The-Counter pharmaceuticals
PE	Pharmaceutical Expenditure
POM	Prescription-Only Medicines
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
QALY	Quality Adjusted Life Year
QKKB/NCDC	Qëndra Kombëtare e Kontrollit të Barnave/National Center for Drugs Control
SEE	South East European
SFSH/PTU	Sindikata e Farmacistëve të Shqipërisë/Pharmacists Trade Union
SHGSH/WAA	Shoqata e Grosistëve të Shqipërisë/Wholesalers Association of Albania
SHI	Social Health Insurance
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
UFSH/AOP	Urdhëri i Farmacistëve të Shqipërisë/Albanian Order of Pharmacists
VAT	Value Added Tax
VHI	Voluntary Health Insurance

WHO	World Health Organisation
WP	Work Package

PPRI Pharma Profile Template 2008

Rationale

In the beginning, the Pharmaceutical Pricing and Reimbursement Information (PPRI) project was a 31 month-project (2005-2007) commissioned by the Health and Consumer Protection Directorate-General (DG SANCO) of the European Commission and co-funded by the Austrian Federal Ministry of Health (Bundesministerium für Gesundheit, BMG). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organisation (WHO) Regional Office for Europe. The PPRI project has established a network of 51 participating institutions (competent authorities and other relevant organizations) in the field of pharmaceuticals.

Within the course of the PPRI project, country reports on pharmaceutical pricing and reimbursement systems, the "so-called PPRI Pharma Profiles", were produced (cf. http://ppri.oebig.at) → Publications → Pharma Profiles. These PPRI Pharma Profiles refer, in general, to the year 2006/2007.

Despite of the official end of the research project in 2007, the PPRI network participants have agreed to continue the network and up-date the PPRI Pharma Profiles. The PPRI Pharma Profile Template was therefore adapted for the year 2008.

Outline

The PPRI Pharma Profile Template consists of six chapters plus an appendix:

- Chapter 1 (Background) gives a brief overview of the demographic, economic and political situation and a brief introduction to the health care system.
- Chapter 2 (Pharmaceutical system) provides a description of the pharmaceutical system; the regulatory framework, the pharmaceutical market, the market players and the funding of pharmaceuticals and the methods of evaluating the system.
- Chapter 3 (Pricing) covers a description of the organisation of the pricing system, the pricing policies, the pricing procedures, exceptions to these procedures, as well as a section on margins and taxes and pricing related cost-containing measures.
- Chapter 4 (Reimbursement) covers a description of the organisation of the reimbursement system, the reimbursement scheme including the eligibility criteria, the reimbursement categories and rates and the reimbursement lists. Also described in this chapter is the reference price system, the private pharmaceutical expenditure, the reimbursement in the hospital sector and the reimbursement related cost-containing measures.
- Chapter 5 (Rational Use of Pharmaceuticals) is a description of the methods used to improve rational use of pharmaceuticals including the impact of pharmaceutical budget, prescription guidelines, patient information, pharmaco-economics, generics and consumption.
- Chapter 6 (Current challenges and future developments) is a concluding chapter on the current challenges and future plans for developments in the pharmaceutical sector.

1 Background

1.1 Demography

Albania is located in South-Eastern Europe on the Balkan Peninsula, bordered by Serbia and Kosovo to the northeast, Montenegro to the northwest, the Former Yugoslav Republic of Macedonia in the east and Greece in the south. To the west are the Adriatic and Ionian seas. The country covers an area of 28.750 km2 and is primary mountainous, apart from its flat coastline.

According to figures provided by the Institute of Statistics (Instituti i Statistikave/ INSTAT), the current population amounts to 3,152,625 (51% female and 49% male). Population has been growing at an average of one percent per year. The projected life expectancy at birth for females is 78 and 72 for males. One third of its population is under the age of 15, and 40% is younger than 18. INSTAT declared a birth rate of 15.13 per 1000 population in 2003. Infant mortality rates have decreased from around 41.5 per 1000 live births in 1990 to 23 in 1999 and 16.8 in 2003.

A high proportion of Albanian's population lives in rural areas, amounting to 58% in 2001. However, since restrictions on freedom of movement were lifted in 1990s, there has been an unprecedented level of internal migration from rural to urban areas in Albania. In 1979, only 33.5% of the population was urban. The figure rose to 35.5% in 1989, and in 2006 it reached 42.1%.

About 97% of the Albanian population is ethnic Albanian and 1.9% Greek, while other groups are represented in small numbers. A unified form of the Albanian language has been used since the early 1970s.

The Albanian population enjoys a reasonable long life expectancy. With changing disease patterns more Albanians are now suffering from non-communicable diseases such as hypertension, diabetes and cancer. The most leading causes of mortality are the circulatory system (45%), Neoplasm (14%), and poisoning and external injuries (12%). Non communicable diseases, especially diabetes and disease of the circulatory system are recognised as the major health problem and account for the majority of deaths as well as the largest financial burden to the health system.

Table 1.1: Albania – Demographic indicators 2000 – 2007

Variable	2000	2001	2002	2003	2004	2005	2006	2007
Total population 1 January (000)	3,473,835	3,063,318	3,084,148	3,102,781	3,119,546	3,134,982	3,149,147	3,152,625
Population density per km^2	n.a.	106.6	107.3	107.9	108.5	109.1	109.5	109.7
Population aged 0-14 (in % of total)	n.a.	29.5	28.8	28.1	27.3	26.5	25.7	24.9
Population aged 15-64 (in % of total)	n.a.	63.0	63.5	64.1	64.6	65.2	65.7	66.3
Population aged > 64 (in % of total)	n.a.	7.4	7.7	7.9	8.1	8.3	8.6	8.8
Life expectancy at birth, total	75.4	75.4	75.4	75.4	75.4	75.4	75.4	75.4
Life expectancy at birth, females	78.6	78.6	78.6	78.6	78.6	78.6	78.6	78.6
Life expectancy at birth, males	72.1	72.1	72.1	72.1	72.1	72.1	72.1	72.1

Sources: Institute of Statistics (INSTAT)

1.2 Economic background

The Albanian national currency (NCU) is the Albanian Lek. According to the Bank of Albania, in 2006, per capita income was Lek 294,008 / € 2,391. The official unemployment rate is 13.8% and 18.5% of the population lives below poverty line. Almost 60% of the workers are employed in the agriculture sector, although the construction and service industries have been expanding recently, the latter boosted significantly by ethnic Albanian tourists from throughout the Balkans. In 2007, GDP per capita was Lek 30,961/ Euro 251.5. GDP is comprised of agriculture (approximately 24%), industry (approximately 13%), service sector (approximately 39%), transport and communication (12%), construction (11%) and remittances from Albanian workers abroad – mostly in Greece and Italy (approximately 12.8%).

Albania was the last of the central and eastern European countries to embark upon democratic and free market reforms. Further, Albania started from a comparatively disadvantaged position, due to Hoxha's catastrophic economic policies. Transition from a centrally planned economy to a market-orientated system has been almost as difficult for Albania as the country's communist period.

The democratically elected government that assumed office in April 1992 launched an ambitious economic reform program meant to halt economic deterioration and put the country on the path toward a market economy. Key elements included price and exchange system liberalisation, fiscal consolidation, monetary restraint and a firm income policy. These were complemented by a comprehensive package of structural reforms, including privatisation, enterprise and financial sector reform and creation of the legal framework for a market economy and private sector activity.

Results of Albania's efforts were encouraging. Led by the agriculture, real GDP grew, and the Albania's currency, the Lek was stabilised. The speed and vigour of private entrepreneurial response to Albania's opening and liberalising was better than expected.

In recent years the Albanian economy has improved. In 2007, the annual economic growth rate run at 5.5%. Fiscal and monetary discipline has kept inflation relatively low, averaging roughly 2.5% per year from 2004 to 2006. Albania's public debt reached 57.5% of GDP in 2006 and the growing trade deficit was estimated at 25% of GDP.

In 2006, Albania trade had Lek 316 billion/ € 2.5 billion in imports, and Lek 80.5 billion/ € 655 million in exports. Albania has concluded Free Trade Agreements (FTAs) with Macedonia, Croatia, UNMIK (Kosovo), Bulgaria, Romania, Bosnia and Moldova. In April 2006, these bilateral agreements were replaced by a multiregional agreement that entered into force in May 2007 and that is based on the Central European Free Trade Agreement (CEFTA) model.

However, combined trade with all these countries constitutes a small percentage of Albania's trade, while trade with EU member states (mainly Greece and Italy) accounts for nearly 68%. U.S. two-way trade with Albania is very low. The Albanian Government signed FTA with EU as part of its Stabilization and Association Agreement negotiations. The interim agreement entered into force in December 2006 and it foresees a duty free regime for almost 90% of agriculture and industrial products. On the fiscal side it will significantly reduce revenue collection.

Albania is trying to attract foreign investment and promote domestic investments and to this aim it is implementing several strategies and new ones are being drafted. The Albanian Government faces the daunting task of rationalising and uniformly applying business laws, improving transparency in business procedures, restructuring tax systems (including tax collection), reducing corruption in the bureaucracy and resolving property ownership disputes.

Table 1.2: Albania – Macroeconomic indicators 2000 – 2007

Variable (in Lek or percentage)	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**
GDP in (million Lek)	523043	583369	622711	694098	751024	817374	893000	979000
GDP / capita in Lek	171013	190437	201907	223702	240748	260727	283569	309611
GDP / capita in PPPa	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Annual economic growth rate in %[2]	6.7	7.9	4.2	5.8	5.7	5.8	5.5	5.9
General government expenditure (GGE) in million Lek	170333	186050	192516	201153	222438	232339	258816	285328
GGE in % of GDP	32.6	31.9	30.9	29.0	29.6	28.4	29.0	29.1
Exchange rate (Lek per €), annual rate	132.58	128.47	132.36	137.51	127.67	124.19	123.08	123.07

GDP = Gross Domestic Product, GGE = General government expenditure, PPPa = Purchasing Power Parity

Sources: Ministry of Finance (MF), Department of Macro-economy

1.3 Political context

The constitution of Albania was passed by referendum in November 1998 and is an adequate basis for proper development and implementation of democratic principles and fundamental freedoms, including political pluralism, freedom of expression and religion and respect of minorities.

The unicameral People's Assembly (Kuvendi Popullor, KP/PA) consists of 140 seats, 100 of which are determined by direct popular vote. The remaining seats are distributed by proportional representation. All members serve 4 year terms. The Speaker of Parliament has two deputies, who along with eight permanent parliamentary commissions assist in the process of legislating Albanian affairs.

The president is the head of state and elected by a three-fifths majority vote of all Assembly members. The president serves a term of 5 years with the right to one re-election. Although the position is largely ceremonial, the Constitution gives the President authority to appoint and dismiss some high-ranking civil servants in the executive and judicial branches. The president is also commander in chief of armed forces and chairs the National Security Commission (Komisioni i Sigurimit Kombëtar/KSK/NSC). The current President's term expires on July 23, 2012.

The Prime Minister is appointed by the president and approved by a simple majority of all members of the Assembly. The Prime Minister serves as the Chairman of the Council of Ministers (Këshilli i Ministrave, KM/CM), which consists of the Prime Minister, Deputy Prime Minister and other ministers. Members of the Council of Ministers are nominated by the Prime Minister, decreed by the president and approved by a parliamentary vote.

Albania's civil law system is similar to that of other European countries. The court structure consists of a Constitutional Court, a Supreme Court and multiple appeal and district court. The Constitution Court is comprised of nine members appointed by the Assembly for one 9- year term. The Constitution Court interprets the Constitution, determines the constitutionality of laws and resolves disagreements between local and federal authorities. The Supreme Court is the highest court of appeal and consists of eleven members appointed by the President with the consent of the Assembly for 9–year terms. The president chairs the High Council of Justice, which is responsible for appointing and dismissing other judges. The High Court of Justice is comprised of 15 members – the President of the Republic, the Chairman of the High Court, the Minister of Justice, three members elected by the Assembly and nine judges of all levels elected by the National Judicial Conference. The remaining courts are divided intro three jurisdictions: criminal, civil and military.

Decentralisation process has continued to make slow but constant progress and additional autonomy has been granted to local government units. The exclusive functions of municipalities and communes have become clearer, while the role of the perfect has a tendency to increase. Substantial fiscal authority has been assigned to local governments, while competences are now decentralised.

Concerning civil society, various actions have been implemented by civil society organizations in order to contribute to the development of the country and initiatives have been undertaken to encourage collaboration between state institutions and these organisations. Albanian Public Administration is undergoing continuous reforms in order to be further strengthened to guaran-

tee adequate implementation of the central instruments of the Stabilization and Association Process.

Human rights and fundamental freedoms are guaranteed by the Albanian Legislation. Albania ratified the European Convention on Human Rights (ECHR) in 1996 and some efforts towards approximating Albanian legislation with this convention have been made, for eg. Adoption of a new Family Code claimed to be compatible with ECHR.

1.4 Health care system

1.4.1 Organisation

The Health System in Albania involves a number of structures, organisations and stakeholders. MOH accounts for nearly all health service delivery in Albania. It remains the major founder and provider of health care services in Albania. There are three levels of health care in the country: primary, secondary and tertiary.

Total number of out-patient visits is 5,596,680 visits per year with an average of 1.6 visits per capita.

The private sector consists largely of dentistry and pharmacy and some clinics in the urban areas. However, the number of private service providers is rapidly growing. 90% of the health workforce is employed in the public sector, a figure which is high if compared with Western European countries in its ratio to the population.

The Albanian health system is in the process of undergoing significant changes. Many aspects of health care policy in Albania continued to follow the Soviet Semashko model. In 1990 and with the collapse of the communist regime, government services have suffered several problems and the emphasis was switched to hospital care. During the years of transition, the Albanian has made extraordinary efforts to solve these problems aided by international donors. Kosovo crisis in 1999 brought many new health donors and donations reached the amount of Lek 200 billion / € 160 million helping improving the health system in Albania. Currently we have Bismarkian solidarity health insurance system based on contractual relationships and quasi-public arrangements.

As one of the most important sectors for human development, the health sector is defined as one the priorities of the government of Albania. To this purpose, under the Albania's Integrated Planning System, (IPS), the National Strategy for Development and Integration (NSDI) will emerge as a synthesis of a comprehensive set of sector and crosscutting strategies. The MOH is in charge of designing and coordinating the health system strategic plan.

When the 12 regional prefectures were created in 1993, some administrative authority was shifted to those prefectures from the centre. Each prefecture comprises an average of three districts and each district is responsible for administering district hospitals and polyclinics, specialist hospitals (such as tuberculosis hospitals and PHC centres). The 1993 Law on Local Gov-

ernment, which regulates the election and powers of local authorities, shifted some responsibility for PHC to rural areas.

The local government authorities of all 315 rural communes now own their PHC facilities and are thus partially responsible for PHC. The Ministry of Finance gives them earmarked grants for equipping, maintaining, operating and upgrading PHC centres and posts, as well as for paying of some staff salaries. In urban areas, MOH district offices still own and administer such services.

Under MOH, the responsibility for health protection particularly the prevention and control of infectious diseases and the national vaccination programme, environmental health and the monitoring of drinking water and the air quality is with the Institute for Public Health. It works at the primary level mainly through the district public health services.

State funded health insurance in Albania is still fairly limited, both in terms of the population and the services it covers. Established in 1995 and managed by HII, the health insurance scheme pays salaries to GP-s (including family doctors) and offers patients free consultations with GP and subsidies on more than 300 pharmaceuticals. The scheme is financed by social taxes and wages (approximately 56 percent); however the formal economy is estimated to represent only 65.9 percent of total economic activity. By law, all economically active individuals (employees, employers, the self employed, or unpaid family workers) are obliged to contribute to the scheme, while the state bears responsibility for the contributions of children, full-time students, retirees, the disabled, the unemployed, pregnant women and citizens under compulsory military service. Coverage among farmers, despite low premiums set for them, is particularly low due to their inability to afford the scheme, their lack of awareness or their lack of incentive to join. HII has also started to be involved in financing secondary hospital services. In 2001, the insurance fund began funding the Durres regional hospital through a Pilot Project.

In the Tirana Prefecture, which includes two districts, a decentralisation initiative stronger than that of districts has been piloted since 2000. The Tirana Regional Health Authority (Autoriteti i Shëndetësisë Rajonale / ASHR/TRHA) is responsible for planning and managing primary health care services and public health programs. A regional health board has been set up and is responsible for endorsing the proposed regional policies, plans and budgets.

Some of the main Albanian laws and policy documents relating to health care reform since the collapse of Communist regime are listed as follows:

Council of Ministers Decree No. 449, On the Reorganization of the Health Services in State Enterprises

1992 Law No. 7664, on Environmental Protection

1992 Law No. 7708, On the Order of Physicians (Requires compulsory registration of physicians)

1994 Law No. 7850, On Health Insurances (reimbursement for drugs and GPs)

1994 Law No. 7975, On Narcotics and Psychiatric Drugs

1994	Council of Ministers Decree No. 613, on the Status of Health Insurance Institute (gives HII autonomy)
1995	Council of Ministers Decree No. 343, On Financial Coverage of General Practitioners by the Health Insurance Institute
1995	Council of Ministers Decree No. 323, on approval of the first List of Reimbursement Drugs
1996	Law No. 8092, on Mental Health (psychiatric care and patient rights)
1997	Law No. 8193, On Organ Transplants
1999	Albania health system reform: a document on policy and strategies for Albanian health system reform. Ministry of health policy document
2000	Law, on the Order of Physicians in the Republic of Albania (modifies and updates Law No. 7708 (1993)
2000	Council of Ministers Decree No.394, On the Establishment, Organization and Functioning of Tirana Regional Health Authority
2000	Council of Ministers Decree No. 560, On Health Insurance Financing of Primary Health Care Services in Tirana on a Pilot Basis
2000	Council of Ministers Decree No. 560, On Health Insurance Financing of Durres Hospital Services on a Pilot Basis
2001	Council of Ministers Decree, On Integration of the National Directorate of Health Education and Promotion with the Institute of Public Health
2001	Law, on Reproductive Health
2002	Amendment to Health Insurance Law to establish HII as the single source of Finance and Primary health care and all health care system
2003	Law No. 9150 on the Order of Pharmacists in the Republic of Albania
2004	Law No. 9323 (amended), on pharmaceuticals and pharmaceutical service
2006	Council of Ministers Decision No. 857, on financing of Primary Health Care service from the health insurance compulsory scheme
2008	Council of Ministers Decree No.780, on approval of the List of Reimbursement Drugs
2008	Law No.1661 on “The Financing of the Hospital Services from the Health Insurance Scheme”

The main authorities and bodies at the local and central level that provide health service are as follows:

The Governmental sector:

Ministry of Health: Provides comprehensive public health services, primary preventive and curative care services through its facilities.

Ministry of Finance: Allocates money to all ministries including Ministry of Health and provides local government with earmarked funds

Health Insurance Institute: Aims to offer a broader range of health services, control administrative cost and ensure equity.

Ministry of Defense: Provides curative care including hospitalization, physician specialist and ambulatory care, pharmaceuticals.

Ministry of Public Order: Provides free health and medical care for police

Ministry of Justice: Is a Third Party Payer of Prisoners

Ministry of Education and Science: Provides research and medical education for MOH

Non-governmental organisations: Provides health related programs mostly in some cases they provide primary health care medicine and firs aid kits to urban and rural organizations related to raise public awareness and public health care.

Foreign Donors: International aids paid to the government of Albania.

Private sector: Hospitals, dental clinics and pharmacies owned by private individuals operating in the private sector.

Household (out-of-pocket): Spending by people on health services provided by health providers for them.

An uninsured out-patient gets health service from GP-s or specialists by paying a certain tariff. Patient co-payments are set at a low level and are not intended to be a major source of revenues. They apply principally to out-patient services and pharmaceuticals, but not to in-patient care. Concerning reimbursement of pharmaceuticals the co-payment scheme is being applied for certain categories of individuals (cf. 4.2.2).

1.4.2 Funding

In terms of administration health funds, other than the household, the Ministry of Health and Health Insurance Institute (HII) are the main agents handling health funds. Ministry of Health resource allocation is skewed mainly toward primary and out-patient care at the health centres and health posts to cover the entire country. It is financed through budget derived from general revenues (taxes) and donations from donors. Contributions of the insured people are collected by the Ministry of Finance through taxes on HII account.

Albanian health services are funded through a mix of taxation and statutory insurance. The majority of funding still comes from the state budget. Health care is financed as follows: about 59% from the state budget, 29% from household payments, 4% from employer health insurance contributions and 8% from foreign donors.

Sources of funds are the Ministry of Finance (Ministria e Financave, MF); Employer funds, Household funds, Donors Funds. Contributions for health insurances administered by HII amount to a total of 3.4 % of the salary, out of which 1.7% is paid by the employer and 1.7 by the employee. The self-employed pay 7% of the minimal salary. Another source of contributions is the voluntary insurance that stands at 3.4% of the minimal wage.

All these rates are defined according to the Law "On Health Insurances". Persons who request voluntary insurance, in compliance with Voluntary Insurance Regulation No.2, dated 30.09.2003, have to make a contract with the Regional Directorate of Health Care Insurance (Drejtoria Rajonale e Sigurimeve Shëndetësore; DRSSH/RDHCI), in which the contribution rate to be paid, the way of payment and benefits from the scheme are specified.

To all the individuals paying health insurance contributions, such services as reimbursed drugs, free of charge visits by GP-s and specialist, various medical analyses are offered at public health institutions.

In 2007, the total incomes of HII amounted to Lek 9,972 mio. / € 81 mio., while expenditures amounted to Lek 9,068 mio. / € 74 mio. In 2007, the structure of revenues performance fragmented according to contributions is presented as such: Lek 4,155 mio. / € 33.8 mio. are health insurances contributions, Lek 5,545 mio. / € 45.1 mio. state contributions and Lek 272 mio. / € 2.2 mio. are other revenues.

In 2006, budgetary expenditures for all health (MOH expenditures) and HII run at 3.2% of GDP. Total health expenditures (THE), which include out of pocket payments for health and budgetary expenditures runs at 2.65% of GDP.

The state remains the major source of health care financing: The MOF allocates money to the Health Insurance Institute, mainly to cover unwaged groups and to the Ministry of Health. It also allocated earmarked funds to local governments, mainly for primary care and fund for some staff salaries and capital funds to upgrade and maintain health centres and health posts.

Table 1.3: Albania – Health expenditure, 2000 – 2007

Health expenditure	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**
THE in million Lek	12,334	13,722	13,719	15,698	19,312	21,616	23,690	n.a
THE in % of GDP	2.36	2.35	2.20	2.26	2.57	2.64	2.65	n.a
THE per capita[1] in Lek	4,032.7	4,479.5	4,448.2	5,059.3	6,190.6	6,895.1	7,522.7	n.a
Public HE in % of THE	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Private HE in % of THE	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a

GDP = Gross Domestic Product, HE= Health Expenditure, THE = Total Health Expenditure, Lek = National Currency Unit

Source: Ministry of Finance 2008

1.4.3 Access to health care

Administrative data suggest that Albanians have significantly less out-patient contacts with health care providers than the people of other countries in the ECA Region. This may be partly a reflection of growing, although still small, utilisation of private out-patient facilities by those frustrated with the low quality of care provided in public facilities. Out-patient utilization varies considerably across regions. Contact rates in Durres and Tirana cities are higher due to high presence of formal private providers in these cities. They may also reflect higher health insurance coverage and lower likelihood of having to pay for out-patient care in these cities than elsewhere in the country.

Albania's in-patient admission rates are similar to those in other South East European countries. In-patient admission rates appear to have remained relatively stable over the past decade, despite the upheavals during the early and mid 1990s. There are marked regional variations in hospitalization rates. The substantially higher incidence of surgeries in Tirana suggests that a large share of the population from across the country travels to the capital for hospital treatment, as the relevant services are not available or the quality deemed inadequate in hospitals nearby.

The vast majority of those seeking health care do so in a public facility, but the utilisation of private providers was increased slightly between 2002 and 2004. In both years, around 90 percent of the population sought care from a public facility. However, the share of those seeking private care increased for both chronically and acutely ill over the two-year period. But 2004 data shows that over 40% of those who were sick sought care at a polyclinic or a hospital, than at the primary care level.

1.4.3.1 Out-patient care

A basic PHC system orientated towards the health of mothers and children was established prior to 1990 through a nationwide network of health centres and health posts. Primary health care is provided through a network of health centres and health posts, supplemented by polyclinics in urban areas. Polyclinics are the responsibility of the respectively district hospital or regional hospital with which they are affiliated and provide specialist care. Out-patient care may be also offered in hospitals when recommended by GPs, or polyclinics specialists.

Ownership of some primary care facilities in rural areas was transferred to the local government in the mid 1990s. All primary health care facilities operate under the general administration of the MOH regional and district's affiliates. The exception is with Tirana region. Under a decentralisation pilot project, the Tirana Regional Health Authority was established to administer all PHC, including polyclinics and public health in the region.

Out patient care in the public sector is provided in health centres, health posts, polyclinics and through some private visits. Health centres are staffed by one to three GPs and nursing staff. In rural areas, a typical health care centre is staffed by one GP and two or three nurses while a health post is staffed by a nurse of a midwife. Polyclinics are staffed by specialists as well by GPs, the latter being posted there to serve as the first point of contact for all the patients coming to the polyclinic. Primary care teams led by GPs in PHC facilities are supposed to act as a gatekeeper for secondary care.

GPs are paid by HII on a modified capitation basis (base salary plus capitation supplement depending on location and register patient), which in principle depends on the number of registered patients. While the system allows for higher payments in remote areas to attract and retain GPs in such areas, it does not include any reward linked to performance and quality targets.

Household survey data show that the possession of a health insurance booklet neither significantly reduces the amount of out-of-pocket expenditures for out-patient care nor affects the likelihood of having to pay for care, particularly outside Tirana. This suggest that doctors at primary care facilities tend to not enforce fee payment for those without insurance, while those with insurance incur expenditures for drugs, diagnostic and informal payment similar to those without insurance.

Table 1.4: Albania – Out-patient care 2000 – 2007

Variable	2000	2001	2002	2003	2004	2005	2006	2007
Total number of doctors[1]	3,629	3,618	3,656	3,699	3,700	3,730	3,745	3,760
Number of doctors[1] per 1,000 inhabitants[2]	1.004	1.181	1.185	1.192	1.186	1.189	1.189	1.192
Total number of out-patient doctors	1,700	1,710	1,726	1,750	1,757	1,790	1,820	1,843
thereof General Practitioners[3]	*1,522*	*1,515*	*1,546*	*1,598*	*1,602*	*1,583*	*1,628*	*1,626*
thereof dentists	*n.a*	*n.a*	*n.a*	*970*	*n.a*	*n.a*	*n.a*	*n.a*
No. of out patient doctors per 1,000 inhabitants[2]	0.489	0.558	0.559	0.564	0.563	0.570	0.577	0.584
No. of out-patient clinics departments ("ambulatories")	1,505	1,433	1,375	1,501	610	610	610	405

[1] No number of retired and non-practicing doctors as well as for dentists available, n.a. = not available

Source: Ministry of Health and Health Insurance Institute

1.4.3.2 In-patient care

Hospitals remain publicly owned, most of them by the MOH, except the Military Hospital. There are plans to reorganise hospitals at three levels: national, regional (prefecture) and district. In-patient health services are offered by 50 hospitals and a network of specialized polyclinics, public and private, which are mainly situated at urban areas. The number of beds per population is 3.1 per 1,000 inhabitants, while average length of stay in hospitals is 6.9 days, which is lower compared to the average length of stay in Western European countries (8.2) and that of European countries.

There are no private hospitals though the Hospital Act allows for establishment of private in-patient facilities. Public hospitals are headed by a chief head physician who is in charge of overall hospital operations and management, but not trained to manage hospitals. Public hospitals have limited financial and administrative autonomy.

All health personnel is recruited and assigned to specific hospitals centrally by the MOH following a norm-based request by the head physician.

A decision to establish a three-tired hospital system with district and regional hospitals and tertiary care in Tirana has not yet been fully implemented, as agreement could not always be reached on the downgrading of certain hospitals to district facilities and the upgrading of others.

Tertiary care is offered in Tirana by the Tirana University Hospital, the Tirana Obstetric and Gynaecology Hospital, the Lung Disease Hospital and the Military hospital. The latter is under the Ministry of Defence, specializes in traumatology and contains the university orthopaedic department. There currently also remain nine rural hospitals, directly reporting to district hospitals and operating as an integral part of district hospitals. They offer Pathology and Paediatric services. Two psychiatric hospitals, located in Vlora and Elbasan cities, with 680 debs in total, specialize in the treatment of chronic and acute psychotic patients. In addition to the tertiary hospitals, there are three specialized institutions: the National Centre for the Well-being ad Development of Children, the VIP Clinic, and the Helicopter Centre.

Although Albanian legislation provides for free in-patient hospital care for all, out-of-pocket expenditures in the event of hospitalisation are substantial with informal payments accounting for at least one quarter of all payments. Government decisions allow for charges for certain diagnostic procedures. Patients are often also asked to bring their own drugs. According to LSMS data virtually everyone that is hospitalized incurs out of pocket expenditures, averaging about 21,000 Lek/€ 171. An informal payment may be also considered in case a patient requires certain treatments and the supplies are not available at the providing institution, the patient may be required to either purchase their own supplies or reimburse the attending physician or nurse fort the supplies they purchased from own funds. The lack of a formal co-payment system for hospital care further perpetuates informal payments.

With the exception of Durres hospital, hospital providers are financed through the MOH with an input-based line item budget. Hospital managers have limited expenditure management and managerial autonomy. Input based financing gives providers no incentive to improve performance, nor does it lead to resource allocation based on outputs or local needs.

Table 1.5: Albania – In-patient care 2000 – 2007

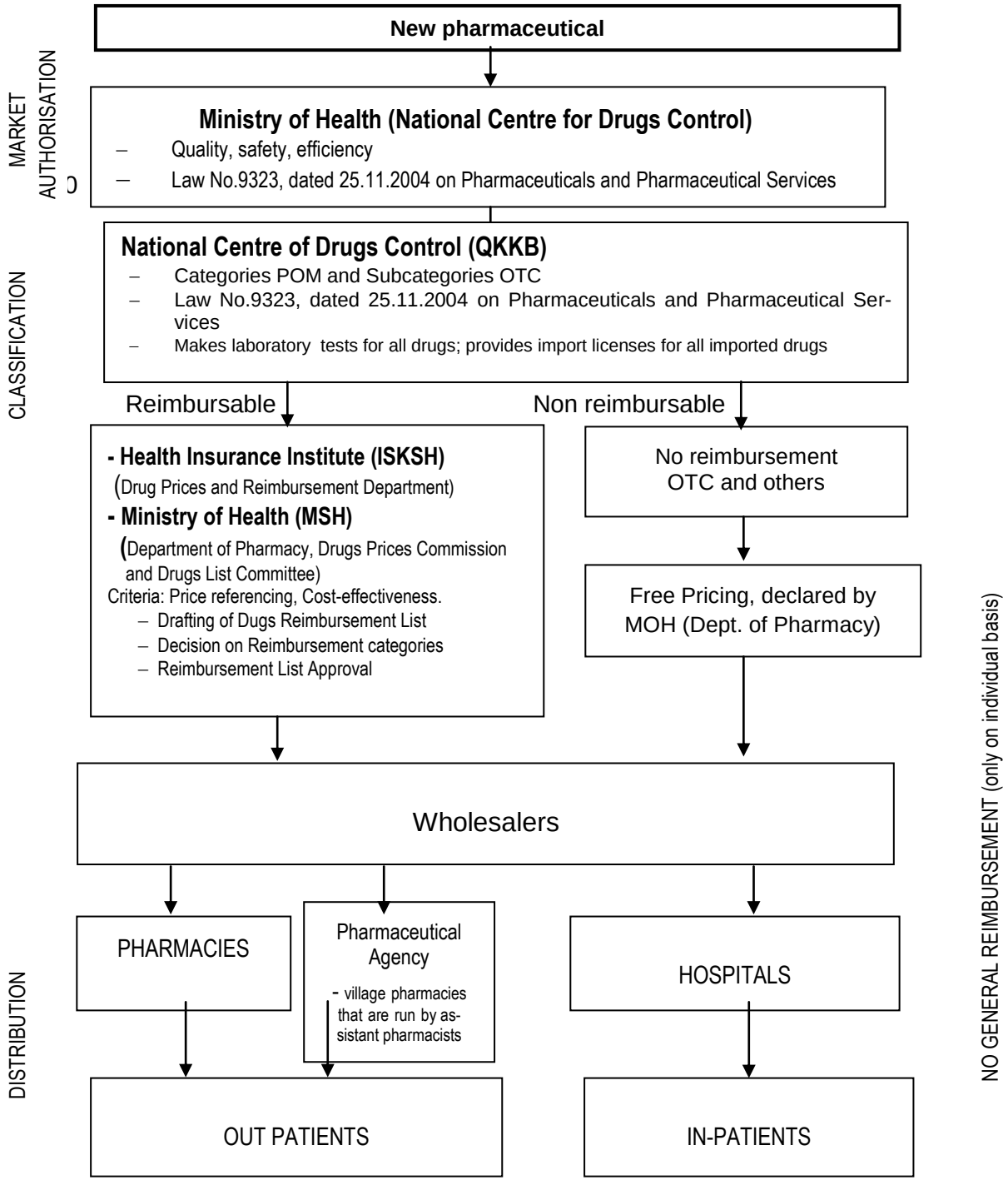
Variable	2000	2001	2002	2003	2004	2005	2006	2007
Number of in-patient doctors	1,700	1,710	1,726	1,750	1,757	1,790	1,820	1,843
Number of in-patient doctors per 1,000 inhabitants	0.489	0.558	0.559	0.564	0.563	0.570	0.577	0.584
Number of hospitals	50	48	48	48	48	48	48	50
Number of acute care beds	8,900	8,874	8,874	8,874	8,874	8,874	8,874	8,900
thereof in private sector	n.a	n.a	n.a	n.a	n.a	n.a	50	50
Acute care beds per 1,000 inhabitants[1]	2.562	2.896	2.877	2.860	2.844	2.830	2.817	2.823
Average length of stay in hospital	6.9	7.0	6.7	6.6	6.8	6.8	6.9	6.9

Source: Ministry of Health

2 Pharmaceutical system

2.1 Organisation

Figure 2.1: Albania – Flowchart of the pharmaceutical system 2008



2.1.1 Regulatory framework

2.1.1.1 Policy and legislation

Albania strives to align its pharmaceuticals legislation and administration with that of European Union. Recent policy changes point in the direction of policies established in other European countries. A new drugs law, which seeks to address the key shortcomings of the 1994 Law on Medicines and to align Albania's drugs policy closer to that of EU countries, was enacted in early 2005.

Some of the key laws and Council of Ministers Decrees (CMD) approved for the sector of pharmaceutics after 1990 are:

1993 Law No.7835, On Drugs (regulates drugs and reimbursement for essential drugs)

1993 Council of Ministers Decree No.60 on the Foundation of the National Centre for Pharmaceuticals Control, associated with MOH.

1993 CMD No. 325, on Export-Import and fabrication of Pharmaceuticals

1994 Law No. 7850, On Health Insurance (reimbursement for drugs and GPs)

1994 Law No. 7975, On Narcotics and Psychiatric Drugs

1994 Law No. 7815, On regulations for the pharmaceuticals fabrication, imports-exports, trading, utilisation and quality in the Republic of Albania

1995 CMD No.182, On Pricing of pharmaceuticals, which was amended in 1996 upon DCM No. 288 and in 1998 upon DCM No.307

2000 CMD No.190, on amendment to DCM No. 789/1998 concerning "Reimbursed rates of drugs price coverage".

2003 Law No. 9150, on the Foundation of the Albanian Order of Pharmacists associated with MOH

2003 CMD No. 85, on the biding of contracts between HII and pharmacies and pharmaceuticals storages.

2003 CMD No. 88, on the approval of HII status

2004 Law No. 9323, On Drugs and Pharmaceutical Service

2004 CMD No. 383, on the Approval of procedures, fees and coverage rate for the unique and tertiary examination services included into the health insurances

2005 CMD No. 56, on the Definition of mark-ups for pharmaceuticals fabrication and trading.

2006 Law No. 9644, for some supplements and amendments to the Law No. 9323 on Drugs and Pharmaceutical Service.

2006 CMD No.87, on the administration and coverage of expenditures for reimbursed receipts

2006 CMD No.857, dated 20.12.2006 on “Financing of Primary Health Care Service from the Compulsory Scheme of Health Care Insurance”

2007 CMD No. 504, on the setting up and operation of the Drugs Pricing Commission

2008 CMD No. 1661 dated 29.12.2008 on “Financing of Hospital Services from the Health Insurance scheme”

2008 Law No. 10 008 dated 27.10.2008 for some changes on the Low No. 9323 dated 25.11.2004 on “Drugs and Pharmaceutical Service”.

Among the key changes introduced by this legislation are the following:

- Simplification of the registration process for drugs approved in Europe or the United States
- Mandatory adherence of local procedures to EU standards or current Good Manufacturing Practice within 2 years
- Increased Independence of the National Centre for Drugs Control (NCDC)
- Price negotiation for more expensive, single source medicines with importers/manufacturers based on reference prices from other countries
- Introduction of price sticker system for drugs
- Detailed definition of a penal code for various types of violations and revocation of the professional license for doctors or pharmacists in more severe cases.

2.1.1.2 Authorities

The most important players in the Albanian pharmaceutical system are as follows:

- The Ministry of Health (MSH/MOH), which is a planning and legislative authority and in charge of reimbursement decisions and also of licensing of pharmacies.
- The Health Insurance Institute (HII) / Instituti i Kujdesit Shëndetësor (ISKSH), which is responsible for primary health care financing, offers a broader range of health care services for out-patients such as reimbursement of drugs, the reimbursement of medical examination.
- The National Centre for Drugs Control (NCDC)/ Qendra e Kombetare e Kontrollit te Barnave (QKKB) of all pharmaceuticals sold in Albania.

The Ministry of Health (MOH) / Ministria e Shendetesise (MSH) remains the major payer and provider of health care services in Albania. Although the Ministry is partially reorganised it continues to assume the leading role in most areas of health care and it devotes most of its efforts to health care administration, rather than to policy and planning. Until 31 December 2006, Health directorates were organized in a hospital directorate and a PHC directorate and administered through the Ministry of Health district bodies. Starting from January 2007, PHC is administered by HII district directorates in compliance with CMD No.857, dated 20.12.2006 on “Financing of Primary Health Care Service from the Compulsory Scheme of Health Care Insurance”.

The Law on Medicines requires that all pharmaceuticals sold in Albania be registered and licensed by **the National Centre of Drugs Control (NCDC) /** Qendra Kombetare e Kontrollit te

Barnave (QKKB). Currently, decisions on drugs registration are made by the Nomenclature Commission appointed by the Ministry of Health. NCDC is under the responsibility of MOH. The new law foresees an independent status for NCDC much like that of similar agencies in EU. The objective would be to ensure the autonomy of its operations and decisions subject to appropriate oversight. The NCDC is financed primarily from the State budget, with secondary funding arising from drug registration (a registration fee of Lek 58,000/ € 470 per drug plus Lek 20,000/ € 150 renewal fee), the inspection tariff of new facilities and drug analysis for private clients.

National Centre of Drugs Control (QKKB/NCDC) is also in charge of drug quality testing, although it has limited physical and human capacity to realize this, such as for testing biological, including blood products or vaccines. Random testing is not undertaken unless a product is sent to the NCDC on the basis of a complaint. The new law also foresees increased financial autonomy for the NCDC.

Recently introduced simplifications of the registration process are aimed at encouraging pharmaceutical companies to register new drugs in Albania. Under the simplified procedures, drugs that are approved by a major agency such as EMEA or FDA can receive registration and marketing authorisation by means of acceptance of the respective certificate without further scientific of technical evaluation. Generics from other countries need to obtain a marketing authorisation in an EU member country, Canada or the United States first in order to be registered in Albania. Some unregistered drugs can still be used in the country with special ministerial permission, but the number has been reduced from about 50 to eight. The goal is to register all drugs that are required to provide state-of-the-art treatment and thus eliminate the need for special permission,

The licensing of private institutions, including manufacturers, pharmacies and drug depots is the responsibility of the Licensing Commission of the MOH. Licenses are now valid for 5 years and in case of re-licensing for 10 years. The new drug law foresees that licensing will be transferred from MOH to the Order of Pharmacists.

Several special commissions operate as formal decision making bodies. The Nomenclature Commission decides on the registration of drugs; the Licensing Commission endorses licenses for all medical and pharmaceutical professionals and businesses; and the Reimbursement Commission approves new drugs for inclusion into the HII reimbursement list, sets prices and reimbursement margins and eliminates outdated or economically obsolete drugs. Some commissions have 30 or more members, mostly representatives of the medical profession, academia, the Ministry and other administrative bodies.

The Health Insurance Institute (HII) / Instituti i Sigurimeve te Kujdesit Shendetesor (ISKSH) reimburses a defined list of out-patient drugs for the estimated 40-45 percent of the population that benefit from effective HII coverage. The current reimbursement list includes 402 different active ingredients. Eight drugs were removed in 2004 because they were obsolete or because better treatment options became available. Decisions regarding inclusion on HII positive list are made by the Reimbursement Commission established by the Ministry of Health. The Reimbursement Departments at HII manages the list, while the 12 regional HII offices are responsible for issuing the serial coded and coloured Prescription forms (colours signal the reimbursement

level) and for the reimbursing of the contracting pharmacies. A controlling department analyzes prescriptions and investigates cases of alleged abuse or fraud. Contracting with physicians, pharmacies and wholesalers allows HII to collect data for monitoring prescribing behaviour and to catch those who try to play the system for their own benefits.

Reimbursed drugs are dispensed through a network of approximately 700 private pharmacies and pharmaceutical agencies across the country, which have contracts with HII. In rural areas, in the absence of a qualified pharmacist, a restricted list of drugs is stocked in what is called a pharmaceutical agency staffed by a high school educated "assistant pharmacist".

Since January 2007, the regional directorates of HII are responsible for the administration of the Primary Health Care Service in compliance with CMD No.857, dated 20.12.2006 on "Financing of Primary Health Care Service from the Compulsory Scheme of Health Care Insurance".

Table 2.1: Albania – Authorities in the regulatory framework in the pharmaceutical system, 2008

Local name (Abbreviation)	Name in English	Description	Responsibility
Ministria e Shendetesise (MSH)	Ministry of Health (MOH)	Regulatory body, Competent Authority	Overall planning and legislative authority Manages all the pharmaceutical sector, in charge of procurement and tendering procedures in hospitals
Qendra Kombetare e Kontrollit te Barnave (QKKB)	National Centre for Drug Controls (NCDC)	Medicines Agency (subordinate to the Ministry of Health)	In charge of market authorisation and market survey, classification, and vigilance
Instituti i Sigurimeve te Kujdesit Shendetesor (ISKSH)	Health Insurance Institute (HII)	Semi-autonomous Agency accountable to the Parliament Third Party Payer	Manages the Health Insurance System In charge of managing the reimbursement list, monitors prescribing behaviours, contracts with pharmacies, administers Primary Health Care service etc.
Instituti i Sigurimeve Shoqerore (ISSH)	Social Insurance Institute	A body under the supervision of MOF	Collects social and health insurance contributions
Ministria e Financave (MOF)	Ministry of Finance	Financial Policy	Allocates funds to MOH and HII

Source: Health Insurance Institute (HII)

2.1.2 Pharmaceutical market

2.1.2.1 Availability of pharmaceuticals

As the manufacturing of pharmaceuticals in Albania plays only a minor role, most of the medicines need to be imported. The number of registered pharmaceuticals is almost the same as the number of drugs on the market.

Pharmaceuticals available in the market are divided into:

- Over-the-counter (OTC) pharmaceuticals (The MOH approves a list of OTC drugs annually).
- Prescription- only medicines (POM), which are provided with physician's prescription and mainly for out-patients and in-patients.
- Hospital –Only Medicines (HOM)
- The positive list of drugs (all the reimbursed pharmaceuticals are included)

Under the simplified procedures, drugs that are approved by a major agency such as EMEA or FDA can receive registration and marketing authorisation by means of acceptance of the respective certificate without further scientific of technical evaluation. Generics from other countries need to obtain a registration in an EU member country, Canada or the United States first in order to be authorised in Albania. Drugs that are in the market already do not lose their registration, but may have to meet the new standards for renewal. Some unregistered drugs can be still used in the country with special ministerial permission, but the number has been reduces from about 50 to eight. The goal is to register all drugs that are required to provide state-of-the art treatment and thus eliminate the need for special permission.

Parallel trading is not permitted by Albanian law.

The market authorisation rests upon the responsibility of the National Centre for Drugs Control (NCDC/QKKB). The classification process in POM and OTC is made by the Nomenclature Commission affiliated to the NCDC/QKKB. Reimbursed group of drugs is administered by the Health Insurance Institute (HII/ISKSH).

There is a positive list, which contains a restricted number of pharmaceuticals compared with the total number of drugs under circulation in the country. This positive list is updated on annual basis. The reimbursable medicines pertain to the prevailing diseases (chronic and acute diseases).

Table 2.2: Albania – Number of pharmaceuticals 2000 – 2008[1]

Pharmaceuticals	2000	2001	2002	2003	2004	2005	2006	2007	2008
Authorised	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	2,782	3,228	3,462
On the market	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
POM	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Reimbursable	611	627	650	791	724	722	748	824	865
Generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Parallel traded	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Hospital-only	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

POM = Prescription-Only Medicines, n.a. = not available

[1] as of 1 January

Method of counting: incl. different dosages

Source: National Centre of Drugs Control (NCDC) and HII Statistics

2.1.2.2 Consumption

The rate of prescriptions has been growing steadily in the last years. Table 2.3 shows only the number of reimbursed prescriptions and the value of reimbursed prescriptions per year as the Ministry of Health does not possess statistics on the total number of prescriptions.

Table 2.3: Albania – Annual prescriptions and consumption, 2000 – 2007

Consumption	2000	2001	2002	2003	2004	2005	2006	2007
No. of prescriptions per year (in volume)	2,542,615	2,390,903	2,272,970	2,227,978	2,717,604	2,898,297	2,415,048	2,333,150
No. of annual prescriptions in value (in million Lek)	1,690	1,693	1,692	2,345	3,617	4,128	3,361	3,590
No. of annual consumption in packs	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
No. of annual consumption in DDD	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a

DDD = Defined Daily Doses, Lek = Albanian National Currency, n.a. = not available

Source: HII Statistics Department 2008

2.1.2.3 Market data

In 2004, total HII drug expenditure accounted for 63 percent of HII expenditures and HII for the first time exceeded its budget for drugs mainly due to the elimination of co-payments for retired people, expansion of the reimbursed drugs list and increased prescribing of innovative medicines.

With the inclusion of more pharmaceuticals in the reimbursement list and additional patient groups becoming exempt from co-payments (cf. 4.4.2), the number of prescriptions as well as

the percentage of prescriptions that are fully reimbursed has increased substantially over the last years, thus contributing rapidly expanding HII drug outlays.

The number of registered drugs has increased substantially over the past decade, from 400 in 1994 to roughly 3.000 in 2005. Albanian doctors and patients have access to a respectable portfolio of well established generic as well as innovative medicines. Parallel trade is not permitted in Albania.

Local importers estimate that the overall pharmaceutical market in Albania at wholesale level amounts to about Lek 7 billion / € 57 million with a current growth rate of 10% per year. Reimbursements from HII covered Lek 3.7 billion / € 26 mio. in 2004 and Lek 4.1 billion / € 32.5 mio. in 2005. Whereas in 2008, HII covered Lek 4.2 billion / € 34.5 mio.

Table 2.4: Albania – Market data 2000 – 2007

In million NCU = LEK/€	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**
Pharmaceutical sales								
Sales at ex-factory price level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at wholesale price level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at pharmacy retail price level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at hospitals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales of generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales of parallel traded pharmaceuticals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Exports and imports								
Total pharmaceutical exports *	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total pharmaceutical imports*	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

* Please indicate if this is finished products and / or raw material

Table 2.5: Albania - Top 10 best selling pharmaceuticals by active ingredient, 2008

Position	Pharmaceutical, by active ingredient
1	Deferasirox 250mg
2	Valsartan 80mg
3	Lecarnidipine 10mg
4	Losartan potassium 50mg
5	Human Insulin Biosynthetic Neutral
6	Letrozol 2.5mg
7	Erythropoietin beta 2000 Nj.N
8	Enalapril 20mg
9	Human Insulin Biosynthetic Bephasic Izophan 30/70
10	Risperidon 1mg/1ml-30ml

Source: HII statistics, Reimbursement Analyses and Contracts Sector

2.1.2.4 Patents and data protection

Patent pharmaceuticals are not produced in Albania and on the other hand patent medicines imported from international pharmaceutical companies circulate in the domestic market in compliance with European legislation. Albanian Legislation on intellectual property has been improved on annual basis with the intention to become complied with international standards. There have been no problems with copy products in Albania. But there were some isolated cases of illegal parallel trading of pharmaceuticals, which have been minimised due to the periodical controls by respective authorities. The Albanian law on drugs doesn't permit parallel trading of pharmaceuticals.

2.1.3 Market players

2.1.3.1 Industry

The three pharmaceutical manufacturers that are actually operating in Albania are Profarma, Euromedica and Radofarma. "PROFARMA, L.S.C" is a joint stock company, 100% state owned since 1995. The company produces a number of essential generic pharmaceutical products, including perfusions, solutions for injections in small volumes, pills, creams, drops and ointments. Its products are distributed through the state-owned wholesale distributor FUFARMA to a network of approximately 400 pharmacies and hospitals throughout the country.

"EUROMEDICA" is also a joint stock company established in 1996 with a capital of Lek 280 million / € 2.3 mio. Its main activity is the production of finished pharmaceutical products, mainly oral tablets and antibiotics injections. The company is certified with the GMP Certificate and fulfils requirements of EU rules for production of pharmaceutical products. The company is presently exporting its products to Germany and the Netherlands. "RADOFARMA" is a pharmaceutical company, which mainly produces antibiotics and is situated in Shkodra city.

The number of pharmaceuticals produced by these companies has been continuously increased. Since, these companies have lower sale prices compared to pharmaceuticals they obtain a significant place in the positive list of drugs.

Table 2.6: Albania – Key data on the pharmaceutical industry 2000 – 2007[1]

Pharmaceutical industry	2000	2001	2002	2003	2004	2005	2006	2007
Total no. of companies	3	3	3	3	3	3	3	3
– research-oriented	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
– generic producers	3	3	3	3	3	3	3	3
– biotech	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Number of persons employed[2]	264	200	250	240	270	272	260	260

[1] as of 1 January

[2] counted per head

Source: Health Insurance Institute and MOH

2.1.3.2 Wholesalers

Local importers estimate the overall pharmaceutical market in Albania at a wholesale amount of about Lek 7 billion / € 57 mil. with a current growth rate of 10 percent per year. There are approximately 140 drug depots, out of which 80 wholesale depots have contracts with the Health Insurance Institute (HII). Pharmacies and hospitals (through procurement procedures) are supplied by wholesalers. The Wholesalers Association of Albania (Shoqata e Grosistëve te Shqipërisë; SHGSH/ WAA) has access to the drug commissions affiliated to the Ministry of Health, and participates in decision making. Parallel trade is not relevant in Albania.

Table 2.7: Albania – Key data on pharmaceutical wholesale 2000 – 2007[1]

Wholesalers	2000	2001	2002	2003	2004	2005	2006	2007
Total number of wholesale companies	60	58	62	64	55	60	63	65
Total number of importers	52	50	52	49	50	50	50	49
Total number of outlets	1	1	1	1	1	1	1	1

[1] as of 1 January

Source: MOH and HII statistics

2.1.3.3 Pharmaceutical outlets / retailers

Pharmaceuticals are regulated by Law No. 9323, dated 25.11.2004 “On the pharmaceuticals and pharmaceutical service”, which is partially aligned with EU Transparency Directive 2001/83/EC and “The Community Code concerning medical products for human usage.

Pharmaceuticals for out-patients are provided at pharmacies only, or drug agencies in rural areas. Pharmaceuticals for in-patients are received at hospital pharmacies only.

2.1.3.3.1 Pharmacies

Above mentioned Law No. 9323 “On the pharmaceuticals and pharmaceutical service” sets rules for the structure of the pharmacy market. It defines a target of one pharmacy per 3,000 inhabitants and limits pharmacies to be at least 150 meters apart. The law also contains a restriction of one pharmacy per pharmacist and prohibits the establishment of pharmacy chains. The density in urban areas like Tirana is high, whereas rural areas are under-served.

In the year 2008 there were a total of 924 POM dispensaries in Albania, 575 of them were pharmacies contracted by HII, 174 were pharmaceutical agencies (almost all of them contracted by HII) and the rest were pharmacies not contracted by HII. According to official figures, the retail market amounts to Lek 9.4 billion / € 77 mio. All the pharmacies actually operating in Albania are private and there are no state owned pharmacies.

In the central pharmacy of the Tirana University Hospital, each department has its own pharmacy, which orders supplies from the main hospital pharmacy warehouse. Many of the department pharmacies at this hospital are not integrated within the main department, but are physically in separate buildings.

Each individual graduated in Pharmaceuticals having a work experience of three years is entitled to get a license from MOH to open a private pharmacy, but this licence can’t be inherited.

In 2003, upon Law No. 9150, the Pharmacist Association was transformed into the Albanian Order of Pharmacists (Urdhëri i Farmacistëve të Shqiperise, UFSH/ AOP), associated with the MOH. The president of AOP is a member of some decision making commissions in MOH and HII. The Pharmacists Trade Union of Albania (Sindikata e Farmacistëve të Shqipërisë, SFSH/PTU) was founded in 2002 and it plays a major role concerning pharmaceutical policies.

Pharmacists still have a financial incentive to dispense expensive pharmaceuticals, as they are paid a margin that is a percentage of the product’s price. This is the only remuneration of pharmacists. The fixed mark-up system with comparatively high mark-ups protects the current structure and offers no incentive to reduce the fragmentation in the distribution market.

Pharmacies are supplied by wholesalers with all the types of drugs circulating at the Albanian market. Wholesalers apply different marketing policies concerning pharmacies. So, they may apply discounts and rebates.

Table 2.8: Albania – Retailers of pharmaceuticals 2000 – 2008[1]

Retailers	2000	2001	2002	2003	2004	2005	2006	2007	2008
Number of community pharmacies[2]	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Thereof: No. of private pharmacies	n.a.	n.a	n.a.	n.a	n.a	n.a	n.a	753	750
No. of HII contract pharmacies	751	751	751	751	739	702	677	627	575
No. of hospital pharmacies for out-patients	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a
No. of other POM-dispensaries: "Pharmaceutical agencies"	250	242	242	239	240	227	225	195	174
Total number of POM-dispensaries	1,001	993	993	900	979	929	902	948	924
Total number of POM-hospital dispensaries for in-patients	50	48	48	48	48	48	48	50	50
No. of internet pharmacies	0	0	0	0	0	0	0	0	0
No. of OTC dispensaries like drugstores besides "Pharmaceutical agencies"	0	0	0	0	0	0	0	0	0

OTC = Over-The-Counter Pharmaceuticals, POM = Prescription-Only Medicines; No. = number

POM dispensaries = including branch pharmacies, self-dispensing doctors, and other university pharmacies (FI), policlinic pharmacies (NL) and hospital pharmacies acting as community pharmacies

[1] As of 1 January

[2] incl. branch pharmacies

Note: total number of POM-dispensaries is the number of pharmacies together with pharmaceutical agencies. Not all the POM-dispensaries licensed by MOH are contracted by HII.

Source: Health Insurance Institute and MOH 2009

2.1.3.3.2 Other pharmacy outlets

In villages, pharmaceutical services are in general covered by pharmacy assistants who have 4 years of specific high school training incl. a diploma. They run so-called "pharmaceutical agencies" and they can dispense a limited number of POM according to a specific list of drugs annually approved by the MOH. OTC medicines can be dispensed as well.

There are no pharmacy outlets besides the above mentioned pharmacies allowed to dispense pharmaceuticals in Albania.

2.1.3.3.3 Internet pharmacies

There are no internet pharmacies yet in Albania.

2.1.3.3.4 Dispensing doctors

Doctors are not allowed to dispense or sell pharmaceuticals. Upon Law No.9323, dated 25.11.2004 “On pharmaceuticals and pharmaceutical services”, pharmaceuticals are dispensed only by pharmacies and drugs agencies licensed from the MOH.

2.1.3.4 Hospitals

Hospital drugs are covered through MOH budget and are in principle provided free of charge to in-patients. Each hospital has its own pharmacy. In the central pharmacy of the Tirana University Hospital each department has its own pharmacy, which orders supplies from the main hospital pharmacy warehouse.

From 2002-2004, drugs in hospital pharmacies were provided through centralised tendering procedures organised by the MOH. Hospitals annually sent their requests to the MOH for both the types and the quantity of the drugs based on historical use. These requests were filtered by the MOH committees. Tenders following Albanian procurement law are organised annually. On average, five to six competitors participated in the tenders leading to discounts up to 30 percent.

The reimbursement scheme is not applied for pharmaceuticals served at hospitals. Hospital Service is not part of health insurance scheme yet, but it is expected to be included in the framework of the overall reform being implemented with respect to health insurances in Albania.

2.1.3.5 Doctors

The Order of Physicians is the main doctors association and it’s head is member of several policy making bodies.

Doctors at Primary Health Care are part of the Health Insurances scheme and are paid according to the rules set out in this scheme. Hospital doctors and specialists are not yet part of health insurance scheme and are paid by MOH.

In compiling the reimbursed drugs list, suggestions presented by hospital doctors are taken into consideration and they are entitled to propose new drugs to be included into the reimbursement list. HII compiles the new drugs reimbursement list form summarising information on drugs and treatment protocols.

For in-patient drug use, the Tirana University Hospital and the Faculty of Medicine has developed standard treatment protocols for a wide range of diseases. However, as long as these protocols are not mandatory, their uptake and use in clinical practice will remain limited.

2.1.3.6 Patients

Household surveys indicate that about 40-45 % of the population benefit from effective coverage under mandatory health insurance system, indicating that the majority of the population pay for medicines out-of-pocket. While HII reimburses those medicines covered for drugs on its

positive list with varying co-payments an estimated 60% of the population pay for their medicines out-of pocket.

There are six categories of patient groups with regard to pharmaceutical benefits, ranging from 100 percent reimbursement for a smaller number of life-saving and cancer drugs to 50 percent for other drug categories (cf. Table 4.2). For multi source products reimbursement is limited to the price of the cheapest alternative with the same ingredient and dosage. If a more expensive drug is prescribed, the patient has to pay the difference out-of-pocket. Higher priced, innovative products may be reimbursable as long as there is no generic on the market. Pharmacies are not allowed to deviate from co-payment charge of any reimbursable pharmaceutical (cf. 4.4.2).

The pharmacy retail price (PRP) is uniform all over the country. The National Centre for Drug Control (QKKB) is the responsible institution that supplies all the importers with the price label for each package. Each drug package traded in pharmacies is required to have a label that states the retail price, the name of the drug, the importer and the batch number. The drug labelling system has been introduced in order to increase the hurdles for illegal importers and to eliminate a widespread practice of overcharging patients for medicines.

2.2 Funding

2.2.1 Pharmaceutical expenditure

In 2006 the total of public expenditures on pharmaceuticals amounted to 47% of total health expenditures. In 2007, the total expenditures of Health Insurance Institute on reimbursed pharmaceuticals were Lek 3 494 mio. / € 28 mio. or 0.92 % of GDP.

In 2004, total HII drug expenditure accounted for 63 percent of HII expenditures and HII for the first time exceeded its budget for drugs. The budget for pharmaceutical expenditures in 2004 was Lek 2.8 billion / € 20 mio, real expenditures were 3.5 billion (€ 25.8 million), mainly due to elimination of co-payments for retired people, expansion of reimbursable list and increased prescribing of innovative medicines. With the inclusion of more pharmaceuticals in the reimbursement list and additional patient groups becoming exempt from co-payments (cf. 4.4.2.2), the number of prescriptions as well as the percentage of prescriptions that are fully reimbursed has increased substantially over the last 2 years.

Recent developments show that there is a trend to prescribe newer and more expensive drugs, leading to substantial increase in reimbursement expenditures.

The level of the total pharmaceutical expenditures is more that of with middle income countries and is lower than the average for Southern European neighbour countries.

Table 2.9: Albania – Total pharmaceutical expenditure 2000 – 2007

Pharmaceutical expenditure	2000	2001	2002	2003	2004	2005	2006	2007
TPE in million LEK (reimbursed pharmaceuticals)	1,705	1,681	1,697	2,483	3,671	4,371	3,370	3,509
TPE in % of Total Health Expenditure	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
TPE per capita in LEK (reimbursed pharmaceuticals)	37	36	38	51	75	84	67	70
Public PE in % of THE	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Private PE in % of THE	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

GDP = Gross Domestic Product, TPE = Total Pharmaceutical Expenditure, PE = Pharmaceutical Expenditure, LEK = Albanian National Currency

Source: Health Insurance Institute Statistics

2.2.2 Sources of funds

The main sources of public pharmaceutical funding are the public budget and health insurance contributions. The public budget allocated for pharmaceutical expenditures is a lump sum. In 2007, HII revenues comprised of 55% from the public budget and 42% from health insurance contributions and 3% other revenues. MOF allocates money to the Health Insurance Institute mainly to cover the unemployed population.

Patient's co-payments are set at a low level and they apply principally to out-patient service including pharmaceuticals though not to in-patient care. Official out-of pocket payments account for an increasing proportion of health care revenue, but the full extent of such payments in unknown. According to some estimates, out-of-pocket sources, excluding health insurance contributions constituted 24.6% of total health expenditures.

2.3 Evaluation

There is no system for monitoring the outcome of pharmaceutical policy established in Albania. The only accurate statistics are those that are provided by HII concerning reimbursed drugs. As far as out-pocket expenditures are concerned there is no exact monitoring system.

3 Pricing

3.1 Organisation

A system of free pricing for all pharmaceuticals at manufacturer level is in place. All the pharmaceutical companies that are drugs importers or producers may set the prices of the drugs upon their own free will. Concerning over-the counter- drugs (OTC) and hospital pharmaceuticals there is no regular pricing policy applied. For a number of expensive drugs with a significant impact on HII expenditures, NCDC and HII have entered into negotiations with manufacturers or importers, using external reference prices.

The Reimbursement Department (Departamenti i Rimbursimit dhe Cmimit te Barnave) DCRB/PDRD) at HII in collaboration with Pharmaceutical Directorate in MOH (Drejtoria Farmaceutike/DF) prepare all the proper information on all the drugs (reimbursed and non-reimbursed pharmaceuticals) on annual bases. There is also a Drugs Pricing Commission attached to MOH. All the drug importers and domestic producers report to this commission on annual bases about the pharmaceutical prices. Representatives from HII, MOH, MOF and Ministry of Economy are members of this commission

The Drugs Reimbursement List Commission (Komisioni i Lists së Barnave të Reimbursueshme/KLBR) headed by the Minister of Health, makes the final decision on the reimbursement list (cf. 4.2 and 4.3). There is a positive list, which contains a restricted number of pharmaceuticals compared with the total number of drugs under circulation in the country. Prices of reimbursed drugs are negotiable at the manufacturer level (CIF) whereas prices of pharmaceuticals not included in the positive list are set on free bases. That means that all the drugs prices of non-reimbursed drugs are set on free bases and are subject to mark-ups decided according to the enforced law. Drugs included in the positive list are selected according to the following criteria: product specific criterion, disease criterion and economic criterion.

No formal pricing algorithm is in place for multi-source drugs. However the generic drug with the lowest price is given a preferred position on HII reimbursement list, meaning that it will have the lowest co-payment and therefore potentially the biggest share of the HII reimbursed sales volume. Thus the reimbursement system stimulates price competition for generic drugs.

The positive list is usually compiled after the period of prices declarations to the Drug Prices Commission is terminated.

3.2 Pricing policies

Recent policy changes in drug pricing point in the direction of policies established in other European countries. A new drugs law, which seeks to address the key shortcomings of the 1994 Law on Medicines and to align Albania’s drugs policy closer to that of EU countries, was enacted in early 2005.

Drug prices are set based on the CIF price (Cost, Insurance, and Freight) submitted by the manufacturer, with added statutorily regulated margins for distribution and retail.

Generally speaking, ex-factory (CIF) prices of all the drugs in the pharmaceutical market are set on free basis. There is no difference in pricing mechanism between different types of pharmaceuticals (e. g. generic drugs, on-patent products, and OTC).

But in the case of products included in the reimbursement list, i.e. positive list, more expensive drug prices are negotiated. For a number of expensive drugs with a significant impact on Health Insurance Institute (HII/ISKSH), HII enters into negotiations with manufacturers or importers, using reference prices from neighbouring countries to demand lower prices. The generic drug with the lowest price is given the top position on the positive list of drugs, meaning that it will have the lowest co-payment and therefore potentially the biggest share of the Health Insurance Institute (HII/ISKSH) financed sales volume. Thus the reimbursement system stimulates price competition for generic drugs. Simultaneously in-patient pharmaceuticals are publicly procured by MOH. The drug prices are declared by the manufacturers or importers annually.

Table 3.1: Albania – Ways of pricing of pharmaceuticals

	Manufacturer Level	**Wholesale Level**	**Pharmacy Level**
Free Pricing	Free pricing for all products set by the manufacturer/ importer.	Not applied	Not applied
Statutory Pricing	Not applied	Prices of selected reimbursable pharmaceuticals (POM) are set through a regressive mark-up scheme. For all other products a fixed percentage mark up is applied.	Prices of selected reimbursable pharmaceuticals (POM) are regulated through a regressive mark-up scheme. For all other products a fixed percentage mark up is applied.
Price Negotiations	Negotiation procedures only for expensive drugs on the positive list.	Not applied	Not applied
Discounts / rebates	Yes, cost related discounts	Yes, in wholesaler-pharmacy level.	Not applied
Public Procurement	Public procurement for all pharmaceuticals *used* in hospitals (not only HOM but also for others). Not relevant in out-patient sector, except for vaccinations.		
Institution in charge of pricing	Hospitals Department at MOH. Drug Prices Commission at MOH. Reimbursement List Commission at MOH in collaboration with HII.		
Legal Basis	Low on Medicines amended in 2005. Government decree on drug Margins, No.56, dated 25.01.2005. Government Decree on Reimbursement List and reimbursement drug margins, no.107, dated 22.02.2007.		

POM =Prescription-Only Medicines, OTC = Over-The-Counter pharmaceutical

Source: Albania Health Sector Note (World Bank), HII legislation.

Hospital Service is not part of health insurance scheme yet, but it is expected to be included in the framework of the overall reform being implemented with respect to health insurances in Albania. All drugs (hospital only-medicines and drugs used for in patient treatment) and medicine devices in Hospitals are provided via public procurement by MOH Commissions.

3.2.1 Statutory pricing

Statutory pricing is applied only at wholesale and pharmacy retail level via a regressive mark-up scheme in compliance with Council of Ministers decision No.56, dated 28.01.2005 “On the setting of pharmaceuticals fabrication and trading margins”.

The price margins (wholesale and retail margins) are regulated annually upon the Council of Ministers Decisions and according to the proposal put forth by the Prices Commission after negotiations with local and foreign producers, or their representatives and holders of the registration certificate.

The authorities involved in the procedure are the Ministry of Health (MSH/ MOH), Health Insurance Institute (ISKSH/HII) and Council of Ministers (KM/CM). External price referencing is applied only for reimbursed drugs.

The procedures are regulated by Law on Medicines No. 9323 (amended).

3.2.2 Negotiations

Price negotiations are used only for some very expensive drugs that are asked to be included in the positive list of drugs and at manufacturer level (CIF level).

Drug Prices Commission (KCB) in Ministry of Health has the authorisation to enter into negotiations with manufacturers or importers, using reference prices from neighbouring countries to demand lower prices. Part of the Drug Prices Commission in Ministry of Health is the Department of Pharmacy that runs the negotiations procedures through this Commission.

If the negotiation process does not lead to an acceptable price for the manufacturers/importers they may decide not to offer a particular product to the Albanian patients.

However, in most occasions the negotiation led to an acceptable price and to the inclusion of the product in the reimbursement list.

3.2.3 Free pricing

Free pricing is only applied at the manufacturer level. There is no difference in pricing mechanism between different types of pharmaceuticals (e.g. generic drugs, patent, and OTC drugs) as well as for the reimbursed drugs.

All drug importers and domestic producers report their prices to the KÇB (Drugs Pricing Commission) on annual basis about the pharmaceutical prices. Prices of reimbursed drugs are not

allowed to change during the year regardless of the exchange rate fluctuations, as the reimbursement list of drugs is compiled once a year.

3.2.4 Public procurement / tendering

Tendering is applied for hospital drugs and all in-patient drugs. As already stated above the reimbursement scheme is not applied in hospital services yet.

From 2002 on, drugs in hospital pharmacies were provided through centralised tendering procedures organised by MOH. Hospitals annually sent their requests to the MOH for both the type and the quantity of the drugs they require based on historical use. These requests were filtered by the MOH committee. Tenders were organised annually following Albanian procurement law. On average, five to six competitors participated in the tenders leading to discounts up to 30 percent.

As drug distribution was problematic in the first two years of the centralised tender process, in 2004, the MOH hired Fufarma (a remnant of the former public distribution system and is 65 private and 35 percent state owned) to distribute drugs to all hospitals. However, in the long term it was assumed that this would probably lead to the creation of a distribution monopoly and for this reason in 2006, centralised tenders for hospital drugs from the Ministry of Health were introduced again.

3.3 Pricing procedures

Table 3.2 gives an overview on pricing procedures applied in Albania.

Table 3.2: Albania – Pricing procedures

Pricing procedure	In use: Yes/No	Level of pricing[1]	Scope[2]
Internal price referencing	Yes	Ex-factory	Only expensive reimbursable pharmaceuticals
External price referencing	Yes	Ex-factory	Only expensive reimbursable pharmaceuticals
Cost-plus pricing	No	-	-
Other, e. g. indirect profit control	No	-	-

Source: Health Insurance Institute (HII)

3.3.1 External price referencing

External price referencing is used for reimbursed pharmaceuticals only and not for all the drugs included in the list, but for the most expensive ones that have a significant impact on the public financing.

External price referencing is applied at ex-factory price level. HII and MOH are using reference prices from neighbouring countries. The selection of reference countries has been somewhat opportunistic to date, depending on good contacts with other administrations that have supplied price data.

Attempts are made to ensure optimal outcomes through a more systematic approach using a potentially broader range of reference countries and independently provided data. Drug prices and reference prices of other countries are declared at ATC-4 level.

3.3.2 Internal price referencing

Internal price referencing is applied only for pharmaceuticals on the positive list. The reimbursed list of drugs is drafted basing on ATC-5 level classification. The price for one product is set per unit dose of the main active ingredient. Generic drugs with the cheapest price are reimbursed and this price is used as a reference price for all other drugs with the same dose (strength) of the same active ingredient.

The final reference price includes the ex-factory price plus wholesale mark-up and the retail mark-up. A formulation may be reimbursed at the same therapeutic cost as pharmaceuticals with the same mode of application, or same brand name, or at a lower price.

In the case of an original preparation for which a generic version has not yet been produced, it can be reimbursed at the price of active ingredient calculated basing on the manufacturer price declared by the importer.

The company that applies for the reimbursement of a medicament must provide information about the way of using this medicament and its effect.

3.3.3 Cost-plus pricing

Cost-plus pricing is not applied in Albania.

3.3.4 (Indirect) Profit control

Profit control, as e.g. in the UK, is not applied in Albania.

3.4 Exceptions

3.4.1 Hospitals-only

Hospital drugs are covered through the MOH budget and they are basically provided free of charge to in-patients. Drugs for in-patient use are provided through centralised tenders organized by MOH. Hospitals send their request to the MOH annually concerning both the types and quantities of the drugs.

Tenders in compliance with the Albanian procurement law are organised annually. It is estimated that the centralised tenders have resulted in five to six competitors, on average, presenting per class offering discounts generally reaching 30 percent (cf. 3.2.4 for details).

3.4.2 Generics

The system for the pricing generic drugs is basically the same as the pricing for all drugs. However, internal referencing - as explained in 3.3.2 - plays an important role.

Higher priced, innovative products may be reimbursed as long as there is no generic on the market. The HII makes use of the reimbursement ceiling and internal reference pricing to control costs. The reimbursement system stimulates price competition for generic drugs. All generics circulating into the Albanian market have to be registered at the National Center of Drug Control.

3.4.3 Over-The-Counter pharmaceuticals

According to Law No.9323, dated 25.11.2004, “On drugs and pharmaceutical services”, the free pricing procedural system is applied for all drugs in Albania including OTC. For wholesale and pharmacy mark-ups see Table 3.3.

3.4.4 Parallel traded pharmaceuticals

Parallel traded pharmaceuticals are of no relevance in Albania yet. The Pharmaceutical Department in the Ministry of Health has presented proposals for some amendments to the Law “On drugs and pharmaceuticals services”, according to which parallel traded pharmaceuticals are permitted in Albania. But the new Law on Drugs approved on October 27, 2008 has not permitted the parallel trading.

3.4.5 Other exceptions

There are no other exceptions in Albania.

3.5 Margins and taxes

The dispensing of pharmaceuticals in the market is remunerated via mark-ups, both for distributors/wholesalers and pharmacists. The wholesale mark up is divided between distributors/wholesalers and wholesalers. There are is no further remuneration like fee-for-service charges.

Table 3.3: Albania – Regulation of wholesale and pharmacy mark-ups, 2008

Wholesale mark-up			Pharmacy mark-up		
Regulation (yes/no)	**Content**	**Scope***	**Regulation (yes / no)**	**Content**	**Scope***
Yes	Linear percentage mark-ups added to the manufacturer price.	All pharmaceuticals - different rates for + expensive reimbursable POM, + standard reimbursable pharmaceuticals and + non-reimbursable pharmaceuticals (incl. all OTC).	Yes	Linear percentage mark-ups added to pharmacy purchase price.	All pharmaceuticals - different rates for + expensive reimbursable POM, + standard reimbursable pharmaceuticals and + non-reimbursable pharmaceuticals (incl. all OTC).

* Regulations concerning mark-ups do not always apply to all pharmaceuticals

POM = Prescription-only medicine, OTC = Over-the-counter medicine

Source: Council of Ministers Decree, No.107, dated 28.02.2007.

3.5.1 Wholesale remuneration

Different levels of margins are applied for reimbursable and non-reimbursable pharmaceuticals.[2] The wholesale mark-up is a linear add-on of 18% on the manufacturer price for non-reimbursable pharmaceuticals and of normally 12% for reimbursables. The 18% wholesale mark-up is usually divided between the importer, who receives 12.5% and the distributor whose share is 5.5%. Also according to Council of Ministers Decree No.107, dated 28.02.2007, the 12% mark up is divided between the importer and the distributing wholesaler.

However, selected expensive reimbursable POM are subject to a different wholesale mark up. All concerned pharmaceuticals are explicitly named in above mentioned decree.

[2] Council of Ministers Decree No.107, dated 28.02.2007

Table 3.4: Albania – Wholesale mark-up scheme 2008

Type of product	Wholesale mark up in % of Ex-factory price
For 17 reimbursable pharmaceuticals, e.g. somatropin 6mg 18 Nj.N	8%
For 11 reimbursable pharmaceuticals, e.g. insulin glargine 100NJ.N/ml-3ml	10%
For 34 reimbursable pharmaceuticals, e.g. Valsartan 80mg	12%
For all other reimbursable pharmaceuticals (only POM)	12%
For non reimbursable pharmaceuticals	18%

Source: Council of Ministers Decree No.107, dated 28.02.2007 and HII Positive List Regulation 2008

3.5.2 Pharmacy remuneration

Pharmacies are remunerated via a linear mark up according to Council of Ministers decrees No.107, dated 28.02.2007 and No. 56, dated 28.01.2005.

The standard pharmacy mark up is a linear add-on of 33% on the pharmacy purchase price for non-reimbursable pharmaceuticals and of 29% for reimbursables.

For some of the most expensive reimbursable POM[3] a different, lower mark up is applied. All concerned pharmaceuticals are explicitly named in above mentioned decree.

Table 3.5: Albania – Pharmacy mark-up scheme in % of PPP, 2008

Type of product	Pharmacy mark-up in % of PPP
For 17 reimbursable pharmaceuticals, e.g. Somatropin 6mg	15%
For 11 reimbursable pharmaceuticals, e.g. insuline glargine	20%
For 34 reimbursable pharmaceuticals, e.g. valsartan 80mg	24%
For all other reimbursable pharmaceuticals (only POM)	29%
For non reimbursable pharmaceuticals	33%

Source: Council of Ministers Decree No.107, dated 28.02.2007 and Decree No. 56, dated 28.01.2005.

3.5.3 Remuneration of other dispensaries

There are no other remuneration techniques in Albania.

[3] The same that are subject to a different wholesale mark up.

3.5.4 Value-added tax

The standard VAT for all imported products in Albania is 20%. All pharmaceuticals are exempted from taxes.

3.5.5 Other taxes

Other taxes are not in place in Albania.

3.6 Pricing related cost-containment measures

Expenditures for drugs, both in the out-patient and in-patient care, are increasing on an annual basis. Basing on HII data, a continuous increase of expenditures for reimbursed drugs is evident. For this reason, HII authorities in cooperation with the Ministry of Health and other international organisations such as the World Bank have been looking for ways to reduce public pharmaceutical expenditures. Measures taken concerning prices are e. g. negotiations with pharmaceutical companies to reduce the prices of the drugs with the highest financial impact.

3.6.1 Discounts / Rebates

There is no legal basis either for discounts or rebates in the pharmaceutical services. In the in-patient sector, drugs are provided via procurement procedures and the prices are fixed in agreement between the Ministry of Health and importers.

3.6.2 Margin cuts

The pharmacy mark-up scheme was last modified in 2007 by the Council of Ministers decree No.107, dated 26.02.2007.

The first mark-up scheme on pharmaceuticals in Albania was introduced in 1995 and was 15% for wholesalers over the CIF prices and, 35% for pharmacies over wholesale prices.

In May 1998 a new mark-up percentage of 12% for the wholesalers and 27% for the pharmacies was introduced by the Albanian authorities.

In 2005 mark-ups were changed to 18% for the wholesalers and 33% for the pharmacies. For some reimbursable and expensive drugs lower mark-ups were applied.

The last mark-up scheme on pharmaceuticals which still applies is 12% for wholesalers and 29% for pharmacies for all reimbursable drugs. For others that are not in the positive list the mark-ups are 18% for wholesalers and 33% for pharmacies.

3.6.3 Price freezes / Price cuts

Drugs prices are declared in Euro by pharmaceutical companies once a year. And this price must stay unchanged during the whole year in spite of currency fluctuations. These prices are made public by Health Insurance Institute via the Reimbursed Drugs List, i.e. the Albanian positive list (cf. 4.2.3). The Ministry of Health is publishing the reimbursed and non-reimbursed drugs in a booklet which is up-dated annually.

3.6.4 Price reviews

Health Insurance Institute reviews and redrafts the reimbursed drugs list annually. The reviewing process intends seeing the price changes and considering the new proposals about innovative drugs.

4 Reimbursement

4.1 Organisation

The reimbursement policy is regulated by several decrees and acts, including those listed below:

1994 Law No. 7850, On Health Insurance (reimbursement of drugs)

1994 Council of Ministers Decree No. 613, on the Status of Health Insurance Institute (gives HII autonomy)

1995 Council of Ministers Decree No. 343, On Financial Coverage of General Practitioners by the Health Insurance Institute

The reimbursement scheme is designed in such a manner that it covers the most essential drugs and a broad scope of diseases. OTC drugs are not included in the reimbursement scheme. The HII reimbursement scheme involves the whole country and the whole population and it covers all the medical services with the exception of hospital care. Medical examinations and pharmaceutical service for out-patient care are reimbursed by HII through contracts with GP-s and pharmacies.

The Reimbursed Drugs List Commission (KLB) has decision making powers in defining the Albanian Reimbursement Drugs List, i. e. the positive list. Members of the KLB are high representatives from HII, the Ministry of Health (MSH/MOH) and medical services and it is headed by the Minister of Health. After the approval from afore- mentioned Commission, the reimbursed drugs list is submitted for the final approval to the Council of Ministers.

Pricing and reimbursement policies are always interlinked (cf. Figure 2.1). All the pharmaceuticals included in the reimbursement list should be registered by the National Centre for Drugs Control (NCDC) under the responsibility of MOH. The companies must present:

- Relevant scientific evidence concerning the drug efficiency
- Data on the profile of side effects of the proposed drug,
- Comparison of the therapy cost with the existing drugs in the reimbursement drugs list
- Data related to the form doses, the administration rout, the daily dose, the criterion of the beginning and conclusion of the therapy.

The positive list is valid for one year and cannot be changed during the year.

4.2 Reimbursement schemes

The Albanian reimbursement scheme is designed to cover a broad range of drugs that are reviewed annually.

The current reimbursement scheme was first introduced in 1995 with a limited number of drugs. The reimbursed list has been continuously expanded with more innovative drugs and for a broader spectre of diseases.

The whole population is included in this scheme but there is a categorisation of the population such as pensioners, children under one year old, war veterans etc, who receive different level of reimbursement (cf. Tables 4.1 and 4.2). A person with a newly diagnosed illness may register with HII and will receive immediate coverage without a waiting period or an exclusion of pre-existing conditions.

The Drugs Reimbursement List is compiled once a year and all the proposals that may arise consequently concerning the new drugs are considered once a year when the list is up-dated.

The EU Transparency Directive is not applied in Albania.

4.2.1 Eligibility criteria

Reimbursement in Albania covers only the out-patient service. All the drugs that have received permission from the National Centre of Drugs Control to enter the Albanian market may be included in the Reimbursement Drugs List. Previous to drafting of the list, other criteria are taken into consideration such as:

- the financial impact on the HII budget
- requirements from the patients
- lack of alternative therapies
- reference price (cf. 3.3.1 and 3.3.3)

4.2.2 Reimbursement categories and reimbursement rates

Originally, reimbursed pharmaceuticals were divided in five groups according to their reimbursement rate, starting from a rate of 50% to 100%. These groups are determined by the Drug Prices and Reimbursement Pharmaceutical Directorate (DCRB) at HII.

In the meantime there are six reimbursement categories (cf. Table 4.1), ranging from a 100 percent reimbursement for a small number of life saving and cancer drugs to 50% for other drug categories. Pensioners, children under 12 months, orphans, disabled people and war veterans always receive a 100 percent reimbursement. Reimbursement therefore depends on the type of product and on the status of the patient.

Table 4.1: Albania – Reimbursement of pharmaceuticals, 2009

Reimbursement groups	Reimbursement rate	Characteristic of groups
Group I	100%	Drugs treating cancer, multiple sclerosis, growth hormone deficiency, etc. for pensioners, war veterans, children under 12 months.
Group II	85%-95%	Insulin for diabetics, drugs treating epilepsy, depression, Parkinson, osteoporosis, etc.
Group III	75%-85%	Drugs for chronic conditions such as coronary heart disease, hypertension, asthma, etc.
Group IV	65%-75%	Gynaecologic drugs, other drugs treating ulcer, urinary infections, etc.
Group V	55%-65%	Drugs treating cough, mycosis, rheumatisms, etc.
Group VI	50%	Antibiotics, dermatologic drugs, etc.

Source: Health Insurance Institute

There are some exceptions in the reimbursement scheme:

- For some certain diseases which need a special treatment, a patient pertaining to a poor population group may apply to HII for reimbursement of a special medicament in a quantity larger than it is permitted. War veterans and invalids profit free of charge all the pharmaceuticals irrespective of the fact they are included or not in the reimbursement list.

  In both cases, the reimbursed prices of pharmaceuticals are set basing on the retail prices.

- In cases of people needing a monthly dosage of medicaments higher than provided for reimbursement in the reimbursement list, they are able to get this over dosage after a decision issued by HII. (e.g. people suffering from diabetes who need higher dosages of insulin).

- For multi-source products, reimbursement is limited to the price of the cheapest alternative with the same ingredient and dosage (cf. 4.3). The HII thus makes use of the reimbursement ceiling and internal reference pricing to control costs. If a more expensive drug is prescribed, the patient has to pay the difference out-of-pocket. Higher priced innovative products may be reimbursable as long as there is no generic alternative on the market.

4.2.3 Reimbursement lists

Since 1995, Albania has compiled a positive list of drugs eligible for reimbursement. This Reimbursement Drugs List, i.e. positive list is administered by Health Insurance Institute. Both HII and MOH are also responsible for compiling the reimbursement list. The decision making body concerning the list's composition is the Commission of Drugs List Drafting (Komisioni i Hartimit të Listës së Barnave, KHLB/CDLD). The positive list is updated and changed on annual basis.

The drug's list is compiled according to ATC classification. The reimbursement system is delivered only to out-patient service.

Before drafting of the list, other criteria are taken into consideration such as:

- the financial impact
- requirements from the patients
- lack of alternative therapies
- reference price

There is no explicit negative list in place, but usually OTC are not eligible for reimbursement by HII.

The number of products on the positive list has been changed annually since from 1995 when the first list of reimbursed drugs was introduced. The first positive list was drafted under the directions of the WHO Office and, was an essential drugs list with 118 active substances and 174 products. The list was approved by the government on 26.06.1995 with the Council of Ministers Decree No. 323.

Since then the positive list has been subject of changes every year and the number of pharmaceutical products on it has been growing. The positive list of 2008 had 222 active substances and 865 products approved by the government on 14.5.2008 with the Council of Ministers Decree No.780.

4.3 Reference price system

Reference prices are established basing on the cheapest drug with the same active substance and dosage within a group, i.e. on ATC 5 level. They are changed on annual basis just like the reimbursement drugs list depending on the drugs and the relevant prices offered by pharmaceutical companies. If a more expensive drug is prescribed, the patient has to pay the difference out-of-pocket.

However, there is no mandatory generic substitution in place but the pharmacist is allowed to substitute a drug with its generic of the same substance, strength and form on a voluntary basis (cf. 5.5.1).

The Drugs Prices and Reimbursement Department (DCRB/DPRD) at HII in cooperation with the Department of Pharmacy at MOH are in charge of defining the reference price of reimbursed drugs. In general prices are freely set in accordance with the prices declared by the pharmaceutical companies and the same can be said even for the reimbursement drugs.

4.4 Private pharmaceutical expenses

Depending on the category of a reimbursed product and its status (war veteran, etc., cf. Table 4.2) patients receive prescribed drugs without any payment or paying a small percentage of the real price (= gross retail price) of the drugs (the co-payment system). For the reimbursed drugs, the private pharmacies are refunded the rest of the money from HII after they have delivered the reimbursed receipts to HII offices.

4.4.1 Direct payments

There are groups of pharmaceuticals which are not covered by health insurance scheme such as lifestyle products, OTC products or non-reimbursable POM (i.e. those prescribed without the reimbursable receipt). In all these cases, the patient has to pay the full amount of the gross pharmacy retail price.

4.4.2 Out-of-pocket payments

While HII reimburses those drugs that are included in its positive list with varying co-payments, an estimated 60 percent of the population pays for their medicines out-of-pocket.

The whole population is – based on their age, health status, income and other criteria - divided into 20 categories, where 10 of these categories are reimbursed at a 100 percent rate and 10 others are partially reimbursed.

This categorisation is regulated by Law No. 7870, Article 8, dated 10.04.1995 “On Health Insurances”. According to this law, the number of categories was initially lower and it has been continuously increased reaching to 20 categories at present.

Table 4.2: Albania – Reimbursement rates and patient co-payment rates, 2007

Reimbursement categories	Year 2007 expenses in terms of reimbursement	Reimbursement rate in %
Children up to 12 months	5.849.000 Lek/ € 47.526	100%
Fully disabled	916.641.000 Lek/ € 7.448.127	100%
War disabled	10.235.000 Lek/ € 83.164	100%
Tuberculosis Patients		100%
Cancer Patients	228.189.000 Lek/ € 1.854.140	100%
Veterans	269.909.000 Lek/ € 2.193.134	100%
Pensioners	1.679.875.000 Lek/ € 13.649.752	100%
Special cases	75.506.000 Lek/ € 613.520 €	100%
Orphans	535.000 Lek/ € 4.347	100%
Blind people	3.898.000 Lek/ € 31.673	100%
Partially reimbursed		
Partially disabled	24.992.000 Lek/ € 203.071	55-95%
Students over 14 years	14.569.000 Lek/ € 118.380	55-95%
Partial pensioners	12.116.000 Lek/ € 98.448	55-95%
Physically + mentally ill	7.7726.000 Lek/ € 631.559	55-95%
Unemployed , economic subsidies	70.469.000 Lek/ € 572.593	55-95%
Maternity leave women	131.000 Lek/ € 1.064	55-95%
Soldiers	47.000 Lek/ € 381	55-95%
Voluntarily insured	333.000 Lek/ 2.706	55-95%
Children 1-14 years	32.782.000 Lek/ € 266.369	55-95%
Active population	163.104.000 Lek/ 1.325.294	55-95%
Others		50%

*1 € = 123.07 Albanian Lek.

Source: HII statistics, year 2007

In addition, as mentioned in section 4.3 patients have to pay the difference between the reimbursed reference price and the actual retail price out-of-pocket.

4.4.2.1 Fixed co-payments

Are not applicable in Albania.

4.4.2.2 Percentage co-payments

There are two categories of co-payment in Albania. We have two categories of population, where a part of the population receives a 100% reimbursement and the rest pays for a part of drugs according to the percentage of their coverage for each separate drug (cf. Tables 4.1. and 4.2).

- 0% co-payment applies:
  - to drugs that treat cancer, multiply sclerosis, growth hormone deficiency and
  - to all pensioners, war veterans and disabled people.
- Partial co-payment applies:
  - to specific patients according to Table 4.2 and
  - to specific pharmaceuticals (see below)

Pharmaceuticals are divided in six groups according to the percentage of the reimbursement coverage. According to percentages they are divided into groups as follows:

- 100% drugs that treat cancer, etc.
- 85-95% insulin for diabetics, etc.
- 75-85% drugs for chronic conditions, such as coronary heart disease, etc.
- 65-75% drugs for urinary infections, etc.
- 55%-65% drugs treating mycosis, rheumatisms, etc.
- 50% antibiotics, etc.

4.4.2.3 Deductibles

Not applicable.

4.5 Reimbursement in the hospital sector

The reimbursement scheme in the hospital sector is recently being reformed. Until January 2009 the reimbursement in hospital sector differed from that in the out-patient sector. The most important difference was the payer: In hospital care all services including the pharmaceuticals were not paid by HII but by the state through the Ministry of Health. The MOH was also the owner of the hospitals. The reimbursement of pharmaceuticals in the hospital was operating according to the “old” scheme. Hospital drugs were fully covered through the MOH budget and were provided free of charge to in-patients.

The reimbursement scheme offered by Health Insurance Institute is now entering the hospital sector throughout the country according to the Council of Ministers Decree No.1661 dated on 29.12.2008 on “The Financing of the Hospital Services from the Health Insurance Scheme”.

According to this Decree the whole administration scheme of the hospital care is subject of changes. Each hospital in Albania will be contracted by the HII and paid for every health service that hospitals will delivery.

The reform is still in the very first phase.

4.6 Reimbursement related cost-containment measures

4.6.1 Major changes in reimbursement lists

As it is previously mentioned, the reimbursement scheme is not operating in the case of in-patient hospital service. The hospital pays for all the services.

4.6.2 Introduction / review of reference price system

There are no major changes in the system during the last five years.

4.6.3 Introduction of new / other out-of-pocket payments

According to the new strategy of the health care system that has been approved by the Albanian government to start from January 2009, the reimbursement scheme for pharmaceuticals will be applied for the hospital care as well.

4.6.4 Claw-backs

Not applicable

4.6.5 Reimbursement reviews

Not applicable

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

The Health Insurance Institute (HII) receives annually a certain budget from the Ministry of Finance for the reimbursement of drugs on the positive list. Expenditures for the coverage of the drugs reimbursement have been continuously increased due to different reasons, such as expansion of the health insurance scheme, reimbursement of innovative drugs, the tendency of the physicians to prescribe expensive therapies, etc.

For these reasons, physicians are strictly monitored by HII auditors. Since 2004, every GP has a limited annual “budget” for the reimbursed drugs they have to prescribe. This budget is planned by HII experts and is based on the working performance of a GP during the previous year.

Physicians who deviate from the expected prescribing track are being audited by the controllers. If the deviation is based on real medical need, the budget is increased. Otherwise, the physician is advised to adhere to rational prescribing rules. Obvious cases of wasteful over-prescribing or fraud (collusion with patients and pharmaceuticals) will lead to fines and claims for compensation. If this behaviour is repeated, or if the volume of the damage exceeds a certain amount, the contract with the physician is expected to be terminated.

5.2 Prescription guidelines

HII has contractual relationship with all the physicians that offer medical service and their liabilities are set out in the articles of this contract.

Physicians that prescribe reimbursement drugs have to observe the procedures defined by HII experts. There are treatment protocols (“guidelines”) for all the reimbursement drug lists and the physicians have to observe the treatment protocols during the prescribing procedures. It must be observed by all physicians while prescribing reimbursed drugs. In addition, some pharmaceutical manufacturers or importers use questionable marketing practices to influence prescribing behaviour.

5.3 Information to patients / doctors

The Law on “Pharmaceuticals and Pharmaceutical services”, No. 9323, dated 25.11.2004 provides for OTC promotion. This promotion is realised through mass media and is permitted only for OTC. As for other pharmaceuticals promotion is done only through literature or professional scientific activities.

This law also sets out that all the drugs marketed in Albania must be accompanied by the respective indication label translated into Albanian language.

The National Centre for Drugs Control (QKKB) and the Pharmaceutical Department in the MOH are the main authorities which control the law's implementation. According to the enforced law, regulations on drugs advertisement and promotion are approved by the Minister of Health.

5.4 Pharmaco-economics

When the new reimbursement drug list is reformulated, the following factors are taken into consideration:

- all the financial impact the new pharmaceuticals will probably have
- decisions to be taken with regard to drugs reimbursement must reconcile with the annual budget accorded for the drugs reimbursement
- during the price negotiations, the adherence to the pharmaceutical budget must have been taken into consideration
- Only cost –effective and essential pharmaceuticals can be reimbursed

All the analyses concerning cost-effective and the financial impact of the reimbursable drugs are made by the Drug Prices and Reimbursement Directorate in HII.

5.5 Generics

Generics (i.e. multi-source products) play a major role in the Albanian system, especially as a reference price system is in place (cf. 4.3).

According to the list of pharmaceutical products registered in Albania from National Centre of Drugs Control (QKKB/NCDC) the majority of these products are generics.

There are no statistics of pharmaceutical products divided in generics, patents or hospital use available.

5.5.1 Generic substitution

Pharmacists are allowed to substitute a drug with a generic of the same substance, strength and form. The generic substitution is voluntary. In every case the pharmacist should inform the patient for the substitution and get his/her permission. When the doctor has prescribed a brand name and has indicated that the substitution is prohibited the pharmacist respects the doctor's prescription.

However, if a patient refuses substitution with the least expensive product as the reference price he/she has to pay the difference between the reference price and the gross retail price (cf. 4.3).

In Albania, the Reimbursement Drugs List is mostly composed of generics, so they have the biggest share in the pharmaceutical market.

The pharmacists receive a proportional share of the dispensed products, so they don't have any financial incentive to prescribe generic pharmaceuticals.

5.5.2 Generic prescription

Not long ago, doctors had to prescribe the drugs by using the International Non-proprietary Name (INN). As for now the doctors are obliged to prescribe the drugs according to their trade names due to the fact that each drug alternative in the reimbursable list has a special code. Pharmaceutical companies influence somewhat the prescription process.

5.5.3 Generic promotion

Different pharmaceutical companies make promotions of their generic drugs with patients, doctors and pharmacists. The main intention of this promotion is to ensure access of patients to a greater variety of pharmaceuticals, to enhance local generic manufacturers or for cost-containment reasons.

5.6 Consumption monitoring

Individual consumption data is monitored for reimbursed drugs only. This monitoring is done by the Department of Informatics and Statistics Analyses (DIAS) at Health Insurance Institute (ISKSH), through its branch offices.

Concerning the reimbursed volume of drugs, HII possesses exact statistics which are processed on a monthly basis. These data contain the patient's name and number, the diagnosis, prescription number, the drugs volume and drugs value according to the volume.

There is no an essential drug policy in place.

6 Current challenges and future developments

According to a Document of the World Bank “Albania Health Sector Note, Report No. 32612-AL”, Albania has taken important steps towards enhancing the functioning of pharmaceutical sector but further challenges remain.

As the Health Insurance Institute (HII) reimbursement coverage is extended to a larger share of the population, additional measures for cost containment are necessary. Health finance reforms aimed at improving the insurance coverage of a wider population group, together with stricter registration requirements for generic drugs, are likely to put additional pressure on drug expenditures.

The most important challenge for the HII is the inclusion of the hospital care in the health insurance scheme. This is a reform that during 2007-2008 has been on the studying process from both parties, the Ministry of Health and HII and on January 2009 have been undertaken the initial steps for its realisation. T

According to the most recent Council of Ministers Decision No 1661 dated in 29.12.2008 HII will be the main purchaser of the hospital services in Albania through specific agreements that has already been contracted.

The role of National Centre of Drugs Control (QKKB) should be clarified promptly by finalising the necessary by laws.

The structure and level of margins for distributors and pharmacists should be further reviewed. There are many small importers and wholesalers in Albania. Concentration of this fragmented sector would allow for scale economy induced cost savings, but the current fixed margins create little incentive for consolidation and savings.

Drug price negotiations with importers of innovative drugs could be further strengthened by adopting a more standardised approach to the use of reference prices. A price volume agreement should be taken into consideration for reimbursed drugs.

Hospital drug management capacity needs to be improved to enhance efficiency and reduce the scope for abuse. In the medium term, modern IT based solutions should be considered within the framework of the development of overall improved hospital management systems.

Physician capacity for rational prescribing should be strengthened as an integral part of efforts to improve the quality of care and establish a continuous education system for physicians. Standard treatment guidelines for primary care and hospital care should be developed.

The marketing practices of the pharmaceutical companies and their representatives should be regulated according to European Federation of Pharmaceutical Industry Associations (EFPIA) standards.

7 Appendixes

7.1 References

- Albania Health Sector Note – Report No.32612-AL, 2006 – A document of the World Bank
- Albania National Health Accounts, 2003 - *Albania Health Recovery and development Project Funded by the World Bank*-
- Primary Health Care Reform in Albania: A pilot project to Provide Evidence for Health Policy, 2005 –USAID Study
- Draft health System Strategy 2007-2013 (2007) – USAID Albania
- US Department of State Bureau of European and Eurasian Affairs, September 2007- Background Note Albania
- European Observatory on Health Care Systems, Albania
- Personal Consultation with National Centre of Drugs Control (QKKB)
- Personal Consultation with respective Directorates at Ministry of Health
- Personal Consultation with respective directorates at Health Insurance Institute
- Personal Consultation with the Ministry of Finance
- Personal Consultation with the Institute of Statistics (INSTAT)

The most important laws and decrees:

1993 Law No.7835, On Drugs (regulates drugs and reimbursement for essential drugs)

1994 Council of Ministers Decree No.60 on the Foundation of the National Centre for Pharmaceuticals Control, associated with MOH.

1993 CMD No. 325, on Export-Import and fabrication of Pharmaceuticals

1996 Law No. 7850, On Health Insurance (reimbursement for drugs and GPs)

1994 Law No. 7975, On Narcotics and Psychiatric Drugs

1994 Law No. 7815, On regulations for the pharmaceuticals fabrication, imports-exports, trading, utilisation and quality in the Republic of Albania

1995 CMD No.182, On Pricing of pharmaceuticals, which was amended in 1996 upon DCM No. 288 and in 1998 upon DCM No.307

2000 CMD No.190, on amendment to DCM No. 789/1998 concerning “Reimbursed rates of drugs price coverage”.

2003 Law No. 9150, on the Foundation of the Albanian Order of Pharmacists associated with MOH

2003 CMD No. 85, on the biding of contracts between HII and pharmacies and pharmaceuticals storages.

2003 CMD No. 88, on the approval of HII status

2004 Law No. 9323, On Drugs and Pharmaceutical Service

2004 CMD No. 383, on the Approval of procedures, fees and coverage rate for the unique and tertiary examination services included into the health insurances

2005 CMD No. 56, on the Definition of mark-ups for pharmaceuticals fabrication and trading.

2006 Law No. 9644, for some supplements and amendments to the Law No. 9323 on Drugs and Pharmaceutical Service.

2006 CMD No.87, on the administration and coverage of expenditures for reimbursed receipts

2007 CMD No. 504, on the setting up and operation of the Drugs Pricing Commission

7.2 Web Links

www.isksh.com.al (Health Insurance Institute)

www.moh.gov.al (Ministry of Health)

www.minfin.gov.al (Ministry of Finance)

www.instat.gov.al (Institute of Statistics)

www.qkkb.gov.al (National Centre of Drugs Control)

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