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Pharmaceutical pricing and reimbursement reform in Kyrgyzstan



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Abstract

This report explores the causes of high out-of-pocket (OOP) payments for outpatient medicines in Kyrgyzstan and develops policy recommendations to reduce them. The analysis consisted of a review of current reimbursement mechanisms and an assessment of their ability to protect the Kyrgyz population from high OOP payments. The analysis showed that Kyrgyz patients have been confronted with increasing co-payments for reimbursed medicines in the outpatient sector. Compared to the 2013 figures, co-payments for medicines prescribed and dispensed under the reimbursed drug package increased by 20% in 2015. A contributing factor for this increase is the absence of price regulation for medicines. Another reason for observed price increases may be related to currency devaluation. Based on the findings of the analysis, this report proposes several policy options to address high OOP payments, including: introduction of price regulation including control of retail margins, review of reimbursement processes, strengthening of information systems for monitoring and evaluation, and capacity building of the stakeholders.

Keywords

FEES, PHARMACEUTICAL
FINANCING, PERSONAL
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Authors

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Abbreviations

ADP	additional drug package
ATC	Anatomical Therapeutic Chemical (WHO classification system)
DRA	Drug Regulatory Agency
DTCA	direct-to-consumer advertisement
EEU	Eurasian Economic Union
EML	Essential Medicines List (of WHO)
EPR	external price referencing
FGP	family group practice
FMC	family medicine centre
HAI	Health Action International
INN	international nonproprietary name
IPR	internal price referencing
MeTA	Medicines Transparency Alliance
MHIF	Mandatory Health Insurance Fund
NEML	national essential medicines list
NMRA	National Medicines Regulatory Agency
OOP	out-of-pocket (payments)
SGBP	state-guaranteed benefit programme
TB	tuberculosis

Executive summary

The WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (Pharmacoeconomics Department, Austrian Public Health Institute) was commissioned to perform an analysis of the Kyrgyz outpatient pharmaceutical system.

Aims and methods

The aim of this research was to explore the causes of high out-of-pocket (OOP) payments for outpatient medicines in Kyrgyzstan and to develop policy recommendations to reduce them. The analysis consisted of a review of current reimbursement mechanisms and an assessment of their ability to protect the Kyrgyz population from high OOP payments. This entailed a retrospective analysis of the development of co-payments for reimbursed outpatient medicines during 2013–2015 and a discussion of hypotheses to explain such possible variations. Based on the findings, the authors drew conclusions and developed policy recommendations.

The study was based on a series of face-to-face interviews with key stakeholders in Kyrgyzstan from 30 May to 2 June 2016, as well as an analysis of quantitative data. The latter included data on reimbursed medicines under the additional drug package (ADP) provided by the Mandatory Health Insurance Fund and of imported medicines provided by the National Medicines Regulatory Agency. These data were analysed in close cooperation with the WHO Regional Office for Europe. Previous publications and reviews of the Kyrgyz pharmaceutical market were also considered. The focus of this activity was on public pharmaceutical spending in the outpatient sector through a review of the ADP, which represented only a fraction of the total outpatient medicines market in Kyrgyzstan. The reason for the focus on this specific subset of the pharmaceutical sector related to data availability limitations at the national level at the time of the study.

Key findings

In the last decade a steady increase in health expenditure, both public and private, has been observed. Total health expenditure in Kyrgyzstan amounted to KGS 25.758 billion (US\$ 477 million) in 2014, accounting for 6.0% of gross domestic product (versus 5.8% of gross domestic product in 2005). In 2014, 56% of total health expenditure was publicly funded, whereas in 2005 the figure was 44%. Between 2005 and 2014, total health expenditure quadrupled, with an annual growth rate of around 18%.

The relevance of formal or informal OOP payments in Kyrgyzstan has been subject to analyses in previous years. A 2015 WHO publication (compiling three rounds of surveys performed between 2006 and 2014) estimated that mean expenditure on medicines (both prescribed and non-prescribed) increased significantly between 2006 and 2014, from KGS 161 to KGS 745 in nominal terms (the monthly average amount paid for medicines among those who sought outpatient care in the past 30 days). The mean expenditure for prescribed medicines was three times higher in 2014 than in 2006 (KGS 638 and KGS 228 in nominal terms) and increased by 20% even in real terms. When asked the main reason for not purchasing medicines, 64% of participants in the 2014 survey reported that they were “too expensive”, compared to 40% in 2009.

Public coverage of medicines is provided through the state-guaranteed benefit programme and the ADP. The state-guaranteed benefit programme ensures free access to health services, including medicines (theoretically), for patients with specific conditions. The ADP list is rather short, and includes 76 items

in the outpatient sector for which patients have to co-pay 50% of a centrally calculated reimbursement amount (baseline price). This leads to situations where patients end up paying more than 50% of the price of these medicines, as these are not regulated at the pharmacy retail level.

The reimbursement processes appear to be lengthy and resource-intensive. Baseline prices for medicines on the ADP list are determined by the Mandatory Health Insurance Fund, based on prices collected from wholesalers. Given the lack of a mechanism that obliges wholesalers to report regularly, calculation of baseline prices is resource-intensive, and revision of the full ADP list might take 4–6 months. When comparing medicines on the ADP list with the ones on the WHO Essential Medicines List, there is room to ensure that they align with priority diseases and health care programmes.

In recent years, the number of prescriptions reimbursed under the ADP has decreased but expenditure on these medicines has increased. Between 2013 and 2015, the number of medicines dispensed under the ADP in the public outpatient sector decreased by 14%, while the average amounts reimbursed per prescription increased in nearly all Anatomical Therapeutic Chemical groups. For medicines with a large number of prescriptions – such as those for the treatment of cardiovascular diseases – the increases tended to be smaller (by 17% from 2013 to 2015).

This research highlighted the fact that OOP payments pose a serious problem in the pharmaceutical sector, confirming the findings of previous studies. Based on the latest data from the Mandatory Health Insurance Fund, the analysis showed that Kyrgyz patients have been confronted with increasing co-payments for reimbursed medicines in the outpatient sector. Compared to the 2013 figures, co-payments for medicines prescribed and dispensed under the ADP increased by 20% in 2015. A contributing factor for this increase is the absence of price regulation for medicines. Despite attempts to implement price regulation in 2012, Kyrgyzstan does not currently regulate ex-factory, wholesale or retail prices. As a result, knowledge of pharmacy retail prices is limited and can only be gained through onsite price surveys (such as those conducted with the methodology developed by WHO and Health Action International). It was reported that prices of medicines in pharmacies in remote areas tend to be higher than those in chain pharmacies in urban areas.

Another reason for observed price increases may be related to currency devaluation. The Kyrgyz economy is largely intertwined with other economies in the central Asian region. The economic crisis in the Russian Federation, a key trading partner for Kyrgyzstan, led to a depreciation of the Russian rouble versus the US dollar, and as a result the Kyrgyz som also lost value against the US dollar. Thus, while the imports of medicines in 2015 were at around the same level as in 2013 in terms of volume, Kyrgyzstan had to pay nearly 20% more for them.

Policy recommendations

Based on the findings of the analysis, this report proposes several partly interlinked policy options to address high OOP payments, including the following.

Pricing

- A legislative framework for the introduction of price regulation should be established. The authors highly recommend introducing price regulation for medicines, since unregulated prices tend to result in high overall prices, and no instrument is in place to control future increases. As the list of reimbursed medicines (which are only funded by around 50%) is rather short and all other medicines are to be paid OOP in full by patients, a new attempt to control medicine prices – including pharmacy margins – appears to be crucial. An essential prerequisite for regulating medicine prices

is to establish the legislative framework for the introduction of price regulation. The draft law on modernization of the pharmaceutical sector (in its version of mid-September 2016) should thus enter into force as soon as possible. The implementation of price regulation should be done through a stepwise approach, first focusing on the ADP medicines and then being extended at a later stage.

- Regulated pharmacy mark-ups should be introduced. Price regulation should also address the actors in the supply chain, so pharmacy mark-ups are recommended, at minimum for medicines on the ADP list, but ideally to be extended as soon as possible to the private sector.

Reimbursement

- **The reimbursement process should be strengthened.** An update to the legislation regarding criteria and processes for listing and delisting of medicines into and from the reimbursement list is recommended. In particular, this should aim to improve alignment of the inclusion criteria with priority diseases.
- **The process of internal price referencing should be updated.** While the current reimbursement system under the ADP could be considered de facto as Anatomical Therapeutic Chemical level 5 internal price referencing, expansion into a fully fledged internal price referencing system could be considered as a policy option for multisource medicines.
- **The efficiency of lower-priced medicines should be increased.** Demand-side measures to enhance the uptake of generics and lower-priced medicines, such as generic substitution and prescribing by international nonproprietary names, should be enforced. This should ideally be linked to other measures in the area of pricing and reimbursement, such as prescribing and dispensing targets and an appropriate design of pharmacy mark-ups. These efforts should be supported by policy information and dissemination activities targeted at patients and health professionals.

Monitoring, enforcement, information activities and capacity-building

Monitoring and evaluation should be enhanced. Introduction of a mechanism to monitor policy measures to support policy-makers in taking informed decisions and corrective actions is recommended. In the area of medicine prices, regular price monitoring and revision should be undertaken.

Information should be shared between countries and capacity-building of authorities increased. Kyrgyz pricing and reimbursement authorities are recommended to continue their capacity-building activities and their involvement in international networks.

Agenda of the reform

Introduction of price regulation is seen as the highest priority action to address high OOP payments. The Ministry of Health is therefore recommended to ensure that the law on modernization of the pharmaceutical sector is adopted as quickly as possible to provide the legislative framework for introducing price regulation; to develop a process to ensure one single maximum pharmacy retail price for all medicines under the ADP throughout the country; and to launch a pilot project. As medium-term policy objectives, strengthening the reimbursement process is recommended, through the development of clinical guidelines for selected diseases, better alignment of the inclusion criteria for priority diseases and an improved process for data collection of reimbursement prices.

This study focused on analysis of the outpatient pharmaceutical pricing and reimbursement policy. Since policies and their implications are frequently interconnected, however, action in further sectors may be required, in particular in terms of quality improvements in the regulatory field. Furthermore, an assessment of the hospital sector for potential efficiency gains is also necessary as part of a comprehensive national medicine policy.

1. Introduction

The WHO Regional Office for Europe commissioned the WHO Collaborating Centre for Pricing and Reimbursement Policies, affiliated to the Pharmacoeconomics Department of the Austrian Public Health Institute (Gesundheit Österreich GmbH), to conduct an analysis of the current pharmaceutical system in Kyrgyzstan. The general objective of this activity was to study the causes of high out-of-pocket (OOP) payments and to develop policy recommendations for reform of the system, with a focus on medicines dispensed and reimbursed in the outpatient sector.

1.1 Scope of activity

The particular aims of the research were:

- an assessment of the outpatient pharmaceutical market and the general policy framework, as a basis for further analyses (Chapter 3);
- a review of current reimbursement mechanisms with regard to their effectiveness in protecting people from high OOP payments (Chapter 4);
- a retrospective analysis of the development of OOP payments for reimbursed medicines (Chapter 5).

Based on the findings, the authors drew conclusions and developed policy recommendations (Chapter 6; a list of the detailed recommendations is presented in the Annex).

The analysis was limited to pharmaceutical pricing and reimbursement policies for medicines prescribed and dispensed in the outpatient sector, with the aim of supporting Kyrgyzstan in maximizing health gain through prudent use of resources and policy follow-up as required. This in-depth report is accompanied by a policy brief.

1.2 Evidence from previous projects

1.2.1 Health system reforms

After the collapse of the Soviet Union in 1991, Kyrgyzstan undertook three major reforms of its health system: *Manas* (1996–2006), *Manas Taalimi* (2006–2010) and *Den Sooluk* (2012–2016). Each of the reforms aimed to address certain challenges during the transformation of the health care system. The *Manas* programme launched comprehensive structural changes for health care delivery, financing and management. One major achievement was the introduction of a social health insurance system and the creation of the Mandatory Health Insurance Fund (MHIF), whose task is to administer this system. The *Manas Taalimi* programme focused on reducing the financial burden for the poorest and making improvements in access and equality in utilization of health services (1). Despite the remarkable achievements of both programmes, some shortcomings remained. The *Den Sooluk* programme was designed to address improvements in health indicators for cardiovascular diseases and maternal and child health, as well as changes in population health behaviour and improvements in health care service quality (2).

1.2.2 The Medicines Transparency Alliance project

The Medicines Transparency Alliance (MeTA) initiative, initiated by United Kingdom's Department for International Development and supported by WHO, aims to improve access to quality-assured essential medicines in low-income countries through a multistakeholder collaboration involving representatives of the public sector, the private sector and civil society. Kyrgyzstan is one of the seven participating countries (with Ghana, Jordan, Peru, Philippines, Uganda and Zambia) (3).

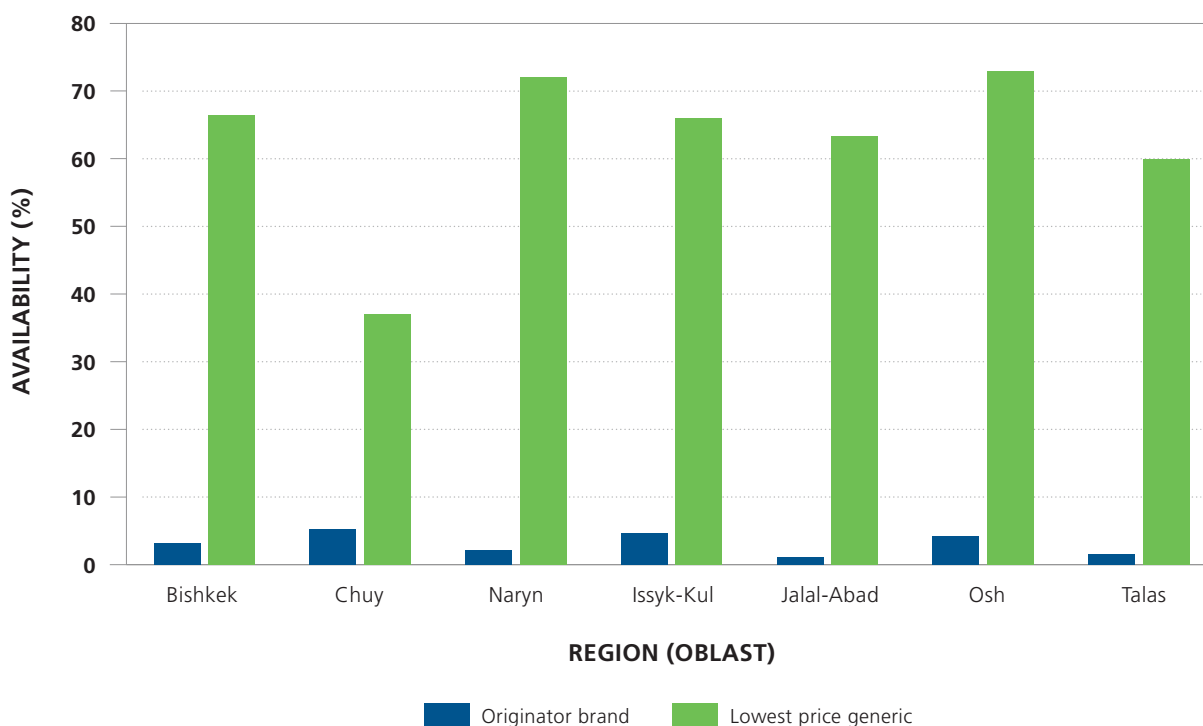
The MeTA project was launched in Kyrgyzstan in April 2009, bringing together public, private and civil society stakeholders in the medicines market. It aimed to increase transparency in the pharmaceutical supply chain, thereby strengthening health care governance and encouraging responsible business practice (4). The goal of all these activities was to increase access to quality-assured essential medicines and to improve their availability and affordability. The pilot phase ended in 2010 and MeTA published a report in which the pharmaceutical sector was analysed, existing data on the pharmaceutical sector were compiled and information gaps were identified. Based on the analysis, the MeTA project consortium prepared 11 recommendations to overcome perceived problems related to access to medicines in Kyrgyzstan (5).

In 2010 the MeTA project entered phase 2, which was built on the achievements of the pilot phase, including collecting studies and any health- and pharmacy-related reports. The objective of the second phase was to continue supporting the government in improving availability and affordability of quality-assured essential medicines in the public as well as the private sector. For phase 2, development and strengthening of pharmaceutical policies related to procurement, pricing and distribution was identified as a target work area. At the request of the Ministry of Health, a national medicine policy was developed for 2014–2020; this was approved by government decree in July 2014. Chapter 2 of this decree targets affordability of medicines and medical devices. The policy acknowledges the importance of improving current procedures and practices and identifies measures in the following areas:

- selection of medicines for the positive list¹
- public procurement
- regulation of medicine prices
- rational use of medicines (6).

In line with the recommendations of the pilot phase to close information gaps, the MeTA project conducted a third national survey of availability, prices and affordability of essential medicines. The survey was performed in 2015 using standard survey methodology developed by WHO and Health Action International (HAI). The survey report showed that procurement prices achieved in tenders by public health facilities at the regional level had decreased over a five-year period. The main driver for price reduction was the market entry of generics: the median prices of the lowest-priced generics decreased almost twice and were consistent with international reference prices. The prices of originator brands also decreased, but their median price was up to seven times the international reference price. In the private sector, the median prices of generics also declined, but were still higher than the comparable international prices. The report found that availability of originator brands was very low compared to generic medicines in all regions (Fig. 1). It recommended better monitoring of prices and price components to study the barriers to access to medicines in the distribution system (7).

¹ The list of medicines that may be prescribed at the expense of a third party payer.

Fig. 1 | Mean availability of medicines, by region, 2015

Source: MeTA (7).

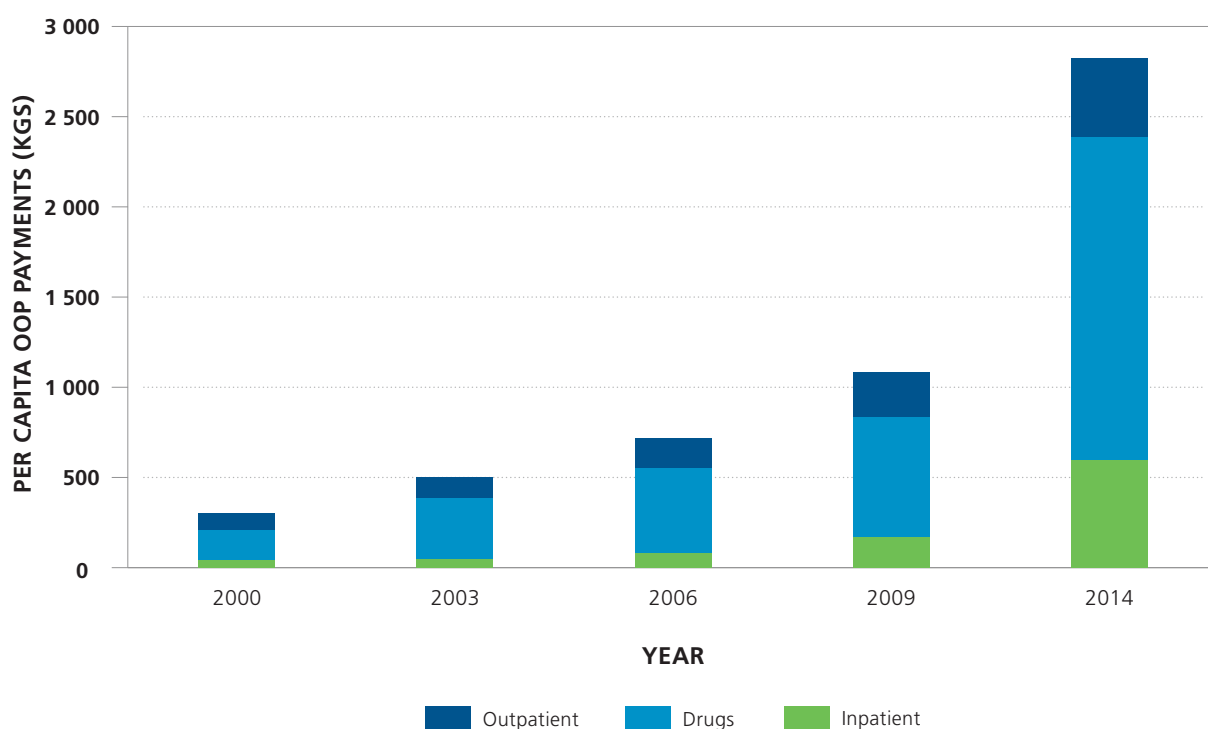
1.2.3 Analyses of OOP payments

WHO performed analyses to explore formal and informal OOP payments in health care. OOP payments for health care services have been increasing steadily since 2000 (Fig. 2). In 2000 annual mean OOP payments per person interviewed were KGS 304 (US\$ 6.37);² these increased ninefold to KGS 2824 (US\$ 52.62) in nominal terms (KGS 1007 in real terms) in 2014. Between 2000 and 2009 real annual growth of mean OOP payments was around 10%, whereas from 2009 onwards this increased to 19%. Comparing the composition of OOP payments between 2000 and 2014, the main drivers for the rapid increase are unclear. In 2000 payments for medicines constituted 55% of all OOP payments. This proportion rose to 67% in 2003 but decreased to 65% in 2006 and to 61% in 2009. In 2014 a slight increase to 63% was observed.

OOP payments for services in the outpatient sector initially followed an opposite trend to that of general OOP payments. From 2000 to 2003 the proportion decreased from 14% to 10%, but it increased steadily thereafter to 21% in 2014.³ Jakab et al. (8) concluded that the increase in total OOP spending was attributable to OOP payments for outpatient medicines. The increases in OOP payments for medicines in the outpatient sector were attributed to both the quantity and the price effects: people were found to purchase more medicines, and medicines were more expensive. Comparing the OOP payments among those reporting contact with the health system between 2009 and 2014 showed that the financial burden among users was substantial, particularly among poorer population groups and especially in the urban areas of Bishkek and Osh (9).

² US dollars calculated at the annual exchange rate of the respective year: 2000: US\$ 1 = KGS 47.7167; 2014: US\$ 1 = KGS 53.6628.

³ Jakab M, Akkaziya B, WHO Regional Office for Europe, unpublished presentation on trends in out of pocket expenditures in Kyrgyzstan: 2000–2015, 2015.

Fig. 2 | Development of OOP payments between 2000 and 2014

Source: Jakab M, Akkazieva B, WHO Regional Office for Europe, unpublished presentation on trends in out of pocket expenditures in Kyrgyzstan: 2000–2015, 2015.

Another WHO analysis performed in 2016 concluded that Kyrgyzstan demonstrated impressive results in the reduction of informal payments in the health system, particularly for medicines, medical supplies and food between 2001 and 2006. The results seemed to erode thereafter, however, as informal payments started to rise; this setback was large enough to offset the previous gains. In its analyses WHO urged policy-makers to address the persistence of informal payments, because their continuing rise represented an unpredictable financial burden for patients, which put them at risk of impoverishment. Furthermore, there was concern that it would undermine the credibility of one of the reimbursement schemes – the state-guaranteed benefit programme (SGBP) (see section 3.4.1 for details) – as it would no longer be to deliver the promised benefits (free access to medicines) for the entire population. To tackle all these problems, WHO recommended a package of systemic measures, including an increase in public and formal private funding, revision of the SGBP, further transformation of the service delivery network, improvement of medicine procurement by health facilities, regulation of outpatient medicines prices, introduction of performance monitoring and an increase in energy efficiency (8).

1.2.4 World Bank analysis

In a series of public expenditure review policy notes the World Bank suggested a number of reforms to improve health outcomes and ensure the financial sustainability of the health sector. The analysis acknowledged that existing reimbursement schemes in Kyrgyzstan (for a full description see section 3.4) were effective instruments in terms of health outcomes, access to health services and financial protection, but noted that there was room for improvement. Priority-setting in reimbursement of medicines did not reflect the fact that the prevalence of noncommunicable diseases was higher than that of communicable diseases. Addressing the funding gap in the reimbursement schemes was recommended, not only by adding financial means but also by improving the effectiveness of

public spending to ensure long-term (financial) sustainability. This would require major decisions on treatment and prevention of priority diseases. The notes suggested creating fiscal space by reforming the system of co-payments, shifting the focus of co-payment exemptions towards poor population groups and improving the system of procurement of hospital medicines and medical supplies (10).

The World Bank recommendations appear to be in line with another publication that argued for a shift in priorities towards prevention and treatment of noncommunicable diseases in Kyrgyzstan. A study on the cost of medical treatment for hypertension found large variations that were attributed to differences in the studied treatment regimens. The authors concluded that, while the generics market would provide enhanced choice in therapeutic treatment of noncommunicable diseases, price regulation was needed to improve access to those medicines, since a large fraction of the population could not afford them. The difference between official data on incidence rates and primary data on use surveyed in the study highlighted gaps in coverage (11).

1.2.5 Major challenges

For years Kyrgyz policy-makers have been working on improving the national pharmaceutical sector, supported by international institutions. Major objectives include improving access to medicines and high-quality health technologies (such as defined medical devices) and keeping medicine prices at affordable levels. The national pharmaceutical policy in Kyrgyzstan was adopted in 2014, and updated medicines and medical devices legislation (a law on modernization of the pharmaceutical sector) was under way at the time of this study.

Recently, the government, MHIF and consumers have been increasingly concerned about rising prices and expenses for medicines and high OOP payments (despite some mixed findings, as reported in section 1.2.2, the latest data show clearly that these are rising). The burden of private expenditure is perceived to be increasing and unsustainable for the population. Attempts to address pricing issues have been made (12), but there is still no price regulation for outpatient medicines and, as a result, authorities have no legal basis on which to influence prices charged for medicines in pharmacies.

Developing a sound generic sector (multisource products) is a policy option in order to offer medicines at affordable prices and to bring prices and expenditure down. It appears, however, that the use of those medicines does not follow what might be expected in general (13, 14). This could be attributable to perceived distrust among health professionals and patients of the quality of generics (15).

2. Methodology

This analysis is based on the following methodological approaches.

- A **literature review** was undertaken of relevant peer-reviewed articles and grey literature about the pharmaceutical market and policy framework in Kyrgyzstan. The starting-point was recommended literature by WHO, accompanied by an iterative search of the published and grey literature using Google Scholar and snowballing from forward and backward citation searching in key documents.

- A **qualitative analysis** was performed, using data collected from several face-to-face interviews with key stakeholders, conducted between 30 May and 2 June 2016. The list of interview partners can be found in Table 1.
- A **quantitative analysis** was performed, using data on reimbursed medicines under the additional drug package (ADP) provided by the MHIF and data on all imported medicines provided by the National Medicines Regulatory Agency (NMRA). These were thoroughly analysed in close cooperation with the WHO Regional Office for Europe, in particular with the aim of exploring the extent and development of OOP payments for outpatient medicines and their possible causes. The years studied were 2013, 2014 and 2015. The analysis focused on public pharmaceutical spending in the outpatient sector under the ADP, given the current status of data availability at the national level.
- The findings of this report and a (draft) policy brief were shared and discussed with WHO Regional Office for Europe and Kyrgyz stakeholders. They were also presented at a **policy dialogue** in Bishkek at end of September 2016.

This study also builds on the report of a visit by two senior WHO experts in April 2016, which aimed to develop further the activities planned under the national drug policy framework and to contribute to the midterm review of the health sector reform project.

Table 1 | Overview of impact assessment studies found in the literature

Organization	Type	Number of interviewees
Ministry of Health	Government	5
MHIF	Public payer	3
NMRA	Regulator	2
Family medicine centre	Provider	2
Clinical hospitals	Provider	2
Hospital pharmacy	Provider	1
Retail pharmacy	Provider	3
JSC Biovit	Pharmaceutical manufacturer	2
JSC MedPharm	Pharmaceutical wholesaler and retail pharmacy chain	1
JSC Neman Pharma	Pharmaceutical wholesaler and retail pharmacy chain	3
Pharm Union	Interest group for pharmaceutical wholesalers	1
World Bank	International financial institution	1

3. The health and pharmaceutical system

3.1 Health and pharmaceutical expenditure

3.1.1 General health expenditure

Total annual expenditure on health in Kyrgyzstan in 2014 was KGS 25 758 million (US\$ 477 million),⁴ which is equal to 6.5% of gross domestic product. Among the five central Asian countries listed in Table 2, Kyrgyzstan spends the second highest amount on health, only surpassed by Tajikistan. In contrast to Tajikistan, health is publicly funded (Table 3). The major part of the expenditure came

Table 2 | Total annual expenditure on health as a percentage of gross domestic product for five central Asian countries, 2007–2014

Country	2007	2008	2009	2010	2011	2012	2013	2014
Kazakhstan	3.2	3.6	4.1	4.4	4.1	4.3	4.3	4.4
Kyrgyzstan	6.9	6.1	6.8	6.7	6.2	7.0	6.7	6.5
Tajikistan	5.3	5.6	5.9	6.0	6.0	6.4	6.8	6.9
Turkmenistan	2.2	1.9	1.9	2.0	2.0	2.0	2.1	2.1
Uzbekistan	5.8	5.9	6.3	5.3	5.6	6.5	6.3	5.8

Source: WHO (17); World Bank (18).

Table 3 | Public health expenditure as a percentage of total health expenditure, 2007–2014

Country	2007	2008	2009	2010	2011	2012	2013	2014
Kazakhstan	56.0	62.0	64.1	57.2	56.0	55.8	50.9	54.4
Kyrgyzstan	51.4	51.5	55.7	55.7	59.9	60.2	56.1	56.1
Tajikistan	22.2	24.6	24.9	26.4	28.6	29.4	30.6	28.8
Turkmenistan	64.3	49.2	61.8	61.6	64.0	64.9	67.2	65.2
Uzbekistan	39.5	42.7	41.5	51.5	50.7	48.2	49.4	53.3

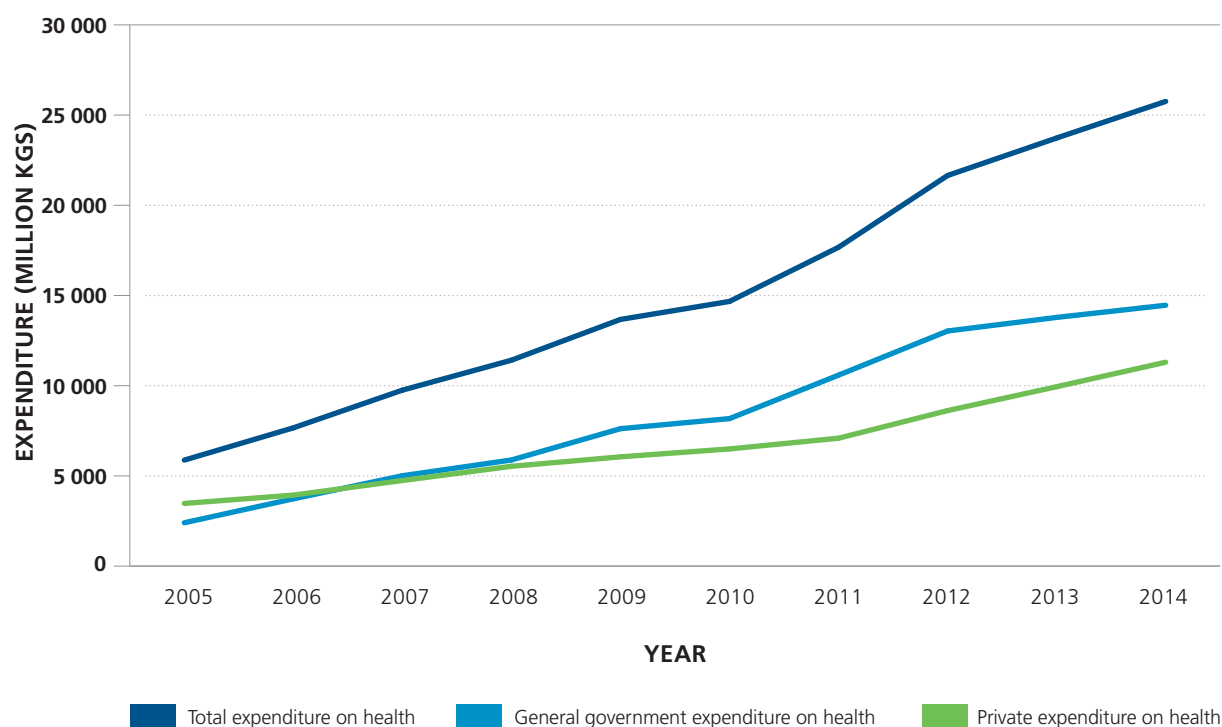
Source: WHO (16); World Bank (17).

⁴ In this report, unless otherwise noted, US dollars are denoted in current US dollars at the 2016 exchange rate.

from public sources and amounted to KGS 14 459 million (US\$ 268 million; 56.1% of total health expenditure). Private expenditure was around KGS 11 300 million (US\$ 209 million, 43.9% of total health expenditure).

Between 2005 and 2014, total health expenditure in Kyrgyzstan quadrupled from KGS 5875 million (US\$ 143 million) to KGS 25 758 million (US\$ 477 million). The average annual growth rate was around 18.1% and the highest increase (30.5%) occurred between 2005 and 2006. In the period 2012–2014, growth rates slowed to below 10%. Analysis of private and public spending shows that in 2005–2006 private spending was higher than public spending, but in the first half of the analysis period public spending growth rates were greater than those of private spending. In 2013 and 2014 this trend reversed and private expenditure seemed to close the gap with public expenditure (Fig. 3).

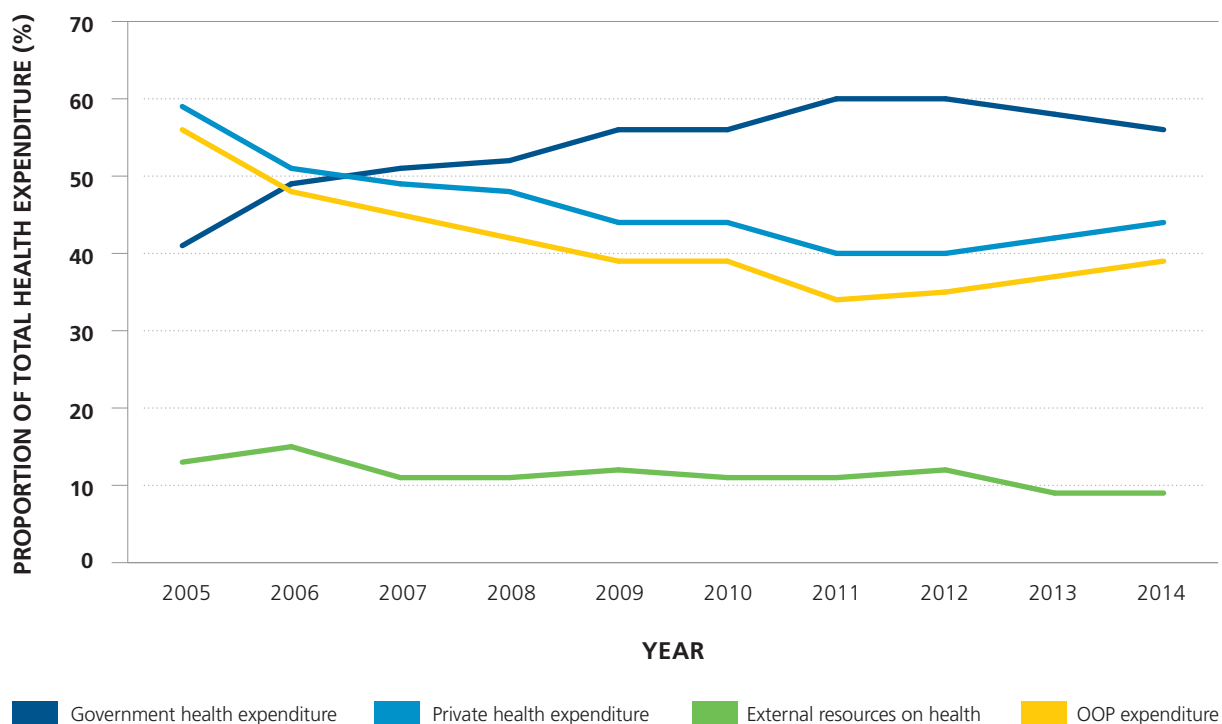
Fig. 3 | Development of total, public and private health expenditure, 2005–2014



Source: WHO (16).

Health expenditure as a proportion of general government expenditure remained roughly the same at around 12–13% throughout the analysis period. In 2014 annual per capita expenditure on health was KGS 4408 (US\$ 82), of which KGS 2474 (US\$ 46) was public expenditure. Per capita OOP payments amounted to KGS 1737 (US\$ 32) and the remainder was borne by external funds. Although the amount of OOP payments has increased continuously over the last 10 years (see section 1.2.3), their share of total health expenditure has decreased from 56% in 2005 to 39% in 2014 (Fig. 4). Nevertheless, this reduction should not hide the fact that OOP payments remain the largest part of private health expenditure (90%).

Fig. 4 | Development of public and private health expenditure as a percentage of total health expenditure, 2005–2014



Source: WHO (17).

3.1.2 Pharmaceutical expenditure and market

The latest available data on total pharmaceutical expenditure from 2008 show an annual total of KGS 3412.91 million (US\$ 93.33 million), which translates to KGS 638 (US\$ 18.6) per capita. Pharmaceutical expenditure accounts for 2.2% of gross domestic product and makes up a third of total health expenditure. Around 25% of total expenditure on pharmaceuticals comes from public sources; this amounts to per capita expenditure on pharmaceuticals of KGS 157 (US\$ 4) (18).

As of January 2016, 6817 pharmaceutical products were registered in Kyrgyzstan, of which 4474 were medicines and 2343 medical devices. During 2015 wholesale suppliers imported pharmaceutical products worth KGS 2710.6 million (US\$ 197.1 million)⁵ through Kyrgyz customs. Decisions of the Ministry of Health Commission for Humanitarian Aid permitted 171 imports of humanitarian aid for medical purposes, at a total value of KGS 1693.9 million (US\$ 26.3 million) (19).

3.2 Key players

3.2.1 Ministry of Health

The Ministry of Health is the competent authority for the regulatory framework of pharmaceutical policies. Its duties comprise:

⁵ US dollars in this paragraph calculated at the 2015 annual exchange rate (US\$ 1 = KGS 64.4797).

- preparing and implementing legislative acts;
- developing and implementing national programmes (such as the national medicine policy);
- developing regulatory mechanisms for health financing and delivery of health services, with a special focus on improving access for socially vulnerable groups;
- licensing medical and pharmaceutical activities;
- pricing health services, medicines and medical devices.⁶

The Ministry is also responsible for conducting centralized procurement for specific programmes (see section 3.5 for details).

3.2.2 MHIF

The MHIF was established in 1997 as an outcome of the *Manas* programme. It is responsible for pooling health funds and purchasing health services; it acts as a single payer – and thus the competent authority for reimbursement – in the health sector. The MHIF is directly responsible to the government but on the use of budgetary funds and other health financing issues it is accountable to the Ministry of Finance. It administers two of the five Ministry of Health programmes – the SGBP and the ADP – that play an important role in improving access to medicines (see section 3.4 for details). The MHIF conducted centralized public procurement for five specific medicines (prednisolone, metronidazole, ampicillin, benzyllpenicillin, ceftriaxone) in 2012 and 2014. The 2014 attempt was stopped by donors, however, because of the sector-wide approach to health in Kyrgyzstan. This approach is a method of working that brings together government departments, donors and other stakeholders, and requires commitment to certain operating principles, one of which states that procurement of medicinal products above a threshold of US\$ 100 000 has to be done by the Ministry of Health.

3.2.3 NMRA

The relevant competent authority for marketing authorization is the NMRA, which is part of the Ministry of Health. The NMRA is also responsible for inspection, import control, licensing, market control, quality control, medicines advertising and promotion, clinical trials control and pharmacovigilance. It is involved in harmonization and collaboration with a number of organizations such as the Eurasian Economic Community Integration Committee, the World Trade Organization and the Organisation for Economic Co-operation and Development. The NMRA is funded not through the regular government budget but via fees for services provided or from revenue derived from regulatory activities.

3.2.4 Family medicine centres/family group practices

During the Soviet era the health care system in Kyrgyzstan was characterized by a strong focus on the inpatient sector. This system was input-oriented (see definition in section 3.3) and led to inflated health care systems in post-Soviet countries (20, 21). When the Kyrgyz health system was reorganized after the collapse of the Soviet Union, the focus shifted towards delivery of care in the outpatient sector. To strengthen the role of primary health care, family medicine centres (FMCs) and family group practices (FGPs) were established on the former premises of ambulatory points of care, polyclinics and rural district hospitals.

⁶ This is executed by the Department of Drug Supply and Medical Equipment, which is an independent legal identity directly accountable to the chief sanitary doctor and deputy minister.

FMCs are the largest outpatient health facilities, offering medical services ranging from general medical care to specialized care and diagnostics, including radiography and ultrasound. Since FMCs often replaced smaller hospitals or polyclinics, minor surgery can be performed at their premises. There are usually 10–20 specialists in each FMC.

FGPs are responsible for providing comprehensive, continuous and integrated primary health services to the whole family. Each has at least one physician in addition to nurses and midwives. Although they are independent entities, they mainly form part of FMCs, which are responsible for them.

3.3 Pricing and reimbursement of medicines in the outpatient sector

Prices of medicines in Kyrgyzstan are not currently regulated. Some interviewees linked this situation to the experience of medicine shortages when prices were regulated in the transition period, 15–20 years ago. The health system at the time was still organized as a Semashko-style system with a focus on input-based payments: health facilities' budgets were determined by the number of beds, employers or equipment, independent of actual utilization (22). The structure of the health sector was inflated, leading to imbalances and delayed payments. As a result, suppliers decided not to distribute medicines to Kyrgyzstan. The government wanted to ensure availability of medicines and decided to open (liberalize) the pharmaceutical system. The measures implemented included allowing wholesalers and retailers to set prices of medicines and privatizing pharmacies. These strategies improved the availability of pharmaceuticals on the Kyrgyz market, but the prices of medicines increased. The national medicine policy for 2014–2020 refers to several pharmaceutical policies to address pricing issues (such as external price referencing (EPR), internal price referencing (IPR) and distribution mark-ups) but so far nothing has been implemented.

Wholesale and retail margins are not regulated in Kyrgyzstan. Retail pharmacy operators do not apply a uniform mark-up across all products, and the costs of operations and income vary with distance from major population centres (23). Price surveys conducted in three central Asian countries provide an indication of average wholesale and pharmacy margins (see Table 4). A 2005 price survey in Kyrgyzstan estimated private wholesale mark-ups in the range of 15–25% for originators and 25–35% for generics, with private retail mark-ups of 5–15% for originators and 15–25% for generics. 2007 data suggested retail mark-ups of between 32% and 244% (24).

Table 4 | Mark-ups in three central Asian countries assessed by surveys

Country	Public wholesale mark-up	Public retail mark-up	Private wholesale mark-up	Private retail mark-up	Date of survey
Kazakhstan	n.a.	n.a.	generics 5–50%	generics 20–30%	2004
Kyrgyzstan	n.a.	n.a.	originators 15–25% generics 25–35%	originators 5–15% generics 15–25%	2005
Tajikistan	n.a.	n.a.	15%	15–30%	2005

Note: n.a. = no data available.

Source: Ball (24).

3.4 Funding of medicines

The Kyrgyz health system is funded from three principle sources: the public sector, private households (mainly in the form of OOP payments) and external funds from international development agencies. Public sources include direct state budget funds (based on general tax revenue) and the MHIF (also based on general tax revenue). Funds from the state budget flow to the MHIF to finance the provision of health care services (including pharmaceuticals). In contrast to its neighbouring countries Kazakhstan, Tajikistan and Uzbekistan, almost no health funding comes from regional budgets via the oblasts. This is a result of the health financing reform in 2006 (*Manas Taalimi*), which strengthened the role of the MHIF.

Revenues collected from insurance premiums for mandatory health insurance are transferred to the MHIF. Premiums are deducted via a payroll tax, or allocated by the government for those who are unable to contribute (1). Currently, 76.3% of the population is covered by mandatory health insurance. Those not covered have to pay for their health care consumption completely OOP. MHIF funding is also relevant for medicines as it co-funds some medicines from the WHO Essential Medicines List (EML) through the SGBP and ADP, as well as via hospital budgets (medicines in the inpatient sector are paid for by hospitals using the budget transferred to them by the MHIF).

3.4.1 The SGBP

Before 1996 Kyrgyzstan had a norm-driven, centrally planned, general revenue-financed health system, in which all citizens were entitled to all health care services for free. For several reasons, however, the system was not able to provide the extent of health coverage it had aimed for. A main issue was the input-based payments, which resulted in large fixed costs, leaving very little available to pay for medicines and supplies (20). With the collapse of the Kyrgyz economy in the first half of the 1990s this inefficient system was no longer affordable. Between 1996 and 2006 policy-makers implemented a major reform programme (*Manas*), which included comprehensive structural changes of the health care system. The aims of the reform were to:

- diversify health sector financing
- centralize the flow of public funds into a national pool (the MHIF)
- clarify entitlement to health benefits
- change provider payments
- strengthen primary care
- rationalize the delivery of hospital services
- update treatment protocols
- broaden consumer choice (25).

The SGBP was a key instrument in specifying the services to which patients were entitled. It was introduced in 2001 as a pilot project in several oblasts and subsequently rolled out nationally. Its main objective was to improve access to defined health services for the most vulnerable groups of the population and to increase the efficiency of health care services. The introduction of the SGBP represented a shift towards an output-based system, with capitation payment in the outpatient sector and case-based payment in the inpatient sector. It is a disease-specific scheme, which ensures access to a defined set of health services (including pharmaceuticals, but also primary and secondary health care) for the entire population with certain medical conditions, regardless of their insurance status. These conditions are acute cardiac infarction, tuberculosis (TB), bronchial asthma, cancer in the terminal phase, mental disorders (schizophrenia and affective disorders), epilepsy, diabetes

and haemophilia (1). Medicines for these conditions should be dispensed free of charge in the outpatient sector but the coverage rate is in fact around 80–90% of the retail price. In 2015 87.9% of the costs of medicines under the SGBP were covered, which translates into KGS 23.7 million (US\$ 0.37 million) (26).

3.4.2 The ADP

The ADP was introduced in 2001 on a pilot basis, followed by a national rollout. Like the SGBP it aimed to improve affordability and accessibility of pharmaceuticals by limiting the financial burden on the population. At the same time it encouraged more rational pharmaceutical prescribing and use, as only evidence-based medicines were included in the list. Another rationale of this programme was to reduce hospitalization related to noncommunicable diseases and to shift patients to outpatient facilities, where treatment is considered more efficient (1).

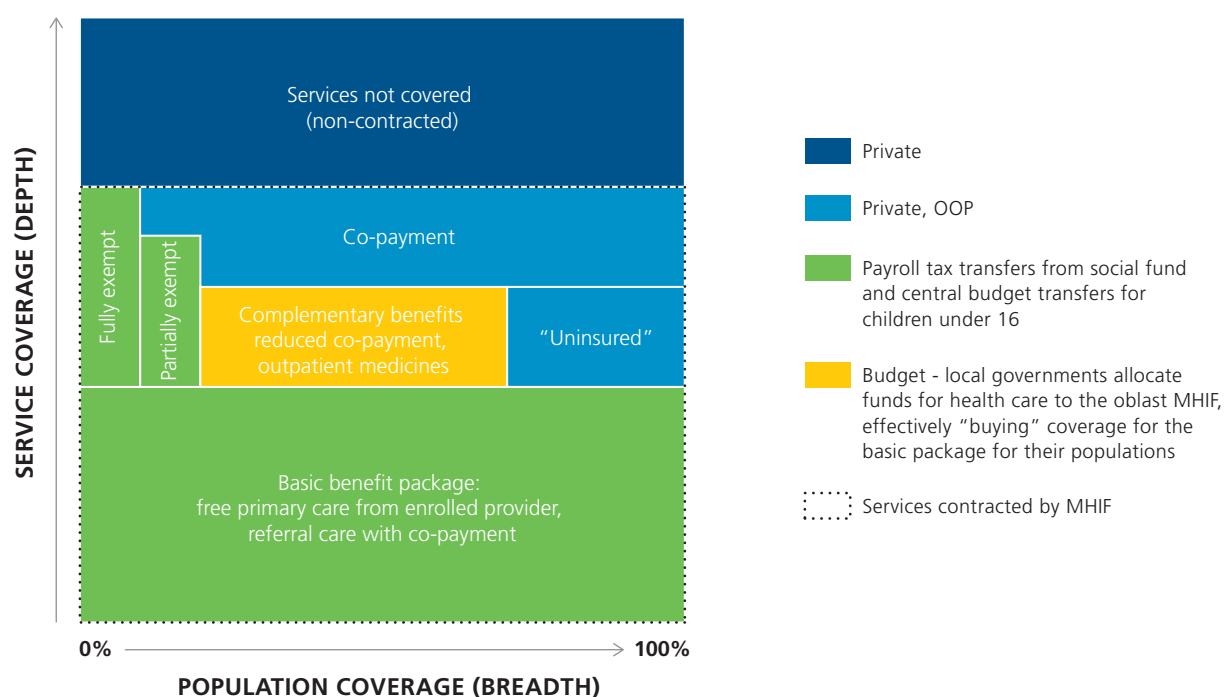
The ADP has characteristics of disease-specific reimbursement schemes, as it mainly targets noncommunicable diseases. It can also be considered population-specific, because only those with mandatory health insurance can benefit from the programme. Insured people have to enrol at their FGP and can then receive special prescription forms from their treating doctor. These prescriptions can only be dispensed in pharmacies that have entered into a contract with the MHIF. The contract allows pharmacies to sell specified medicines at lower prices, as the remainder of the amount is paid by the MHIF. The range and the payment mechanism for medicines dispensed under the ADP are regulated in the contract between pharmacies and the MHIF. In 2008 the MHIF concluded a contract with 231 private pharmaceutical retailers (some of which own networks of more than 200 chain pharmacies) at the primary health care level (1).

As of 2015, the ADP listed 60 items (58 international nonproprietary names (INNs) and two medical devices) for which the MHIF covers the so-called basic price and the difference from the retail price has to be paid OOP by patients. Calculation of the basic price is done by the MHIF via analysis of wholesale prices, which are extracted from price lists provided by wholesalers (usually the largest, although their participation is voluntary) at the MHIF's request. From the prices collected the three highest and three lowest are excluded and the average of the remaining prices is calculated. To this average two different multipliers are applied – one for pharmacies in urban areas and one for those in remote areas – yielding two reimbursement values, with differences of around 9%.

According to information retrieved from the literature, 891 000 items were prescribed under the ADP in 2015 and 53.9% of the costs were covered, which equates to almost KGS 200 million (US\$ 3.1 million) (26). Fig. 5 provides an overview of the health coverage within the Kyrgyz health system. The SGBP is located in the grey “basic benefit package” field and the ADP is included in the gold “complementary benefits” field.

3.5 Pharmaceutical distribution chain

In Kyrgyzstan, the NMRA is responsible for issuing licenses for the production, storage, distribution and sale of pharmaceuticals. A lack of distinction between the various functions makes it challenging to assess the pharmaceutical distribution chain. The majority of pharmaceuticals are imported from other countries. In 2010, 42 licensed pharmaceutical manufacturers were active, but their share of the domestic market was very low (around 3–4% both in value and in volume). During the key stakeholder interviews it was pointed out that those figures are

Fig. 5 | Coverage within the Kyrgyz health system

Source: Kutzin et al. (20).

unreasonably high. A more credible number would be around 30 manufacturers⁷ with a market share of around 1%. This is supported by the last annual report of the NMRA, which indicated a share of 1.3% in value.

No multinational pharmaceutical companies manufacture medicines locally. Large manufacturers enter a contract with only one or two wholesalers, providing them with the exclusive right of distributing their products across the country. Some distributors receive the exclusive right to supply specific medicines; often they have exclusive contracts with several manufacturers for the distribution of their products in certain countries.

In 2009 there were about 2700 pharmaceutical facilities in the country, of which 306 were warehouses, 940 were outpatient pharmacies, 62 were pharmacies in hospitals, 1267 were pharmacists' points and kiosks,⁸ and 55 were facilities for optical or dental products (1, 18). These figures must be used cautiously because a vertically integrated chain pharmacy – i.e. a wholesaler with several warehouses and a network of numerous sale points – is counted as only one pharmaceutical facility. According to the Ministry of Health, in 2016 there are around 200 active wholesale companies in Kyrgyzstan.

Medicines included in one of the programmes – either the SGBP or the ADP – can only be dispensed by pharmacies located in outpatient units⁹ or contracted pharmacies that are usually located close to outpatient units. The health experts interviewed estimated that in 2016 about 200 of the 2000

⁷ Including (chain) pharmacies that produce specific preparations.

⁸ Pharmacists' points and kiosks refer to smaller retail outlets where only a limited set of medicines (defined by the government) can be dispensed to patients.

⁹ Every FMC has at least one pharmacy, but there can be up to seven, of which at least one is contracted under the ADP.

pharmacies had concluded a contract with the MHIF, but this figure underestimates the number of places where patients can procure reimbursed medicines, as a pharmacy chain will count as having only one licence.

Storage and distribution of pharmaceuticals is not only provided by the private sector but can also be found within the public sector. Medicines for the treatment of diabetes (mainly insulin and metformin) and TB, as well as products used during haemodialysis, are centrally procured by the Ministry of Health. These are stored in pharmaceutical warehouses in Bishkek (including, for example, TB medicines in the National TB Centre) and then distributed to the oblasts. From there they are distributed to the health facilities (mainly FMCs), where they are dispensed free of charge to patients in need.

For the majority of pharmaceuticals used in hospitals, procurement is not centralized and each hospital conducts its own tenders, although these are launched through a unique platform operated by the Ministry of Finance. Therefore, prices paid for the same products during the same period can vary from one hospital to another. This is partly attributed to tender specifications that prices of medicines include transport and distribution. In addition, there is no centralized database where hospitals can check the prices paid for medicines by other hospitals.

3.6 Past initiatives and current developments

A review of existing literature about the reforms and developments of the Kyrgyz health care sector in general, as well as the pharmaceutical sector, is set out in section 1.2. The following sections provide further information generated during the key stakeholder interviews of May–June 2016.

3.6.1 Public–private pharmacy services

In 2006 the Asian Development Bank supported a project that aimed to establish rural pharmacy networks in remote areas through public–private partnership. At the time public payers were already covering essential medicines through the creation of the MHIF, but patients in rural areas were benefiting less from that policy because of the shortage or absence of pharmacies in those areas. The core of the Asian Development Bank's project was to create incentives to private retail pharmacies to open stores in villages. These included provision by the government of rent-free facilities for pharmacies, while the project financed an initial supply of essential medicines, equipment and staff training. In terms of the number of pharmacies the project can be considered a success: in 2005 there were less than 100 pharmacies in the poorest rayons/districts. By the time the project closed in 2008 there were an additional 123 pharmacies. The number of villages with FGPs but no pharmacies decreased between 2004 and 2009 from 142 to 102 (1, 23, 27). Experts confirmed the positive effects of this project with regard to access to pharmaceuticals, but they also pointed out that it resulted in unintended negative consequences (such as a missing legal basis for continued operation under the project, which meant that incentives could not be renewed, and migration of retrained health workers to Bishkek).

3.6.2 Harmonization of pharmaceutical registration procedures

After Kyrgyzstan's accession to the Eurasian Economic Union (EEU) in 2015, a plan was made to further integrate the pharmaceutical markets in the next decade, following the example of the European Union. Technical specifications for registration were made stricter and harmonized

regulations for the registration of pharmaceuticals were developed for central Asian countries. To comply with EEU rules, changes in Kyrgyz law were developed, but these had not yet been approved at the time of writing. A transition period until 2025 is foreseen, after which two registration schemes should be available and producers will be able to decide to which scheme they want to apply. The centralized scheme works on a mutual recognition base, meaning that registration in one country leads simultaneously to registration in all EEU countries. If a producer decides to distribute pharmaceuticals only within the Kyrgyz market, national rules will be followed.

3.6.3 Working group on price regulation

Discussion has continued during the past five years about the lack of price regulation in Kyrgyzstan, as this is considered a large problem and a factor contributing to price increases. A unit within the Drug Regulatory Agency (DRA) was commissioned to develop suggestions for possible price regulation in 2012. From 2012 to 2015 the unit developed, in consultation with stakeholders, a proposal to fix wholesale prices and set retail margins for medicines and medical products marketed in Kyrgyzstan. During the stakeholder review phase it was noted that the proposal did not address certain key issues (such as the exchange rate, the range of medicines covered and clear provisions for arrangements to verify information from suppliers, among others) (12). As a result, a working group was established to develop the issue further and to prepare a draft document for regulation of the whole pharmaceutical market. The working group began its work in January 2016 and was chaired by the DRA. It included members from the Ministry of Finance, MHIF, pharmacy associations and other stakeholders. The group was supposed to discuss and suggest policy options, particularly on price and mark-up regulation, but it ceased activity in April 2016 because of the progress of the law on modernization of the pharmaceutical sector (see section 3.6.5).

3.6.4 Pharmaceutical producer association

For years pharmaceutical manufacturers and distributors were jointly represented by one interest group, PharmUnion. Since the Kyrgyz pharmaceutical market is dominated by wholesalers, this was also reflected in the internal structure of PharmUnion. Despite still representing a low share of the medicines on the Kyrgyz market, local production of pharmaceuticals has increased in recent years and complaints were articulated that PharmUnion mainly represented the interests of pharmaceutical distributors. As a result, 13 local producers decided to found their own interest group. As of 2016, 16 companies are members of the local producer association, with JSC Biovit by far the largest manufacturer.

3.6.5 Law on modernization of the pharmaceutical sector

The Kyrgyz Government has prepared a draft law on medicines and medical devices that aims to implement a unified national medicine policy in order to supply high-quality, efficacious and safe medicines to the population of Kyrgyzstan. This new law addresses price regulation; surveillance of medicines turnover; licensing of the production and sales of medicines and medical devices; and access to information about medicines used in the country. At the time of writing in mid-September 2016, however, it had not yet been discussed by parliament and brought into force, although it represents a necessary step for implementation of any further regulation of the system.

4. Analysis of current reimbursement mechanisms

4.1 Reimbursement processes

Kyrgyzstan has a national essential medicines list (NEML) that is publicly available. It was developed in 1996 and last updated in 2012. In 2016 the list included 314 INNs. Selection of medicines for the NEML is undertaken through a written process and coordinated by the Unit on Rational Medicine Use, which is part of the Department of Medicine Supply and Medical Equipment. Each updated version of the NEML has to be approved by the government. All medicines that can be prescribed under the SGBP and ADP are taken from the NEML, and procurement of medicines in the inpatient sector is also based on it. The NEML is not totally aligned with the latest WHO EML, however (see also Table A.1 in the Annex). According to representatives of the Ministry of Health and MHIF, changes in processes to select medicines for the NEML are under review, as the government aims to implement a law on modernization of the pharmaceutical sector (see section 3.6.5). The new law includes a definition of a list of vitally important medicines.

The diseases covered by the SGBP can be administered in both outpatient and inpatient sectors. In general, medicines dispensed under the SGBP¹⁰ are entirely paid by the MHIF, but funding can also work through other channels. Priority programmes such as TB (but also reproductive health, HIV/AIDS, sexually transmitted infections and diabetes) are still contained in separate vertical systems. Medicines are procured via centralized procurement (such as insulin and metformin for the treatment of diabetes) or on a grant basis through international organizations; they are then distributed through public distribution channels.¹¹

Medicines on the ADP list are not entirely reimbursed by MHIF but the so-called baseline price – i.e. the reimbursement amount – is covered. To calculate the baseline price, the MHIF collects wholesale price data of medicines with the same active ingredient and strength but of different package sizes from around 15–20 representative wholesalers. This number of wholesalers is considered sufficient as the 10 largest wholesalers cover 80% of the market. MHIF converts the collected prices into Kyrgyz som per defined daily dose. The sample is adjusted for outliers by excluding the three highest and the three lowest prices, and the average is calculated. This value is further adjusted for regional variation of medicine prices by applying different multipliers for pharmacies in remote areas.¹² The sole criterion for the application of the multiplier is the region in which the pharmacy is located; the same multiplier is used for each pharmacy within an oblast. Calculation of the regional multipliers is done regularly and retrospectively according to data on reimbursed medicines from previous years. In pharmacies with a contract with the MHIF, patients enrolled in the ADP programme usually have to pay the difference between the baseline price and the pharmacy retail price. Baseline prices are published in a positive list (reference book) that includes the list of INNs (with subgroups of pharmaceutical specialities).

¹⁰ These include medicines to treat bronchial asthma, cancer in the terminal phase, mental disorders (schizophrenia and affective disorders) and epilepsy.

¹¹ The National TB Centre is in charge of administering the distribution of TB medicines.

¹² In general, retail prices for medicines vary between pharmacies in Kyrgyzstan, but prices are higher in remote areas in particular. Thus, baseline prices of medicines are adjusted with a higher multiplier to prevent patients having to pay more for medicines in those regions, where average incomes are also lower.

The Kyrgyz system has elements of IPR at Anatomical Therapeutic Chemical (ATC) level 5. IPR is the practice of using the price(s) of identical medicines (at ATC level 5), similar products (at ATC level 4) or even therapeutically equivalent treatments in a country to derive the reference value for setting the reimbursement (reference) price of a product (28). The difference between the reference price and the retail price has to be paid OOP by patients. One goal of such systems is to promote competition among identical medicines (i.e. off-patent medicines), while ensuring that access to the reference products is usually entirely reimbursed. Where IPR systems are subject to regular revisions, authorities can take advantage of price competition (for example, manufacturers might reduce their retail prices and set them near the reference price).

In Kyrgyzstan, the reimbursement rate for medicines included in the ADP list is set at 50% of the calculated baseline price; thus, patients have to co-pay around 50% for co-funded ADP medicines (it rarely ends up being exactly 50% because of the absence of price regulation at the retail level). The rates are not fixed, however, but determined on an individual basis when calculating the baseline price. Legislation requires regular revisions of baseline prices, but in practice this happens on an occasional basis. The last revision took more than two years (from 2012 to April 2015). According to information from the MHIF, the process of recalculation is a matter of staff resources: it can take 4–6 months to revise the whole list. This duration is related in part to the legal provision that revisions have to consider prices covering a three-month period. During the process of price revision, the MHIF collects price lists from different wholesalers and manually extracts the required information to calculate prices. Every time the baseline prices for reimbursement are (re)calculated, this has to be approved by a joint resolution of the Ministry of Health and the MHIF, which contributes to the delay in implementing reimbursement decisions.

Recalculation of baseline prices is one way the MHIF gains information about the prices of medicines funded under the ADP. A further feedback mechanism on high prices and thus high co-payments is a confidential telephone line, via which patients can report instances of pharmacies asking for disproportionately high prices for medicines. The MHIF investigates these cases and sends a letter of warning if the allegations are found to be true.

KEY FINDINGS

- Pharmaceutical reimbursement in Kyrgyzstan is characterized by a **division of competences between the Ministry of Health and MHIF**: the Ministry sets priorities via approval of the selection of medicines for the NEML, while the MHIF funds medicines under the SGBP and co-funds medicines under the ADP. Since ADP medicines are only partially reimbursed, the baseline price of these medicines is calculated by the MHIF. Processes appear to be well defined.
- Well defined and elaborated mechanisms to calculate baseline prices exist, but these processes appear to require **intensive use of staff resources and time**. This particularly concerns the collection of price data as the basis for the calculation of baseline prices. Data need to be collected from wholesalers, and even if the MHIF focuses on collecting data from a selected number of wholesalers, the process of recalculation of baseline price might take up to six months.
- An algorithm is used as a **mechanism to account for regional balance**: it considers regional inequalities throughout the country, setting higher baseline prices in remote areas.
- The MHIF's calculations of the baseline prices for reimbursement could be interpreted as **de facto IPR** (clustering of identical or similar medicines and attributing the same reimbursement levels to this group) at ATC level 5 (molecule level).
- **Authorities do not undertake systematic price monitoring**: they have no knowledge of medicine prices in the outpatient sector, even for medicines they co-fund (via the ADP). Prices should be collected from market actors (wholesalers) or occasionally anecdotal information received from patients.

4.2 Listing and delisting of medicines from the ADP list

According to state regulations, selection of medicines for inclusion in the ADP¹³ is based on:

- proposals of prominent health care practitioners and organizations, based on evidence of using the medicines;
- Ministry of Health strategies on identified priorities, including the diseases monitored in the country;
- presence on the NEML;
- availability of medicines in the standard treatment regimens;
- medicine registration (market authorization);
- price considerations;
- presence of generic/trade names of medicines in the domestic market.

Among these criteria, particular focus was said to be given to the priorities identified by the Ministry of Health. These include contraceptives, maternal health, paediatric health, diabetes testing, cardiovascular diseases, TB and HIV. The priorities are often also reflected in existing national programmes.

Priority is also given to the medicines on the NEML, as these aim to strike the balance between identified priorities and the most efficient use of health resource to achieve them. The ADP list of medicines can include up to 10% of INNs not included in the NEML, however.

The decision of what to include in the list is made by a commission, which includes evidence-based medicine experts, prominent specialists from national centres, health care professionals, Ministry of Health officials and MHIF officials. The commission approves INNs and the MHIF officials draft the list of medicines using INNs as registered in the country. Some medicines without marketing authorization are listed on the NEML, but these can be imported with a Ministry of Health waiver. Often such medicines were registered at the time of NEML listing but the manufacturer has not subsequently sought reregistration of the product.

The timelines for reimbursement list revision have not been formally established. When the ADP was introduced in 2001 revisions were envisaged twice a year, but in practice they rather happen on an ad hoc basis. The positive list is approved by a joint resolution of the Ministry of Health and the MHIF.

Some ADP medicines are not included in the WHO EML, but their share of prescribed medicines has decreased over the years. In 2013, 80.3% of the medicines and medical devices prescribed and dispensed (in volume) under the ADP were listed on the WHO EML. Two years later the figure had increased by eight percentage points (Fig. 6). This was mainly achieved by discontinuing reimbursement for medicines not on the WHO EML.

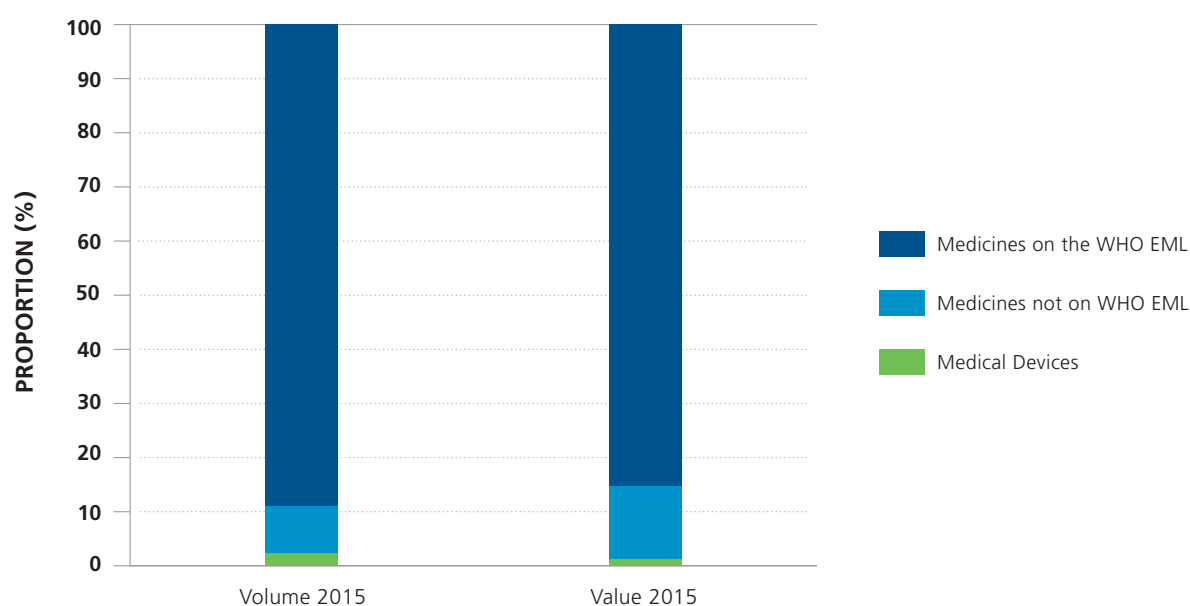
Medicines included in the ADP list in 2015 but not in the WHO EML were found in the following ATC groups (for details see Table A.1 in the Annex):

- three respiratory medicines (aminophylline and theophylline, which have been deleted from the WHO EML, and the combination salmeterol-fluticasone);
- two medicines for cardiovascular diseases (the combination enalapril + hydrochlorothiazide and indapamide);
- two medicines of the nervous system (clonazepam and tramadol);
- one gastrointestinal medicine (bismuth subcitrate).

¹³ Further analysis in this report focuses on medicines funded via the ADP for two reasons. First, its aim is to explore the extent of OOP payments for medicines and identify their causes. Medicines dispensed under the SGBP do not require co-payments, unlike medicines dispensed under the ADP. Second, the funding channels for medicines under the ADP are more homogeneous than for those under the SGBP.

During the key stakeholder interviews respondents gave mixed answers about their perceptions of the reimbursement list. Payers and providers consider it a helpful tool to improve access to medicines, but their views about future avenues diverge. Providers – particularly doctors – would prefer the list to be either deepened (with more trade names of an active ingredient) or broadened (with more medicines for the same indication). Nevertheless, payers expressed their preference for streamlining the list, as in their opinion too many trade names were included.

Fig. 6 | Distribution of medicines prescribed and dispensed under the ADP according to inclusion on the WHO EML, by volume and value, 2015



Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

KEY FINDINGS

- A commission, made up of evidence-based medicine experts, prominent specialists from national centres, health care professionals and Ministry of Health and MHIF representatives, decides which medicines to include in the ADP list. **Criteria and processes for selecting medicines to include** are defined, but some appear vague (for example, one cites “proposals of prominent health care practitioners and organizations”). The focus of the selection was said to be medicines for priority diseases as defined by the Ministry of Health. Despite efforts made in this field in recent years, however, there still appears to be a need to align the ADP medicines better with priority diseases.
- Timelines for **regular revision of the ADP list** have not been formally established, and revisions appear to be performed on an ad hoc basis.
- A review of the medicines included (as of 2015) showed **differences between the ADP list and WHO EML**, although these had decreased. A comparison of these shares in terms of value and volume highlighted how small differences in volume can cause significant differences in value.

4.3 Prescribing and dispensing of medicines under the ADP

In principle, all insured people are entitled to medicines under the ADP, translating into virtual coverage of about 70% of the population (29). According to the findings of a 2011 Ministry of Health survey, 36.6% of patients interviewed were aware of the ADP.

Nevertheless, ADP medicines can only be prescribed and dispensed to patients who are enrolled at a FGP. This is linked to the prescribing budget granted to FGPs. For each registered patient the FGP has a maximum amount of KGS 50 (US\$ 0.77)¹⁴ that can be prescribed within one year. If this ceiling is reached early, no more medicines can be reimbursed under the ADP for the rest of the year, and patients have to pay fully OOP for ADP medicines. In the key stakeholder interviews, doctors considered the prescribing ceiling too low but were still able to manage. It was understood that the prescribing ceiling is not earmarked to individual patients but rather pooled to a virtual total for each quarter, thus giving doctors some flexibility. Each FGP is responsible for monitoring adherence to the ceiling; those affiliated to larger FMCs are given a monthly overview by the FMC of the available budget for prescribing.

Doctors employed by a FMC or FGP under contract to the MHIF are obliged to prescribe by INN, choosing INNs under the ADP. To inform them accordingly, the MHIF shares the ADP list with all contracted FMCs. It was reported, however, that in practice medicines are prescribed by trade name rather than by INN. Doctors were reported to prescribe medicines by INN only in cases where patients could not afford co-payments for branded medicines and asked for lower-priced alternatives.

Three different types of prescription forms are in use, recognizable by colour. White forms are the standard ones for prescription-only medicines; yellow forms are for medicines granted to patients under the SGBP; and blue forms are for patients entitled to medicines under the ADP. White prescriptions can be dispensed at every pharmacy, whereas the yellow and blue ones can only be dispensed at pharmacies with a contract with the MHIF. If doctors prescribe medicines on the yellow (SGBP) or blue (ADP) forms, the prescription information must be recorded via a web-based tool. This was developed by the MHIF and distributed to prescribing doctors and dispensing pharmacies.

Prescription forms under the SGBP or ADP are available in three copies: one stays with the doctor and two are given to the patient for the pharmacy. The pharmacist takes both forms and fills in the retail price at which the medicine is dispensed. One copy stays in the pharmacy while the other is sent to the MHIF. Dispensing pharmacists have to use a web-based tool to complete the information on the prescription, which sends the details electronically to the MHIF. At the MHIF both sources of information are compared and the transfer of the corresponding baseline price to the pharmacy is initiated only if the information matches. Although the computer system automatically compares the electronically documented prescriptions, if only a single character differs, an error message is shown on the screen and an MHIF employee has to complete the comparison manually. While the instrument offers an opportunity to monitor prescribing and dispensing behaviours, it adds an administrative burden to the MHIF. The MHIF acknowledged that the process of comparing prescription copies is very labour-intensive.

In principle, pharmacists have the right to substitute prescribed medicines with generics. When the prescription states the INN they can choose which medicine with the appropriate active ingredient they dispense, but they do not automatically dispense the lowest-priced alternative. Quite often the decision of which medicine to dispense is driven by a patient's request for trade name medicines. But patients may also ask for lower-priced medicines owing to budgetary restraints, so in these cases generics and lower-priced medicines are dispensed. The dispensing and selling of higher-priced medicines is linked

¹⁴ US dollars calculated at the 2015 annual exchange rate (US\$ 1 = KGS 64.4797).

to the lack of price regulation. Pharmacists are not incentivized to dispense and sell generics and other lower-priced medicines which would reduce their income.

Furthermore, knowledge about the legal competences of pharmacists regarding generic substitution appears to be mixed. While interviewed pharmacists knew about their right to substitute prescribed medicines with generics, doctors in FMCs challenged this pharmacy service. Some doctors did not have sufficient confidence in generic substitution, since not all people working in pharmacies were qualified pharmacists. Patients were reported not to trust pharmacists sufficiently; they suspected that pharmacists would follow personal interests when substituting medicines, and would therefore reject substitutes.

A further issue that needs to be tackled in conjunction with INN prescribing and generic substitution is awareness of generics at all levels. Health professionals raised doubts over whether generics imported from certain countries (naming India as an example) were able to deliver the same effect as (European) trade name products. These doubts are fuelled by anecdotes about poor quality checks by the NMRA.

Another concern in this context is the relevance of direct-to-consumer advertisement (DTCA) of pharmaceuticals, including prescription-only medicines. While this is forbidden by legislation in Kyrgyzstan, anecdotes of observed cases of DTCA were reported (for example, doctors reported that patients arrived with cuttings from newspapers).

KEY FINDINGS

- The **administrative processes in the MHIF related to managing medicines prescribed under the ADP appear time- and staff-intensive**, involving three copies of the prescription forms and a double documentation report, both digital and paper-based, to handle.
- Although doctors are obliged to prescribe by INN, it was reported that in practice they preferred using trade names of medicines included in the positive list, and that **INN prescribing was limited**. The current documentation of prescriptions, however, gives an instrument to the MHIF that can facilitate monitoring of doctors' prescribing behaviour.
- In principle, pharmacists have the right to substitute prescribed medicines with generics, but **a low rate of generic substitution was reported**. This perceived low rate is also linked to the current lack of price regulation, which incentivizes pharmacists to dispense and sell higher-priced medicines. For the same reason, pharmacists were also reported to tend to choose higher-priced medicines when dispensing prescriptions written by INN.
- There are indications that **patients and health professionals lack knowledge and distrust the quality of generics**. The doubts are fuelled by unconfirmed anecdotal reports about poor quality checks by the NMRA.
- While Kyrgyz legislation prohibits DTCA of prescription-only medicines, anecdotes of observed cases of pharmaceutical advertisements targeting patients were reported.

4.4 Extent of medicines covered

In 2013, 75 INNs and two medical devices were included in the ADP list. The majority (16 INNs) were in ATC group J (anti-infectives for systemic use and antibiotics). The next largest group (15 INNs) was cardiovascular medicines (ATC group C), of which three were diuretics, two beta blockers and two antihypertensives. A further 13 INNs served to treat diseases of the respiratory system (ATC group R)

and 12 to treat problems of the nervous system (ATC group N). The other INNs fell into ATC groups A (seven INNs), B, G, P (three INNs each), M (two INNs), H and V (one INN each).

A quarter (19) of the 75 medicines on the ADP list were not included in the WHO EML. Between 2013 and 2015, 17 INNs were delisted. As a result, 58 INNs in different ATC groups and two medical devices were on the ADP list in 2015 (Table 5).

Table 5 | List of molecules with INNs included in the ADP list, 2015

ATC level 3	INN	ATC level 3	INN
A02	Bismuth subcitrate	J01	Ciprofloxacin
A02	Omeprazole	J01	Erythromycin
A02	Famotidine	M01	Diclofenac
A07	Rehydration solution	M01	Ketoprofen
A11	Ergocalciferol	N02	Paracetamol
A11	Ferric sulfate + ascorbic acid	N02	Tramadol
B03	Ferric sulfate + folic acid + ascorbic acid	N03	Carbamazepine
B03	Folic acid	N03	Clonazepam
B03	Combination iron supplement	N03	Phenobarbital
C01	Digoxin	N03	Valproic acid
C01	Isosorbide dinitrate	N04	Trihexyphenidyl
C03	Hydrochlorothiazide	N05	Haloperidol
C03	Furosemide	N05	Diazepam
C03	Indapamide	N05	Chlorpromazine
C07	Bisoprolol	N05	Clozapine
C08	Nifedipine	N06	Amitriptyline
C08	Amlodipine	Device	Disposable syringe
C09	Enalapril	Device	Glucose test strips
C09	Enalapril + hydrochlorothiazide	P02	Mebendazole
C09	Lisinopril	P02	Praziquantel
G03	Levonorgestrel + ethinylestradiol	P02	Albendazole
G03	Intrauterine contraception	R03	Aminophylline
H02	Prednisolone	R03	Beclomethazone
J01	Amoxicillin	R03	Ipratropium bromide
J01	Ampicillin	R03	Salbutamol
J01	Benzathine benzilpenicillin	R03	Theophylline
J01	Benzylpenicillin sodium	R03	Salmeterol + fluticasone
J01	Doxycycline	R06	Ketotifen
J01	Metronidazole	R06	Loratadine
J01	Phenoxyethylpenicillin	V03	Potassium iodide

Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

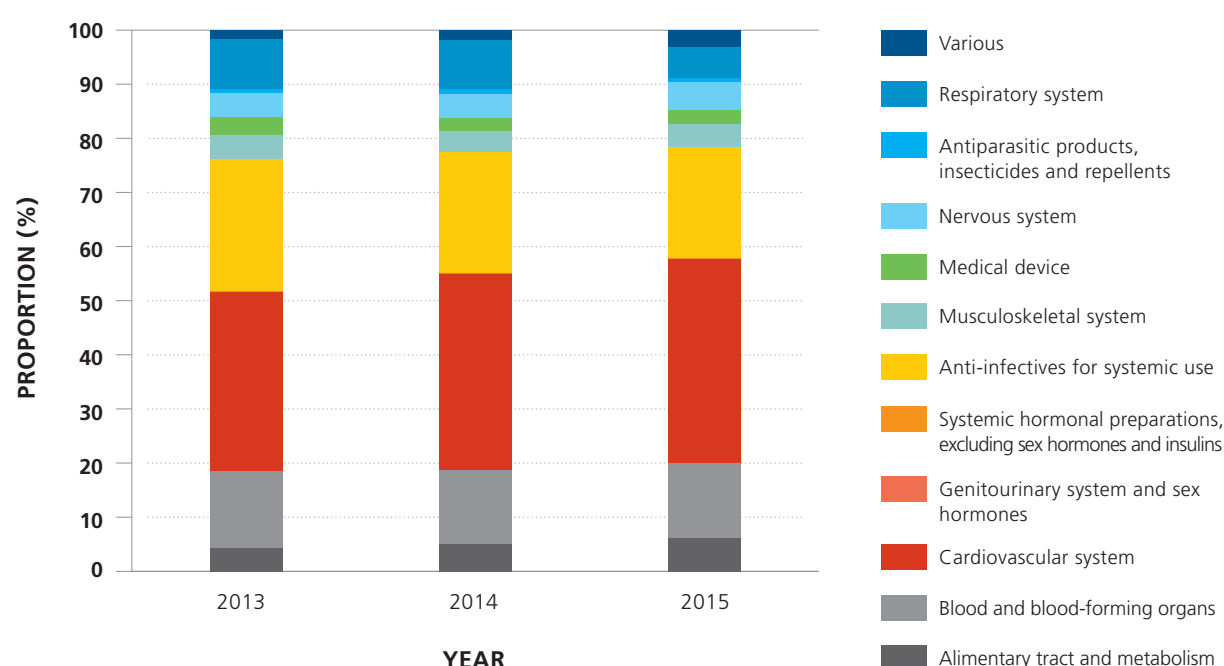
KEY FINDINGS

- **A majority of ADP medicines treat noncommunicable diseases.** The range of medicines included in the ADP list reflects the ongoing transition in treatment priorities from communicable to noncommunicable diseases. Most ADP-listed medicines are of ATC group J. In addition, medicines to treat cardiovascular diseases (group C), medicines of the respiratory system (group R) and the nervous system (group N) account for around 50% medicines on the ADP list.

4.5 Prescription data

In 2013 one third of all ADP prescriptions were to treat cardiovascular diseases and one quarter were for antibiotics. Between 2013 and 2015, the shares of the two largest ATC groups changed: while the proportion of antibiotics decreased, amounting to 20.5% in 2015, the proportion of cardiovascular medicines increased, accounting for 37.6%. Several antibiotics and cardiovascular medicines were delisted during the time period studied. The share of prescriptions in most other ATC groups remained stable – for example, the proportion of medicines treating blood and blood-forming organs (ATC group B) remained around 14%. Medicines treating the respiratory system (ATC group R) had a stable share of around 9.2% in 2013 and 2014 and then decreased by a third to 5.7% in 2015 (Fig. 7).

Fig. 7 | Distribution of medicines prescribed and dispensed under the ADP, by ATC group, 2013–2015



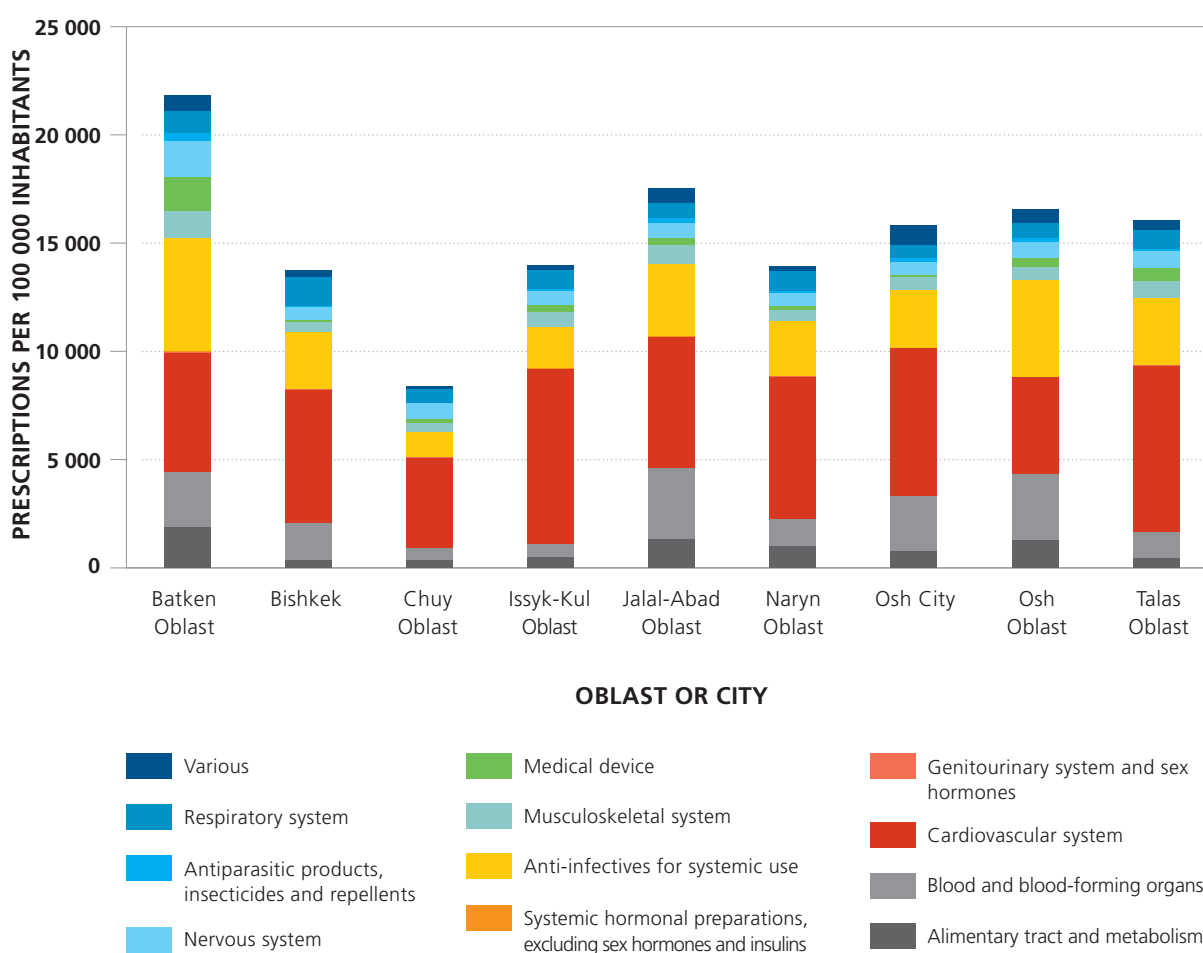
Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

Utilization under the ADP (as expressed by medicines prescribed and dispensed) showed large regional variation, in total as well as for specific medicines, such as cardiovascular medicines, anti-infectives and medicines of ATC group B (Fig. 8). A number of factors may explain this regional variation, including the following.

- Economic variations exist within the country. Although medicines dispensed under the ADP are reimbursed, patient co-payments are required. If patients cannot afford co-payment, they probably do not take the prescriptions to the pharmacy to be dispensed.
- Disease prevalence patterns may differ throughout the country.
- The figures only include those medicines actually dispensed at the MHIF's expense. If medicines are not available, prescriptions may not be dispensed.
- In remote areas health care providers, particularly in specialized care, may face capacity limitations (such as not being able to diagnose specific diseases, possibly because of a lack of medical equipment).

Evidence is lacking, however, on which, if any, of these explanatory factors may be relevant in the Kyrgyz context. Data collection – for example, through regular prescription monitoring and surveys on availability and prices of medicines (using the WHO/HAI methodology, for instance) – could help to produce a better picture.

Fig. 8 | Distribution of medicines prescribed and dispensed under the ADP, by ATC group, 2015



Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

4.6 Proposed actions for the reimbursement system

The current reimbursement system in Kyrgyzstan is based on a clear division of responsibilities between competent authorities (the Ministry of Health and MHIF) and on well defined processes and criteria.

KEY FINDINGS

- **Dispensing of cardiovascular medicines and anti-infectives** accounted for the largest shares of prescriptions under the ADP. The proportion of cardiovascular medicines prescribed and dispensed increased.
- Wide **regional variation was seen in prescribing patterns** under the ADP. There is a lack of sound evidence to explain these differences.

Mechanisms to account for regional imbalances are provided for in legislation. Nevertheless, calculation and updating of the baseline prices is burdened by labour- and time-intensive administrative processes. Authorities lack knowledge about the market, including medicine prices, and are dependent on information provided by stakeholders in response to ad hoc requests. While demand-side measures to enhance the uptake of generics are provided for in legislation, they appear to be poorly followed in practice. Thus, Kyrgyzstan does not take advantage of the efficiency of lower-priced multisource (generic or branded generic) medicines. Distrust and limited knowledge of generics were reported among health professionals and patients; these probably account for the limited generics utilization and the prescription, dispensing and use of higher-priced medicines (mainly originator medicines) instead.

To improve the ADP reimbursement system and take advantage of the efficiency of lower-priced medicines, the following action points are suggested for consideration.

- **Collection of wholesale prices should be facilitated.** The current process of collecting medicine prices from wholesalers (requesting price lists, browsing price lists, extracting price information and so on) required for the calculation of the baseline price appears very time-consuming. A more efficient data collection system could be considered. A solution using information technology (such as a web-based tool) in which wholesalers are asked, or obliged, to provide at regular intervals (every two months, for example) price information for defined medicines could have the potential to improve efficiency. It could reduce the length of time required to obtain information and the periods needed for recalculation. It would also allow authorities to request price information targeted to their needs and requirements.
- **Regular review of the reimbursement list and corrective action should be undertaken.** Decisions on reimbursement reflect national prioritization in the delivery of health care within budgetary constraints. Since both health priorities and economic parameters (affecting the available budget) change over time, performing regular revisions of reimbursement lists to account for current developments is recommended.
- **Medicines should be aligned better with priority diseases.** An analysis of ADP medicines in comparison to the WHO EML suggested opportunities for better alignment of ADP medicines with priority diseases. It is recommended that authorities consider updating legislation regarding the criteria and processes for listing and delisting of medicines in the reimbursement list, in particular to align the inclusion criteria better with priority diseases. While exemptions can be justified in specific cases, the composition of the ADP list should, in general, be aligned with the most recent WHO EML. In this context, development of clinical guidelines for selected diseases that will also serve as an evidence base for reimbursement decisions is also suggested.
- **INN prescribing should be enforced.** INN prescribing is a widely used demand-side generic policy and can – either as standalone measure or in combination with generic substitution – contribute to the uptake of generic and other lower-priced medicines. It is mandatory in Kyrgyzstan under the ADP. Nevertheless, in practice doctors were reported to prefer prescribing by trade names instead

of INNs; this may be because the ADP list also includes trade names. Enhancing INN prescribing is recommended – for example, through prescription monitoring. This could be realized through existing procedures, as doctors have to keep digital records of prescriptions sent to the MHIF. Another possible option to enforce INN prescribing is defining prescription targets for doctors (for example, requiring doctors to prescribe a given proportion of generics, the targets being linked to the doctor's speciality). Enforcement of INN prescribing and of further measures to enhance generics uptake should always be seen in connection with awareness of health professionals and patients about generics, their trust in the quality of generics and the actual quality of generic medicines (see below).

- **A fully fledged reference price system should be established.** While the current reimbursement system contains elements of IPR (i.e. the same baseline prices for INNs) and could thus be considered IPR at ATC level 5, expansion into a fully fledged IPR system, with updated methodology and clusters at ATC level 4, could be considered as a policy option for multisource medicines. Implementation of a reference price system on a pilot basis for a group of medicines (for example, cardiovascular medicines) to assess the budgetary impacts is recommended.
- **Generic substitution should be enforced, with creation of appropriate incentives.** While pharmacists have the right to substitute prescribed medicines by generics, they are often reluctant to do so. Since retail mark-ups/margins are not regulated, they have no incentive to dispense the cheapest treatment option. Enforcement of generic substitution could include making it mandatory. Another option is regulation of pharmacy remuneration that is not, or is less, dependent on the medicine price (for example, regressive mark-ups/margins and dispensing fees), allowing pharmacists to keep and reinvest savings from generic substitution into the pharmacy (see also the recommendations related to pharmacy remuneration in sections 5.4 and 6). To improve trust in generic substitution, this should be allowed only for trained pharmacists and for no other staff in pharmacies.
- **Quality control of generics should be ensured.** A prerequisite for INN prescribing and generic substitution is that generics of adequate quality are made available and that providers and patients trust their quality. This task is related to the role of the NMRA, which, according to some health care professionals interviewed, has room for improvement. Thus, action is needed on quality improvements in the regulatory field: the NMRA should be strengthened with regard to dossier assessment (such as introduction of therapeutic equivalence evaluation) and more effective inspection and enforcement. For instance, the NMRA's mandate on inspections is limited because the entity to be inspected has to be notified 10 days in advance.
- **Awareness and knowledge of generics should be enhanced.** To enforce demand-side measures it is necessary to build trust in generics among patients and health professionals. Public campaigns and capacity-building among health professionals could help change the perception of generics, but awareness-raising measures can only be successful if the quality and bioequivalence of generics are proven. Thus, recommended action in this field again includes strengthening the NMRA's mandate in showing bioequivalence for generics (as discussed above), as well as dissemination activities concerning quality assurance.
- **The ban on DTCA of medicines should be enforced.** Policy-makers are requested to enforce legislation that prohibits DTCA of prescription-only medicines, as interviewees reported anecdotes of observed cases. Dissemination activities targeting patients are recommended.
- While the double-tier approach of documentation in the current reimbursement system is linked to labour- and time-intensive administrative processes, policy-makers could also take advantage of it, considering it as a stage on the path towards e-prescribing. **Developing and implementing web-based solutions for prescribing and dispensing medicines** could streamline procedures, reduce the administrative burden and support necessary monitoring activities. Before implementation of an electronic system, however, it should be ensured that doctors and pharmacists in remote areas are technically appropriately equipped.

5. Analysis of OOP payments for medicines

There are indications of high and increasing OOP payments for medicines in the Kyrgyz outpatient sector. These include payments for non-funded medicines (for which patients have to pay OOP in full) and co-payments for reimbursed medicines on the ADP list. In addition, informal payments can play a role. Evidence is scant on the extent and development of OOP payments for outpatients, however.

According to the latest (outdated) data, in 2008 private pharmaceutical expenditure accounted for 75% of total pharmaceutical expenditure (18). In 2014 the average amount paid for medicines within the last 30 days was around KGS 750 (US\$ 13.98). Almost 25% of the population purchased at least one non-prescribed medicine during that year (9). In contrast, the average monthly salary in 2013 was around KGS 12 285 (US\$ 228.94) (30). The mean informal payment for medicines among those who paid was estimated to be KGS 827 (US\$ 17.08) (8).

According to data provided by the NMRA, the value of all imported medicines to Kyrgyzstan amounted to KGS 10.3 billion (US\$ 159.7 million; €143.9 million¹⁵) in 2015. Under the assumption that the proportion of private spending on medicines remained unchanged, a considerable share – i.e. KGS 7.7 billion (US\$ 119.4 million; €107.6 million) – of import value (which would translate roughly to KGS 10.4 billion at the retail level¹⁶) was paid OOP in full by patients. The respective figure for co-payments for medicines prescribed and dispensed under the ADP amounted to KGS 221.9 million (US\$ 3.4 million; €3.1 million).

To study possible causes of high OOP payments, the following methodological approaches were used. A major part of the analysis was based on a dataset provided by the MHIF giving details of medicines prescribed and dispensed under the ADP in the period 2013–2015. The dataset included the names of the medicines, their pharmacy retail prices, information about volumes prescribed and the region where they were dispensed. The available data only allowed analysis of formal co-payments for medicines under the ADP. This refers to a small proportion of medicines available in Kyrgyzstan (see section 4.4). Besides these co-payments for reimbursed medicines, OOP payments for non-reimbursed medicines also exist. Their amount is not known, however, and cannot be assessed through the ADP dataset.

Section 5.1 describes developments related to prescriptions, price levels and reimbursement amounts for medicines under the ADP; these are relevant to understand the ADP spectrum analysed. Section 5.2 analyses co-payments for ADP medicines by ATC group and region and over time. Since exchange rate changes were reported to have hit the Kyrgyz economy considerably, exchange rate developments as a possible cause for high OOP payments for medicines are studied in section 5.3.

5.1 Developments under the ADP

5.1.1 Prescriptions under the ADP

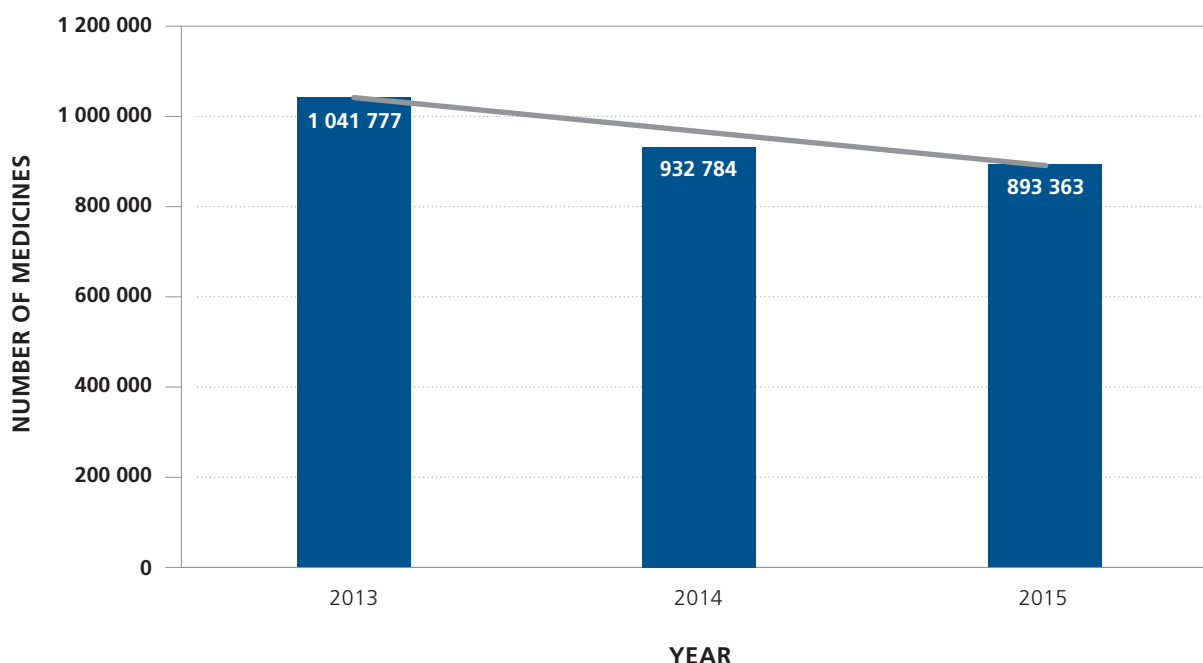
This section analyses the number of prescribed and dispensed medicines under the ADP (partial reimbursement) declared during the period 2013–2015. In 2013, the MHIF counted 1 041 777

¹⁵ Based on annual average exchange rates between the Kyrgyz som and US dollar or euro, provided by the Kyrgyz National Bank.

¹⁶ A 2004 price survey concluded that average wholesale mark-ups amounted to 15% and average retail mark-ups to 20% in the private sector.

prescriptions of medicines that were partly reimbursed. One year later, the figure dropped by more than 100 000 prescriptions to 932 784 and it continued to fall, reaching 893 363 prescriptions in 2015. This corresponds to a drop by 14.2% between 2013 and 2015 (Fig. 9).

Fig. 9 | Medicines prescribed and dispensed under the ADP in all regions, 2013–2015



Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

The decline was not evenly distributed across regions, since some oblasts experienced steeper drops than others (Fig. 10). The changes were considerable, particularly in Osh, the country's second largest city, and its surrounding region. From 2013 to 2014 the number of prescriptions fell in the city by more than a third (35.3%), and in Osh Oblast it decreased by almost a fifth (18.1%). In total figures, the reduction was equal to 27 398 prescriptions in the city and 45 918 in Osh Oblast. The reduction in other regions ranged from 4.33% in Chuy Oblast to 7.67% in Talas Oblast. There was one major exception, however: Bishkek. In the capital city the number of prescribed medicines dispensed remained virtually unchanged.

From 2014 to 2015 the change in number of dispensed medicines was even more dispersed. While in some districts the number increased (10.3% in Talas Oblast and 3.2% in Jalal-Abad Oblast), all other districts experienced a further reduction, with the largest in Chuy Oblast (20%). Chuy Oblast also had the lowest number of prescriptions per 100 000 inhabitants (8367) among Kyrgyz regions in 2015.

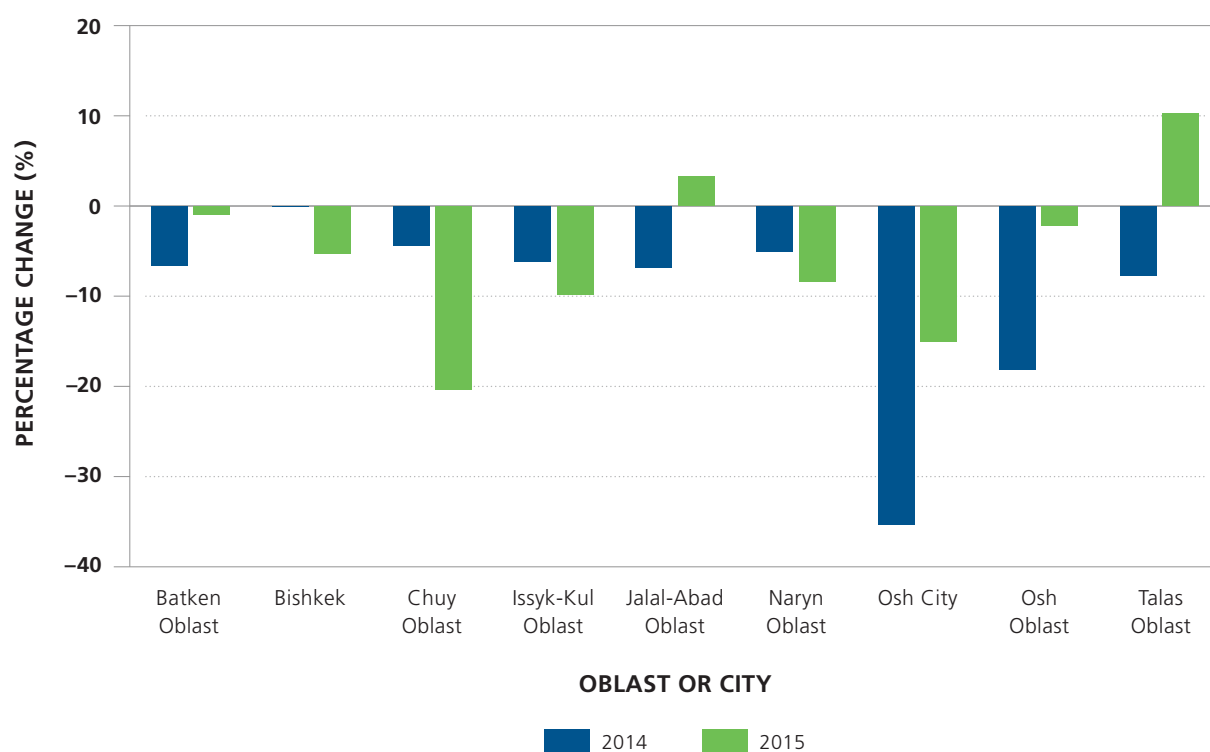
Following up on the analysis of the development of prescribed and dispensed medicines under the ADP by ATC group in section 4.5 (Fig. 7 and Fig. 8), Fig. 11 illustrates the absolute figures for 2013–2015.

5.1.2 Average prices of prescribed medicines

This section describes the study's estimation of the average prices of prescribed and dispensed ADP medicines. The indicator is based on the sum of prices of a medicine per prescription (at INN level) within an ATC group, divided by the number of medicines in a group.¹⁷ The calculation method has

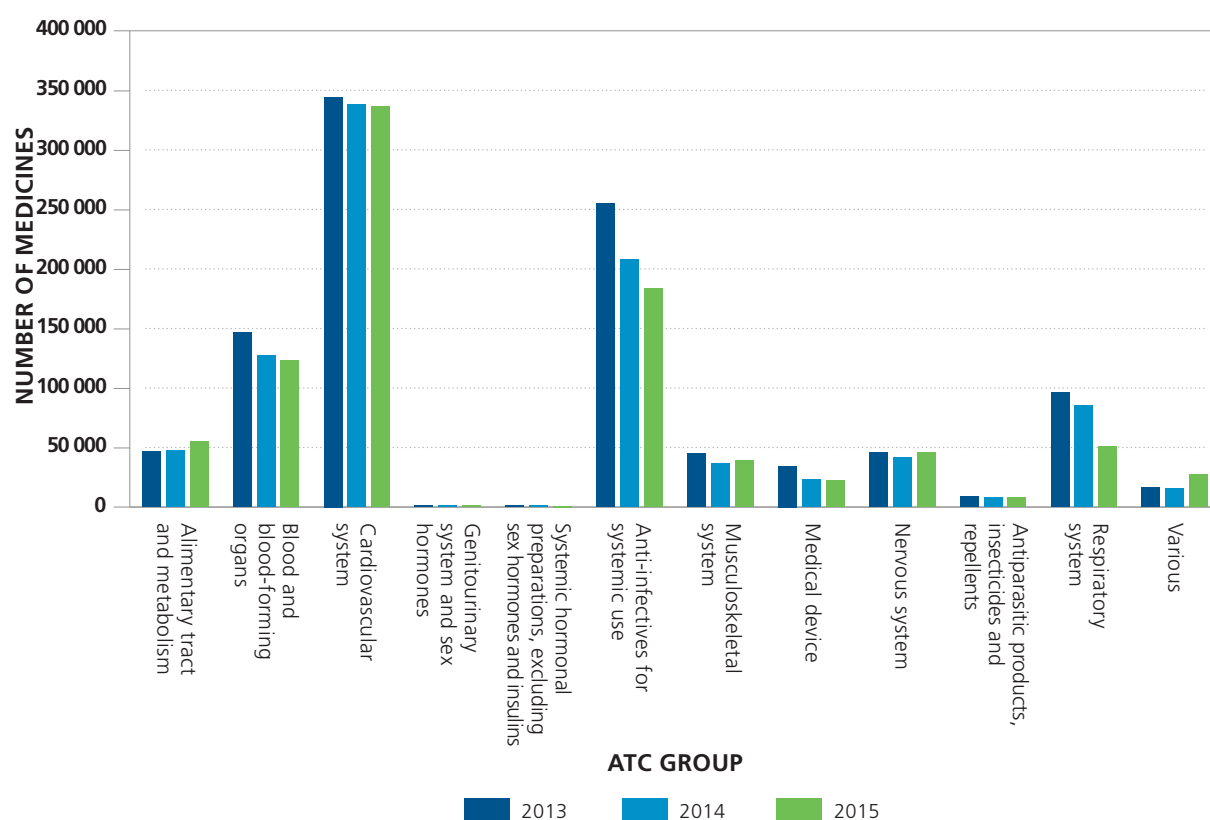
¹⁷ Total expenditure on each active ingredient (public and private fractions) is divided by the number of prescriptions, indicating the expenditure per prescription. The expenditures on medicines in the same ATC group are then added and divided by the number of medicines in this group; this gives an approximation of the average price in the group.

Fig. 10 | Regional variation in changes from the previous year in numbers of medicines prescribed and dispensed under the ADP



Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

Fig. 11 | Numbers of medicines prescribed and dispensed under the ADP, by ATC group, 2013–2015



Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

KEY FINDINGS

- In 2015 fewer medicines were prescribed and dispensed under the ADP. The reduction amounted to 14%.
- The reduction of prescriptions under the ADP was not **evenly distributed across regions**. The city of Osh experienced the steepest drop in prescriptions, followed by Chuy Oblast and Osh Oblast.
- The number of medicines prescribed and dispensed under the ADP **varied between the ATC groups**. Anti-infectives (ATC group J) experienced large reductions, whereas the number of cardiovascular medicines remained stable.
- While there was a general decline in prescriptions dispensed under the ADP between 2013 and 2015, **the extent of the decline varied over time**. From 2013 to 2014 almost all regions (except Bishkek) recorded decreases. In the following year, some regions faced substantial reductions, while the number of prescribed and dispensed ADP medicines increased in other regions.

limitations,¹⁸ and due to its methodology a rise in average price could be indicative of either higher prices or lower numbers of prescriptions in certain ATC groups; or both. Details of the number and prices of prescriptions can be found in Table 6.

Table 6 | Number of prescriptions dispensed under the ADP, by ATC group and average price, 2013–2015

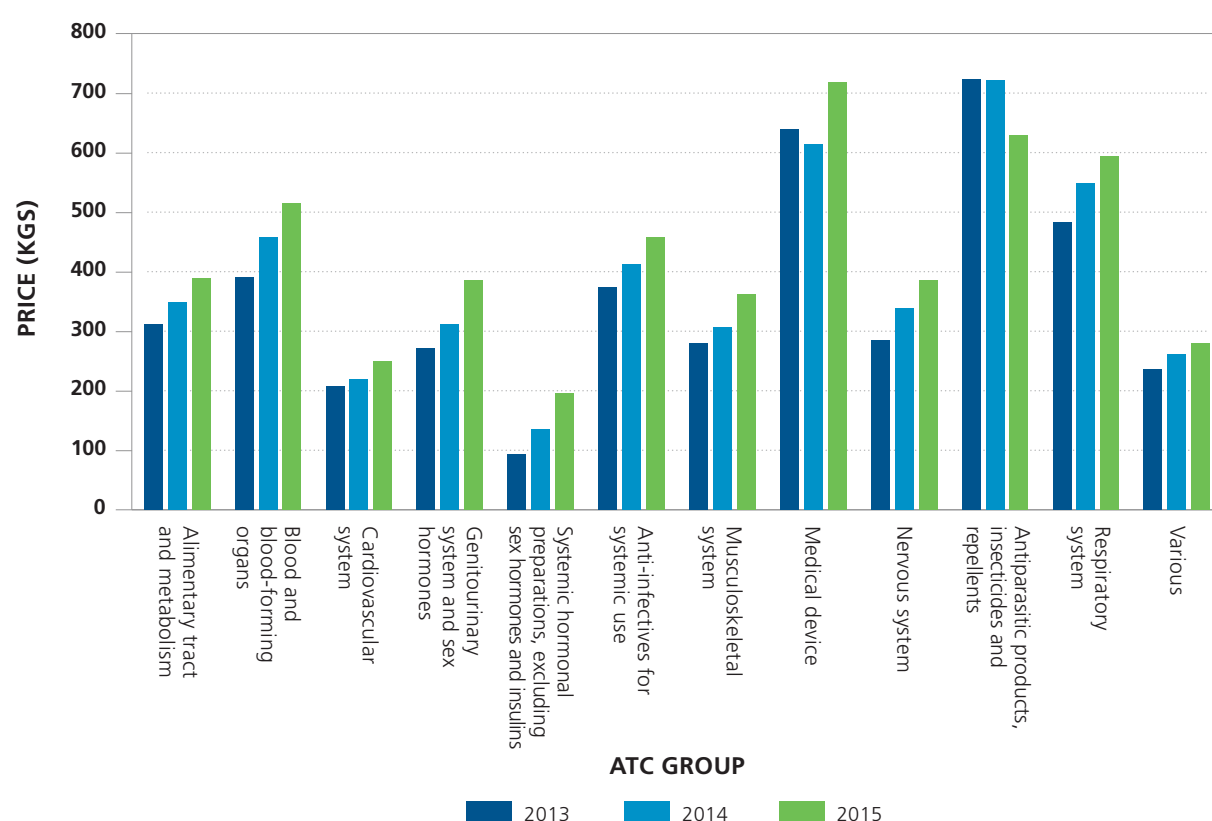
ATC group	2013		2014		2015	
	Number of prescriptions	Average price per prescription (KGS)	Number of prescriptions	Average price per prescription (KGS)	Number of prescriptions	Average price per prescription (KGS)
Alimentary tract and metabolism	46 728	311.03	47 386	348.38	55 383	389.11
Blood and blood-forming organs	146 496	391.23	127 412	457.87	123 460	514.27
Cardiovascular system	344 436	207.07	338 055	218.64	336 269	249.26
Genitourinary system and sex hormones	1 290	272.08	1 006	311.34	1 276	385.86
Systemic hormonal preparations, excluding sex hormones and insulins	1 358	93.67	940	136.01	866	195.32
Anti-infectives for systemic use	254 995	373.72	208 143	413.20	183 283	458.52
Musculoskeletal system	44 746	279.44	36 253	306.16	38 854	362.12
Medical device	34 449	638.44	22 982	614.45	22 280	718.12
Nervous system	46 071	284.73	41 612	339.26	45 661	384.82
Antiparasitic products, insecticides and repellents	8 502	723.07	7 734	721.27	7 891	629.76
Respiratory system	96 287	483.73	85 368	547.93	50 700	593.22
Various	16 419	236.67	15 893	260.85	27 440	279.42

Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

¹⁸ For instance, with regard to classification: medicines in an ATC group are considered part of a homogeneous group, disregarding different packaging or pharmaceutical forms.

In 2013 and 2014 antiparasitic products, insecticides and repellents (ATC group P) showed the highest average price. In 2015 this decreased, while the average price of medical devices (only disposable syringes and glucose test strips are reimbursed under the ADP) increased by KGS 100, meaning that they accounted for the highest average price among all groups. The number of prescriptions for medical devices under the ADP declined by more than 12 000 (from 34 449 to 22 280) between 2013 and 2015, which suggests a large increase in prices. The lowest average price over the three years was observed for systemic hormonal preparations (ATC group H), but this also showed some increases (Fig. 12).

Fig. 12 | Average prices of medicines prescribed and dispensed under the ADP, by ATC group, 2013–2015



Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

The most striking fact apparent from Fig. 12 is the increase in average prices in all ATC groups except P between 2013 and 2015. The increases ranged from KGS 42 for ATC group C (a 20% increase) to KGS 123 (a 31% increase) for ATC group B. Over the period the number of prescriptions decreased in all ATC groups except A and V. The average price per prescription depends on a volume component and a price component. While in some cases the volume component seems to be the main driver of a higher average price (as in ATC group J), in other cases the main driver appears to be growth in medicine prices (as in ATC group C). Both components could also have an impact at the same time.

5.1.3 Amounts reimbursed per prescription

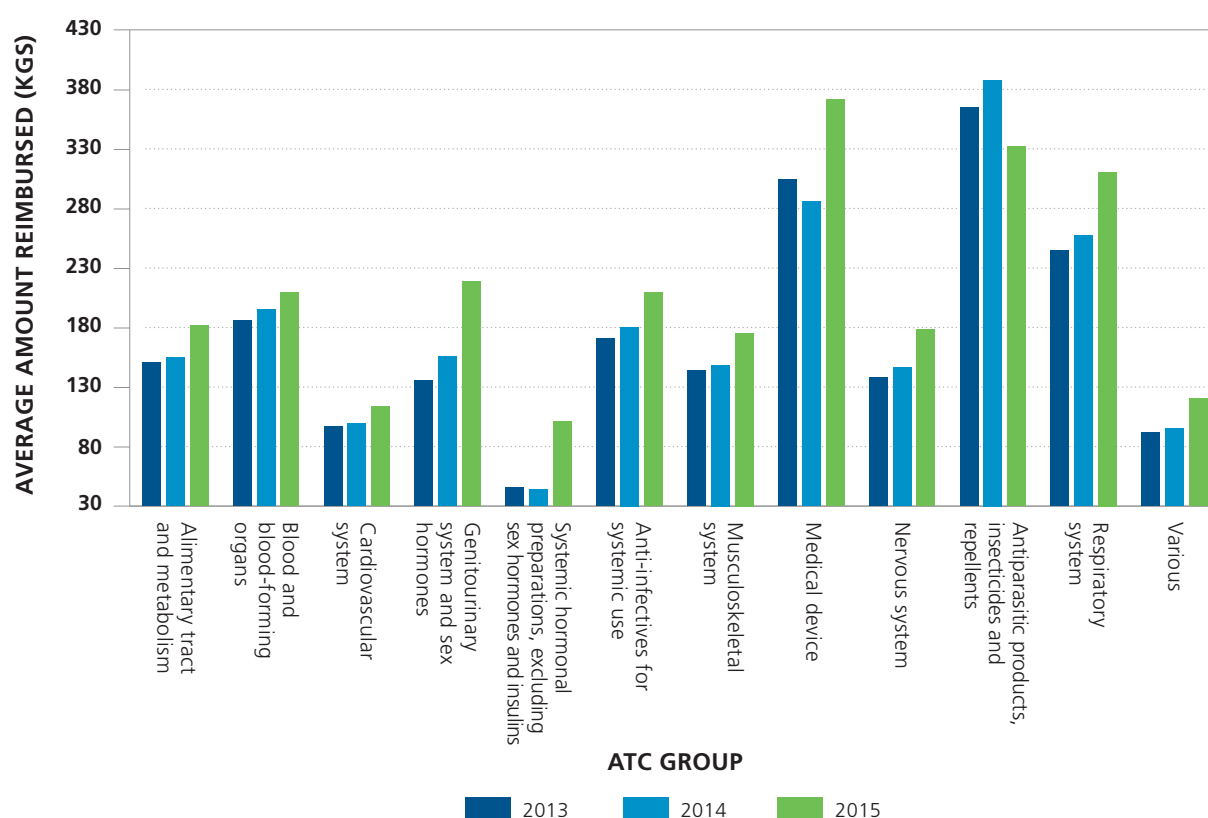
A similar indicator to the one used to collect average prices (section 5.1.2) was created to estimate the amounts reimbursed for INNs within an ATC group. For each prescribed medicine under the ADP the

KEY FINDINGS

- Between 2013 and 2015 **average prices for medicines included in the ADP list rose**. The increases ranged from KGS 42 for ATC group C (a 20% increase) to KGS 123 (a 31% increase) for ATC group B.
- **Different drivers affect the increases in average prices.** While for some medicines the increase appears to result from medicine price increases, it seems attributable to a reduction in the number of prescriptions in the case of antibiotics.

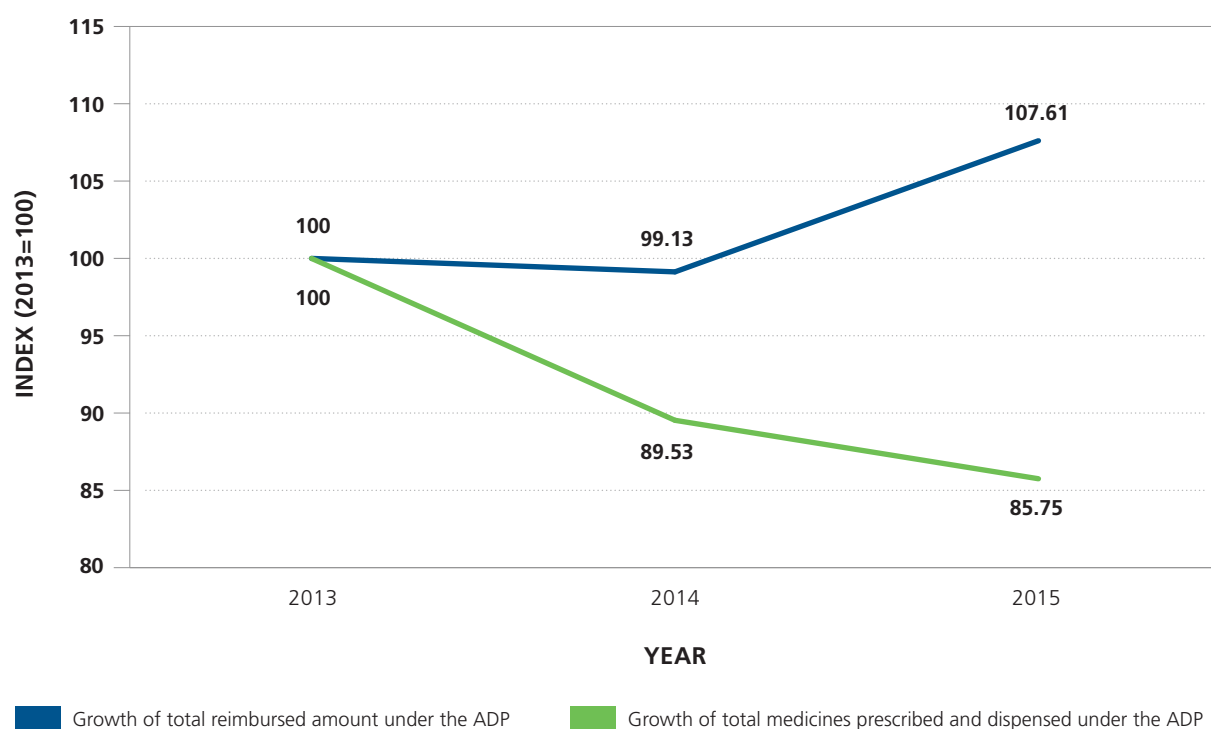
reimbursed amount in Kyrgyz som was collated and divided by the number of prescriptions. The same limitations apply as for the other indicator, and similar patterns can be observed. The highest average amount reimbursed per prescription in 2013–2015 was in ATC group P and the lowest in ATC group H. Overall, the average amounts reimbursed per prescription increased in nearly all ATC groups (Fig. 13).

Fig. 13 | Average amounts reimbursed per medicine prescribed and dispensed under the ADP, by ATC group, 2013–2015



Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

Between 2013 and 2015 MHIF expenditure to cover medicines prescribed and dispensed under the ADP increased by 7.5% (Fig. 14). By contrast, the number of prescribed medicines declined in the same period (see section 5.1.1). In 2014 this figure was 10% lower than in 2013, and in 2015 the trend continued (with almost 15% fewer prescriptions than in 2013). One explanation for this growing disparity could be the prescribing ceiling explained in section 4.3: when doctors reach the ceiling, the number of prescriptions is reduced. In situations of increasing medicine prices this ceiling is reached earlier.

Fig. 14 | Variation in amounts reimbursed and number of medicines prescribed and dispensed under the ADP, 2013–2015

Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

KEY FINDINGS

- The **average reimbursed amount per prescribed medicine increased** in nearly all ATC groups.
- Between 2013 and 2015, MHIF expenditures to cover medicines on the ADP list increased, while the number of medicines prescribed and dispensed declined over the same time, meaning that **more money was spent on fewer medicines**.

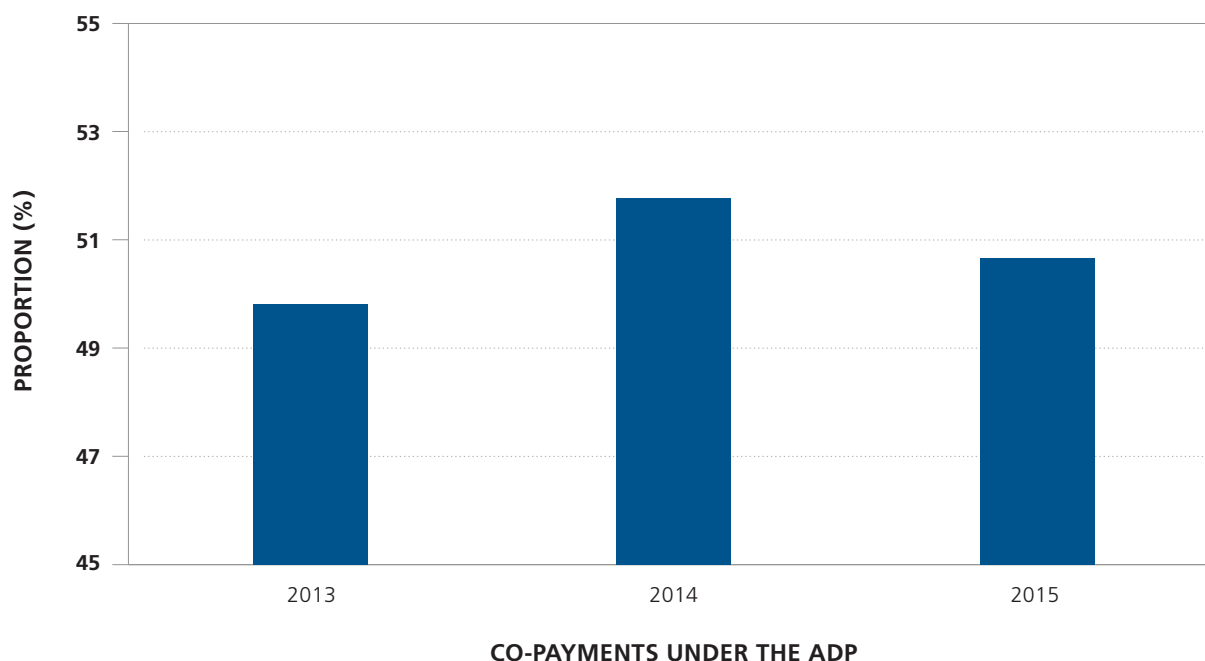
5.2 Relevance of co-payments

5.2.1 Share of co-payments

In 2013 the share of co-payments for medicines dispensed under the ADP was on average 49.8%. In 2014, it increased by two percentage points to 51.8%, then fell to 50.7% in 2015 (Fig. 15).

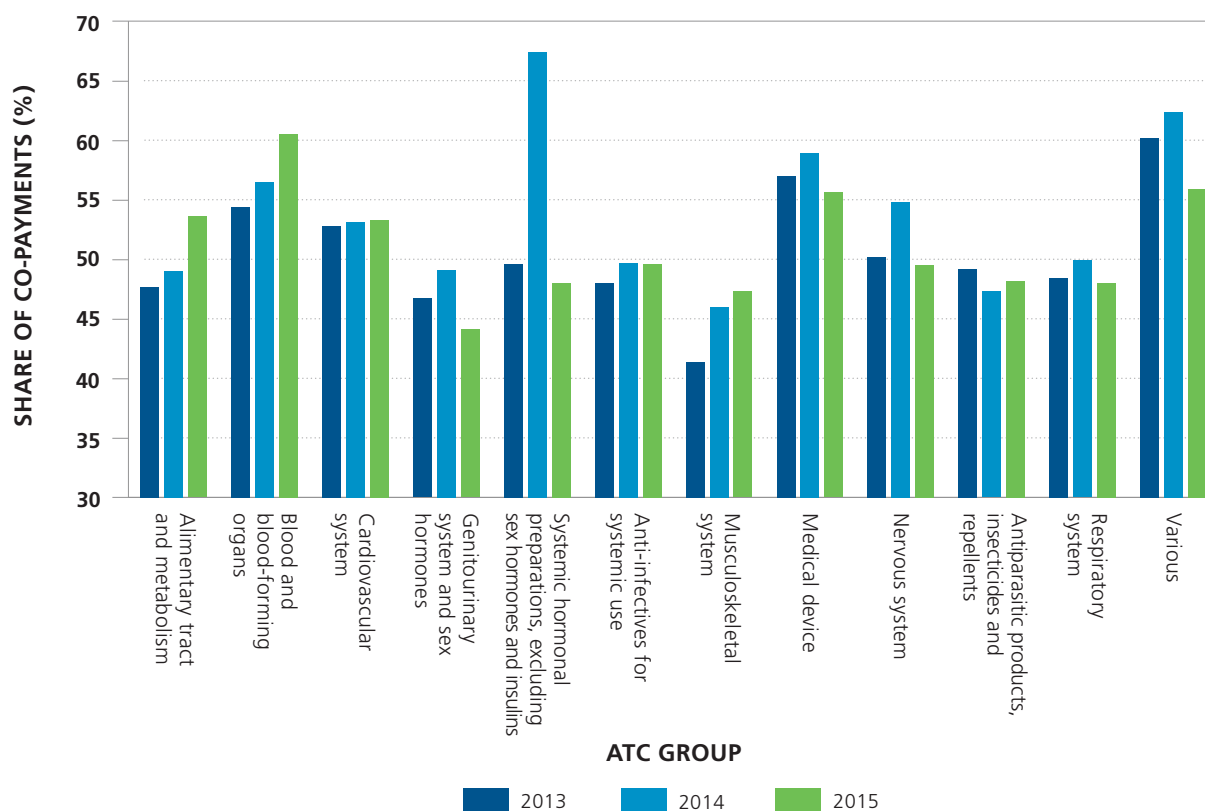
The average shares of co-payments per ATC group are presented in Fig. 16. For medicines most frequently prescribed and dispensed the developments appear comparably moderate and stable. The share of co-payments for medicines to treat cardiovascular diseases (ATC group C) only increased slightly, from 52.8% in 2013 to 53.3% in 2015. Similar developments were observed for anti-infectives (ATC group J). Although the share of co-payment increased by 1.7 percentage points between 2013 and 2014, it remained at 49.6% in the following year.

It is important to relate these trends to the number of prescriptions per ATC group. Among the three groups with a large number of prescriptions (B, C and J) only medicines for diseases related to blood

Fig. 15 | Share of co-payments for medicines prescribed and dispensed under the ADP, 2013–2015

Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

and blood-forming organs experienced a large increase. In 2013 the average share of co-payments for those medicines was around 54.4%; this increased to 60.5% in 2015. The most striking change

Fig. 16 | Share of co-payments for medicines prescribed and dispensed under the ADP, by ATC group, 2013–2015

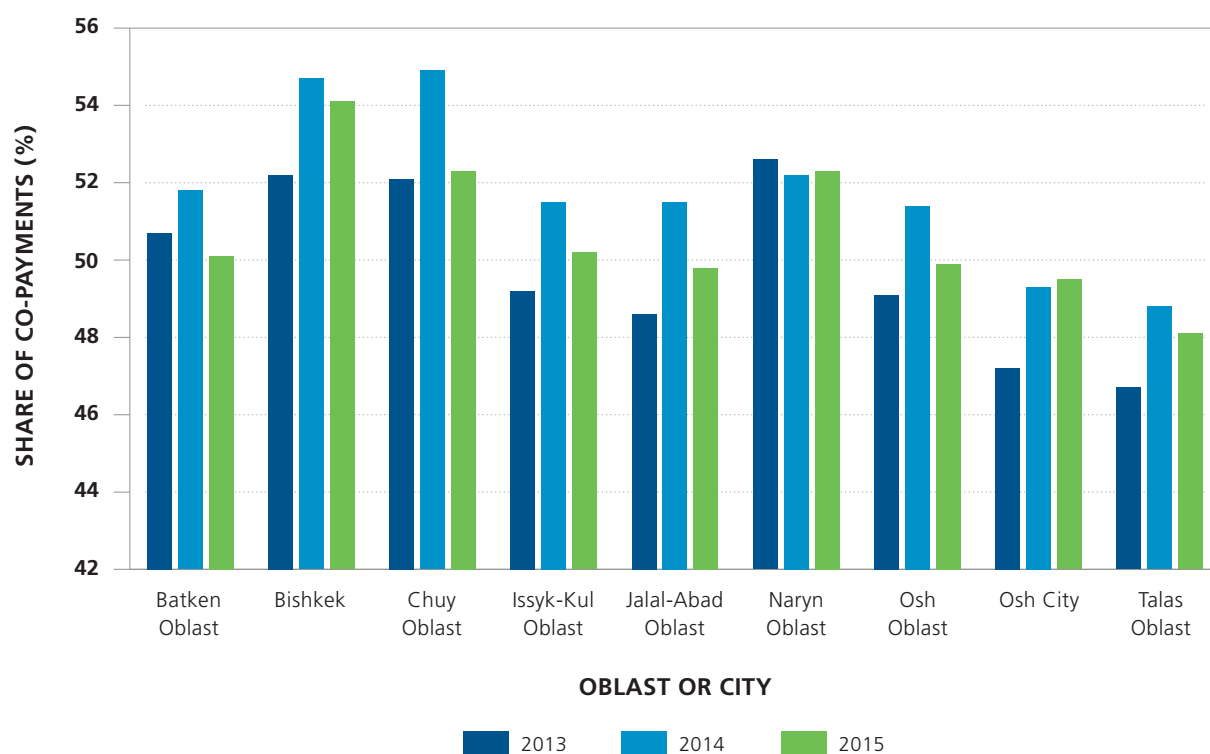
Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

over the period occurred in ATC group H (steroids): in 2013 the average share of co-payments was around 50%; it grew to 67% in 2014 but fell to 48% in 2015. The large increase in co-payments also coincided with a reduction in the number of prescriptions. In 2013, 1358 steroids prescriptions were dispensed; one year later it was around 913 and it decreased further to 839 in 2015. In relation to the total number of prescriptions, however, medicines from ATC group H play a minor role.¹⁹

As explained in section 4.1, the MHIF sets two different baseline prices, with the aim of adjusting for regional variation. The rationale is to create incentives to supply medicines in remote areas and thus improve access to medicines in those – often low-income – sectors. As a result, baseline prices in remote areas tend to be higher and should thus facilitate lower co-payments. This is not necessarily the case, however, because the cost of transportation may offset higher baseline prices. Such patterns were observed in several regions in Kyrgyzstan (Fig. 17). If the number of inhabitants per km² is taken as an approximation to classify remote regions, the most densely populated regions are the cities of Bishkek (5 514 inhabitants/km²) and Osh (1 477 inhabitants/km²). Although Chuy Oblast surrounds Bishkek, it has higher co-payment shares than other regions. Co-payment proportions in Osh Oblast are among the third lowest among all Kyrgyz regions. Scarcely populated regions are Naryn Oblast (6 inhabitants/km²), Issyk-Kul Oblast (10 inhabitants/km²) and Talas Oblast (18 inhabitants/km²). While Issyk-Kul Oblast and Talas Oblast have lower shares of co-payments, Naryn Oblast – which is the least populated and also considered the poorest region in the country – has consistently higher co-payments.

The majority of regions experienced increases in their co-payment shares between 2013 and 2014, with growth ranging from 1.1 to 2.8 percentage points. The only exemption was Naryn Oblast, where co-payments decreased slightly in the period. From 2014 to 2015, co-payment shares decreased reaching levels between the 2013 and 2014 values in most regions. In Osh Oblast and Naryn Oblast co-payments increased slightly between 2014 and 2015 (Fig. 17).

Fig. 17 | Share of co-payments of medicines prescribed and dispensed under the ADP, by region, 2013–2015



Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

¹⁹ The low number of prescriptions may also explain the large variations in average co-payments.

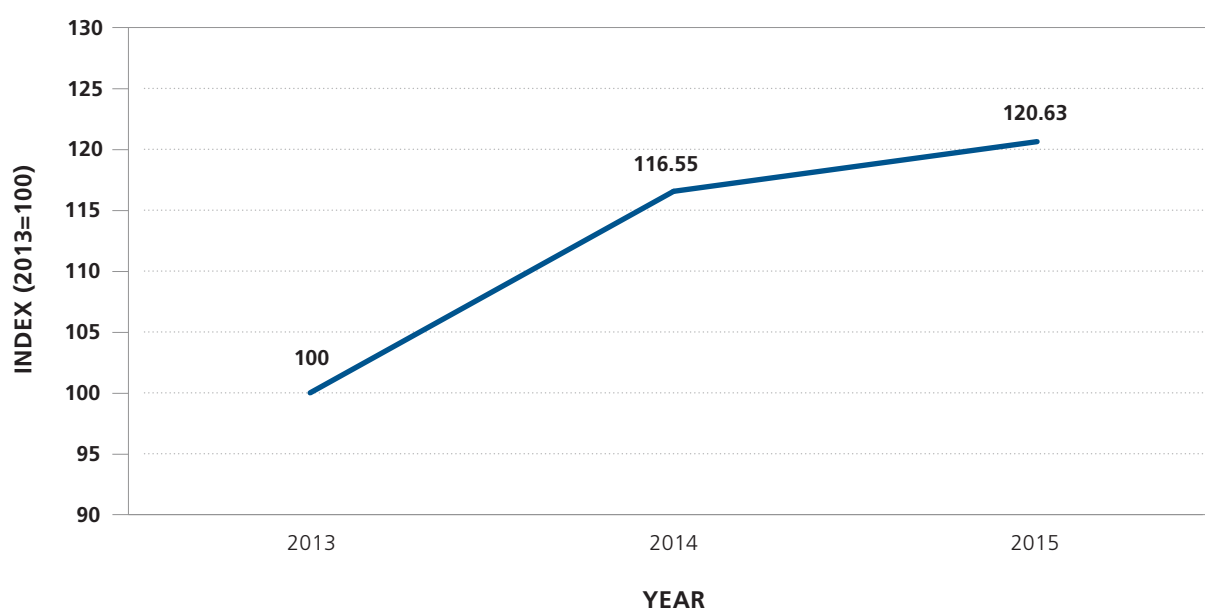
KEY FINDINGS

- The **average share of co-payments for all medicines under the ADP** amounted 50.7% in 2015. This corresponds to an increase of one percentage point compared to 2013.

5.2.2 Growth of co-payments

During the period examined, co-payments for prescribed and dispensed medicines under the ADP increased by 20%. There was a steep increase in 2014, which slowed down in 2015 (Fig. 18). This is a concerning trend, however, as poor households usually have a higher prevalence of disease and suffer more from increased co-payments. A recent WHO analysis examined general (formal and informal) OOP payments in the Kyrgyz health system between 2000 and 2015. Its main finding was that OOP payments had steadily increased over the 15 years and that the financial burden among users particularly affected the poor, especially in the urban areas of Bishkek and Osh.²⁰

Fig. 18 | Growth of patients' co-payments for medicines prescribed and dispensed under the ADP, 2013–2015



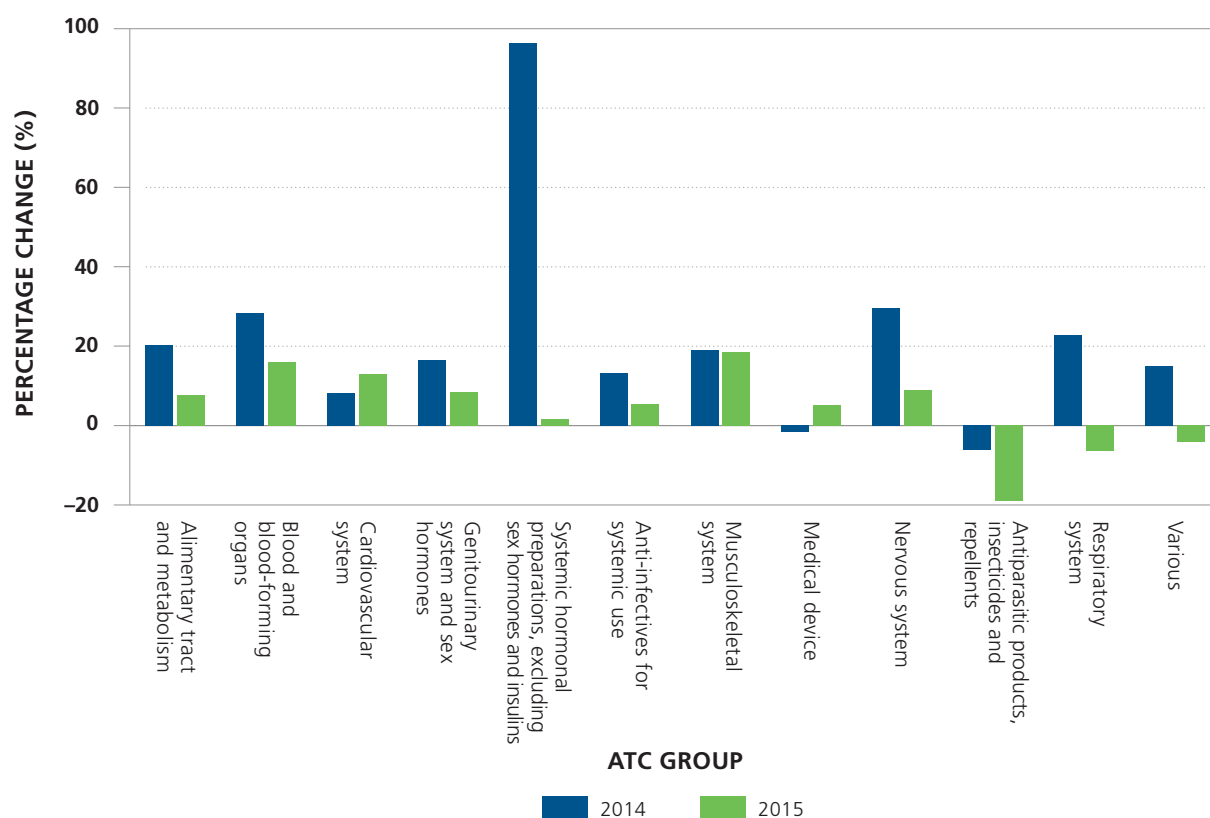
Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

Across almost all ATC groups, the growth of co-payments was larger in 2014 than in 2015. The largest increase occurred for medicines in ATC group H (Fig. 19).

From 2013 to 2015, most patients across Kyrgyz regions faced continuous growth of co-payments for medicines (Fig. 20). Only the city of Osh had a large reduction in co-payments in 2015, but this trend needs to be seen in the context of prescribing patterns: the number of prescribed and dispensed medicines almost halved in the city of Osh during the period examined (see section 5.1.1), reducing access to medicines for patients in the most densely populated area of the country. Overall, higher growth rates of co-payments were observed in 2013–2014 than in 2014–2015 (Fig. 20).

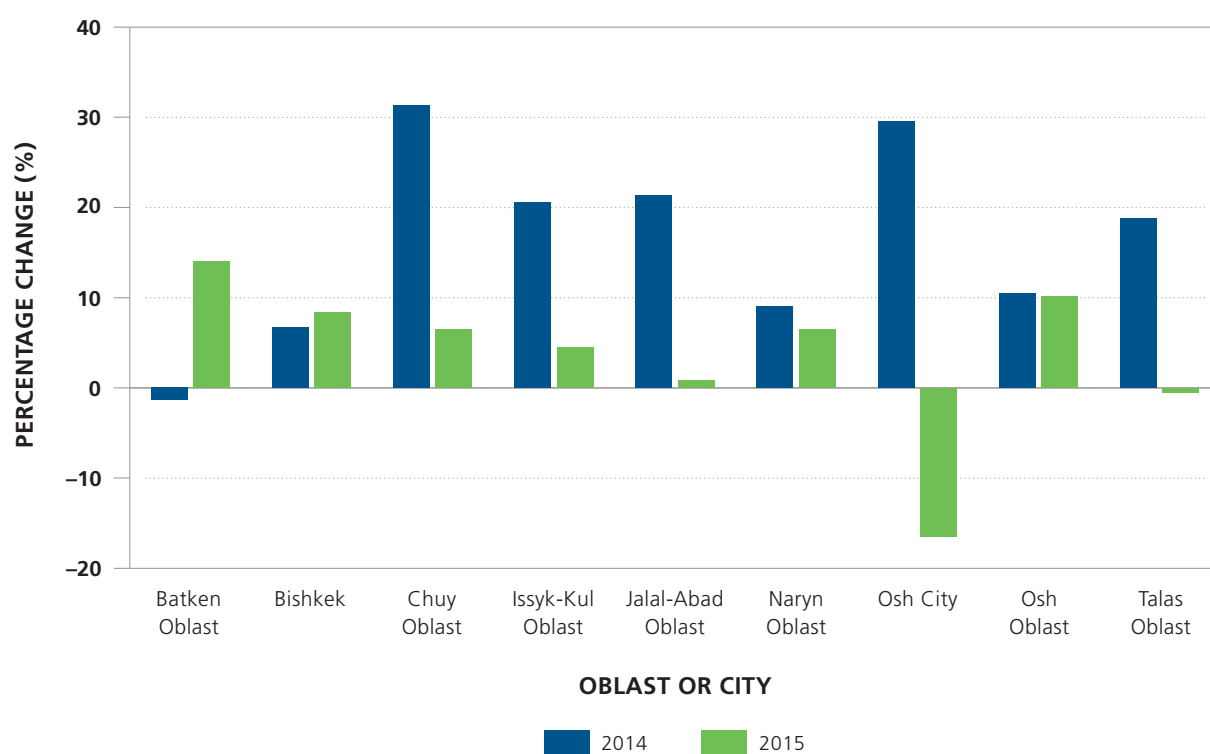
²⁰ Jakab M, Akkazieva B, WHO Regional Office for Europe, unpublished presentation on trends in out of pocket expenditures in Kyrgyzstan: 2000–2015, 2015.

Fig. 19 | Changes from the previous year in co-payments for medicines prescribed and dispensed under the ADP, by ATC group, 2013–2015



Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

Fig. 20 | Changes from the previous year in co-payments for medicines prescribed and dispensed under the ADP, by region, 2013–2015



Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

KEY FINDINGS

- **Variation was seen in growth of co-payments among ATC groups**, including higher growth rates in ATC groups whose medicines had a higher number of prescriptions (A, B, C and J).
- **Regional variation was seen in the growth of co-payments.** Co-payments rose in almost all regions between 2013 and 2015, at higher rates from 2013 and 2014. Between 2013 and 2014 increases of around 30% were observed in Chuy Oblast and the city of Osh.

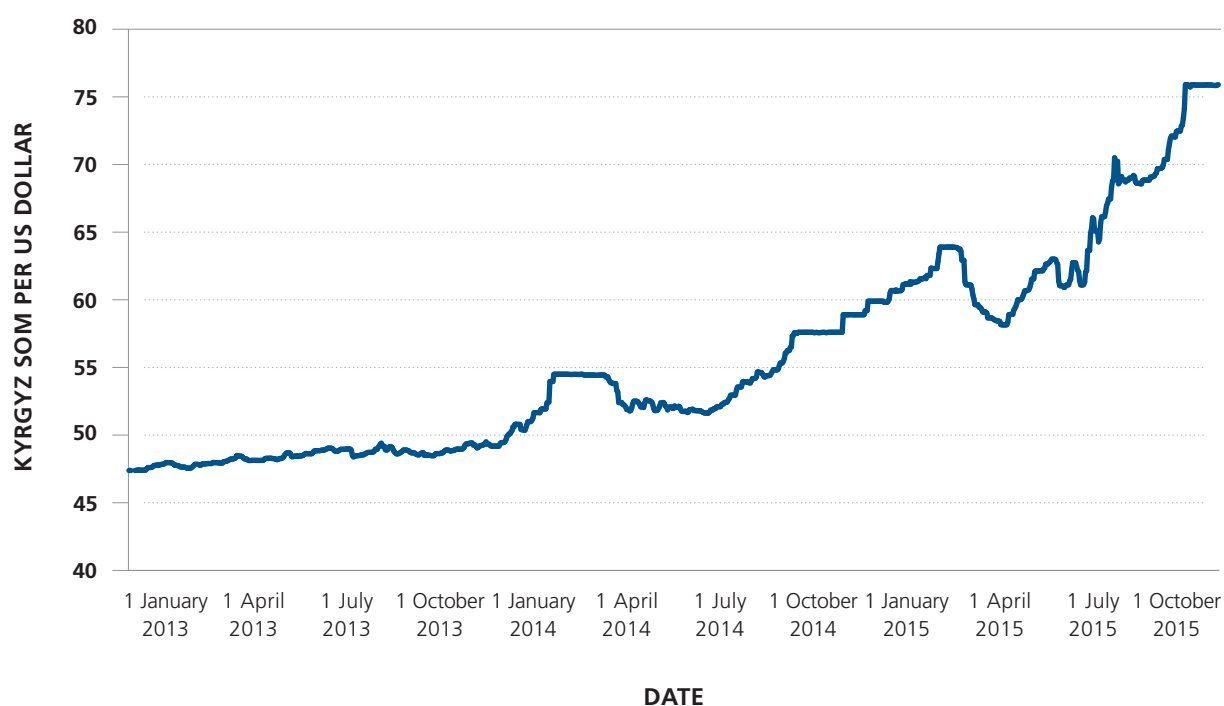
5.3 Exchange rate

During the key stakeholder interviews difficulties in access to medicines during recent years were attributed to changes in the exchange rates between the Kyrgyz som and both the US dollar and the Russian rouble. Representatives from wholesalers and producers highlighted two enforcing effects.

- Since 2014 the Russian economy has been in crisis, resulting in depreciation of the Russian rouble against the US dollar. As the Russian Federation is one of Kyrgyzstan's main trading partners (in both volume and value), the Kyrgyz som also lost value against the US dollar.
- Manufacturers, distributors and wholesalers switched to US dollars rather than Russian roubles when conducting their business.²¹

The development of both these exchange rates, as displayed in Fig. 21 and Fig. 22, confirms statements about exchange rate volatility made in the interviews. In 2013 the exchange rate between the US dollar

Fig. 21 | Development of the US dollar to Kyrgyz som exchange rate, 2013–2015



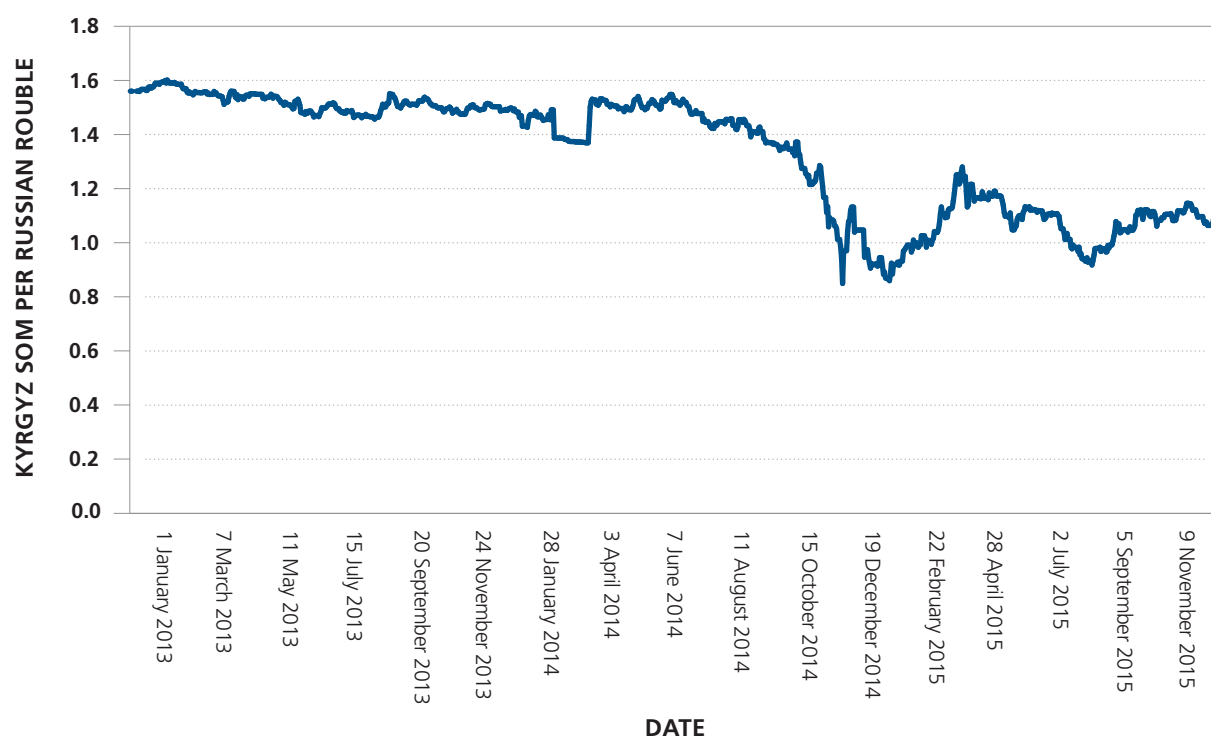
Source: Kyrgyz National Bank.

²¹ In general, international contracts tend to be denoted in currencies that offer the advantage of high convertibility – usually US dollars or euros.

and Kyrgyz som had a slight upward trend but was stable around US\$ 1 = KGS 48. Between 2014 and 2015 the Kyrgyz som lost almost half its value against the US dollar and at the end of 2015 the exchange rate was around US\$ 1 = KGS 75.8993.

The opposite development was observed in the exchange rate between the Kyrgyz som and Russian rouble. From the beginning of 2013 to the middle of 2014 it was in the range Rub 1 = KGS 1.5. Thereafter, the Russian rouble continued to devalue against the Kyrgyz som, reaching a low in December 2014 at Rub 1 = KGS 0.8497. The following year the exchange rate was characterized by large fluctuations between KGS 1.28 and KGS 0.86 for one Russian rouble.

Fig. 22 | Development of the Russian rouble to Kyrgyz som exchange rate, 2013–2015



Source: Kyrgyz National Bank.

Data about imported medicines provided by the NMRA were analysed to explore the effects of changes in the exchange rate (Fig. 23). The total value of imported medicines in Kyrgyz som increased from KGS 8.27 billion (US\$ 170 million)²² in 2013 to KGS 10.33 billion (US\$ 160 million) in 2015. The annual proportional increases in the study period were thus of a similar size, amounting to 11.4% in 2014 and 12.1% in 2015.

In 2014 the value of imported medicines, denoted in US dollars, increased by 10.3%, which was around the same level as the value in Kyrgyz som. The following year, however, it decreased by 9% and was around US\$ 156 million in numerical value, reaching almost the same level as in 2013. Calculating an exchange rate with these values yields KGS 1 = US\$ 0.0188 in 2013, KGS 1 = US\$ 0.0186 in 2014 and KGS 1 = US\$ 0.0151 in 2015. This is roughly in line with the observed developments of the exchange rate above. According to professionals in the Kyrgyz health care sector, the economy is to a large extent prone to the problem of “sticky prices”: due to contractual obligations the effects of

²² US dollars calculated at the annual exchange rate of respective year: 2013: US\$ 1 = KGS 48.4386; 2015: US\$ 1 = KGS 64.4797.

price changes lag behind exchange rate changes. The pattern observed in 2014 is probably related to the announcement of Kyrgyzstan's accession to the EEU. The year prior to the accession wholesalers tended to build up stocks, as some EEU regulations concerned medicines. A similar situation was also reported in the automotive sector.

Fig. 23 | Import expenditure on medicines and medical devices in Kyrgyz som and US dollars, 2013–2015

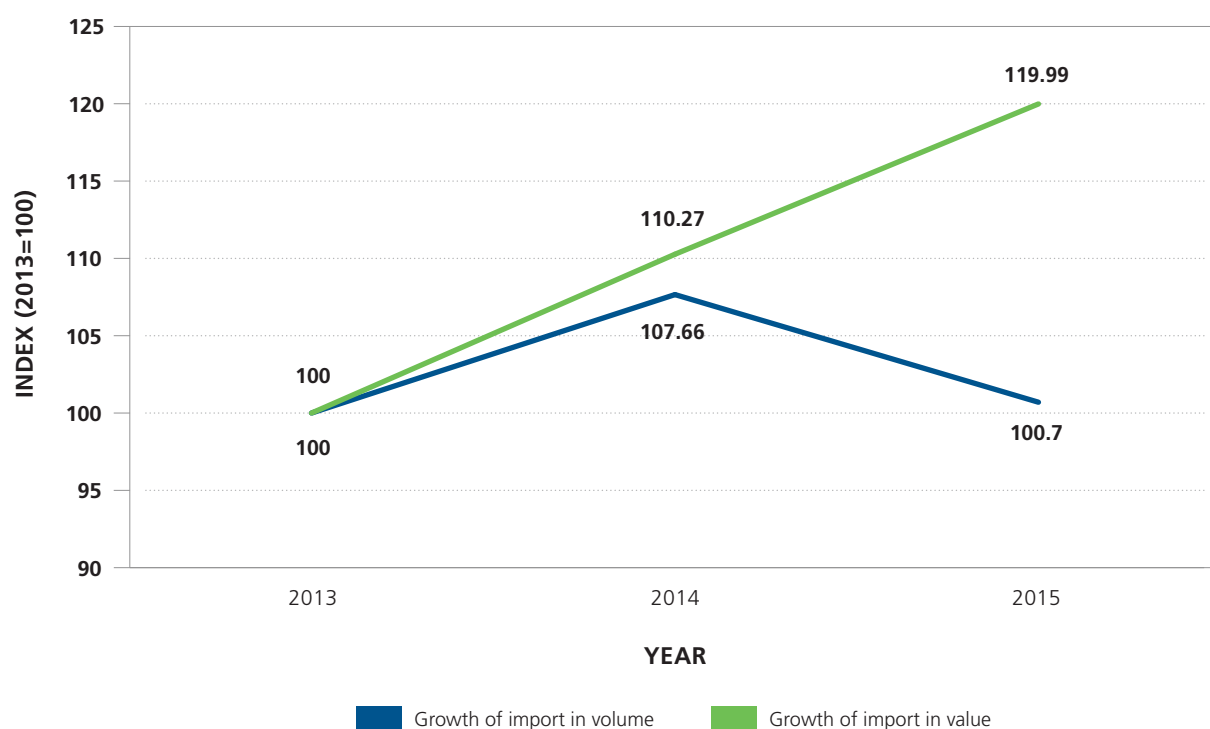


Source: NMRA; analysis undertaken by the WHO Regional Office for Europe.

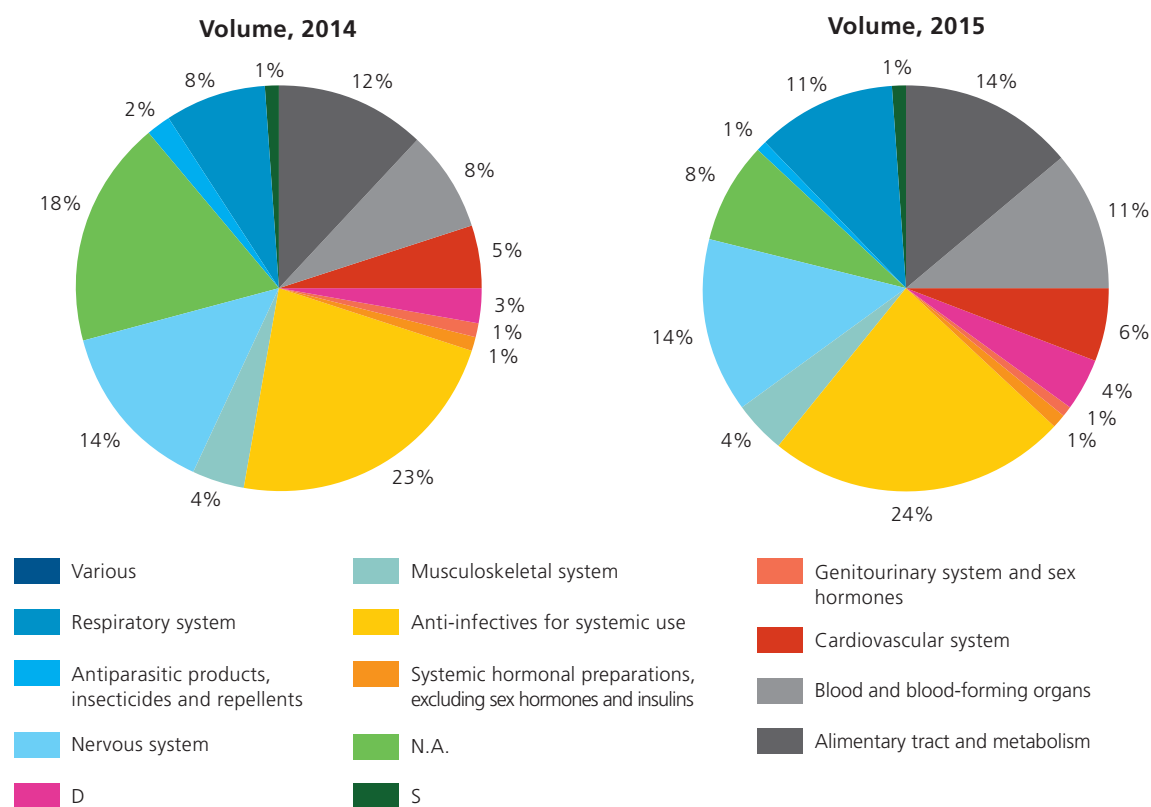
Translating import expenditure on medicines and medical devices denoted in US dollars into growth rates highlights the volatility of exchange rates: while 2015 imports of medicines were at around the same level as in 2013 in terms of volume, Kyrgyzstan had to pay nearly 20% more for this same amount (Fig. 24).

In volume, anti-infectives (ATC group J) constituted the largest group of medicines imported to Kyrgyzstan in 2014 and 2015, accounting for a total of 23% (Fig. 25). In value, these medicines accounted for 13% in 2014 and 10% in 2015 (Fig. 26). These figures suggest a stable share of imports in relation to all other medicines and the value/volume ratio suggests lower prices in relation to other medicines, probably attributed to large utilization of generics.

In general, the volume share of other products seems to be quite similarly distributed. The large reduction in products that could not be assigned to an ATC group between 2014 and 2015 indicates that some progress has been made in reporting and documenting imported medicines. With respect to value, the figures show one striking feature not seen in the volume data: the proportion of medicines to treat cardiovascular diseases considerably increased, with their share of the total value tripling from 8% to 24% between 2014 and 2015. This large volatility in the share of value for ATC C medicines suggests that a very cautious interpretation of the figures is needed. As a result of missing data or errors of coding in the database, all analyses are prone to be biased. Although the documentation has improved over the years, it was not possible to assign a large proportion of medicines to ATC groups.

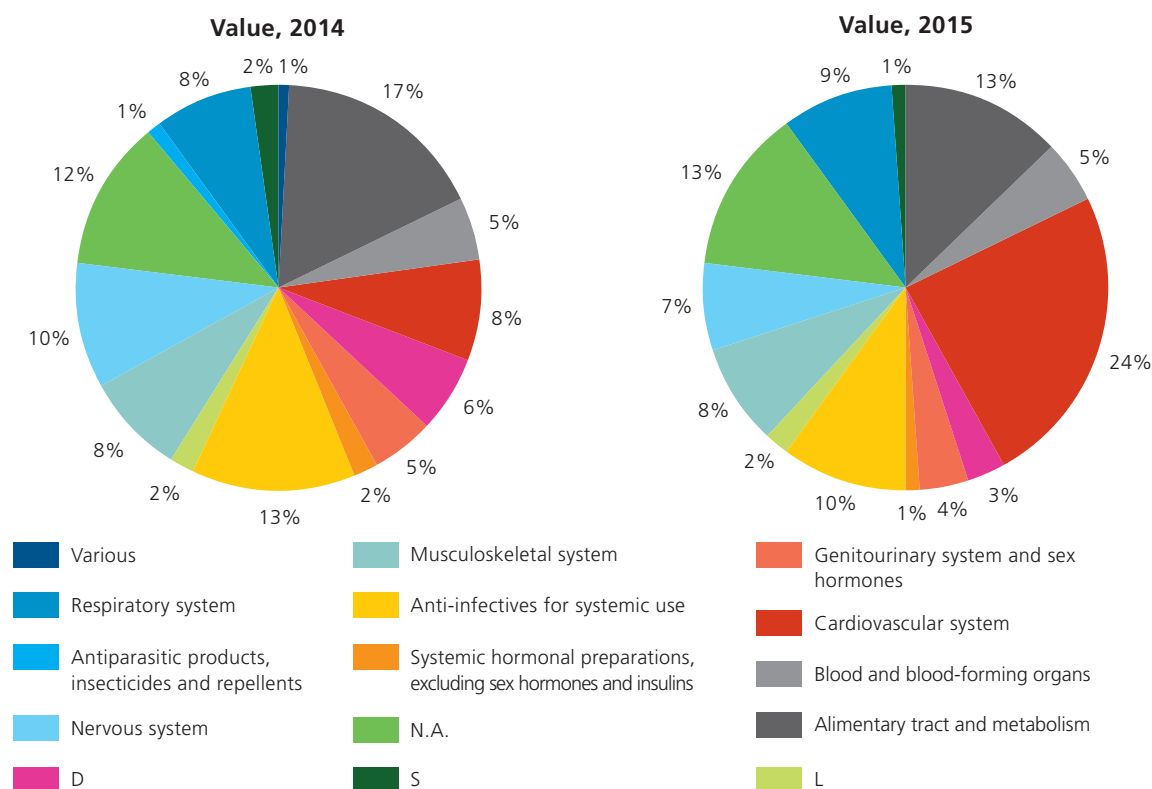
Fig. 24 | Growth in import volumes and import values, 2013–2015

Source: NMRA; analysis undertaken by the WHO Regional Office for Europe.

Fig. 25 | Proportion of the volume of imported medicine, by ATC group, 2014

Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

Fig. 26 | Proportion of the value of imported medicine, by ATC group, 2015



Source: MHIF; analysis undertaken by the WHO Regional Office for Europe.

During key stakeholder interviews, professionals from the Ministry of Health and MHIF indicated that a part of this increase can be explained by procurement and shipment cycles for certain medicines. Since the Kyrgyz market is small, providers' demand for certain medicines is bundled and procurement is done in larger time intervals. Some medicines are procured once a year; others every two years. As bundled medicines are procured from a single provider, such procurement can have relatively large impact on the figures. This is also reflected in Fig. A.1. in the Annex, which shows the proportions of total value of imported medicines classified by country of origin. In 2013 the Russian Federation represented the largest proportion (17%), followed by Germany (15%) and India (10%). In 2014 the value of imported medicines from the Russian Federation fell to 11.6% and it ranked second behind Germany (12%) and followed by India (8.5%). In 2015, the largest share of value of imported medicines came from Hungary (19%), followed by the Russian Federation and Germany, both at around 12%.

KEY FINDINGS

- The **quality of the dataset on imported medicines improved**. While in 2014 18% of all medicines (in terms of value) could not be classified according to their ATC group, the respective figure was as low as 8% in 2015.
- The Kyrgyz economy is largely integrated with its neighbouring countries, which can cause **exchange rate fluctuation**. The economic crisis in the Russian Federation, a key trading partner, led to a depreciation of the Russian rouble against the US dollar; as a result, the Kyrgyz som also devalued against the US dollar.
- **Devaluation contributed to higher prices (and co-payments)**. While imports of medicines in 2015 were at around the same level as in 2013 in terms of volume, Kyrgyzstan had to pay nearly 20% more for the same amount as a result of the devaluation.

5.4 Proposed actions to control OOP payments for medicines

Analysis of recent developments of co-payments for reimbursed medicines under the ADP shows that Kyrgyz patients have been confronted with increasing co-payments for reimbursed medicines in the outpatient sector. Between 2013 and 2015, co-payments for medicines prescribed under the ADP increased by 20%.

The share that patients have to co-pay for prescribed medicines slightly increased during the observation period, but this growth was not evenly distributed between ATC groups. The average proportion of co-payments for all medicines amounted to 50.7% in 2015. For medicines in ATC group B it was around 60%; in group C around 53% and in group J slightly below 50%. This suggests that the MHIF was able to keep the average co-payment at a stable rate for cardiovascular medicines, which accounted for the highest number of prescriptions.

Between 2013 and 2015 the number of prescriptions of ADP medicines decreased, while public pharmaceutical expenditure for the same group of medicines grew. These developments suggest that, overall, more money was spent on fewer medicines. The absolute amount patients had to co-pay for medicines also increased. While the number of imported pharmaceuticals remained stable, spending on medicines appeared to have shifted from public to private funding during the time period studied.

The analysis of ADP medicines confirmed that OOP payments had increased. As co-payments and OOP payments are a major barrier to affordable access to medicines, there is a clear need to address this issue by implementing pharmaceutical policies. The following action points are suggested for consideration.

- Kyrgyzstan currently has no **price regulation on medicines**. In the outpatient sector, prices are not regulated at the manufacturer, the wholesale or the pharmacy levels. It has been argued in the literature that unregulated medicine prices tend to result in higher prices (31–33). The findings of increasing co-payments for reimbursed medicines in Kyrgyzstan confirmed the need for price regulation, also aiming to control future price increases. Even if a stepwise approach is recommended to account for the complexity of price regulation and to allow lessons to be learned from possible pilot projects, the scope of price regulation should ideally include reimbursed medicines (ADP) in the outpatient sector as a first step. Since the list of reimbursed medicines is rather short and the remaining unfunded medicines have to be paid OOP in full by patients, price regulation should be extended to the entire private sector in the longer run. Owing to the characteristics of the Kyrgyz pharmaceutical system, the pharmacy purchasing price (i.e. the wholesale price) appears to be the most appropriate price type to be addressed by statutory regulation. Pharmacy retail prices could be regulated through a pharmacy mark-up scheme.
- Different pricing policies could be applied to different market segments, thus setting up a **plurality of pricing mechanisms**. For multisource products (medicines with competitors), policy-makers should consider choosing appropriate policies from the “toolbox” of generics pricing. Use of price linkages should be considered (multisource products could be priced a specific percentage below the first reference product, which is frequently the originator). Alternatively, in the case of tendering medicines, the prices could be set within a defined price band from the lowest-priced product.
- As a starting-point for price regulation for new medicines and those without a competitor on the market, Kyrgyz prices should be set through benchmarking against neighbouring countries and/or

countries of the EEU: a policy of **EPR**. Nevertheless, while EPR is a useful tool within the spectrum of price regulation, it is only *one* element of pricing reform and should be used in combination with other pricing mechanisms and pharmaceutical policies.

- **Price regulation also needs to address the supply chain, including pharmacy mark-ups/margins.** Introduction of regulation is recommended to limit pharmacy remuneration, at least for reimbursed medicines in the outpatient sector. Given the high OOP payments in Kyrgyzstan, this should be extended to the private sector as early as possible. Pharmacy remuneration would ensure one single maximum pharmacy retail price of a medicine throughout the country. In the light of the existing pharmaceutical system and in line with the WHO guideline on country pharmaceutical pricing policies (34), introduction of a regressive margin/mark-up is suggested, or even a dispensing fee that is not dependent on the medicine price. To improve affordable access throughout the country, higher pharmacy margins/mark-ups could be granted for pharmacies in remote areas than for retailers in towns. Alongside regulation of pharmacy mark-ups, limits should be included on the number of discounts allowed in the supply chain (those granted by wholesalers to pharmacies, or by pharmacies to patients), and these should be supplemented with enforcement mechanisms and a system to monitor supply chain actors' compliance with legislation.
- Due to its strong integration with its neighbouring countries, the Kyrgyz economy is highly vulnerable to exchange rate fluctuations, as observed in 2013–2015. Thus, particular attention should be paid to analysis of the impact of exchange rate fluctuations. With the introduction of EPR, **existing approaches used in other countries to reduce the risks linked to exchange rate volatility should be applied.**
- Price regulation is a complex endeavour, and it is therefore highly recommended to **perform and evaluate time-limited, focused pilot projects** for selected medicines. The SGBP and the ADP were introduced following pilot projects, and this is considered a key factor in their successful implementation. The findings of the analysis suggest that medicines for the treatment of cardiovascular diseases would qualify as possible candidates for a pilot project on price regulation. Measurable targets should be defined and evaluated both during the pilot projects and as later in the process. Based on lessons learned, the design should be revisited and, if necessary, adjusted.
- In order to make informed decisions, policy-makers need evidence based on real-life data and indicators. Key data for performing analyses and regular monitoring are not readily available in Kyrgyzstan. While data from the national customs authority serve as a good practice example of improved indexation and classification that allow further analysis, data availability is still limited in other areas (such as price information from retail pharmacies). The Ministry of Health and MHIF are recommended to **identify and define a few relevant indicators for monitoring and improving data collection.** To monitor price developments, regular (at least every second year) price studies should be performed, covering at least the medicines subject to the pilot project(s) and further medicines that account for high expenditure.
- The extension of the current reimbursement system to a fully fledged IPR system was identified as field for action (see section 4.6). As with price regulation through EPR, **medicines for the treatment of cardiovascular diseases also seem to qualify as candidates for piloting an updated methodology of IPR.** In recent years, cardiovascular medicines accounted for a large share of the total value of medicines imported to Kyrgyzstan, as well as for the highest proportion of medicines prescribed and dispensed under the ADP.

6. Conclusions and recommendations

The research showed that the scope of reimbursed outpatient medicines is limited: the outpatient reimbursement list (ADP) of the MHIF includes 60 items, as of 2015. For those ADP medicines, patients have to co-pay 50% of a centrally calculated baseline price. As pharmacy retail prices (and remuneration in the supply chain) are not regulated, patients can end up paying more than 50% of the price.

In recent years, Kyrgyz patients have been confronted with increasing co-payments for reimbursed medicines in the outpatient sector. From 2013 to 2015, co-payments for medicines prescribed and dispensed under the ADP increased by 20%. During that period, the number of prescriptions reimbursed under the ADP decreased by 14%, while public expenditure for these medicines increased in nearly all ATC groups.

The Kyrgyz economy is largely intertwined with the economies in the central Asian region and suffered from the economic crisis in the Russian Federation. The depreciation of the Russian rouble versus the US dollar also led to a devaluation of the Kyrgyz som against the dollar. While this is a major explanatory factor, the total absence of medicine price regulation (at both the ex-factory price and in the distribution chain) contributed to the deterioration of the situation for payers and patients.

Based on this analysis, the authors propose the following recommendations for pricing and reimbursement in the Kyrgyz outpatient sector in order to maximize health gains in the area of medicines, and particularly to limit the high OOP payments for medicines. Details of the recommendations can be found in Table A.2 in Annex, which sets out possible actions, responsibilities and timelines.

The measures suggested are partly interlinked, and some require major preparation and changes. Reforms of pharmaceutical pricing and reimbursement are long and difficult, and success is uncertain. In the meantime, therefore, some adjustments could be made to the current system to make it more efficient.

Pricing

- **A legislative framework for the introduction of price regulation should be established.** Unregulated medicine prices tend to result in high overall prices, and no instrument is in place to control future price increases. As the list of reimbursed medicines (which are only funded by around 50%) is short and all other medicines are to be paid OOP in full by patients, a new attempt to control medicine prices – including pharmacy margins – appears to be crucial. The draft law on modernization of the pharmaceutical sector provides a legislative framework for price regulation of medicines: this is an essential prerequisite for regulating medicine prices. Thus, this law (in its version of mid-September 2016) should enter into force as soon as possible. The introduction of price regulation is a complex policy intervention that requires sufficient preparation regarding the choice of appropriate methodology, sound legislation, training of the Ministry of Health staff involved and clear communication to stakeholders. In the context of the Kyrgyz setting, the authors suggest regulating, at the first stage, pharmacy purchasing prices (i.e. wholesale prices) and pharmacy retail prices (through a pharmacy mark-up scheme) for medicines used in the outpatient sector.

- **EPR for new medicines should be undertaken.** The authors recommend that this could begin by taking medicine prices in neighbouring countries and/or countries of the EEU as guidance. It should be supplemented by consideration of different economic situations and missing data in the reference countries. Particular attention should be given to exchange rate fluctuations, and the methodology should be designed accordingly (using average exchange rates over longer periods, for instance). While EPR is, despite some limitations, a useful tool within the spectrum of price regulation, it is only one element of pricing reform and should be used in combination with the other measures proposed.
- **Regulated pharmacy mark-ups should be introduced.** Price regulation should also address the actors in the supply chain, so pharmacy mark-ups are recommended, at minimum for medicines on the ADP list, but ideally to be extended as soon as possible to the private sector. Meaningful methodology should be applied to regulating these. In line with the WHO guideline on country pharmaceutical pricing policies (34), designing pharmacy mark-ups as a regressive scheme in order to reduce the financial incentive for pharmacists to dispense higher-priced medicines should be considered. The design could be chosen in a way that supports further policy objectives, such as higher remuneration for pharmacies in remote areas or rewarding pharmacies for dispensing of generics.
- **The number of medicines included in price regulation should be expanded in a stepwise manner.** In the short term, the scope of price regulation has to be balanced between a limited number of medicines (as implementation has to be feasible in a resource-constrained setting) and a larger range that ideally also covers the private sector, with the aim of increasing protection of patients from OOP payments. Starting with a stepwise approach, focusing first on the ADP medicines, is recommended. This will facilitate assessment of whether the methods need to be adjusted and better aligned to the Kyrgyz setting (considering the ongoing health sector reforms). It is recommended that the Ministry of Health should take the lead in the implementation of price regulation, defining the process and methodology and ensuring the collection of required data.
- **Capacity-building on further methods in the longer run is recommended.** As the proposed methodology of EPR has some limitations, as has any pricing policy, capacity-building in the area of health technology assessments and pharmacoeconomics is recommended, with the long-term aim of supplementing the proposed pricing policy with these methods in the future.

Reimbursement

- An update to the legislation regarding criteria and processes for **listing and delisting of medicines into and from the reimbursement list** is recommended (both SGBP and ADP). In particular, this should aim to improve alignment of the inclusion criteria with priority diseases. While exemptions can be justified in specific cases, the composition of the ADP list should, in general, be aligned with the most recent WHO EML. Furthermore, clinical guidelines for selected diseases should be developed that will also serve as an evidence base for reimbursement decisions.
- The process of **IPR** should be updated. While the current reimbursement system contains elements of IPR (i.e. the same baseline/reimbursement prices for INNs), expansion into a fully fledged IPR system could be considered as a policy option for multisource medicines. In such a system clusters would be built for identical and similar medicines, and since multisource medicines would be attributed to these clusters when they come to the market, it could help increase competition and bring down prices. It would also increase the number of reimbursed medicines and thus protect patients. In accordance with a stepwise approach, starting with few therapeutic clusters and building reference price groups at ATC level 4 (considering that *de facto* the current ADP scheme corresponds to ATC level 5 IPR) is recommended.

Monitoring, enforcement, information activities and capacity-building

- **Monitoring, evaluation and data collection should be enhanced.** Introduction of a mechanism to monitor policy measures to support policy-makers in taking informed decisions is recommended. In view of the resource restraints, a complex monitoring system should not be set up; instead monitoring activities and evaluations should be focused and targeted to policy-makers' needs. It is therefore important to select a few meaningful indicators whose data collection is feasible in the Kyrgyz setting. Obliging stakeholders (such as wholesalers), where appropriate, to provide the required data on a regular basis should be considered. Annual or biannual publications on the performance of the pharmaceutical system based on these indicators are suggested; this dissemination activity can help raise awareness of the need for and relevance of evidence. Kyrgyz policy-makers should aim to establish monitoring as an integral part of policy interventions.
- **Pilot projects** should conclude with an evaluation to facilitate learning of lessons and making necessary adjustments.
- **Better enforcement of policies is needed.** This is the case, for instance, in the area of demand-side measures to enhance the uptake of generics. Legislation introduced INN prescribing and generic substitution, but in practice the rates of prescribing, dispensing and use of generics, as well as lower- and lowest-priced equivalent medicines, are comparably low. Understanding reforms in the pharmaceutical sector as a package, pharmaceutical pricing and reimbursement elements should be implemented with the aim of increasing the market share of lower-priced medicines. Suggested examples include prescribing and dispensing targets for doctors and pharmacists, and an appropriate design of pharmacy mark-ups (see above).
- **Information and dissemination activities are recommended.** Policy changes should be accompanied by sufficient information and dissemination activities targeted at patients and other stakeholders. The analysis showed limited knowledge among health professionals and patients about generics and generics policies.
- **Information should be shared between peers and capacity-building of authorities increased.** The development and fine-tuning of the most appropriate mix of pharmaceutical policies that are feasible in a resource-constrained setting such as Kyrgyzstan is a major challenge. Experience from other countries has shown that policy-makers and technical experts benefit from participation in international networks and collaborations, in which they can share experiences about successful and failed policy interventions, as well as technical training. Kyrgyz pricing and reimbursement authorities are recommended to continue their capacity-building activities and their involvement in international networks.

Agenda of the reform

The free medicine market has been developed; now regulation is needed to ensure market efficiency and protect the public. Introduction of price regulation is seen as the highest priority action to address high OOP payments. The Ministry of Health is recommended to put in place the following measures to ensure improved efficiency and price transparency throughout Kyrgyzstan.

- The law on modernization of the pharmaceutical sector should be adopted as quickly as possible to provide the legislative framework for introducing price regulation.
- A process should be developed to ensure one single maximum pharmacy retail price for all medicines under the ADP throughout the country.
- A pilot project should be launched to begin and test this process.
- Since gaps in key data to facilitate more informed decision-making were identified, surveys should be run to collect data – in particular, a WHO/HAI medicine price and availability survey and a prescription and medicine use survey (for both the inpatient and outpatient sectors).

The Ministry of Health should aim to define the process and methodology of price regulation, start the pilot project and conduct the suggested surveys within one year.

As medium-term policy objectives, strengthening the reimbursement process is recommended through the development of clinical guidelines for selected diseases, better alignment of the inclusion criteria for priority diseases and an improved process for data collection of reimbursement prices.

This study focused on analysis of the outpatient pharmaceutical pricing and reimbursement policy. Nevertheless, policies and their implications are frequently interconnected and can require action in further sectors. For instance, information activities to enhance uptake of generics are likely to fail unless health professionals and patients have confidence in the quality of generics. This may require action in terms of quality improvements in the regulatory field, strengthening the NMRA and dossier assessments (including the introduction of therapeutic equivalence evaluations) and more effective inspection and enforcement. While the analysis only addressed the outpatient sector, an assessment of the hospital sector for potential efficiency gains is also necessary as part of a comprehensive national medicine policy.

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Annexes

Table A.1 shows that most medicines listed under the ADP are recommended by WHO. It also shows that those medicines not recommended by WHO have gradually been withdrawn from the ADP list.

Table A.1 | List of molecules with international nonproprietary names (INNs) included in the WHO Essential Medicines List (EML) and the additional drug package (ADP) list

Anatomical Therapeutic Chemical (ATC) level 1	ATC level 3	INN	WHO EML	Withdrawn from the ADP list during the study period (2013–2015)
A	A02	Bismuth subcitrate	No	No
	A02	Omeprazole	Yes	No
	A02	Famotidine	Yes	No
	A03	Drotaverine	No	Yes
	A07	Rehydration solution	Yes	No
	A11	Ergocalciferol	Yes	No
	A11	Ferric sulfate + ascorbic acid	Yes	No
B	B03	Ferric sulfate + folic acid + ascorbic acid	Yes	No
	B03	Folic acid	Yes	No
	B03	Combination iron supplement	Yes	No
C	C01	Nitroglycerin	Yes	Yes
	C01	Digoxin	Yes	No
	C01	Isosorbide dinitrate	Yes	No
	C03	Hydrochlorothiazide	Yes	No
	C03	Furosemide	Yes	No
	C03	Indapamide	No	No
	C04	Nicotinic acid	No	Yes
	C07	Atenolol	Yes	Yes
	C07	Bisoprolol	Yes	No
	C08	Verapamil	Yes	Yes
	C08	Nifedipine	Yes	No
	C08	Amlodipine	Yes	No
	C09	Enalapril	Yes	No
	C09	Enalapril + hydrochlorothiazide	No	No
	C09	Lisinopril	Yes	No

Table A.1 continued

Anatomical Therapeutic Chemical (ATC) level 1	ATC level 3	INN	WHO EML	Withdrawn from the ADP list during the study period (2013–2015)
G	G01	Nystatin	Yes	Yes
	G03	Levonorgestrel + ethinylestradiol	Yes	No
	G03	Intrauterine contraception	Yes	No
H	H02	Prednisolone	Yes	No
J	J01	Amoxicillin	Yes	No
	J01	Ampicillin	Yes	No
	J01	Benzathine benzilpenicillin	Yes	No
	J01	Benzylpenicillin sodium	Yes	No
	J01	Doxycycline	Yes	No
	J01	Metronidazole	Yes	No
	J01	Tetracycline	Yes	Yes
	J01	Phenoxymethylpenicillin	Yes	No
	J01	Ciprofloxacin	Yes	No
	J01	Erythromycin	Yes	No
	J01	Nitroxoline	No	Yes
	J01	Clarithromycin	Yes	Yes
	J01	Midecamycin	No	Yes
	J01	Roxithromycin	No	Yes
	J01	Ciprofloxacin + metronidazole	No	Yes
M	M01	Diclofenac	Yes	No
	M01	Ketoprofen	Yes	No
N	N02	Paracetamol	Yes	No
	N02	Tramadol	No	No
	N03	Carbamazepine	Yes	No
	N03	Clonazepam	No	No
	N03	Phenobarbital	Yes	No
	N03	Valproic acid	Yes	No
	N04	Trihexyphenidyl	Yes	No
	N05	Haloperidol	Yes	No
	N05	Diazepam	Yes	No
	N05	Chlorpromazine	Yes	No
	N05	Clozapine	Yes	No
	N06	Amitriptyline	Yes	No

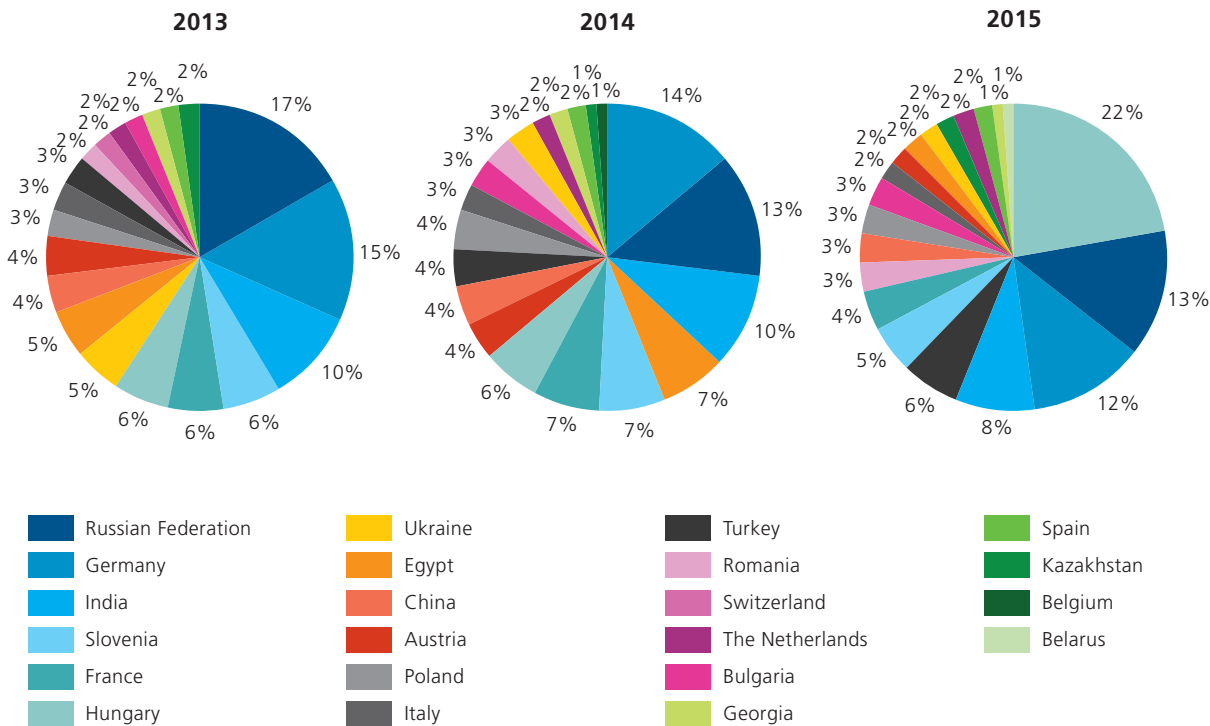
Table A.1 continued

Anatomical Therapeutic Chemical (ATC) level 1	ATC level 3	INN	WHO EML	Withdrawn from the ADP list during the study period (2013–2015)
Medical device	NA	Disposable syringe	NA	No
	NA	Glucose test strips	NA	No
P	P02	Mebendazole	Yes	No
	P02	Praziquantel	Yes	No
	P02	Albendazole	Yes	No
R	R03	Aminophylline	No	No
	R03	Beclomethazone	Yes	No
	R03	Ipratropium bromide	Yes	No
	R03	Salbutamol	Yes	No
	R03	Ipratropium bromide + fenoterol	No	Yes
	R03	Theophylline	No	No
	R03	Salmeterol + fluticasone	No	No
	R05	Bromhexine	No	Yes
	R05	Carbocisteine	No	Yes
	R06	Ketotifen	Yes	No
	R06	Clemastine	No	Yes
	R06	Chloropyramine	No	Yes
	R06	Loratadine	Yes	No
V	V03	Potassium iodide	Yes	No

Source: Mandatory Health Insurance Fund (MHIF); analysis undertaken by the WHO Regional Office for Europe

Fig. A.1 illustrates the variety of countries of import by value and the changes observed across the years.

Fig. A.1 | Share of total value of imported medicines among the top 20 importing countries, 2013–2015



Source: National Medicines Regulatory Agency (NMRA); analysis undertaken by the WHO Regional Office for Europe

Table A.2 presents the report’s recommendations in detail, proposing an institution to be in charge of implementation of each task, as well as possible timings.

Table A.2 | Recommendations in detail

Measure	Recommended actions	Responsible institution(s)	Suggested timetable	Rationale, including international experience
Overarching principles and measures				
1. Data collection to facilitate improved policy monitoring	<ul style="list-style-type: none"> • Introducing a data collection system to facilitate more informed decision-making is recommended. • Three areas considered crucial for data collection include registration and authorization, pricing and reimbursement. • For each of the three areas a small number of indicators that are able to support them should be defined. Possible examples are listed below. • For registration and authorization data collection should include: <ul style="list-style-type: none"> - improved indexing/classification of imported medicines to allow detailed analysis, e.g. by reducing the proportion of medicines that cannot be classified according to general characteristics (e.g. by ATC group); - data on the share of medicines with competitors for which therapeutic equivalence evaluations exist. • For pricing of pharmaceuticals data collection should include: <ul style="list-style-type: none"> - price data on medicines in other (defined) countries; - price data on medicines from Kyrgyz retail pharmacies (e.g. by performing a WHO/Health Action International (HAI) price and availability survey); - information on pharmaceutical retail sales. • For reimbursement data collection should include: <ul style="list-style-type: none"> - pharmaceutical expenditure (public and private); - coverage of medicines with high therapeutic evidence; - regional variations in medicine use; - prescribing behaviour of doctors (e.g. by performing a prescribing and medicine survey); - generic substitution practised. 	NMRA for registration/ authorization; Ministry of Health for pricing; MHIF for reimbursement	<ul style="list-style-type: none"> • Definition of key indicators and methodology for surveys to be defined within 18 months (with a focus on very few indicators in the beginning) • One price and availability survey and one prescribing and medicine use survey to be performed within 12 months • Nationwide monitoring system only to be introduced in the medium and long term 	In order to make informed decisions, policy-makers require evidence based on data. The analysis shows that data collection for imported and for reimbursed medicines has improved since 2013. Nevertheless, large information gaps still exist. For instance, no information is available about retail prices of medicines and the regional variation of those prices, and information about availability of essential medicines in remote areas is missing. ¹

¹ With the adoption of the Sustainable Development Goals, the international community shifted its attention to indicator frameworks and associated monitoring systems. The backbone of monitoring health systems is sound and reliable indicators at the local, regional, national and global levels. Data on financial and human resources invested in health and the impact of these efforts are critical for planning health systems, implementing programmes and allocating budgets. This requires Sustainable Development Goals targets to be turned into management tools (7).

Table A.2 continued

Measure	Recommended actions	Responsible institution(s)	Suggested timetable	Rationale, including international experience
2. Monitoring/regular evaluations	<ul style="list-style-type: none"> Definition of an indicator for each key policy (e.g. pilot internal price referencing (IPR) projects and pricing regulation, as defined below) and collection of data that enable measurement of the policy's impact are recommended. Any new policy should be accompanied by monitoring activities. In addition to policy evaluation, institutional evaluation on a regular basis (e.g. every three years), reviewed by institutions from other countries, could be considered. An option would be to ask for the assessment of regulatory functions offered by WHO (see also measure 14). 	Depending on the measure, Ministry of Health, MHIF or NMRA – including responsibility of the implementing institution for ensuring that policies are accompanied by monitoring (which could be commissioned to external experts)	<ul style="list-style-type: none"> For new measures, monitoring and evaluation to be defined as part of policy introduction during the preparatory phase Period of evaluation to depend on the measure 	Policy-makers need to ensure that policies meet their intended aims as far as possible. To check effectiveness, their implementation should be evaluated. Further, their effectiveness may change (e.g. if settings change) ² , so regular evaluation and monitoring are crucial. Perspectives outside the institution or the country may provide valuable insights. ³
3. Pilot projects	<ul style="list-style-type: none"> The introduction of recommended pharmaceutical policies should be done in a stepwise approach, starting with a pilot project of limited scope (e.g. for only a few medicines). Medicines in ATC group C appear to be an appropriate candidate for inclusion in a pilot project. Suggested steps to for a pilot project include: <ul style="list-style-type: none"> defining the objective and scope of the policy; identifying measurable targets (using SMART methodology, for instance – goals should be specific, measurable, attainable, realistic and time-bound) and ensuring appropriate data collection throughout the project; evaluating and deciding to stop or adjust or to continue with further pilot projects or a national rollout. 	Depending on the measure	<ul style="list-style-type: none"> Depending on the measure, suggested preparatory phase for pilot project: 6–12 months; pilot project duration 12–24 months 	The state-guaranteed benefit programme (SGBP) and ADP were introduced through pilot projects. These practices have shown that a regional pilot phase before national rollout is likely to increase the probability of success. ⁴ Analysis of current developments in the Kyrgyz system has shown an increasing relevance of medicines for the treatment of cardiovascular diseases.

² There is evidence from European countries that the intended impact of a policy may “fade out” after some time, as stakeholders learn how to use the system, so adaptations were required (called the “pendulum effect” (2)). Monitoring is considered a key component of the development of national drug policies (3).

³ This is the Organisation for Economic Co-operation and Development's peer-review process as a tool for cooperation and exchange. At its heart lies the idea that each country's policy in a particular area is examined by fellow members on an equal basis. Countries may learn valuable lessons from peers about what has worked and what has not. This can save time and costly experimenting in designing national policies.

⁴ When designing policies, decision-makers cannot account for all possible contingencies leading to an unexpected impact. Piloting pharmaceutical policies on a limited number of inhabitants (e.g. determined through administrative units like districts or regions) or with limited scope (e.g. covering only a few medicines) has become an approach used widely in European countries. Examples include e-medication in Austria, interprofessional collaboration among health care providers in the United Kingdom and medicine reviews in Finland.

Table A.2 continued

Measure	Recommended actions	Responsible institution(s)	Suggested timetable	Rationale, including international experience
4. Strengthening international collaboration and information sharing	<ul style="list-style-type: none"> Kyrgyz authorities are recommended to intensify their collaboration in international networks for competent authorities in order to learn from other countries, share experiences and build capacity. In particular, capacity-building is suggested for areas in which policy measures might be implemented in the short term (e.g. pricing and reimbursement), as well as for health technology assessment, pharmacoeconomics and evaluations, with a view to implementing such tools in Kyrgyzstan at a later stage. To strengthen quality assurance of medicines, training opportunities offered by WHO for regulatory experts should be considered (see also measure 14). 	MHIF Ministry of Health NMRA	<ul style="list-style-type: none"> Rational selection of networks for collaboration and first contact to explore whether to join them to take place within 12 months Capacity-building to start immediately A realistic period of 4–10 years to build sufficient capacity on health technology assessment and pharmacoeconomics in order to include new elements (e.g. value-based pricing) in pricing, allowing consideration of a change from existing policies to more sophisticated ones 	During the Summer School on Pricing and Reimbursement Policies in Vienna in 2016, organized by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement and the WHO Regional Office for Europe, the Kyrgyz participants stressed the relevance of exchanges with professionals from other countries. Discussions with and learning from other countries help to bring in new perspectives. ⁵
Measures related to pharmaceutical pricing				
5. Regulation of medicine prices: providing a legislative framework	<ul style="list-style-type: none"> To regulate medicine prices, the legal framework must be in place. As a first priority the draft law on medicines (in its version of mid-September 2016) should be adopted immediately. In the context of the Kyrgyz setting, the following features of price regulation appear feasible. <ul style="list-style-type: none"> The scope should start by addressing price regulation for publicly funded medicines (ADP), with extension to the private sector at a later stage, and include on-patent medicines or off-patent medicines with no corresponding originator on the market. 	Ministry of Health	<ul style="list-style-type: none"> Law to be adopted immediately Preparatory phase (definition of process and methodology; launch of pilot project) to take 12 months First pilot project to run for 12–18 months 	Analysis of medicines imported to Kyrgyzstan and of changes in those prescribed and dispensed at the MHIF's expense underlines the need for price regulation to address increasing and excessive prices that, in the light of limited reimbursement in the outpatient sector, translate into high out-of-pocket (OOP) payments for patients.

⁵ Policy-makers need to design pharmaceutical policies appropriately to achieve the intended aims in the country-specific context and to adjust them regularly. Information on pharmaceutical systems in other countries, particularly within the same region, and on experiences with specific policies elsewhere is therefore vital for policy-makers (4).

Table A.2 continued

Measure	Recommended actions	Responsible institution(s)	Suggested timetable	Rationale, including international experience
	<ul style="list-style-type: none"> - The wholesale price/pharmaceutical purchasing price should be considered for regulation. - Regulated prices should be considered maximum prices. - External price referencing (EPR) methodology should be considered as a first step. - The suggested basket of reference countries could include the countries of the Eurasian Economic Union (EEU): Armenia, Belarus, Kazakhstan and the Russian Federation,⁶ and possibly also Uzbekistan and Tajikistan – it should be ensured that comparable price information can be obtained from these countries. - The calculation should use the lowest (unweighted) wholesale price of the suggested reference countries; alternatively, prices in the reference countries could be weighted for economic growth and the average of the weighted data considered. - Due to the low number of reference countries, a minimum requirement of available price data (e.g. two countries) is suggested. If more price information becomes available, this can be considered during price revisions. • The Ministry of Health is recommended to define a process and methodology to introduce price regulation. 		<ul style="list-style-type: none"> • Evaluation and adjustments for further pilot projects (or national rollout) to take place within 2–4 years 	<p>As a first step, price regulation should cover medicines financed by public sources (i.e. reimbursed).⁷ The analysis has shown, however, that the majority of medicines are paid OOP, and that private funding has major relevance.</p> <p>Extending price regulation to further medicines, including in the private sector, could therefore be considered, although only at a later stage.⁸</p> <p>Since the introduction of price regulation is a highly complex and resource-intensive effort, starting with pilot projects (see measure 4) is recommended for a limited number of medicines, selecting a methodology that seems feasible to implement in the Kyrgyz context. Although EPR has some limitations, as does any policy, it appears to be the most feasible method to use. Possible specifications of the proposed methodology are suggested for consideration, taking the Kyrgyz pharmaceutical system and the recommendations of the WHO guideline on country pharmaceutical pricing policies (7) into consideration.</p>

⁶ In 2015 these countries accounted for 60% of the volume of imported medicines to Kyrgyzstan.

⁷ When funding of medicines comes mainly from public sources, the competent authorities for pricing and reimbursement are advised to act as price-setters rather than price-takers, and should regulate pharmaceutical prices. In the European Union, regulation is done for those medicines at ex-factory or wholesale prices (co-funded by the state. This principle of the authority of countries to regulate prices for medicines purchased or reimbursed by the state is also included in the final document of the European Commission's High Level Group on Innovation and Provision of Medicines (5).

⁸ A few countries (e.g. Bulgaria, Romania, Turkey) extend their scope of EPR beyond the publicly funded or prescription-only sector (6).

Table A.2 continued

Measure	Recommended actions	Responsible institution(s)	Suggested timetable	Rationale, including international experience
6. Adjustment for exchange rate fluctuations	<ul style="list-style-type: none"> If EPR is introduced, it is important to design the methodology to account for exchange rate fluctuations, as the reference countries have different currencies. To deal with exchange rate fluctuations the following options should be considered: <ul style="list-style-type: none"> choice of an average exchange rate over a longer period (e.g. yearly average); legal provision to adjust for extraordinary circumstances (huge devaluation); percentage bands within which fluctuations are allowed. 	Ministry of Health	<ul style="list-style-type: none"> To be adopted alongside the introduction of price regulation 	<p>The Kyrgyz economy is largely integrated with its neighbouring countries, as reflected in simultaneous movements of the business cycle or changes in exchange rates.⁹</p> <p>Nevertheless, addressing exchange rate fluctuations requires some kind of price regulation.</p>
7. Regular price revisions	<ul style="list-style-type: none"> To support the introduction of price regulation, a WHO/HAI price and availability survey should be performed. In addition, implementation of regular (annual) price reviews is recommended to collect data about price developments and, once price regulation is introduced, to adjust appropriately. Price reviews should target both wholesale and pharmacy retail prices. Possible steps include: <ul style="list-style-type: none"> defining a methodology for price reviews (scope of reviewed medicines, data sources and providers, plus a backup mechanism in case of non-availability); considering performing an updated price survey in accordance with the WHO/HAI methodology; if an EPR pilot project is launched, surveying medicine prices and comparing Kyrgyz prices with those in the basket of reference countries; nominating and training staff to undertake price reviews; defining mechanisms for analyses; comparing medicine price developments to developments of other economic indicators (general price indices, gross domestic product, household income); defining a mechanism for adjusting prices after review (e.g. recalculation of EPR-based prices, an algorithm to link (regulated) prices to other price developments). 	Ministry of Health	<ul style="list-style-type: none"> One price and availability survey to be performed within 12 months If feasible, annual price revisions to be undertaken of medicines under the ADP and/or included in price regulation (or a pilot project) If limited resources are available, revision of those medicines with highest public expenditure to be the focus in the first year, extending the scope gradually 	<p>The analysis has demonstrated that the MHIF was able to keep the share of co-payments for medicines at a comparably stable level. These developments are probably attributable to regular reimbursement revisions of medicines that account for a large proportion of prescriptions. While this example from Kyrgyzstan is from reimbursement rather than pricing, it suggests the effectiveness of revisions. Evidence on the effectiveness of price revisions is available from other countries.¹⁰</p>

⁹ The question of which exchange rates to apply in EPR is another methodological challenge, since exchange rate fluctuations can have significant effects on pharmaceutical prices (8, 9). Among European countries there is widespread variation between the choices of exchange rate type (daily, three-month, six-month or 12-month average), each with its benefits and limitations (6).

¹⁰ Simulations of price developments for medicines in European countries highlighted the relevance of regular price revisions to account for changes in exchange rates (10) or to realize potential savings (6).

Table A.2 continued

Measure	Recommended actions	Responsible institution(s)	Suggested timetable	Rationale, including international experience
8. Regulation of pharmacy mark-ups	<ul style="list-style-type: none"> Regulation of pharmacy mark-ups is suggested to stop excessive charges. This should be part of the overall regulation of prices for which the Ministry of Health is responsible and is asked to define a process and methodology. In line with the WHO guideline on country pharmaceutical pricing policies (7), the structure of the health system and setting should be considered in the mark-ups. Considering regulation of pharmacy mark-up for all medicines dispensed in the retail pharmacies is recommended. As a first step, for practical reasons, this might focus on medicines under the ADP only. In preparation, assessment of existing pharmacy mark-ups is recommended. Pharmacy retail prices from private pharmacies in the regions should be surveyed in line with the WHO/HAI price survey methodology, as well as existing wholesale prices. For practical reasons, the scope of the survey should be limited; for instance, considering only the 30–40 most prescribed medicines from the ADP list. It is recommended that the mark-up scheme should be regressive rather than fixed percentage mark-ups in order to provide incentives for pharmacists to dispense lower-priced medicines. Introducing two different remuneration schemes – one for pharmacies in rural areas with higher remuneration, and one for urban pharmacies – should be considered. 	Ministry of Health	<p>Timetable to follow that for price regulation in general (measure 5):</p> <ul style="list-style-type: none"> Law to be adopted immediately Preparatory phase (definition of process and methodology; launch of pilot project) to take 12 months First pilot project to run for 12–18 months One price and availability survey to be performed within 12 months 	<p>According to surveys conducted in Kyrgyzstan, retail mark-ups for pharmaceuticals are in the range 32–244%. This variation is high and may lead to excessive medicine prices. Regulation of mark-ups has the potential to contribute to lower prices as part of a comprehensive price regulation strategy. Furthermore, in the current system pharmaceutical wholesale and retail sales are often strongly intertwined; to avoid competitive disadvantages for pharmacies that are not part of a wholesale network, regulation of mark-ups for reimbursed medicines is necessary.</p> <p>Higher remuneration for remote areas is proposed to improve access of medicines in those areas. Regulation of mark-ups will probably have an effect on the viability of some operators, and the operating costs for businesses across geographical regions need to be considered carefully when determining suitable mark-ups.¹¹</p>

¹¹ The design of mark-ups can create incentives and disincentives in the supply chain of medicines – e.g. they can be used to favour domestic medicines. There is evidence from some European countries (Italy, Spain, Nordic countries) that pharmacy remuneration is designed differently for different types of pharmacies, with the aim of favouring smaller, low-income pharmacies and those situated in rural areas. Around 60% of low-income countries regulate wholesale or retail mark-ups in either the public or the private sector. In middle-income countries mark-ups in the private sector are more likely to be regulated (80–90% of all countries) compared to the public sector (around 60% of all countries) (11).

Table A.2 continued

Measure	Recommended actions	Responsible institution(s)	Suggested timetable	Rationale, including international experience
Measures related to reimbursement of medicines				
9. Regular revisions of the national essential medicines list (NEML)	<ul style="list-style-type: none"> Legislation should be changed and regular timelines (at least every two years) defined for revision procedures. A mechanism that encourages regular revisions should be defined. This might include: <ul style="list-style-type: none"> annual reporting of the Ministry of Health to Parliament including information about revisions; failure to perform the revisions requiring explicit justification. Revisions and adjustments of the NEML should be aligned with the most recent WHO EML. 	Ministry of Health and MHIF	<ul style="list-style-type: none"> Mechanism for regular revision to be introduced in the short term: within 12 months 	Medicines prescribed and dispensed under the SGBP and ADP are selected from the NEML. Further, when launching a tender hospitals are required to select (the majority of) medicines from the NEML. Thus, listing and delisting of medicines have important effects on pharmaceutical expenditure (outpatient and inpatient) and should be done in a more regular way. ¹²
10. Regular revisions of the reimbursement list	<ul style="list-style-type: none"> Regular timelines for revision procedures should be established. 	MHIF	<ul style="list-style-type: none"> To be introduced in the short term: within 12 months 	Priorities within the health system may change as a result of different developments (demographic shifts, etc.). ¹³
11. Clear criteria for listing and delisting	<ul style="list-style-type: none"> Clear criteria should be defined or existing criteria refined for the inclusion of medicines in both the NEML and reimbursement list, with particular focus on better alignment with priority diseases. Clinical guidelines should be developed for selected diseases to support better informed decision-making about listing/delisting. Legislation should be updated accordingly. 	Ministry of Health	<ul style="list-style-type: none"> To be introduced in the short term: within 12 months 	Some criteria for selecting medicines for the NEML and the reimbursement list are rather vague or can lead to undesired effects, as they do not reflect priorities within health systems. There appears to be a mismatch between criteria defined in legislation and practice. Clear and objective criteria need to be taken into consideration. ¹⁴

¹² Increasing demand and rising medicine costs pose a large challenge to the financial sustainability of many health systems. This problem is not limited to developing countries; in high-income countries discussions are also ongoing about how to get the best value for money. Regular revisions of appraisals for clinical use or readjustments of clinical guidelines are common systemic approaches (12).

¹³ Legislation in other countries provides for regular revisions of reimbursement lists with respect to either listing or reimbursement. The Danish Medicines Agency aims to review all reimbursed and non-reimbursed medicines regularly to determine their eligibility for inclusion in the list (according to unpublished data from IMS Health, 2016). The National Institute for Health and Care Excellence (NICE) in the United Kingdom schedules regular revisions of its appraisals for medicine utilization (13). In Italy the law includes corrective measures when pharmaceutical spending exceeds a ceiling, one of which is updating the positive list (14).

¹⁴ The EU's Transparency Directive requires that Member States base their pricing and reimbursement decisions on objective and verifiable criteria. The requirement has been implemented in the EU Member States (see, for instance, VO EKO in Austria, the Swedish Pharmaceutical Reimbursement System and Verordnung über die Nutzenbewertung von Arzneimitteln nach § 35a in Germany).

Table A.2 continued

Measure	Recommended actions	Responsible institution(s)	Suggested timetable	Rationale, including international experience
12. Facilitating collection of wholesale prices as basis for reimbursement prices	<ul style="list-style-type: none"> The legislation should be revised to present an obligation for wholesalers to supply specified price data automatically at defined intervals. Wholesalers should be obliged to submit price data electronically, preferably through a web-based solution. A web-based tool via which wholesalers are asked to provide price information for certain medicines at regular intervals (e.g. every two months) should be set up. The legislation should include a sanction mechanism (e.g. the price of the previous year minus a discount will be taken, lower wholesale remuneration will be applied in the case of statutory wholesale mark-ups). 	MHIF	<p>A stepwise approach for the implementation could be considered:</p> <ul style="list-style-type: none"> definition of obligation for wholesalers to supply data within 12 months changing the data collection mechanism within 3–5 years 	The current method of collecting price information is time-consuming and resource-intensive. ¹⁵
13. Introducing an IPR system through a pilot project	<ul style="list-style-type: none"> Legislation should be prepared. Stakeholder information should be collated and a dialogue started. Methodology should be defined. Medicines that qualify for a pilot project should be identified, such as multisource medicines with many competitors on the market (e.g. angiotensin-converting-enzyme (ACE) inhibitors such as enalapril, lisinopril) and those with availability in remote areas. As a first step, starting with a few clusters and building reference price groups at ATC level 4 is recommended (since <i>de facto</i> the current ADP scheme can be considered an ATC level 5 IPR). Only those medicines that are quality-assured generics demonstrated by therapeutic equivalence evaluations should be clustered. Fully reimbursing the least expensive (equivalent) medicine of the cluster is suggested. Monitoring of utilization and budget impact will allow further fine-tuning. 	MHIF with the Ministry of Health	<ul style="list-style-type: none"> A pilot project to be prepared within 1–2 years, running for one year 	<p>The current system provides a good starting-point for the move towards a fully fledged IPR system, as it already has some elements of IPR. Currently, the baseline price for reimbursement is calculated manually and typically accounts around 50% of the pharmacy retail price. The prices are published regularly in the reimbursement catalogue (listing both INNs and trade names) and distributed to health service providers. Moving towards IPR means that those medicines for which comparable competitors exist are explicitly included in IPR, through the establishment of clusters. For medicines attributed to clusters a reference price to be reimbursed would be defined.¹⁶</p>

¹⁵ In Denmark market authorization holders are asked to provide prices for the calculation of reimbursements by competent authorities. In several countries market authorization holders are obliged to provide price information when they apply for prices (6).

¹⁶ The proposed methodology of fully reimbursed reference prices that are set at the price of the lowest-priced medicine in the cluster could incentivize pharmaceutical companies to price lower (next to the reference product) and thus encourage competition. Such developments were observed in European countries when many of them introduced IPR for a proportion of reimbursed medicines in the outpatient sector (15).

Table A.2 continued

Measure	Recommended actions	Responsible institution(s)	Suggested timetable	Rationale, including international experience
Measures related to generics policies				
14. Awareness-raising and capacity-building related to generics and generics policies	<ul style="list-style-type: none"> Information activities targeted at doctors and pharmacists should inform about generics in general and about the legal requirements related to pharmaceutical policies, such as INN prescribing and generic substitution (see also below measures 16 and 17). Information campaigns about the quality of generics and current generics promotion policies should be targeted at the public. 	Joint or at least coordinated dissemination activities advised among Ministry of Health, NMRA, MHIF	<ul style="list-style-type: none"> Outline and modalities of implementing of dissemination activities (including responsibilities between institutions) to be defined within 12 months Dissemination activities targeted at doctors, pharmacists and the public to be performed within 12–36 months (as a staggered process) An evaluation to be performed after each dissemination activities 	A mechanism is needed to improve trust in quality-assured medicines. During the analysis, distrust and limited knowledge of generics and generics policies were identified among health professionals and patients. This was identified as one reason for limited prescribing and use of generics. ¹⁷
15. Ensuring the quality of generics	<ul style="list-style-type: none"> Mechanisms to ensure that only quality-assured generics are brought on the market should be considered. WHO could perform an assessment of the regulatory functions. Training activities for regulatory experts offered by WHO could be used. A requirement for the industry to include a therapeutic equivalence evaluation to the dossier of registered medicines could be introduced. Regulation should be changed to strengthen the role of the NMRA with respect to quality checks on site (i.e. allowing unannounced quality checks). 	NMRA, based on the changes in regulation by the Ministry of Health, for authorization, checks, vigilance; MHIF for reimbursement	<ul style="list-style-type: none"> Assessment of regulatory functions within 12 months Further measures in the medium term (2–3 years) 	Perceived mistrust among patients and health professionals regarding generics has been fuelled by reports of possible quality issues with generics. To convince them to prescribe, dispense and use generics, and thus to ensure that generics policies (see measures 18 and 19) are fully exploited, the quality of generics must be ensured. Recommended action includes strengthening the NMRA's mandate in this field of activity and dissemination activities about quality assurance for generics. ¹⁸

¹⁷ Generics can improve access to medicines and contribute to major savings in health systems when they are perceived as of equal quality. There is evidence from several countries with limited use of generics due to distrust and limited knowledge. Studies have shown that capacity-building and information activities in this field have contributed to more informed and more rational prescribing, dispensing and use of medicines, including generics (16, 17).

¹⁸ The recommendation to consider only medicines with a therapeutic equivalence evaluation is based on the Orange Book in the United States of America, which contains medicines with a therapeutic equivalence evaluation approved by the Food and Drug Administration. The NMRA's activity report could include a similar section.

Table A.2 continued

Measure	Recommended actions	Responsible institution(s)	Suggested timetable	Rationale, including international experience
	<ul style="list-style-type: none"> The results of quality checks and pharmacovigilance issues (including generics) could be published in a regular (annual) activity report of the NMRA. Further, it is strongly recommended that only quality-assured generics are included in public funding. Only medicines for which a therapeutic equivalence evaluation has been submitted in existing formularies (NEML/ADP/SGBP) should be included for any future reimbursement in a future IPR. 			
16. Monitoring and enforcing INN prescribing	<ul style="list-style-type: none"> A reporting mechanism should be introduced to monitor actual prescribing behaviour of doctors, to gain data and, if needed, adjust information and training activities. Possible steps for such a reporting mechanism may include: <ul style="list-style-type: none"> performing regular (i.e. quarterly, in line with disbursement) monitoring of prescribing behaviour of doctors, based on existing documentation; nominating and training staff to monitor INN prescribing and provide feedback; defining a template (reporting system) for documentation; defining a mechanism for feedback if prescription behaviour suggests irresponsible prescribing; defining the focus of monitoring in specific periods of time, preferably starting with a few medicines in a pilot project; including high-level reporting on results of prescription behaviour in the annual report of the MHIF; enforcing INN prescribing; undertaking general information activities for doctors (see also measure 14); addressing the issue of information about INN prescribing during individual feedback to doctors; considering financial incentives/disincentives for doctors related to INN prescribing (e.g. prescribing targets); including training on INN prescribing in the curriculum for doctors. 	<p>MHIF for monitoring, financial incentives and information activities (the latter possibly jointly with the Ministry of Health); Ministry of Health for change in curricula</p>	<ul style="list-style-type: none"> Information activities to be improved within 12 months Curricula to be changed within two years Possible financial incentives to be introduced within 2–3 years 	<p>Although doctors are obliged to prescribe by INN, it was reported that in practice they prefer writing trade names of medicines included in the positive list. To reap the benefits of an IPR system, INN prescribing by doctors is fundamental.¹⁹</p>

¹⁹ A literature review on demand-side policies to encourage the use of generics found that INN prescribing needs to be actively promoted. In Belgium only 7.1% of all prescriptions in 2009 were by INN, whereas in the United Kingdom 82.6% of all prescriptions in 2009 were by INN. The high figures in the United Kingdom are related to the fact that medical students are taught to prescribe by INN and this is also endorsed by pharmaceutical advisers in the community (17).

Table A.2 continued

Measure	Recommended actions	Responsible institution(s)	Suggested timetable	Rationale, including international experience
17. Generic substitution	<ul style="list-style-type: none"> Pharmacists should be encouraged to substitute prescribed medicines with generics. Pharmacists should be encouraged to dispense the lowest-priced therapeutic equivalent product. Therapeutic equivalence is evaluated by the NMRA and only medicines with a therapeutic equivalence evaluation in their dossier can be dispensed at the expense of public payers. Generic substitution should be done by a trained pharmacist, or a trained pharmacist should at least be present in the pharmacy when substitution is done. If regulated pharmacy mark-ups are introduced, financial incentives could be included to support generic substitution. 	Ministry of Health	<ul style="list-style-type: none"> Improved information activities to be instituted within 12 months Further measures to be implemented in line with other measures (e.g. implementation of mark-ups) 	Currently, Kyrgyz pharmacists do not automatically dispense the lowest-priced alternative medicine. The decision is driven by patient requests and the desire of pharmacists to maximize their incomes. ²⁰
18. Considering support for local generics production	<ul style="list-style-type: none"> If a decision to support local generics production is made, possible measures could be: <ul style="list-style-type: none"> including a criterion in public tenders that favours local manufacturers if they can meet the requirements of the tender; considering a "preferred supplier rule" when regulating retail mark-ups (e.g. pharmacies in urban areas may be allowed to apply the mark-ups of remote areas to medicines from local producers). 	Ministry of Health	<ul style="list-style-type: none"> To be introduced in the medium term: within 2–3 years 	Although some figures indicate that local production represents 3–4% of the total pharmaceutical market in Kyrgyzstan, representatives of the local generics industry indicated that the share of sales held by local manufacturers is much lower, at around 1% of the total market. A stronger local generics industry could contribute to greater competition and lower prices of generics.

²⁰ As examples from other countries confirm, legal introduction is not sufficient: generic substitution needs to be enforced to become effective. This can be enhanced by training and dissemination activities. Regulated pharmacy mark-ups could be designed in a way to promote generic substitution (e.g. in France the mark-up for generics is calculated based on the price of originator medicines). The Netherlands once had a provision that pharmacists were granted a third of the savings made by social health insurance due to generic substitution.

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