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The Pharmaceutical Sector of the Western Balkan Countries

Aizhan Imasheva and Andreas Seiter

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Health, Nutrition and Population (HNP) Discussion Paper

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Health, Nutrition and Population (HNP) Discussion Paper

The Pharmaceutical Sector of the Western Balkan countries:

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This paper is part of an overview publication on the health sector in the Western Balkan region

Abstract: There is a strong political will in the Western Balkan states to align the region's pharmaceutical legislation and practice with that of the European Union. Accordingly, recent policy changes were aimed at harmonization of policies with other European countries. Several national drug laws were updated or completely re-written in the last several years. More specifically, provisions were made for the simplification of drug registration requirements, licensing of professionals and businesses in the sector, implementation of ethics standards, price controls and reimbursement of drugs through national health insurance systems. Countries in the region have introduced various measures for cost containment, mostly through positive lists with various co-payment levels or expenditure caps for prescribing physicians. Some institutional buyers are using pooled procurement with open tenders to ensure lower prices. Nevertheless, there are still a number of challenges such as lack of enforcement of rules and standards, limited access to drugs for low income populations, inefficiencies in resource allocation and in the distribution chain, lack of control over physicians prescribing behavior and occasional conflicts between public health and industrial policy objectives. For the foreseeable future, there will be a need for further capacity building in the pharmaceutical sector, with a focus on increased oversight and higher professional standards, more efficient use of limited public resources, equity of access and rational use of medicines. Nevertheless, drug expenditure is set to grow in this region as it did in other countries in Eastern Europe, typically at a rate of about twice GDP growth, due to inevitable factors such as innovation, aging populations, increasing incomes and better access to health care.

Keywords: pharmaceuticals, Balkans, access, regulation, health financing, drug expenditures

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Acronyms

ALIMS	Name of the Serbian medicines agency
BiH	Bosnia & Herzegovina - the entire state consisting of FBiH, RS and Brcko District
cGMP	Current Good Manufacturing Practices
ECA	Eastern Europe and Central Asia
EMEA	European Medicines Agency
EML	Essential Medicines List (not synonymous with the positive list, which is relevant for reimbursement)
EU	European Union
FBiH	Federation of Bosnia & Herzegovina with capital Sarajevo
GMP	Good Manufacturing Practices
GNI	Gross National Income
HBS	Household Budget Survey
HIF	Health Insurance Fund
HNP	Health, Nutrition and Population Hub at the World Bank
HR	Human Resources
ICRC	International Committee of the Red Cross
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IMS	Company that collects market data on drug sales on behalf of the industry
IQCM	Institute for the Quality Control of Medicines (state level)
Km	Convertible Mark - the currency in BiH, fixed exchange rates to Euro 1.95, USD currently 1.61 (depending on Euro fluctuation)
Mkm	Million Convertible Mark
MoH	Ministry of Health (BiH has 13 MoHs, at the entity and canton level)
NHA	National Health Account
NHS	National Health Services
NICE	National Institute for Clinical Excellence (United Kingdom)
OMCL	European Network of Official Medicines Control Laboratories
RS	Republika Srbska with capital Banja Luka
TA	Technical Assistance
WHO	World Health Organization
WBS or WB	Western Balkan States or Western Balkans

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I. INTRODUCTION

The historical development of the pharmaceutical sector in the Western Balkan countries has to be seen in the context of the overall health systems development in former Yugoslavia and Albania under the rule of the communist party. In particular Yugoslavia had built a strong domestic drug industry and a network of public pharmacies to supply the population with generic medicines. The regulatory function was housed within the Ministries of Health. After the break-up of Yugoslavia, Serbia, Montenegro and to a lesser extent Macedonia and Bosnia and Herzegovina maintained the public pharmacy system, while allowing private pharmacies as well. The domestic industry was opened up for international partnerships and the regulatory function achieved greater independence from the Ministries of Health in most countries. In ex-Yugoslavian countries even before 1991, health was financed by payroll contributions; therefore, the change to a health insurance system was less of a challenge than in Albania with its history of state funded health care. Since 1991, political and military conflicts and their economic fallout have adversely impacted health financing in the region. Regulatory systems were negatively affected by fragmentation and had to be rebuilt in the successor states. At the same time, the opening of markets for imported and more expensive drugs placed increasing pressure on politicians and regulators to develop adequate systems for management of drug quality and costs and to make choices that reflect public health priorities.

This paper provides an overview of the current situation in the pharmaceutical sector in the Western Balkan countries, with a particular focus on outstanding policy issues and potential solutions. The underlying assumption is that countries in a given region, who share a similar history (although in some cases a history of century old conflicts), can learn from each other and influence each other in a peaceful "competition" for better policy outcomes. Today's unifying element in the region is the desire to join the European Union one day in the not too far future, and it has led to a significant alignment in legislation and valuation of policy models. Reference pricing is an example of such an alignment: it has become a standard approach among European countries, and several Western Balkan States have begun to adopt it (Mrazek M. and Frank R. 2004 Chp. 14 P. 323-332[1]). Nevertheless, while all health and pharmaceutical systems should seek to improve equitable access to safe and effective drugs and seek to satisfy the health needs of populations, the evidence reviewed herein reveals that there is no single "road" for achieving these goals. Despite regional similarities, countries operate within different historic, economic, cultural, demographic and epidemiological contexts; the development of their drug financing and management systems – and the potential solutions to the challenges they are facing – have been and will continue to be influenced by these country-specific factors.

[1] Mrazek M., de Jonchere K., Petrova G. and Mossialos E. (2004) The pharmaceutical sector and regulation in the countries of Central and Eastern Europe. Chp. 19 p 323- 332 In: E. Mossialos, M. Mrazek and T. Walley (Eds.) "Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality". Maidenhead, Birkshire: Open University Press.

This paper highlights some of the key lessons learned in this region; demonstrate similarities among as well as differences between countries and offer practical recommendations to address the remaining pharmaceutical policy challenges.

II. PHARMACEUTICAL LEGISLATION AND ADMINISTRATION

There is a strong orientation towards the European Union (EU) in the Western Balkan States (WBS), leading to an effort to align pharmaceutical legislation with EU directives. While the first post-socialist legislation on pharmaceuticals dates back to the mid-1990s, revised versions were released more recently in a few countries (2004 in Serbia and 2005 in Albania and Montenegro) or are currently in preparation as in Bosnia and Herzegovina (BiH) and Macedonia. New bylaws were adopted that cover specific aspects of pharmaceutical policy such as registration, licensing of manufacturers and distributors, pharmacovigilance, marketing and clinical trials. Within the scope of these bylaws, provisions were made for the simplification of registration requirements, licensing of professionals and businesses in the sector, implementation of ethical norms and price controls. While some countries retained the technical regulation functions within the Ministry of Health (MoH), others set up independent drug agencies (Serbia, Albania). The reasoning behind setting up independent drug agencies is a higher degree of political independence, which allows staff to focus on technical issues and ensures some consistency during periods of political change. Independent agencies also have greater flexibility to offer bonuses or other benefits to retain key staff, which creates a new issue of low salary levels in the government bureaucracy.

BiH still has two drug agencies, one in the Federation and one in the Republika Srbska (RS), and this leads to coordination problems (a product registered by one of these two agencies can legally be sold in the entire territory).

While the legislative and regulatory framework has improved significantly, all countries in the Western Balkans are experiencing problems with enforcement of rules and standards. Inspectors responsible for controlling manufacturers, wholesalers and retail pharmacies have relatively low salaries and sometimes lack the necessary means (e.g., offices, cars, equipment) to adequately perform their jobs. It is difficult to fill open positions under these conditions. Furthermore, antiquated control routines (i.e., sampling of drugs at customs and analysis performed as part of the registration process) not only bind human and lab capacity but also prevent in-market controls. This causes reason for concern, given the fact that counterfeit drugs have been found in the local markets on some occasions. With a rapidly growing pharmaceutical market and in the absence of routine controls in retail pharmacies, such incidents could develop into a more serious problem in the future. One consequence could be an erosion of public trust in the quality of drugs, in particular generic drugs imported from other countries.

Such perceptions are fuelled by those (doctors and pharmacists) who have an interest in marketing more expensive drugs imported from Western countries (both generics and brands). These perceptions can trigger cost increases and make the implementation of

rational, generic drug policies more difficult. Some countries have responded by instituting new registration requirements, for example allowing registration only for drugs that are registered in an EU country or in a country with trusted oversight. Another problem is illegal imports to escape taxes and tariffs, which of course also increases the risk that counterfeit drugs are entering the market. Albania and Kosovo introduced labeling systems (official stickers on each pack), but it is known from other countries that such systems also carry risks of falsification or fraudulent manipulations.

III. DRUG EXPENDITURE MANAGEMENT

The range for drug expenditure is between 10% of total health expenditure in some Scandinavian countries, 14% in the OECD, and over 50% in poor African countries with few alternative options for health spending. Western Balkan States (WBS) are spending about 15-30% of their total health expenditure on drugs. This has to do with the universal availability of drugs (at least in the private sector), whereas more sophisticated health technology and complex treatment procedures take up a higher share of funds in developed countries. More important as an indicator for the reach of the system in terms of access to medicines is the absolute spending level, which is still significantly below USD 100 per capita in WBS, compared to about USD 400-600 per capita in developed countries (Table 2). Nevertheless, given the relatively low prices for generic drugs in the region, the available funds suffice in providing an acceptable package of essential drugs and some non-essential drugs to all those in need, assuming that resources are spent well. There is not enough money to provide funding for a wider range of modern, patented drugs; this creates tensions between the health insurance fund managers and the providers who are influenced by the manufacturers and who want to have access to the same drugs that their colleagues are using in Austria, Germany and the US, for example.

While public budgets are growing only slowly, the share of out-of-pocket spending on drugs is increasing at a higher rate. This is mainly driven by the behavior of people with higher incomes, who bypass the insurance systems and purchase drugs directly, in particular those drugs that are not covered or have high co-payments. Overall drug expenditure in Middle Income Countries typically grows at about twice the rate of GDP even if managed well.

While there is insufficient long term data from Middle Income Countries, OECD country data over the last two decades demonstrate that even in relatively saturated health markets the share of drug expenditure was only going up (Figure 1). Main (and inevitable) drivers for expenditure growth are aging populations, higher standards of living with more disposable income, better utilization of health systems once their quality improves and introduction of new, expensive medicines that become essential for certain patients. (OECD Health Data 2004[2])

[2] Organisation for Economic Co-operation and Development (OECD) Health Data, 2004 (http://www.oecd.org).

Table 1 Socio-demographic and fiscal indicators

Indicators	Albania[3]	Bosnia & Herzegovina	Macedonia	Montenegro	Serbia	Kosovo (2002 data)[4]
Population (minimum)	3.1	3.9	2.0	0.63	8.3	2.2
Average annual population growth (%)	0.6	-0.1	0.2	3.5	-2.1	1.6
Average life expectancy at birth (years)	77.0	77	73.9	74		69
GNI (USD billion)	8.1	9.5	2.0	2.0 (2006)	25.0[5] (w/o Kosovo)	3.3[6]
GNI per capita (USD)	2580	2440	2830	3130 (2006)	2680 (w/o Kosovo)	1440
Inflation in consumer prices (annual %)	2.5	2.4	0.5	4.3	9.7	1[3]

Source: World Bank, 2005.

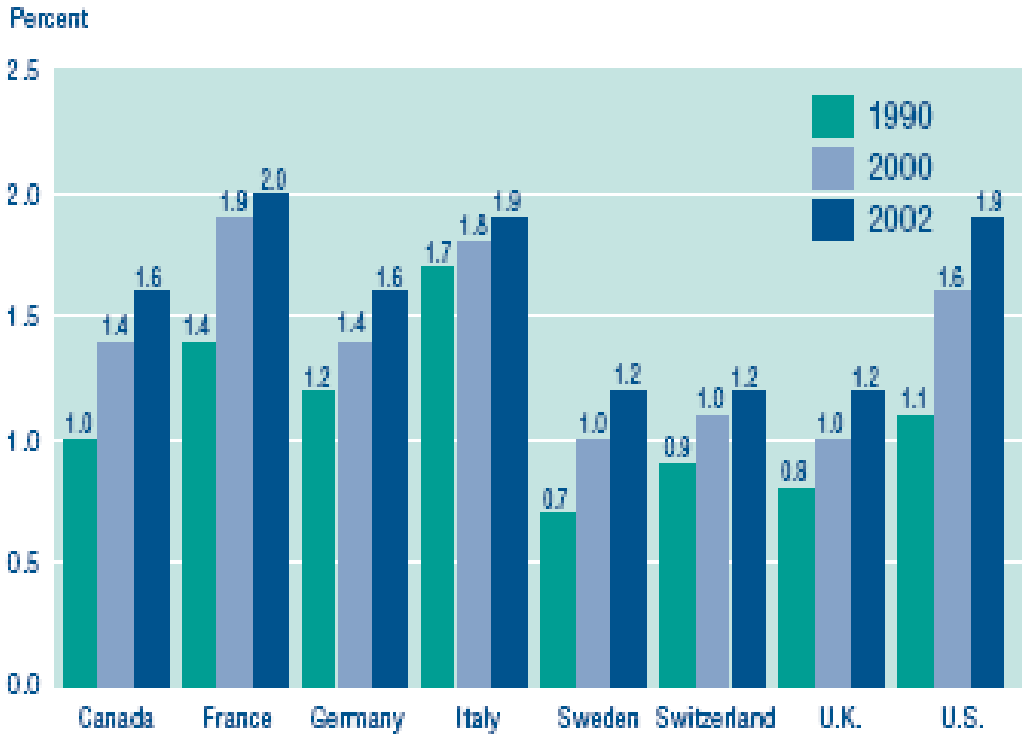
[3] World Development Indicators 2005

[4] Kosovo Institute of Public Health data 2005

[5] The Republic of Serbia: A Policy Agenda for a Smaller and More Efficient Public Sector; World Bank, December 01, 2005: GNI 2005: 1492 billion CSD

[6] Public Expenditure and Institutional Review (PEIR). World Bank.

Figure 1 Drug expenditure as a share of GDP in eight OECD countries



Source: Patented Medicines Prices Review Board, Canada, 2004.

These factors are also affecting the Western Balkan countries, which are likely to face continued growth in pharmaceutical expenditures in the short to medium-term. Countries need to strengthen their system efficiency and tackle abuse, in order to neutralize at least some of factors driving cost. Measures for improving system efficiency include supply-side mechanisms (e.g., price controls, positive lists, pre-approval for expensive drugs, competitive procurement and volume controls) and demand-side mechanisms (e.g., co-payment for prescription drugs, budget or quota system for physicians). (Mrazek M. and Frank R. 2004 Chp. 14 P. 245[7])

[7] Mrazek M. and Frank, R. (2004) The off-patent pharmaceutical market. Chp. 14 p. 245 -247 In: E. Mossialos, M. Mrazek and T. Walley (Eds.) "Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality". Maidenhead, Birkshire: Open University Press.

Table 2 Pharmaceutical expenditure in the Western Balkan countries in 2005

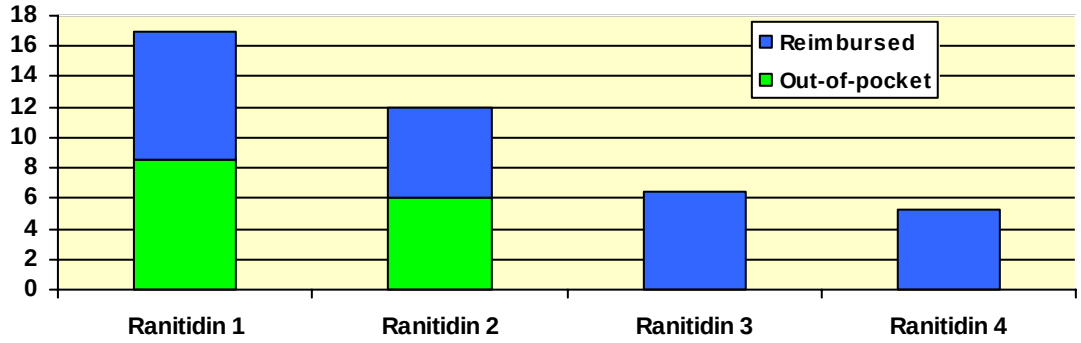
	Albania	Bosnia & Herzegovina	Macedonia	Montenegro	Serbia	Kosovo
Total pharmaceutical expenditure = market size (USD)	93 (2004)	180	130	39	450	65-80
Market growth rate, local currency	>10%	10-15%	N.A.	15%	20%	10% (est.)
Total pharmaceutical spending including out-of-pocket payments, as a % of health care expenditures	23-32%[8]	12.4%	8-15%	14.9%	14.8%	30%
Drug expenditure per capita (USD)	26.5	< 50	65	65	60	33-40

Note: Data are estimates based on discussions with various stakeholders. Exact data are not available for these markets.

Most of the WBS implemented a national "positive list", defining the drugs that are covered by the national health insurance funds (HIF). In BiH, there are separate lists for the RS and each of the cantons of the Federation as well as the Brcko District. Kosovo does not have a health insurance fund and operates with a very limited essential drugs program, procured and delivered directly through the MoH. In the Bosnian Federation, depending on the funding available and the skill of local health insurance managers to negotiate with industry, coverage for the various cantons varies significantly. In some cases, the out-of-pocket payment for a drug covered by insurance is even higher than the full price of an equivalent drug not covered by insurance (see Figure 2).

[8] Inconsistent data: Household surveys suggest higher drug expenditure than market research data in the private sector.

Figure 2 Reimbursement and co-payments in a real-life example from a pharmacy in a BiH cantonal capital



Note: Ranitidines 2 and 3 are brands from manufacturers owned by Barr resp. Sandoz, compliant with EU GMP standards.

Comparing positive lists between two different cantons in BiH shows how effective good public procurement can be even if the market size is small (both cantons have a population of roughly 300,000 people). In the case of Tuzla, the available public funds allow a significantly larger benefit package than the other canton, with more choices as well as lower co-payment levels (Table 3).

Savings due to generic procurement with open tenders can reach more than 80% for high volume drugs. Savings for low volume drugs and intrinsically expensive drugs (e.g., insulin) are lower but still relevant. As Tuzla alone does not reach sufficient volume to get maximum rebates for certain drugs, pooling at the state or federation level would probably lead to better results. Similarly, price comparisons between Serbia and Montenegro show that the much smaller Montenegro is able to get lower prices for several drugs, based on a competitive tender mechanism for defining the positive list drug prices *(Table 4).*

Table 3 Price comparison between the positive lists in Tuzla and a canton of comparable size

Generic name	Dosage	Number	Highest price	Lowest price*	Savings %
Ranitidin	150 mg	20	14.76	2.17	**85**
Omeprazol	20 mg	14	24.9	11.00	**56**
Glibenclamid	5 mg	30	3.66	1.70	**54**
Metformin	850 mg	30	4.39	4.02	**8**
Human insulin R	100 i.u.	5x3 ml	57.54	51.70	**10**
Ferrum Complex	350 mg	30	3.37	3.04	**10**
Digoxin	0.25 mg	20	1.5	1.25	**17**
Glyceryl Trinitrat	0.5 mg	100	5.33	4.68	**12**
Furosemid	40 mg	10	1.12	0.44	**61**
Furosemid	500 mg	20	17.77	10.30	**42**
Atenolol	50 mg	20	4.3	3.30	**23**
Amlodipin	5 mg	20	5.91	3.07	**48**
Verapamil	40 mg	30	2.09	1.66	**21**
Lizinopril	5 mg	20	9.71	6.37	**34**
Amoxicillin	500 mg	15	5.60	2.20	**61**
Cefalexin	500 mg	16	10.08	4.20	**58**
Cotrimoxazol	480 mg	20	3.24	2.40	**26**
Fluconazol	100 mg	7	46.50	8.78	**81**
Fluconazol	150 mg	1	15.50	8.10	**48**
Fluoxetin	20 mg	20	23.94	10.20	**57**
Salbutamol	2 mg	60	8.00	6.34	**21**

* In some cases re-calculated for different package sizes, for example 30 instead of 20 tablets; prices in km (local currency).

Table 4 Price comparison for some frequently prescribed drugs from positive lists for Serbia and Montenegro (wholesale price level, with lower price in bold)

Generic name	Form, Dosage	No. Units	Serbia (€)	Montenegro (€)
Ranitidin	Tbl, 300 mg	30	4.70	**2.17**
Omeprazol	20 mg	14	5.06	**2.58**
Ondansetron	4 mg	10	**12.43**	19.55
Glibenclamid	5 mg	30	0.67	**0.45**
Metformin	850 mg	30	0.75	**0.66**
Human insulin R	100 i.u.	5x3 ml	**24.36**	29.00
Digoxin	0.25 mg	20	0.30	**0.22**
Isosorbid Mononitrate	20 mg	30	0.79	**0.64**
Furosemid	40 mg	10	0.29	**0.26**
Amlodipin	5 mg	20	2.65	**1.65**
Verapamil	40 mg	30	0.33	**0.29**
Lizinopril	5 mg	20	1.13	**0.68**
Simvastatin	20 mg	28	**7.15**	8.25
Amoxicillin	500 mg	16	0.97	**0.73**
Cefalexin	500 mg	16	1.77	**1.22**
Cotrimoxazol	480 mg	20	0.73	**0.52**
Fluconazol	50 mg	7	4.95	**3.20**
Fluoxetin	20 mg	30	11.49	**6.00**
Salbutamol	2 mg	60	1.18	**0.76**
Fluticazone aerosol	60 x 125 mcg	1	**9.84**	9.93

Note: Serbian prices were converted into Euros for the purpose of this list (Dinar price divided by 85).

A problem for all countries that have an insurance mechanism and a positive list is the pressure from industry and providers to include new active ingredients, usually available only in the form of branded, patented products from major international manufacturers. In Albania, the inclusion of a significant number of new drugs, in parallel with an expansion of the covered population to include all pensioners, led to a temporary financial crisis of the insurance fund in 2005. So far, the Western Balkan countries lack the capacity to do a pharmacoeconomic analysis prior to the inclusion of a new drug. The process leading to inclusion on the reimbursement list is “opinion based” and the responsible commissions tend to be dominated by clinical experts, who in general have a higher social status and more political clout than the bureaucrats representing the payer

side or the MoH. However, signs of change are emerging in those countries that have experienced the above-enumerated financial problems. All countries in the region have some kind of co-payment system. The level of co-payment for drug expenditures varies from country to country or even within countries (BiH). Co-payments can be defined as a percent of the drug price (typically 25% for less important drugs and up to 75% for the more expensive ones) or as a flat amount (dispensing fee). Co-payments for essential drugs tend to be low, whereas for many other drugs that would be seen as standard treatment in developed countries (generic statins, H2-antagonists, proton-pump inhibitors, ACE inhibitors) rather high co-payments can be charged, shifting significant costs for acute and chronic medications to patients. Typically, there are exemptions from co-payments for socially vulnerable groups of populations such as the retired, children under the age of 12 months, orphans, the disabled, war veterans or patients with severe diseases requiring expensive, long term treatment (e.g., AIDS, TB, renal failure, organ transplant and cancer). In some countries these exemptions are so broad that only very few patients actually pay a co-payment. This was the case for example in Albania; it subsequently introduced a flat dispensing fee that excluded the notion of exemptions.

In general, health insurance funds in the Western Balkans do not pay for over-the-counter medications.

Republika Srbska (RS) as an entity in the BiH with independence in pharmaceutical policy decisions will soon be introducing a new reimbursement system with 100% reimbursement for a limited list of essential drugs, 50% for a wider list of important drugs and 15% for all other drugs including life-style drugs such as Viagra®. It will be interesting to see how RS will be able to manage the budget under this new regime. What needs to be taken into consideration is that RS has a fairly effective system of enforcing drug budgets on health facilities. Each facility has a budget that is administered by and controlled at the public pharmacy linked with the facility.

Once the budget has been used up, the pharmacists are no longer reimbursed for drugs dispensed to patients who come with a prescription from the facility. This has a rationing effect – towards the end of the budget period, doctors reduce their prescribing.

High co-payments for drugs in combination with lack of enforcement of prescriptions (in all WBS, the majority of prescription drugs can be purchased in pharmacies without prescription) creates a “bypass effect”, meaning that patients go directly to the pharmacy and pay out-of-pocket for medicines, foregoing their entitlement to a drug benefit (see Box 1).
Such behavior not only increases the risk of adverse drug reactions or inadequate use of drugs, it also weakens political support for the insurance system over time because patients perceive it as a cost factor that is not matched by an adequate benefit.

Box 1. Bypassing the insurance system in Albania

In Albania, some outpatients eligible for drug reimbursement through the Health Insurance Institute prefer not to visit their general practitioner in order to avoid long waiting lines and formal/informal payments. Instead they get drugs at private pharmacies at full cost, which overall is less expensive and time-consuming. This is possible due to weak inspection capacity that results in poor enforcement of the legal requirements for a prescription.

IV. DRUG PRICE REGULATION

Prices for medicines are regulated in most Western Balkan States (WBS). For innovative (single source, patented) drugs, reference pricing schemes are in place that set the price based on prices in neighboring countries and some EU countries at the lower end of the EU price range.

Typically, the lowest of the comparator prices is chosen to define the national maximum price. For generic drugs, manufacturers usually have the right to submit and justify a price, which then leads to negotiations and concludes with a (maximum) price being set (Mrazek M. and Frank R. 2004 Chp. 6 P. 114-126).

Price regulation does not mean that all drugs are reimbursed at the officially defined price levels set by the health insurance funds (HIF). Reimbursement decisions are made separately and usually based on the lowest price drug in a given category.

A different pricing system is practiced in Montenegro (see Box 2), Macedonia and Tuzla canton (BiH): instead of regulating prices, the public buyers purchase drugs through open tenders. The results show that this system is clearly superior to the regulatory approach in terms of maximizing limited public resources. As an exception to this practice, Kosovo does not have any pricing regulation in the private sector market, which accounts for about 85% of the total market. Yet, a limited amount of essential drugs is procured directly by the MoH and distributed for free in public health facilities.

Box 2. Drug pricing system in Montenegro

In Montenegro medicine prices are not centrally regulated, but defined by a rather effective central procurement system with tenders. Since open tenders for HIF funded positive list drugs were introduced, prices for 40 selected "marker drugs" came down by 30%. An initial comparison with neighboring countries suggests that prices in Montenegro tend to be at the low end of the spectrum. Certain cantons in BiH, with similar numbers of citizens as Montenegro, pay three or four times the price for some high volume, multi-source drugs compared to the price in Montenegro. Prices in Serbia are in the same range, sometimes higher, than in Montenegro, for a population more than ten times the size (Table 4).

An important component of the price is the distribution margins. Currently drug prices are negotiated and set by the governments based on the CIF price (Customs, Insurance and Freight prices included) submitted by the manufacturer. Then wholesale and retail margins are added, defining the retail price. For example, in Serbia the wholesale margin is 6-8%, the retail margin 12%. In Albania, the distribution markup is between 8% and 18% and retail markup can be 15-30%, depending on the price of the drug (Table 5). The purpose of such a regressive margin is to reduce the incentive for pharmacists to recommend expensive, branded drugs over cheaper generics (Mrazek M. and Frank R. 2004 Chp. 6 P. 114-126)[9].

Table 5 Regressive margin system for medicines in Albania

	Importer and wholesale margin	Retail margin
Very expensive drugs	8%	15%
	10%	20%
	15%	30%
Least expensive drugs	18%	33%

Source: MoH of Albania 2005-2006

For a number of expensive drugs with a significant impact on public expenditure (e.g., drugs for cancer, AIDS, organ transplant), local insurance funds have negotiated special prices or arrangements with manufacturers or importers. Such negotiations have been partially successful: In Albania for example it led to savings of USD 4 million based on 30 drugs.

V. REIMBURSEMENT

While some expensive drugs for severe illnesses (e.g., cancer, AIDS, transplant) are purchased centrally by Ministries of Health (MoH) or health insurance funds (HIF) and dispensed to patients at selected centers for free or for a small co-payment, all other outpatient drugs are provided through a network of public (Serbia, BiH) and private pharmacies.

Whether and how much the patient has to pay out-of-pocket is defined in the positive lists issued by the HIF. If a drug is reimbursed, the patient has to pay only the defined co-payment; the rest is paid directly from the HIF to the pharmacist.

[9] Mrazek M. and Mossialos E. (2004) Regulating pharmaceutical prices in the European Union. Chp. 6 In: E. Mossialos, M. Mrazek and T. Walley (Eds.) "Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality". Maidenhead, Birkshire: Open University Press.

Decisions about inclusion of a drug on the positive list are made by committees, based on a set of criteria that are largely opaque. The positive list commissions have three "control knobs" for managing the impact of new additions on the budget of the insurance funds: (i) the decision whether or not a new drug is included at all, (ii) the level at which it is reimbursed and (iii) the triggers for releasing the drug in a specific case (for example, only after pre-approval by a health insurance expert).

Reimbursement levels are set based on medical need, with life saving drugs usually reimbursed at the highest rate – 90% or 100%. Given the limited funds available, certain drugs that are not life saving but are deemed important and cost-effective generally have high co-payments (i.e., drugs for treating stomach and duodenal ulcers). For generic drugs that are offered by various manufacturers in similar quality and interchangeable dosage forms and strengths, most countries introduced reimbursement ceilings at the level of the cheapest provider. This means that patients who want another brand, for example an import instead of a locally made generic, have to pay the difference out-of-pocket (in addition to the co-payment they may have to make on the baseline drug).

Box 3. Example for reimbursement ceilings

Amlodipine A is priced at equivalent to $3 US dollars (USD) and reimbursed at 50 % – meaning that the patient has to pay USD 1.5 out-of-pocket. The patient prefers Amlodipine B from a foreign manufacturer, priced at USD 5; the out-of-pocket payment is now USD 1.5 plus the price difference of USD 2 for a total of USD 3.5.

If the reimbursement levels are set by the positive list commission and remain static, there will be a tendency of "regression to the baseline price": all manufacturers will price their drugs so that patients have the same co-payment. Price competition ceases below this baseline price, unless lower prices would lead to lower co-payments for patients (which is typically not the case in a slow bureaucratic system).

What happens under such circumstances is that manufacturers try to compete for market share by giving volume "bonuses" to wholesalers and retailers. Example: an order of 100 packs will be topped up by 50 packs for free, or generous payment terms are granted that translate into a cash gain for the distributor. As the insurance fund and patient have to pay for every single pack whether it was paid for by the pharmacists or received as a free bonus, it becomes clear that this type of competition benefits only the distribution chain, at the expense of the insurance fund.

The fact that some countries in the region have a large number of independent drug wholesalers (up to 100 or more compared to only two or three in some EU countries) demonstrates that large inefficiencies in the distribution chain are taking away from the limited funds available for drug benefits.

Montenegro, Macedonia and Tuzla canton exemplify a more efficient system that uses tenders to create competitive conditions. Only the winner(s) of the tender is (are) reimbursed. Other manufacturers are excluded and have to wait for the next tender even if they lower their prices later. In such a system, there is no benefit for the manufacturer in offering free goods to wholesalers; the wholesaler is better off in competing for the tender and lowering the price for the health insurance fund. One issue that can undermine the positive effect of a competitive tender system or any other attempt to get lower drugs prices is poor payment history. If providers have experienced significant delays in bill payment, they will charge higher prices or even refrain from bidding in a given tender. This is still a problem given the chronic shortage of funds in many public institutions.

Hospitals in the Western Balkans usually procure drugs only for inpatient needs, meaning that patients who are on a chronic outpatient medication may have to bring their own drugs. Open tenders are standard for hospital purchases of inpatient (hospital) drugs, but contracts usually are awarded at the wholesaler level.

Furthermore, price is not always the sole criteria for awarding tenders and other criteria may not be truly quantitative and objectively measurable (such as quality and reputation). The impact of the latter on the awarding of tenders appears to be limited.

Winners of tenders are in most cases regional and domestic companies, many of which do not yet offer products made according to European cGMP standards. The products offered however, are very cheap in comparison with those offered by EU manufacturers. There is clearly a trade-off between cost and quality of supplies, but the transition time foreseen in the legislation for local manufacturers should resolve this issue in the next four to five years.

If companies have to raise prices in order to recover investments necessary for GMP certification, it is possible that this will contribute to an increase in acquisition costs for essential medicines.

In some countries there is an issue with procurement committees being composed of representatives from the Ministry of Health, academia and local manufacturers. Clearly this presents a conflict of interest since provider representatives should not be members of committees that award tenders. Instead the industry perspective could be represented by a neutral person, for example from the Chamber of Commerce.

VI. PHARMACEUTICAL MARKET AND MANUFACTURERS

The Western Balkan States (WBS) have a number of local pharmaceutical manufacturers, some of them with significant production volumes. Local producers export part of their production, sometimes as much as 50 to 60% of their volume, to neighboring countries; the rest is sold in local markets.

So two global consolidation of the generic drug industry has had an impact on the WBS: the Icelandic Actavis Group for example took over the Serbian company Zdravlje and is investing in EU compliant manufacturing facilities whereas local manufacturers may have problems finding the capital needed to upgrade their manufacturing sites in order to remain competitive once full compliance with EU GMP standards are required. A further consolidation of the industry with mergers and acquisitions is therefore likely.

In countries with a significant manufacturing base, for example Serbia, there are potentially conflicting policy objectives between public health and industrial policy makers. The Serbian authorities give preference to local manufacturers if it comes to defining the reimbursement list. However, the current policy provides incentives for manufacturing of a wide range of products, at price levels that are low by European standards. All local companies compete on the positive list with similar products (branded generics) at unified list prices. This forces the local companies to offer significant rebates and favorable payment conditions for wholesalers and retail pharmacies, in an effort to boost volume by filling the pipeline.

Such a strategy creates a “race to the bottom” in terms of profitability and may prevent local manufacturers from making the necessary strategic adjustments required for survival in an open market with high quality standards.

To address this issue, equal treatment in terms of pricing, quality standards and access to public tenders for both foreign and domestic companies should become the norm.

However it could lead to an initial increase of prices for generic drugs because the domestic companies would be forced to make investments in order to meet the same quality standards as their importing competitors.

Table 6 Market size and number of large local manufacturers

	Albania	Bosnia & Herzegovina	Macedonia	Montenegro	Serbia	Kosovo
Market size: total sales in retail prices (USD million)	93	180	130	39	380-450	65-80
Number of significant national manufacturers	3	1	4	None	3	2
Names of major manufacturers	Propharma	Bosnalijek	Alcaloid		Galenica Zdravlje (Icelandic Actavis group) Torlak Institute (vaccines and biologicals) Hemopharm	Farmakos Kondiroli

International manufacturers are represented through marketing offices in major cities and have a small association in Sarajevo (AIPM Bosnia) that is a member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

VII. WHOLESALERS

In all countries in the region the wholesale sector is very fragmented. This points towards high inefficiencies in the supply chain; in Western Europe pharmaceutical distribution at the wholesale level is in the hands of a few large logistics specialists. The concentration of the sector is beginning but current procurement practices still favor small, local wholesalers in many cases. It has to be considered also that the large number of small wholesalers makes it impossible for regulators to get around in inspecting all the wholesale businesses on a regular basis since it is time consuming and inefficient use of limited human resources at the government.

Table 7 Number of wholesalers in the Western Balkan region

	Albania	Bosnia & Herzegovina	Macedonia	Montenegro	Serbia	Kosovo
Market size: total sales in retail prices (USD million)	93	180	130	39	380-450	65-80
Number of wholesalers	140	100	180	75	>1000	60

VIII. PHARMACIES AND PHARMACISTS

Usually the official training period for pharmacist is five years. Each country has at least one training center, which normally is the Department of Pharmacy at the State University of Medicine and is funded by the government. Due to significant economic constraints, schools often lack basic equipment and reagents. The training curricula, on the other hand, needs to be upgraded by including more courses on evidence-based methods of research and introducing management training. Currently students undertake only one year of additional (optional) clinical practice. The shortage of hospital pharmacists is even higher than general pharmacists.

Table 8 Number of pharmacies and pharmacists in the Western Balkan States in 2005

	Albania	Bosnia & Herzegovina	Macedonia	Montenegro	Serbia	Kosovo
Number of pharmacies	1000	800	700, of which 300 are contracted with HIF	16 (public), private unknown	3000	300-400
Trained pharmacists per 100,000 population[10]	40	9.5	15.9	15.8	24.8	N. A.

Pharmacists are organized in professional associations, which mainly act as lobbying groups for the profession. Government regulators and in some countries pharmaceutical

[10] Average number of pharmacists in EU countries: 71.9 per 100,000 population

chambers have the power to issue and withdraw licenses (i.e., cases of unethical behavior). This is the case in BiH, which is absent an active process of monitoring members.

Officials act only if inspectors refer a case to them and so far not a single case has been reported. In Kosovo, a problem occurred where the professional association effectively uncovered fraud with faked licenses. This led to the establishment of a second association with weaker standards – and supported by certain MoH officials. Subsequently the MoH officials lost their jobs and discussions are under way to merge the two competing associations.

The rates of admission to pharmacy schools are quite high according to feedback from various MoH officials, but the attrition rate appears to be relatively high as well.

There is a little incentive to work in the public sector especially for the younger generation of pharmacists; income perspectives in industry or as a pharmacy owner are more attractive. According to official WHO data from 2004, significant shortages in trained pharmacists pervade in the region. On average there are only 15 to 20 pharmacists per 100,000 persons compared to 71 in EU countries (Table 8). (World Health organization report 2004)[11]

In rural areas there is a particular shortage of trained pharmacists. It is not surprising that in some villages, pharmaceutical services are provided by pharmacy assistants who have only four years of high school training.

Some countries set restrictions on the number of pharmacies, for example in Albania (see Box 4). The reality is that the pharmacy density in urban areas is higher whereas rural areas are underserved.

[11] World Health Organization report 2004 Geneva: WHO

World Bank internal documents.

IX. ACCESS AND EQUITY ISSUES

Most countries in the Western Balkans (poorer BiH cantons being the exception) have sufficiently broad positive lists for reimbursable drugs, offering reasonable treatment choices. Of similar status to the BiH cantons, Kosovo has a rather limited essential drug list (positive list) and no universal funding mechanism - just a small budget (about USD 4 per capita) for central procurement of such drugs.

For most countries, it can be said that the level of access to medicines is equivalent to the level of access to health care in general. The majority of citizens in the countries of the former Yugoslavia is covered by health insurance institutions - the range is about 60-90% (the lower end representing those countries that have experienced severe disruptions of their systems due to war and displacement).

For Albania, the rate is lower (less than 50% according to household surveys). The cost for the part of the population that is not paying contributions, for example due to displacement or unemployment, is picked up by the government. In practice, a significant number of people in all countries that are not yet registered, although on paper they are entitled to insurance benefits. As there is no waiting period after registration before benefits can be received, this may just mean that these people have other things to do than to register for health benefits as long as they feel healthy, or they are too far away from existing health providers and would only be captured by the system once provider infrastructure is improved. Here is again a link to potential future drug expenditure increases; improved health service infrastructure and quality is likely to lead to an increasing number of patients seeking treatment and using their entitlement to insurance benefits, which will inevitably increase drug expenditure.

While the health systems are designed to provide equitable access, in reality there remain access barriers to medicines in the form of:

(1) relatively high co-payments for many important, although not essential drugs according to WHO definition
(2) rationing - for example budgets for health centers that lead to patients being turned away if they come towards the end of the budgeting period and the available funds have been used up (Republica Srpska, BiH)
(3) informal payments for seeing a doctor and obtaining a prescription
(4) transport costs and loss of income for the travel and waiting time needed to obtain a prescription

Box 4. Regulation of the number of pharmacies in Albania

The current law Albanian defines a target of one pharmacy per 3000 population and requires pharmacies to be at least 150 m apart. With a population of 3.6 million people and roughly 1,200 pharmacies, the maximum ratio of 1:3000 already has been realized.

(5) rent-seeking behavior of pharmacists who may recommend a more expensive drug than necessary in order to make more profit.

Given the chronic underfunding of public health institutions not only do issues exist with the scope of drug benefits but also with the quality of care in general. Wealthier people in urban areas are increasingly bypassing the public system and getting health services in a growing private sector. Over time this could erode political support for the public health insurance model.

X. GOVERNANCE AND CORRUPTION

Corruption is difficult to prove, but what can be assessed is the vulnerability of a given system for abuse and corrupt practices. The Western Balkan States (WBS) have introduced or are introducing legislation that improves governance and reduces vulnerability, if enforced properly. As stated above, enforcement is the weak point, given the constraints in terms of budget and human capital. Significant differences in the outcome of procurement procedures point at potential irregularities. A weak point is the fragmentation of buyers in some countries, reducing possible gains from larger volumes and increasing the number of interfaces that would need to be monitored in order to avoid corruption. Another problem is abuse of the systems by doctors and pharmacists, for example through fraudulent claims. This happens in many countries that introduce third party coverage for health care costs and needs to be contained through monitoring and sanctions, for example withdrawal of licenses or termination of contracts in severe cases.

Another problematic interface is the registration authority and the reimbursement commission. Registrations are based on procedures that are grounded in laws leaning on European standards, and the assessment of dossiers is done according to transparent criteria. There is reason to assume, therefore, that corruption is not a major problem in the registration process. When it comes to reimbursement, things are less clear because criteria are not always transparent and expert members of committees typically have some sort of conflict of interest (e.g., regularly working with the company that submits the application). It should be noted that there is a limited number of experts available on the one hand to carry out clinical trials and train physicians and on the other to advise administrations.

XI. RATIONAL USE OF DRUGS

In Albania, health insurance fund data suggest a tendency to replace cheap generic medicines with more expensive innovative drugs. This is much less the case in Serbia, Montenegro and BiH, partially due to the fact that the choices on the positive list are more limited. There appears to be a higher degree of cost consciousness among prescribers (in most cases physicians) in these countries, given the significant price differences between generic drugs from local manufacturers and imported brands. In general, more expensive products have a higher co-payment (for example 50% instead of 25% for the cheaper local brand), creating a hurdle for prescription as long as the patients' purchasing power remains limited.

Influencing provider behavior in terms of prescribing habits requires first a system that allows monitoring of prescriptions, broken down by every single doctor and patient and coded for the type of drug, strength, dosage and form as well as the indication. Interestingly, one country in the region has implemented a system that could be seen as "Best Practice": Montenegro developed a computerized system that links all contracted pharmacies with the insurance fund and through a set of barcodes on drug packages and prescription forms, collects all the data needed to get a complete picture of provider behavior. The rumors preceding the introduction of the system were sufficient to cause a significant change in prescribing practice, so that the investment was already amortized by the time it became functional!

XII. ASSESSMENT AND RECOMMENDATIONS

Out of their own capacity and with external assistance, the Western Balkans (WB) have achieved significant progress in moving towards a regulatory framework that is compliant with European Union (EU) standards. As a general theme, it can be said that still more needs to be done on the enforcement and capacity building side. In some WB countries more urgently than in others, management of limited resources should be improved in order to achieve better quality of pharmaceutical services and higher coverage rates respectively more comprehensive benefit packages.

From a global perspective, it should be noted that the problems and weaknesses observed are not specific to the region and reflect an overall shortage of resources – financial as well as human resource capacity and managerial experience. In most countries, there is a significant risk that underfinanced public health systems with perceived low service quality lead to a shift of private resources into a private market for health services and drugs that is not well regulated. If middle class patients prefer to pay out-of-pocket for drugs and are discouraged from using their insurance entitlement vis-à-vis a combination

of informal payments, waiting times, high co-payments and bad service in the public system, then there is a risk that public systems become politically marginalized.

Specific recommendations for a mid-term pharmaceutical policy agenda for the Western Balkans are listed below, grouped by policy areas.

(1) Enforce drug quality standards throughout the distribution chain (important not only for public health reasons but also to increase consumer confidence in generic drugs, improve chances of national manufacturers to export into EU countries and reduce the risk of counterfeit drugs entering the market)

   a. Build capacity for inspections by improving training, working conditions and supervision of inspectors; regular field sampling of the drugs that are potentially attractive for counterfeiters and could create significant health risks if counterfeited

   b. Consider a private sector solution, for example a contract with a specialized provider who monitors drug quality in the market as well as adherence to internationally accepted Good Practice standards (World Health Organization (WHO) or European Medicines Agency (EMEA)) on the provider side and reports to the Ministries of Health and drug agencies. This could be done in form of a regional partnership, which might enhance transparency and political acceptance.

   c. Set a clear transition schedule for industry with gradual tightening of Good Manufacturing Practice standards and enforcement over three to five years

(2) Stimulate competition in the wholesale sector to force the sector to consolidate and reduce the wholesale margin to levels observed in Western and Northern Europe, with a positive impact on retail drug prices and health insurance budgets. This can be achieved in different ways, by stricter regulation of wholesale operations and enforcement and/or a change in procurement practices: contracting directly with manufacturers and defining “landed prices” that include distribution costs, creating an incentive for manufacturers to organize distribution more efficiently

(3) Review retail margin system and modify if needed to eliminate incentives for pharmacists to recommend more expensive brands. Some countries have introduced flat retail margins, but this leads to higher prices for low cost drugs and therefore may not be a good option for the out-of-pocket part of the market

(4) Eliminate disadvantages for domestic manufacturers where they exist (for example price controls in the private sector that are not applied to importers and reduce the profitability of domestic companies as well as make them less attractive for foreign investors)

(5) Review price regulation and make changes in cases in which regulated price ceilings for generics have shown to reduce competition (regression to the ceiling price or reimbursed price). Important is in particular the linkage between price regulation and health insurance reimbursement: Insurance funds and large institutional buyers should be free to establish competitive procurement mechanisms and use their purchasing power to get lower price offers in exchange for preferred positions on the reimbursement list. This will require flexibility in the regulation of co-payments so that insurance funds can apply differential co-payments as an incentive for manufacturers to offer lower prices in exchange for higher market shares.

(6) Review positive lists for potential savings, for example by setting a ceiling for reimbursement not only for single molecules, but for comparable and therapeutically equivalent molecules (such as statins, proton-pump inhibitors, etc.). Savings can be re-allocated to reduce co-payments for important drugs and/or include additional drugs into the positive list.

(7) Develop robust procedures for selecting new drugs for inclusion into the positive lists. These should be based on clear rules/criteria and a transparent process; accountability for economic consequences is an important consideration, conflicts of interest of members of decision making bodies must be avoided or at least declared openly.

(8) Apply strict volume controls to new drugs that usually are priced much higher than older alternatives. Potential options are pre-approval by health insurance experts, price/volume contracts with manufacturers or centralized purchasing (as done today for several expensive drugs) and delivery only in specialized public institutions.

(9) Implement systems to monitor prescription patterns where reimbursement is available via public funds – similar to what Montenegro has done already.

   a. Performance of individual doctors should be monitored, ranked and communicated back to them

   b. Training programs for rational use of drugs can be targeted and updated based on monitoring data

c. Incentives for compliance and sanctions for bad prescribing practices can be introduced based on such data

d. Over time, these systems can be upgraded into expert systems that already flag and prevent certain obvious violations of prescription rules at the point of sale

(10) Consider pooled procurement for hospitals where not yet done. Hospital formularies are very similar, and pooled procurement can save significant amounts of money by increasing scale and reducing the number of potential entry points for corruption. Contracts should be signed with manufacturers based on landed costs to reduce dependency on small, inefficient, local wholesalers.

(11) Hospital drug management capacity can be improved, utilizing modern IT based solutions.

(12) Marketing practices of the pharmaceutical companies and their representatives should be regulated according to EFPIA (European Federation of Pharmaceutical Industry Associations) standards. Adoption of the EFPIA code could be made a licensing requirement for manufacturers and importers. In the absence of regulatory capacity, self-regulation can work if there is independent validation (for example through a review board that has a majority of non-industry and non-health care participants including consumers) and if sanctions are in place for companies that violate the code.

It would be desirable to prioritize these recommendations; however, given the fact that policy implementation is national and that there are differences between countries with regard to priority issues, one would have to design a specific package for each country (see Table 9 for a first approximation).

In Albania for example one priority action would be to develop and implement an IT system that allows permanent monitoring of prescribing and dispensing by contract doctors and pharmacies, while Montenegro already has such a system and BiH/RS has a different approach to ensuring physician compliance with the positive list and budget through decentralized budget caps.

Table 9 Suggested reform priorities by country

	Albania	Bosnia & Herzegovina	Macedonia	Montenegro	Serbia	Kosovo
Priority areas for policy reforms or improved management systems	Rational and economic use of drugs, hospital drug management, volume controls for new drugs	Review of positive list selection criteria, transparent procurement; improved market surveillance and national integration of regulatory function	Rational and economic use of drugs, hospital drug management, volume controls for new drugs	Raise quality standards for drugs on the market to EU level; improve utility of HIF monitoring system as a means to achieve rational use of drugs	Eliminate price discrimination against local industry; improve enforcement of regulatory standards and market surveillance	Fix basic system for public sector drug benefit program; strengthen enforcement of regulatory standards

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