Assessment of Medicine Pricing and Reimbursement Systems in Health Insurance Schemes in Selected African Countries
Assessment of Medicine Pricing and Reimbursement Systems in Health Insurance Schemes

Summary of Findings, Lessons and Recommendations

July 2016
Acknowledgements

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### Acronyms

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<th>Description</th>
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<tbody>
<tr>
<td>CBHI</td>
<td>Community-Based Health Insurance</td>
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<tr>
<td>CNAMGS</td>
<td>Caisse nationale d’assurance-maladie et de garantie sociale (National Social Health Insurance Fund of Gabon)</td>
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<tr>
<td>DRG</td>
<td>Diagnosis-Related Group</td>
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<td>EFY</td>
<td>Ethiopian Fiscal Year</td>
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<td>ERP</td>
<td>External Reference Pricing</td>
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<td>ETB</td>
<td>Ethiopian Birr</td>
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<tr>
<td>FMHACA</td>
<td>Food, Medicine and Health Care Administration and Control Authority</td>
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<td>FMOH</td>
<td>Federal Ministry of Health</td>
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<tr>
<td>GNI</td>
<td>Gross National Income</td>
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<td>GOE</td>
<td>Government of Ethiopia</td>
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<td>HAI</td>
<td>Health Action International</td>
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<td>HC</td>
<td>Health Centres</td>
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<tr>
<td>HF</td>
<td>Health Facility</td>
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<tr>
<td>HH</td>
<td>Household</td>
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<td>HIC</td>
<td>High-income County</td>
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<td>HP</td>
<td>Health Post</td>
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<td>HTA</td>
<td>Health Technology Assessment</td>
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<td>IRP</td>
<td>Internal Reference Pricing</td>
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<tr>
<td>IMF</td>
<td>International Monetary Fund</td>
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<tr>
<td>LIC</td>
<td>Low-income Country</td>
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<td>MDG</td>
<td>Millennium Development Goals</td>
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<td>MIS</td>
<td>Medical Insurance Scheme</td>
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<td>MPDD</td>
<td>Medical Procurement and Distribution Department</td>
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<td>MSH</td>
<td>Management Sciences for Health</td>
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<td>NEML</td>
<td>National Essential Medicines Lists</td>
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<td>NHA</td>
<td>National Health Accounts</td>
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<tr>
<td>NHIA(S)</td>
<td>National Health Insurance Authority (Scheme) of Ghana</td>
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<tr>
<td>OOP</td>
<td>Out-of-pocket</td>
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<tr>
<td>PE</td>
<td>Pharmacoeconomic (analysis)</td>
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<td>PFSA</td>
<td>Pharmaceutical Fund and Supply Agency</td>
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<tr>
<td>PHC/U</td>
<td>Primary health care/Unit</td>
</tr>
<tr>
<td>RAMA</td>
<td>Rwanda’s Medical Insurance Agency (“Agence Rwandaise d’Assurance Maladie”)</td>
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<tr>
<td>RSSB</td>
<td>Rwanda Social Security Board</td>
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<tr>
<td>RWF</td>
<td>Rwandan Francs</td>
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<tr>
<td>USD</td>
<td>United States Dollar</td>
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<td>WB</td>
<td>World Bank</td>
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<td>WHO</td>
<td>World Health Organization</td>
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## Concepts and definitions

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<th>Term</th>
<th>Description</th>
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<tr>
<td>Benefit package</td>
<td>The term ‘benefit package’ describes how services are organized into different levels of care in the public sector. It also defines the types of services that are considered as achievable for the country commensurate with its resources.</td>
</tr>
<tr>
<td>Capitation</td>
<td>Fixed payment to providers per person enrolled in the insurance scheme. Providers paid by capitation bear the financial risk of providing a defined package of services to their beneficiary population.</td>
</tr>
<tr>
<td>Case-based reimbursement (DRG)</td>
<td>Retrospective payment of an administratively predetermined amount per case or episode of illness. Individual services are bundled into distinct case categories that are reasonably homogeneous with respect to resource cost, and providers are reimbursed a fixed amount per case in each category.</td>
</tr>
<tr>
<td>Coinsurance</td>
<td>Percentage of the total charge for a service that those covered must pay for out-of-pocket.</td>
</tr>
<tr>
<td>Contribution mechanism</td>
<td>The means by which funds are mobilized for insurance. Sources of funds include allocations from general tax revenues, mandatory contributions for an identifiable insurance fund, and voluntary contributions.</td>
</tr>
<tr>
<td>Co-payments</td>
<td>Flat amounts that those covered must pay out-of-pocket for each service used.</td>
</tr>
<tr>
<td>Cost sharing</td>
<td>Any direct payment the users of health services make to the providers of services. Modalities of cost sharing include co-payments, coinsurance, and deductibles.</td>
</tr>
<tr>
<td>Coverage</td>
<td>This refers to the beneficiary population, for instance, the percentage of people who are covered by insurance or defined population groups (such as employees and dependents) who are covered.</td>
</tr>
<tr>
<td>Covered services</td>
<td>See benefit package.</td>
</tr>
<tr>
<td>Deductibles</td>
<td>Amount that those covered must pay out-of-pocket before the benefits of the insurance programme become active.</td>
</tr>
<tr>
<td>Excluded services</td>
<td>Services or methods of using services that are not covered in the benefit package of an insurance scheme. Individuals are liable for the full costs of excluded services.</td>
</tr>
<tr>
<td>External Reference Pricing</td>
<td>Also called cross-country referencing and international price comparison – benchmarks product prices in one country against prices of the same product in a selected basket of other countries.</td>
</tr>
<tr>
<td>Fee-for-service</td>
<td>Retrospective payment per item of service provided, that is, payment after those covered have reported the use of covered services. Fee-for-service reimbursement rates can be determined either by market forces or through administratively determined or negotiated fee schedules.</td>
</tr>
<tr>
<td>Generic medicine</td>
<td>Any product that contains an off-patent medicine (WHO, 2015)</td>
</tr>
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</table>
**Promotion of generic medicine**

Generic medicines are produced and distributed without patent protection. Promotion of the use of quality assured generic medicines is a method of managing pharmaceutical prices. The various approaches used include facilitated market entry of generics, generic substitution by dispensers, external reference pricing, strategies to foster competition in the market, and schemes to encourage use of generics among providers and consumers (WHO, 2015).

**Health Technology Assessment**

The International Network of Agencies for Health Technology Assessment defines HTA as “The systematic evaluation of properties, effects, and/or impacts of health care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods.” HTA in relation to pharmaceuticals (pharmacoeconomic/PE analysis) encompasses evaluations relevant to price setting or pricing policies. (WHO, 2015). Four key methods are applied in HTA/PE

- **Cost minimization analysis**: cost of two alternative products with similar outcomes are assessed and the one with the least costly treatment is selected.
- **Cost effectiveness analysis**: cost per unit of therapeutic outcome in natural units such as ‘symptom free days’ are compared
- **Cost benefit analysis**: cost per unit of benefits measured in monetary benefits are compared
- **Cost utility analysis**: outcomes are measured in non-monetary terms such as Quality Adjusted Life Years (QALY) (Drummond et al., 2005; Nguyen et al., 2015).

<table>
<thead>
<tr>
<th>Price taker/acceptor</th>
<th>Country/scheme that pay the price the pharmaceutical company/retailer charges</th>
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<tbody>
<tr>
<td>Provider payment</td>
<td>The mechanisms by which resources are allocated from the insurance fund (or national health service) to institutional service providers (for instance, hospitals) or individual service providers (For example, doctors). Options include the following: budgets or salaries, capitation, fee-for-service reimbursement, case-based reimbursement, and various combinations of these options.</td>
</tr>
<tr>
<td>Purchaser</td>
<td>The institution responsible for purchasing health services from providers. This always includes the insurance fund itself, but some schemes involve additional purchasers as well, including entities that are also service providers. See fund holder.</td>
</tr>
<tr>
<td>Risk pool</td>
<td>Group of people covered by the same insurance scheme.</td>
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1. Introduction

Recently, universal health coverage (UHC) has become key aspiration for low and middle-income countries. The 2013 World Health Report gave leverage to this policy objective. UHC has been defined as “ensuring that all people can use the promotive, preventive, curative, rehabilitative, and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship” (WHO, 2013). Thus, UHC captures three issues, that is, proportion of the population that has access, the type of service/comprehensiveness of services for which access is created and financial protection for households. More and more African countries are shifting their priority towards UHC.

One of the major challenges that health systems face in developed and developing countries alike is cost escalation. In the case of developing countries, the challenge is demonstrated in the form of mismatch between revenue and expenditure for health care thus limiting access for a substantial part of the population and leaving them to cater to their health care needs in the form of out-of-pocket (OOP) payment. One major cost driver in the health sector is pharmaceuticals. Globally, pharmaceutical expenditure is rising. Studies show that medicine expenditure consumes 20% to 60% of health spending in low and middle-income countries (LMIC) compared to 20% in Organisation for Economic Co-operation and Development (OECD) countries (WHO, 2015). Evidence from high-income countries (HICs) shows that they have been using variety of pricing and purchasing (reimbursement) methods to contain this soaring pharmaceutical expenditure (Nguyen et al., 2015). In HICs, most payments for pharmaceuticals are made by the state or insurance schemes, which give them an edge to influence prices. In LMICs, on the other hand, more than half and sometimes up to 90% of expenditures on medicines are out of pocket (Bigdeli, Laing et al., 2015) hence; it has not been easy to implement pricing and purchasing policies with significant results. As a result, there is limitation of evidence on the implementation and effects of various medicine pricing and reimbursement measures. LICs also lack adequate global experience from which to draw lessons.

The other major challenge in the health sector, notably LMICs, is the high rate of medicine wastage and inappropriate use. It has been documented that medicines are major sources of health system inefficiency (Bigdeli, Laing et al., 2015). In addition, according to the World Medicines Situation 2011, only 30% to 40% of patients in LMICs are treated according to treatment guidelines (Bigdeli, Peters and Wagner, 2014). Some of the major causes for this situation include, issues with quality of medicine in the market such as substandard and falsified medicine, high medicine price, and inappropriate medicine use, exacerbated by poor knowledge of patients, prescribers and dispensers and shortage of adequately trained professionals (Bigdeli, Laing et al., 2015; Bigdeli, Peters and Wagner, 2014).
A case study was conducted in five countries in the African region including Ethiopia, Gabon, Ghana, Rwanda and Senegal to fill this evidence gap by documenting medicine pricing and reimbursement experiences. The countries were selected based on their experience in the implementation of social health insurance system and/or prepayment mechanisms. For each country, a consultant was identified and worked with a country team under WHO/AFRO guidance. Country case studies covered topics including information on population and socioeconomic status; background on the pharmaceutical sector; management of medicines within the health insurance schemes; major challenges related to selection, supply, expenditure, pricing, and reimbursement of medicines; measures taken or planned to mitigate the major challenges; and conclusion and recommendations. However, the country reports did not cover the issue of medicine utilization appropriateness and equity. Insurance experiences of the countries are varied ranging from more matured schemes, which have managed to cover a large proportion of the population as in Rwanda and Gabon, to a highly fragmented system in Senegal and a pilot CBHI in Ethiopia.

This report summarizes findings of the country case studies, identifies challenges, and draws on lessons from the case study countries and from other countries with regard to medicine pricing and reimbursement under health insurance system. In addition, the report suggests recommendations to improve medicine pricing and reimbursement in the African region.
2. Summary of case studies

2.1. Ethiopia

Background on the country and its health system

Ethiopia is the second most populous country in sub-Saharan Africa with a population of 94.1 million. Ethiopia managed to achieve an average economic growth of 10.8% per annum between 2002/03 and 2012/2013. The country aspires to attain middle-income status by 2025. The per capita gross national income stood at US$ 629 in 2013/14. The broad-based growth has helped to reduce the proportion of Ethiopians that live below national poverty line from 38.7% in 2004/05 to 29.6% in 2009/10.

Ethiopia has a three-tier health service delivery system classified under primary, secondary and tertiary levels. Primary health care has three points of service: health posts, health centres and primary hospitals. The secondary level of care comprises general hospitals. The tertiary level of care is made up of federally-run, specialized and teaching hospitals. The primary health service coverage increased from 45% in 1996/97 to 93.6% in 2012/13. The public sector is the predominant health service provider including medicine. Nonetheless, the role of the private sector, specifically the for-profit sector, has been increasing overtime, especially in major urban areas and becoming the preferred service point for wealthier households and those discouraged by the long waiting time in public HFs.

The health care system is financed by four main sources: the government, households, external assistance and the private sector. Total health expenditure stood at US$ 20.77 in 2010/11, a significant increase over previous years. However, the sum is still low compared to expenditure in other countries of similar economic status and global estimates of expenditure needed to meet essential health care. NHA findings show that share of government financing has declined while that of external resource has increased sharply. Households’ out-of-pocket payment has levelled off at a high share of 34%.

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1. It refers to the percentage of population covered by the existing health centres and health posts in catchment area. According to the standard (FMOH, 2015), a health centre caters to up to 25 000 population in rural areas and 40 000 in urban settings. A health post has a catchment of up to 5,000 population and is located only in rural areas.
Background on the pharmaceutical sector

Ethiopia developed the first National Drug Policy in November 1993. Subsequently, the Policy on Anti-Retroviral Drug Supply and Use was developed in July 2002 complementarily to the National Drug Policy. The Drug Administration and Control Authority, the pharmaceutical regulatory body was established in 1999 and was transformed into the Food, Medicine and Health Care Administration and Control Authority in 2009. The mandate for the regulatory body expanded from regulating medicine solely to include food, environmental health, health professionals, health and health-related institutions. Subsequently, essential medicine list, list of medicine and standard treatment guidelines for different tiers of service, and medicine formulary was developed.

To address the problems with pharmaceuticals in public health facilities, the government, in 2007, developed the Pharmaceutical Logistics Master Plan and established the Pharmaceutical Fund and Supply Agency (PFSA), a national medicine procurement and distribution agency. There are four main reasons why PFSA came into existence. First, to streamline supply as there were duplication of efforts in the past. Second, the rationale was to reduce wastage through appropriate management of medicines and integration of funds, if necessary. Third, to make supply in a pool system function according to customers’ needs. Fourth, to improve the physical distribution (transportation) system (FMOH, 2011).

Description of insurance system

To date, Ethiopia has yet to launch a national risk pooling mechanism. Ethiopia developed a Health Insurance Strategy to launch social health insurance for the formal sector and community-based health insurance scheme for the informal sector in 2008. CBHI has initially been piloted in 13 districts spread across four regions, pilot has expanded and scale up plan has been designed. The launching of SHI is scheduled for January 2016. This report will review experience of medicine pricing and reimbursement in the CBHI pilot.

The main sources of finance for CBHI are premium and registration fee collected from members, general subsidy from federal government and targeted subsidy from region and woredas covering expense of indigents that average around 10% of total membership in each scheme. Households conduct membership after village (kebele) residents reach insurance membership decision. Insurance risk and fund are pooled at district level and there is no risk pooling at regional or central levels. Fee for service is the selected provider payment modality.

Medicine pricing and reimbursement

National level bulk procurement of medicine and other supplies is conducted by PFSA, which is the main supplier, especially for public health facilities. PFSA distributes medicine and supplies to HFs at a wholesale price and public health facilities add up 15% to 25% mark up to set a retail price2. CBHI does not conduct medicine pricing and is rather a price taker as it reimburses HFs based on the retail price they set. The price list for medicines is shared with CBHI on regular basis.

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2 See the country case report for details of how pricing is conducted.
CBHI does not have medicine list for reimbursement. Members are entitled to access all services rendered within contracted government health facilities except for tooth implantation and eyeglasses. Prescribers need to follow standard treatment guidelines and the list of medicines for the respective level of health facility. Hence, any medicine, which falls within this list, can be reimbursed by CBHI. In the public sector, prescriptions should be made in generics.

The major source of medicine for insurance members is within public health facilities. CBHI only covers prescribed medicines. In cases where medicine is not available within the contracted HF, users can purchase the medicine in private medicine retail outlets by paying out of pocket and request reimbursement later on. However, there is a huge transaction cost for members in processing reimbursement. There is no co-payment for medicines or services at the outpatient or inpatient level.

Contracted HFs request reimbursement on a quarterly basis. The scheme will automatically pay 75% of the requested amount; the remaining 25% will be paid once the scheme checks the report and conducts monitoring in the contracted HF by taking sample of patients that utilized the service and checking their medical as well as respective financial records. In principle, the scheme should reimburse HFs within two weeks of receiving reimbursement request. However, in some districts, there is a delay in reimbursement due to financial difficulty.

The scheme does not have a systematic mechanism to monitor service delivery or medicines in contracted health facilities. HFs are monitored when inaccuracies are observed in the reimbursement request from HFs or if clients forward complaints. Clinical audits are being designed to improve monitoring and evaluation.

### 2.2. Gabon

**Background on the country and its health system**

The population of Gabon was estimated at around 1.8 million in 2015. About 84% of the population lives in urban areas. Gabon has a GNP of US$ 16,977 per capita classified as an upper middle-income country. However, close to 33% of the population lives below the poverty line and it is ranked 112th out of 187 countries based on HDI.

Gabon is subdivided into 10 health regions and 52 health districts. The health system is based on three sectors: the civilian and military public sector, the semi-public sector and the private for-profit and private non-profit sectors. The public health sector has three levels: central level comprising central directorates including teaching hospitals, regional level comprising regional directorates and regional hospitals, and the peripheral level comprising medical centres, dispensaries, urban health centres and health stands.

According to the 2013 NHA, pharmaceutical spending consumed about 28% of total health expenditure. Pharmaceutical expenditure is financed by the Government (25.6%), public health insurance (15.4%), private health insurance (4.7%), household (54.2%) and donations (0.06%). Pharmaceuticals also consume 20% of public and private insurance expenditures.
Background on the pharmaceutical sector

The management and regulation of medicines is the duty of the Department of medicines and pharmacy (DMP). There is a central purchasing body (OPN) responsible for supplying, storing and distributing medicines to public health facilities. A national essential medicines and medical devices list by level of health facility was drawn up way back in 1998 and is regularly revised every two years.

Standardized treatment regimens for the management of common illnesses in dispensaries were developed in 1998. Certain disease control programmes such as the HIV/AIDS, tuberculosis and malaria control programmes have drawn up specific STGs for those diseases. However, these documents were not revised subsequently.

Description of insurance system

In 2007, Gabon established a mandatory health insurance scheme. The National Social Health Insurance Fund (CNAMGS) is a public body that incorporates three funds: a fund for low-income Gabonese, another for civil servants and a third for employees of the private and semi-public sectors and self-employed persons. CNAMGS is financed by employer-employee contributions, tax levy, state subsidies, bequests and other revenue generated by the Fund’s own activities. In 2014, CNAMGS had about 900,000 members accounting for 60% of the population. Total spending (technical and operational expenses) for the same year came up to about US$ 66.3 million. In addition to the social insurance scheme, the country also has a number of private health insurance companies, which cover about 10% of the population. Discussions are underway to make private insurances schemes complementary to the mandatory insurance.

Medicine pricing and reimbursement

Medicine pricing is regulated by a Decree whereby the Ministry of the Economy sets the margin at 1.58 of the purchase price of the medicine in Libreville, and 1.7 for Port-Gentil and the other towns of Gabon.

CNAMGS has a list of reimbursable medicines prepared by a technical committee and revised every two years. Generic medicines represent about 25% of products in the list. Medicines provided by certain programmes in the Ministry of Health such as vaccines, ARVs, tuberculosis medicines and medicines considered palliatives are excluded from the list. Only prescribed medicines on the list are reimbursed at the rate of 80% for common illnesses, 90% for long-term health conditions or chronic illnesses, 100% for maternity and 50% for costly products. The remaining cost of medicine is covered by patients as a co-payment. There is no upper limit for co-payment. There is an attempt to cover the cost of health care for the poor through the National social assistance fund (FNAS); however, the mandate of this structure is not yet quite clear for the community.

Reimbursement is done directly to pharmacies for medicines used in outpatient care, and in hospitals for medicines used by hospitalized patients. Pharmacies and hospitals send their bills to the insurance companies for reimbursement. The latter have a contractual time limit of one month to conduct checks and settle the bills. However, payment delays have been reported as a challenge which is exacerbated by lack of remote transmission of bills, insurance claim forms and an electronic database.
CNAMGS neither has a database on medicine pricing, nor a system to monitor the evolution of prices in relation to medicines supplies. However, CNAMGS has set up a system to track mega-prescribers and mega-users through computerization.

2.3. Ghana

Background on the country and its health system

Ghana follows a decentralized system of governance, divided into 10 regions and 216 districts covering about 25.9 million inhabitants in 2013. Ghana is a lower middle-income country with a GNI per capita of US$1,590 in 2014. However, in recent times, Ghana is facing high fiscal deficit.

There are four main categories of service delivery: public (55%), private-not-for-profit (19%), private-for-profit (23%), and traditional system (3%). Public health services are delivered through a hierarchy of hospitals, health centres, maternity homes and clinics including a Community-based Health Planning and Services (CHPS) strategy.

In 2012, total health expenditure was estimated at US$1,933 billion. The health sector is financed by government funds (57%), private funds-companies and households (34%) and international funds (9%). Health sector financing is faced with uncertainties with dwindling external resource, increasing household OOP payment, and increase in government funds, which is consumed by wage bills.

Background on the pharmaceutical sector

Because of the NHIS and the related dramatic increase in government funding, the country is well on track to achieving universal access to essential medicines, with increased patient numbers and high levels of patient satisfaction.

On the other hand, public procurement of pharmaceuticals is done at health facilities level leading to loss of economies of scale. As a result, the pharmaceutical sector is inefficient and rather costly, mainly because of decentralized procurement, incomplete quality assurance, absence of medicines pricing policy and regulations and insufficient critical analysis of reimbursement by the NHIS, which allows for unbridled overprescribing and high medicine costs.

Description of insurance system

Ghana’s National Health Insurance Scheme was set up in 2003. Currently, there are three types of health insurance schemes namely District mutual schemes (DMHIS), Private mutual schemes and Private commercial schemes. DMHIS is a public/non-commercial scheme and anyone resident in Ghana can register under this scheme. The scheme covers indigents through funding it receives from the central government. The private mutual scheme caters to any group of people (for instance, members of a church or social group) who start contributing to provide for their health needs based on services approved by the governing council of the scheme. Private mutual health insurance schemes are not entitled to subsidy from NHIF. Private commercial health insurance schemes are operated by approved companies and do not receive subsidy from NHIF. Whatever form of health insurance one signs up to, entitles him/her to some minimum outpatient and inpatient services.
NHIS, however, has an explicit and extensive negative list. There is no financial pooling across the Schemes.

Active membership in NHIS was 36.8% in 2013. There is policy of free enrolment of the poor, pregnant woman, children under 18 and people above 70 years. Thus of the total members, only 30% pay premium. The premium to be paid per person per annum ranges from US$ 1.9 to US$ 12.63 with an average contribution of US$ 5.79. There is no cost sharing in NHIS. NHIF is financed by National Health Insurance Levy (NHIL), which is a kind of VAT on selected goods and services, contributions to the Basic National Social Security Scheme, premium paid by members, support from the government, return on investments made by the Authority, grants, donations, Gifts and any other voluntary contributions made to the Fund. In 2013, NHIL constituted 72% of total NHIF income; SSNIT funds accounted for 20%, returns on investment represented 4.7%, premiums collected from the informal sector was 3.4%, and other income, 0.1%.

In 2013, total expenditure on NHIS excluding staff cost was US$ 445 million. This expenditure was made on inpatient services excluding medicines (17.49%), outpatient services excluding medicines (23.34%), medicines (34.45%), investment on equipment (4.65%), running cost (16.45%), interest on loan (0.60%) and support for public health interventions (3.03%). NHIS is the major financer of public health service. About 82% of all Internally Generated Funds of health facilities mainly essential medicines, are financed from NHIS.

**Medicine pricing and reimbursement**

Standard Treatment Guidelines (STGs) are available and the last issue was published in 2010. Based on STGs, the Essential Medicines List (EML) was issued. EML serves as basis for public procurement and is used in defining the Medicines List of the National Health Insurance Authority (NHIA). The last version was published in January 2014.

NHIA medicines’ list defines which drugs are reimbursable under NHIS and at what price they are reimbursed. The NHIS pharmaceutical reimbursement list covers more than 80% of medicines required to treat diseases of common occurrence in Ghana. The reimbursement price is set annually based on median prices found in the local market. Medicine pricing in NHIS is done through survey of market prices of generic medicines in both the public and private sectors. The median prices and not the average prices are used for reimbursement since the average prices are affected by extremities. The reimbursement list is reviewed annually. This approach is, however, negatively affected by the inefficiencies of the local market and threatens the sustainability of insurance scheme.

Prescribing of medicines by generic names is mandatory in the public sector and generic substitution is permitted. The private sector is not necessarily obliged to comply with STGs and EML but those who are providers under NHIS are compelled to do so through the scheme’s pharmaceutical reimbursement system.

According to NHIS regulation, claims shall be reimbursed after ninety days. The reality, however, is that sometimes it takes over one hundred and eighty days to reimburse claims. Such delays have led to situations in which providers sometimes refuse to dispense medicines to insured patients unless they pay cash even though co-payments are not allowed. Recently, electronic centralized
claim processing systems are being established to address the challenges. NHIA also developed a database for prescription from which it conducts medicines utilization analysis, feedback mechanism and clinical audits. The database captures information such as patient bio-data, type of medicines dispensed, formulation and dosage forms, level of care, and number of medicines per prescription and cost of treatment.

The scheme is implementing various cost containment strategies. The establishment of a clinical audit and strengthening of the internal audit has resulted in huge cost savings for NHIS. In 2013, clinical audit alone recovered a total of US$ 710 526 from 203 service providers audited. Other strategies include a consolidated premium account which will permit proper monitoring of premium collection, uniform prescription forms with unique security features and prescriber identification, linking diagnoses to treatment to ensure monitoring rational use of medicines under the scheme, support diseases prevention activities to reduce disease burden on the scheme, regular review of benefit packages, prescribing by levels of care and a gate keeper system.

2.4. Rwanda

Background on the country and its health system

Rwanda's population was estimated to be over 11 million in 2015. Since 1994, the country has made significant developmental progress. Between 2001 and 2014, real GDP growth averaged around 9% per annum. The poverty rate fell from 59% in 2001 to 45% in 2014, which has benefited the greatest part of the population since 2005. Remarkable improvements on key health indicators have also been observed including reductions in under-five mortality and maternal mortality, life expectancy at birth has increased from 29 in 1995 to 65.7 in 2015.

Rwanda has a decentralization system of governance and health service administration. The entire health care system is under the oversight of the Ministry of Health and comprises public, faith-based and private health facilities. Faith-based health facilities are recognized by the MOH as part of the public health care system and follow the norms, standards and programmes of the public sector. They represent approximately 40% of all facilities in Rwanda; most of these are health centres. The first line of service delivery is provided by community health workers at the village level. Subsequently, services are provided by a range of health facilities: five national referral hospitals, 42 district hospitals, 479 health centres and 44 health posts. Since 2006, public health and faith-based health facilities are autonomous entities responsible for the management of financial and human resources for health. However, they are still required to follow national norms and standards on service delivery and quality.

In 2009/10, the major sources of financing were donors (61%), private sector (18% was household OOP payment) and the public sector (18%). The health sector financing still relies heavily on external aid, however, share of OOP has declined over the years.

Background on the pharmaceutical sector

The Pharmacy Task Force within the MOH is responsible for policy formulation, implementation and regulation for both the public and the private pharmaceutical sector. The Medical Procurement and
Distribution Department (MPDD) is the primary supplier of pharmaceutical commodities, including generic essential medicines, medical supplies, and laboratory test kits and reagents. In each of the 30 districts of the country, a district pharmacy distributes pharmaceutical commodities to district hospitals and health centres. About 85% of requests from health facilities are provided by MPDD, while the remaining supply is covered by other supply agencies.

As part of the East African Community Medicines Regulatory Harmonization project, several guidelines have also been developed to promote regional integration including Good Manufacturing Practices, Quality management System, Medicine evaluation and registration, Information management system and other quality and regulatory systems. In addition, various measures are undertaken to strengthen the national commodity supply chain. Hence, in 2015, there was no stock out tracer drugs in 98% of HFs as compared to 55% in 2011.

**Description of insurance system**

Rwandan health insurance system is composed of different insurance schemes catering to different population groups:

1. The Community-based health insurance (CBHI) also commonly known as “Mutuelle de santé” covers the great majority of the insured population (94%). Most of the beneficiaries are from the informal sector and live in rural Rwanda. Before its move to Rwanda Social Security Board (RSSB) in July 2015, CBHI was under the oversight of the Ministry of Health;

2. The Medical Insurance Scheme (MIS) of RSSB covers 4.4% of the insured population. This scheme is mandatory for all public servants but also reaches out to private companies. Spouses and legal dependents are covered for the same benefits as members;

3. The Medical Military Insurance (MMI), which covers 0.8% of the insured population, provides compulsory health insurance coverage for military forces; and

4. Employers and private insurers together cover 0.9% of the insured population.

Co-payments or co-insurance is different depending on the type of health insurance scheme registered in. For the beneficiaries of the main health insurance scheme (CBHI), a flat co-payment fee of US$ 0.3 at the health centre (including medicines) and 10% co-insurance at the hospital level (including medicines) is mandatory. The poor and other vulnerable people are exempted from co-payments or coinsurance at the point of care.

MIS Members are expected to pay coinsurance of 15% of the total cost (consultation, laboratory tests, medicines etc.) for outpatient as well as inpatient services. On the other hand, insurance premiums for the poor and other vulnerable people are fully subsidized by the government (about 24% of the population) under CBHI. They are also exempted from co-payments or coinsurance at the point of care. The poor are identified based on the socioeconomic classification developed by the Ministry of Local Government in 2001, known as ‘Ubudehe’.
From about 1% of the population covered by pilot prepayment schemes in three districts of the country in 2000, health insurance coverage rose dramatically to reach 70% of the population in 2013/14.

**Medicine pricing and reimbursement**

The management of medicines in health insurances is not clearly outlined in the national health insurance policy of 2010. RSSB-MIS issues the list of reimbursable medicines in private health facilities and in private pharmacies. Preference is given to generic medicines where they are widely accessible. RSSB-MIS covers medicines for outpatients as well as inpatients as per the approved lists of reimbursable medicines. All types of medicines included on the list are covered. Some branded products with more available equivalent generics are not reimbursable. Prescription with a total value of more than US$ 53 requires medical advisor's authorization. This will be affected after discussions with the prescriber or after verifying the patient's file.

Medicines that are fully subsidized through vertical programmes (such as HIV/AIDS, TB, STI and vaccines for children, etc.) are excluded from the reimbursement system. The medicine list is revised annually for content and bi-annually for price.

To determine the price for each medicine on the list for the private sector, RSSB-MIS uses prices obtained from survey results and apply a maximum of 40% profit margin. The lowest price is used for reimbursement, except when it is too low to question the quality of the product. For the public sector, prices in health facilities should follow MOH instruction (maximum of 20% of total cost as profit margin). Recently, it was decided that the Executive Secretary Office of Rwanda Health Insurance Association would revise the list together with representatives from heath insurers. However, an assessment on paediatric medicine in 2012 showed that final patient prices were 23.4% higher than procurement prices for generic equivalents in the public sector, whereas in the private sector they were priced 89.2% more than in the public sector.

Patients are prescribed medicines either from all pharmacies run by public health facilities or from partner private pharmacies. The prescription of medicines by generic names is neither mandatory in the public sector nor in the private sector. Pharmacists are allowed to substitute generic medicines.

The process of submission and processing of claims for reimbursement is described as follows: the patient pays 15% of the total costs of prescribed drugs directly to the provider (in this case, the retail pharmacy). Thereafter, providers submit their monthly claim to RSSB-MIS for reimbursement of the remaining 85%. It takes on average 30 days to process claims for medicines reimbursement. Service providers are reimbursed on fee for service basis.

First edition of STGs was published in October 2007. Subsequently treatment guidelines were developed for various medical disciplines. National Essential Medicines List was also developed the latest version of which dates back to September 2015.

RSSB-MIS archives all prescriptions in hardcopies, as they are currently not recorded in an electronic system. These archived prescriptions are used for further studies or any investigation on a particular disease or any investigation on fraudulent cases. The scheme also archives all versions of retail price
list of reimbursable medicines. RSSB-MIS uses the results of the Rwanda Market Survey conducted among wholesalers’ pharmacies (comparative list of prices) to monitor medicine prices.

MIS does not have a system for monitoring the availability of quality medicines provided through service providers. It should normally be done at the national level but the country does not currently have a functional National Medicine Quality Control Laboratory. Neither does RSSB-MIS have a system for monitoring medicine-prescribing practices per se. However, a kind of monitoring is done during the claims verification process. For example, there should not be more than four products per medical prescription. Only prescribers who are found guilty of malpractice receive feedback. Currently, the scheme has a system for monitoring expenditure on medicines. The pharmaceutical and medical verification units which verify invoices for services and medicines provided by partner pharmacies and HFs to beneficiaries do monitoring manually.

2.5. Senegal

Background on the country and its health system

Senegal has a population of about 14 million inhabitants. Several reforms have been undertaken which brought about an improvement in the running of health sector in terms of drug availability and financial viability. Health insurance has recently reached an extension phase in Senegal. Much as such extension remains generally sluggish and inadequate, the movement is real and seems irreversible.

Background on the pharmaceutical sector

The Directorate of Pharmacy and Drugs is a national regulatory authority responsible for initiation and implementation of the pharmaceutical policy, the inspection and registration of drugs. The regulatory and legislative framework, which was largely inspired by French regulations, is made up of a collection of mostly old texts, not often adapted to market specifics, and hardly applicable because of weak institutions and inadequate human, technical and financial resources available to the Directorate.

Description of insurance system

Senegal has multiple and highly fragmented insurance systems through which the country managed health coverage for only 20% of the population. The major categories are listed below.
<table>
<thead>
<tr>
<th>Type of insurance</th>
<th>Beneficiary/ target group</th>
<th>Source of finance</th>
<th>Benefit package</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-contributory Plan</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>National health insurance</strong></td>
<td>Concerns mainly the public sector (civil servants, military personnel, their spouses and children and students)</td>
<td>State through the national budget</td>
<td>Covers 80% of medical costs excluding medicine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>State fund and university’s income through welfare centres</td>
<td>Consultation, drugs, diagnosis, dental care and cost of hospitalization in recognized public and private HFs</td>
</tr>
<tr>
<td><strong>Exemption for certain population groups/services</strong></td>
<td>SESAME plan–persons aged 60 years and above</td>
<td>National budget</td>
<td>100% coverage for pharmaceutical products available in public HFs for outpatient and inpatient care following referral to approved public or private HFs</td>
</tr>
<tr>
<td></td>
<td>Children aged 0 to 5 years</td>
<td>A fixed amount budgeted pro-rated at the number of cases expected. Payment made through treasury cheque.</td>
<td>Free care for children under 5</td>
</tr>
<tr>
<td></td>
<td>The destitute</td>
<td>Ministry of Finance–for certificate issued by an administrative authority Council Office – when issued by the Mayor. Hospital internal revenue – when eligibility approved by social services</td>
<td>Covers pharmaceutical products featuring on the list of essential products, either generic or brand name, available in the public HF (outpatient or hospitalization)</td>
</tr>
<tr>
<td></td>
<td>Childbirth and Caesarean section (introduced in the poorest 5 regions)</td>
<td>Free distribution of kits containing basic pharmaceutical products US$ 82 paid in advance to the hospital for each Caesarean section</td>
<td>Normal deliveries in health posts and health centres and Caesarean sections in levels 1, 2 and 3 public health establishments</td>
</tr>
<tr>
<td></td>
<td>Antiretroviral, tuberculosis drugs and simple antimalarial drugs.</td>
<td>Government and donors</td>
<td>Access these medicines free of charge in public health facilities</td>
</tr>
<tr>
<td>Type of insurance</td>
<td>Beneficiary/ target group</td>
<td>Source of finance</td>
<td>Benefit package</td>
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<tr>
<td>------------------------------------------</td>
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</tr>
<tr>
<td><strong>Compulsory contributory insurance plan</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health Insurance Institutions (IPMs)</td>
<td>Independent IPM for enterprises employing &gt;100 persons. Those employing less should group together or join an existing IPM</td>
<td>Members contribution at 6% of their salary and up to a ceiling of US$ 98 and the employer’s contribution is at least equivalent to wage-earner</td>
<td>Partial coverage (40% to 80% cost of consultations, drugs, hospitalization, medical certificates) depending on the IPM. Medicine list varies between IPMs. Medicines used in curative treatment are often approved.</td>
</tr>
<tr>
<td>Social Security Fund</td>
<td></td>
<td>Contributions by employers</td>
<td>Covers industrial accidents and occupational diseases. Consultations, medicine, diagnosis, surgery and any necessary intervention are covered 100%. Medicines irrelevant for the treatment are excluded.</td>
</tr>
<tr>
<td>Motor Vehicle Guarantee Fund</td>
<td></td>
<td></td>
<td>Care to corporal damage from accidents caused by perpetrators who are unknown, uninsured, or insolvent. Full coverage for all services related to the accident.</td>
</tr>
<tr>
<td><strong>Voluntary contributory plan</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mutual health insurance companies</td>
<td>Provide full or supplementary coverage mainly the informal sector</td>
<td>Mainly financed by members’ contribution, sometimes government and donors (at the beginning or from inception). There is co-payment</td>
<td>Usually cover 40% to 80% of medical bills including medicines. Some cover 100% of medicines for hospitalization. Reimbursable medicine list is limited.</td>
</tr>
<tr>
<td>Private insurance companies</td>
<td>Provide full or supplementary coverage to individuals with high level of income such as business persons, industrialists, high-level executive workers of enterprises.</td>
<td>contributions paid by insured persons and from investments proceeds</td>
<td>Varies from 50% to 100% of medical expenses, including medicine for services in approved public and private health facilities.</td>
</tr>
</tbody>
</table>
**Medicine pricing and reimbursement**

Given the fragmentation of the insurance system, medicine pricing and reimbursement mechanisms greatly vary between the various schemes.

The Sesame plan does not have a medicine list neither does it conduct medicine pricing as it does not cover such costs. District health office collects all requests for reimbursement from the health facilities and forwards them to the Plan within the Ministry of Health, where payment is made.

Regarding free maternal and child health, at the end of each month, the health structure sends a monthly report, supporting documents and reimbursement request to the district office. Within 10 days, the district office verifies and makes a summary of all the documents, then forwards a report, accompanied by a request for reimbursement to the medical region. After verification, the medical region makes payment to its districts and HF's. Five days after payment, the region sends invoices and other supporting documents to the central office.

Under the IPM, the subscriber’s co-payment is paid directly to the service providers by the member and payment to service providers is done through a mixed system: paying agent and third-party guarantor. Certain mutual insurance companies have limited ceilings for the reimbursement of costs of pharmaceutical products, for hospitalization and outpatient treatment alike.

Regarding private schemes, medicine list is updated every six months and the basic criterion is the therapeutic interest of the pharmaceutical product in question. The service providers establish bills for pharmaceutical products (accompanied with the patient’s card and the original prescription) which are submitted to private insurers. The reimbursement system is mixed and comprises: (i) simple paying agent whereby the insurer pays up to the full rate of the guarantee; (ii) full paying agent where the insurer pays the full bill and recovers the subscriber’s co-payment, if available, from the insured person; and (iii) third-party guarantor where the insurer reimburses the insured person who has prepaid the bill for pharmaceutical products.
3. Challenges identified in the case study countries

3.1. Common challenges

Reimbursement

Lack of or non-comprehensive medicine list: In Ethiopia, CBHI has not yet developed a medicine list that is eligible for reimbursement based on the benefit package. Any medicine prescribed in contracted public HFs, on the list of medicine for the tier of health service, is reimbursed. The reimbursable medicine list in Gabon, on the other hand, is not comprehensive. Hence, many physicians prescribe medicines that are not on the list, which obliges patients to cover costs for such prescriptions. The absence of an updated treatment regimen is a related problem in Gabon.

Uptake of generic medicine: In Gabon, the proportion of generic medicines on the list of reimbursable medicines is very low averaging around 25%. In Rwanda, prescription of medicines by generic names is mandatory both in the public and private sectors.

Pricing

Lack of medicine pricing policy or weak adherence to mark-up policy: In Ethiopia, CBHI schemes is a price taker, assuming the price charged by contracted health facilities. In Ghana, the lack of pricing policy, decentralized system of medicine procurement and weak adherence to the mark-up policy has resulted in high medicine price in the local market, which can be as high as 300% of international reference prices. In Rwanda, there is regulation that determines a maximum of 20% of total cost as profit margin for the MPDD (public procurement agency). In the private sector, 40% profit margin is commonly applied. However, assessment in 2012 showed that final patient prices were 23.4% higher than procurement prices for generic equivalents in the public sector, whereas in the private sector they were priced 89.2% more than in the public sector. In addition, medicine pricing is mainly based on market survey results from main wholesale pharmacies but sometimes wholesale pharmacies determine prices based on the availability of the medicines among them.

Insurance design issues

Limited fund: In Ethiopia, some of the schemes like in Yirgalem, which is the only pilot in urban settings among the phase one pilots, face financial limitation. One of the causes for the shortage is
lack of risk and financial pooling between CBHI schemes. Thus, there is delay in reimbursement to HFs. In Ghana, due to lack of funds, there is indebtedness and delays in reimbursement between facilities and the ten Regional Medical stores, between RMSs and Central Medical Stores, and from NHIA to facilities (3-6 months). This is causing insecurity in the insurance system and obliging providers sometimes to refuse dispensing medicines to insured patients unless they pay in cash. The mutual insurance companies in Senegal are faced with weak contributory capacity of households and absence of government subsidy which impact revenue generation capacity.

Regulation

Weak or absence of regulatory capacity: The Food and Drugs Authority in Ghana does not have adequate drug regulatory capacity, and the private sector does not adequately self-regulate as well. Hence, there is an issue with medicine quality assurance. In Rwanda, on the other hand, a national medicine regulatory authority is yet to be established. In addition, the national medicine quality control laboratory is not yet operational.

Supply side issues

Shortage of medicine, medical supplies: There is shortage of medicines and supplies in public HFs in Ethiopia, thus patients are referred to private MROs. However, modality for reimbursement of private MROs is not well articulated. Patients might therefore end up paying out of pocket. On the other hand, HFs complain about shortage/unavailability of pharmaceutical supplies at regional medical stores (PFSA hubs). It is a challenge for public HFs to procure from private wholesalers unless they get drug unavailability evidence from the public medical store. Similarly, in Rwanda, the national supply of medical commodities is still an issue; there is capacity limitation on the part of MPDD, which is the public sector purchaser.

Issue with quality of care: In addition to shortage of medicine and medical supplies in Ethiopia, there are issues with quality of service in contracted public HFs. The outstanding gaps include unavailability of some diagnostic facilities and service, long waiting time, poor courtesy of staff, etc.

Monitoring and information management

Gap in monitoring and information management: In Ethiopia, there is no systematic mechanism to monitor quality of service or medicines in contracted health facilities. Only random medical audits are conducted before reimbursing HFs. The scheme is grappling with shortage of high-level health professionals to conduct monitoring. In addition, there are significant gaps in generating, sharing, and using data at all levels. Basic information such as membership renewals, premium collection, reimbursement details to health facilities, members’ service and medicine utilization is often inconsistent, out of date, and not readily available at scheme levels. In Gabon, there is no pharmaceutical pricing database or a system for monitoring supplies and price evolution within CNAMGS. Similarly, in Ghana, clinical audit of claims has revealed challenges such as wrongful application of tariffs, irrational use of medicines by prescribers (poly-pharmacy), inadequate critical analysis of reimbursement by NHIS, and unauthorized co-payment. Weak monitoring capacity and system is also a common hurdle in Senegal.
**Computerization**

In Gabon, the absence of remote transmission of bills, insurance claim forms and an electronic database is an obstacle. In the same vein, Rwanda needs an electronic system to improve the management of archived prescriptions. In addition, the pharmaceutical and medical verification unit of RSSB-MIS reports regularly about real expenses made. However, an ICT application is needed to improve medicine expenses monitoring.

### 3.2. Country-specific challenges

**Gabon** is faced with high co-payment issues as there is an absence of a declining co-payment arrangement or an upper limit for co-payments.

**In Rwanda,** there is a gap in information dissemination, monitoring and enforcements. Although comprehensive pharmaceutical legislation exists (laws, regulations, guidelines), there is a need to increase awareness among all potential users/stakeholders, strengthen the monitoring of their use and effectively enforce their compliance on the national territory.

This system in **Senegal** is plagued by inadequacies brought about by the State’s inability to set up a framework for managing health insurance.

**Insurance design issues:** Regarding health insurance for state workers, the health risk coverage is partial, that is, members receive 80% coverage for cases excluding pharmaceutical products. However, drugs constitute a greater part (60%) of the cost of one episode of illness. Regarding the free treatment initiative, there is no delineation between financing and service provision functions and no reimbursement for full cost of services (for example, delivery). IPMs and mutual insurance companies have issues with fragmentation. There is lack of financial solidarity between IPMs. They face problems such as varied benefit policy, limited risk pool and weak risk management measures.

**Management issues:** Coverage for the destitute suffers from insufficient budget, administrative bottlenecks, absence of clear targeting criteria, ignorance of the destitute about these facilities, and the absence of coordination of interventions. IPM does not have a procedural manual. IPM and mutual insurance companies do not have cooperation agreements with HFs. There is weak documentation and capitalization on experiences among mutual insurance companies. Moreover, there is poor management capacity, absence of medical control and irregular meeting of management body as members work on a voluntary basis.

**Regulatory issue:** IPMs reel from outdated and weak legal regulatory framework.
4. Lessons from the case studies and best practices from other countries

4.1. Common lessons from case studies

Positive lessons

Presence of national medicine list and treatment guidelines: Ethiopia has a national essential medicine list, medicine list for various tiers of HFs and standard treatment guidelines for the various tiers of HFs. However, these documents are not updated regularly. Rwanda also has standard treatment guidelines for the various medical disciplines, which help to standardize care and encourage health providers to prescribe safe, efficacious, and cost-effective medicines. However, STGs need to be revised regularly and their use closely monitored. In addition, there is adult and pediatric essential medicine list. The NEML are the result of the work of a technical committee composed of clinicians, public health programmes specialists, laboratory specialists and public pharmaceutical procurement specialists under the coordination of the Ministry of health/Clinical and Public Health Services.

Reimbursable medicine list: In Gabon, CNAMGS has established a list of reimbursable medicines, which is revised every two years. NHIA in Ghana updates its reimbursable medicine list and price annually.

Multidisciplinary committee to prepare/revise medicine list: Gabon has a technical committee comprising CNAMGS, the Department of Medicines and Pharmacy, the Inspectorate of Pharmacies, the Order of Pharmacists and Physicians, the Union of Pharmacists, various prescribers by specialty, learned societies and WHO. The committee is responsible for updating the list of reimbursable medicines. Patients’ groups and other members of the civil society are not involved in the process. Ghana also has a similar experience, whereby an ad hoc committee is set up for revision of medicines list. Membership in the committee is drawn from the Office of the Chief Pharmacist, National Drugs Programme, Government and Hospital Pharmacist Association, Pharmaceutical Society of Ghana and National Health Insurance Authority. Selection of pharmaceuticals for reimbursement is based on essential medicines list. Pharmaceuticals on EML were selected based on relevance to the pattern of prevalent diseases, proven efficacy and safety, adequate scientific data and evidence of performance in a variety of settings, adequate quality, favorable cost-benefit ratio, desirable pharmacokinetic properties, possibilities for local manufacture, and availability as single compounds.
**Pricing:** There is an attempt to regulate medicine pricing with a tap on maximum price for different cities in Gabon. NHIA in Ghana sets reimbursement price annually using a combination of pricing methods including that of WHO/HAI. Price is set through market survey and by taking median price in the local market without any reference to international price. This method reflects the existing inefficiencies in the local market. (see section 4.2).

**Promotion of generic medicine:** Ethiopia and Ghana promote generic medicine at least in the public sector. The national essential medicines list, list of medicines and standard treatment guidelines for the various levels of HFs are developed based on generic names of medicine. In addition, prescription in public HFs should be made in generic names. In Rwanda, RSSB-MIS also gives preference to generic medicine where they are widely accessible when developing a list of reimbursable medicine in private health facilities and private pharmacies. Some branded products that have more available equivalent generics are not reimbursable.

**Institutional setup and reforms in pharmaceutical logistics:** PFSA was established as the national purchaser of medicine, medical devices, and supplies to the public sector. PFSA procures medicine through international competitive tender thereby helping to negotiate a lower price and take advantage of economies of scale in procurement. A pharmaceutical logistics master plan has been developed. There is an ongoing reform to computerize supply chain management and dispensing of medicines in the public sector. Gabon has the Department of Medicine, which is responsible for management and regulation, while OPN conducts central purchasing, storing and distribution. Rwanda has institutionalized pharmaceutical quality assurance, and is improving human and institutional capacity. The Rwandan Food and Medicines Authority is also established. Measures are taken to strengthen commodity supply chain by way of modern warehouse construction, electronic logistic management system launching, accurate forecasting, setting up central medicine procuring body and implementing rational distribution of drugs and health commodities. As part of its engagement in the East African Community, Rwanda is strengthening good manufacturing practices, quality management system, medicine evaluation and registration, information management system and other regulatory systems. Rwanda has exempted all taxes including VAT on medicines and medical products of national priority.

**Respect of the referral system:** In Ethiopian CBHI system, access to secondary and tertiary HFs is strictly through referral. CBHI members that do not respect the referral system will cover 50% of cost of care at higher levels. Thus, 87% of health service utilization by members is at HC level. The SESAME plan in Senegal has been effective in increasing efficiency and containing costs. Insurance members have to follow the referral system in order to get coverage.

**Strengthening of monitoring/computerization:** In Gabon, CNAMGS has set up a system to track mega-prescribers and mega-users. The system makes it possible to record all medical claim forms of patients, which indicate the name of the attending physician as well as all the prescriptions that the particular physician has made for the insured persons. Thus, the Fund can track the prescriptions of physicians who are bound by contract to it, and the spending of each insured person. Where there is suspicion of over-prescription or over-use, the Fund may resort to a number of measures, including a simple call to order, suspension of its agreement with the health facility or withdrawal of the insured person's insurance card, and even initiation of legal proceedings.
Ghana has launched various measures to strengthen monitoring. First, a consolidated premium account has been set up which will permit proper monitoring of premium collection by the schemes. Second, uniform prescription forms with unique security features and prescriber identification have been established. Third, a database for prescription has been set up to help NHIA to conduct medicines utilization analysis, feedback mechanism, clinical audits, and link diagnosis to treatment, detect poly pharmacy and patient induced prescribing as well as determine the cost drivers of claims reimbursement. Fourth, NHIA conducts clinical audit, which helps improve quality of care for members and provides huge costs saving for the scheme. In 2011 alone, NHIA saved about US$ 2.6 million due to clinical audit. Fifth, NHIA has started electronic claim processing to boost efficiency and transparency. The Authority also launched a nationwide ICT platform with a single national ID for all subscribers. This helped members to enjoy portability and HFs to verify eligibility of subscribers.

In Rwanda, reimbursement is closely monitored; some medicines are reimbursable following the authorization of a medical advisor who can discuss with the prescriber or verify the patient file. In addition, prescription with a total value of more than US$ 53 requires a medical advisor’s authorization.

Negative experiences

Lack of or limited reimbursable medicine list: CBHI schemes in Ethiopia do not have a reimbursement list, hence they reimburse all prescription medicines within contracted public HFs which pushes up expenditure on medicine. In Gabon, on the other hand, the reimbursable medicine list is not comprehensive. Hence, many prescriptions fall outside of the list. This is a burden to households, as they have to purchase such medicine OOP.

4.2. Country-specific lessons

Positive lessons

Ethiopia

Central medicine purchasing: PFSA is the national government body responsible for procuring medicine, medical supplies, devices and equipment for the public sector and distributing few limited items to the private sector. This has enabled the sector to benefit from economies of scale in procurement.

Promoting equity: Regional/district government provides targeted subsidy to cover insurance adherence premium for indigent households. In addition, central government provides general subsidy to strengthen CBHI schemes financially.

Ghana

Influencing private sector operation: The private sector is not necessarily obliged to comply with STGs and EML but providers under NHIS are compelled to do so through the scheme’s pharmaceutical reimbursement system. In this way, NHIS has been able to influence prescribing and dispensing practices in the private sector.
Negative experiences

Ethiopia

Absence of medicine pricing strategy: The CBHI scheme is price taker. This pushes up medicine expenditure.

Ghana

Decentralized procurement of medicine at tier level has resulted in loss of economies of scale and inefficiency thereby increasing medicine prices. Prices for insurers and OOP purchasers are 300% of international reference price.

Issues with drug regulatory capacity: First, the regulatory mechanism has not been able to ensure that medicine and medical supplies are of acceptable quality. Second, while there is a mark-up policy for medicine, HFs and other retailers are not following the policy and mark ups are variable. As a result, NHIA’s medicine bill is increasing.

Rwanda

Lack of functional national medicine quality control laboratory has resulted to difficulty in monitoring quality medicine availability in the country.

Senegal

Fragmentation: The insurance system is highly fragmented and hence the country has not been able to benefit from the efficiency and equity gain that comes with pooling risk and resource.

4.3. Best practices from other countries

4.3.1. Policies, regulations, strategies and guidelines

Guidelines: South Africa has a National Standard Treatment Guidelines for the most common illnesses. Specific STGs cover primary care, secondary care and paediatric conditions. These were last updated in 2008, 2012 and 2013 respectively. The National Medicines Formulary was first published in 1988. The most recent version of the formulary was published in 2014.

Regulation: The Government of South Africa runs an active national medicines price monitoring system for retail prices. Regulations mandate that retail medicine price should be publicly accessible through the South African Medicine Price Registry. The pricing structure of pharmaceutical manufacturers, wholesalers and service providers (public and private) is completely transparent. The cost of drugs is monitored by a national database and benchmarked against developing and developed countries. Price increases are regulated.
4.3.2. Pricing

Taiwan implemented a drug classification system to govern drug pricing. As regards (1) new drugs, NHIA invites medical and pharmaceutical experts to engage in the review and approval process; (2) the compound and special specification drugs paid the same minimum price as other drugs of the same composition; (3) brand-name drugs are subdivided into two categories: those that have no bioavailability/bioequivalence (BA/BE) generic drugs as alternatives in the market, and those that have BA/BE generic drugs as alternatives. Drugs of the former category were priced according to international drugs with average market prices while the price of the latter category must not exceed 85% of the average market price of international drugs ((Hsu and Lu, 2015).

a. Fixed mark-up

In order to reduce the gap between procurement prices of service providers and insurer reimbursement price, NHIA in Taiwan implemented a fixed mark-up strategy. Accordingly, NHIA conducted medicine price surveys to assess wholesale price from pharmaceutical companies and procurement price from hospitals. Wherever it found a price gap of 30% or more between average procurement price and NHIA reimbursement price, NHIA adjusted its reimbursement price. However, the result has been that price reduction on specific targeted medicine reduced the use and expenditure on the specific medicine. This gave incentive for physicians to prescribe medicine whose prices were not reduced or non-targeted medicines. Hence, there is no clear evidence if this measure has helped to reduce overall pharmaceutical expenditure (Hsu and Lu, 2015).

b. External reference pricing

The use of external reference pricing (ERP) as a pricing mechanism is widely applied: 24 of the 30 OECD countries and approximately 20 of the 27 EU Member States use it (WHO and HAI, 2011). Studies show that it is also becoming popular among developing and transitional countries. However, despite increase in its use, information on how countries actually implement ERP is limited and few studies documented effects of this policy (ibid).

Most commonly, prices are checked for reimbursable products only, but sometimes non-reimbursable products are also included. Prices are usually set at the producer’s level (ex-factory price), and sometimes at the wholesaler’s level (pharmacy purchase price, i.e. ex-factory price plus wholesaler’s profit mark-up) or the pharmacy’s level (pharmacy retail price, i.e. ex-factory price plus wholesaler’s and pharmacist’s profit mark-up plus VAT) (Carone, G. et al., 2012). Most European countries use ex-factory price for comparison as it eliminates price difference that occurs due to difference in distribution mark-up (Nguyen et al., 2015). Countries of similar economic situation that are geographically close are chosen as a reference. Most commonly, the lowest or an average price within the specified basket prices of other countries is selected. Some experts recommend that at least 10 countries should be selected in the reference group (Nguyen et al., 2015).

The major plus for ERP is its simplicity, as it does not require extensive data or technical/analytical capacity as compared to other price control mechanisms such as cost-plus or pharmacoeconomic analysis (WHO and HAI, 2011). Despite paucity of evidence, here are some alleged consequences/drawbacks of using ERP. First, literature indicates market launch delays in low-price countries. Second, ERP might produce convergence in international pricing because companies could try to impose a single price worldwide and be unwilling to offer lower prices to any country, especially those that
are/might be used as a reference by other countries. Third, if reference countries have set their prices too high or too low, then any country later applying the ERP method may run the risk of repeating the same mistake (ibid).

c. Internal reference pricing

Internal reference pricing (IRP) is most commonly used in the EU where it is applied by at least 20 members (Carone, G. et al., 2012). A condition to implement IRP is to have therapeutically interchangeable medicines, often generics, available on the market. Such medicines are grouped often by the same active ingredient or therapeutic actions. Within each group a reference price is defined, which can be the lowest price or the average of a set of medicines in each group. Pharmacoeconomic evaluation may be needed to develop relevant therapeutic groups (Nguyen et al., 2015).

Available evidence from HICs shows that, IRP would result in savings for the third party payer such as insurance because of additional income from co-payment, reduction in price and reduction in the use of more expensive products within the reference group (Aaserud et al., 2006; Espin and Rovira, 2007; Carone, G. et al., 2012). Based on experience in HICs, there is no proof of adverse health effects, limitation of access or disincentives to pharmaceutical innovation.

IRP has several advantages. Firstly, IRP makes patients and physicians more price sensitive, especially if patients have information about alternatives. If a patient wants a more expensive medicine within the same reference group, he/she has to pay the difference between the chosen medicine and the reference price. Secondly, it pushes pharmaceutical companies to compete by price i.e. reducing their price with respect to the reference price. However, it also has some limitations as it limits the level of price reduction by way of a price cap. In countries with an already high generic market share, free market competition is found to be better in lowering price as generic firms compete on prices (Dylst and Simoens 2011; Carone, G. et al., 2012).

d. Risk sharing–price volume agreement

The objective of price volume agreements, also known as pay back mechanisms, is that pharmaceutical companies share the financial risk of insurers/governments and pay for the drug when an agreed volume or budget is exceeded, or intended clinical outcomes are not achieved. Agreements are made between a payer and a pharmaceutical company after negotiating the price of a product and/or total spending depending on volumes sold, clinical outcomes achieved or patient populations who receive the drug (Hsu and Lu, 2015).

Risk-sharing agreements are particularly useful to limit the use of pharmaceuticals to those population groups where it has the highest benefit potential. They may also be used to control prescriptions of pharmaceuticals for unapproved indications or unapproved segments of population (Carone, G. et al., 2012). The use of risk-sharing arrangements are recommended to be limited to innovative pharmaceuticals with uncertain benefit and linked to health priority diseases with likely health gain within a limited time and with no low-cost alternative, and in a situation where the administrative load is manageable (ibid). Evidence shows that many countries in the Asia Pacific region are adopting risk-sharing agreements (Hsu and Lu, 2015). This approach is commonly applied in France to products that have high sales potential (Nguyen et al., 2015). However, the method is relatively new and hence systematic assessments are lacking regarding its effect (Espin, Rovira et al., 2011; Carone, G. et al., 2012).
4.3.3. Reimbursement/purchasing

a. Provider payment mechanisms

Among the various provider payment mechanisms, capitation/case-based payments, diagnosis related group (DRG) and pay for performance are recommended as possible alternative approaches based on experience in other countries as having a potential to control total pharmaceutical expenditure without substantially compromising care quality (Hsu and Lu, 2015). In designing capitation, a good experience from South Africa is designing a risk-adjusted formula, which takes into account factors such as population size, age, gender and disease/epidemiological profile. However, integrating such a mechanism requires availability of a system to generate and process such data.

However, lessons show that each of the provider payment modalities gives different incentives to HFs and professionals. Hence, it is crucial to integrate a complementary design feature to curb negative effects. In the mid 1990s, Taiwan introduced the so-called internal audit pricing approach. Thus hospitals were reimbursed on a fee for service basis while primary care facilities were reimbursed on ‘fixed fees by days of supply’ approach whereby one day of supply of any medication was reimbursed at NT$ 35, two days of supply at NT$ 70 and three days of supply at NT$ 100 irrespective of procurement price. The result was that some patients were transferred to hospitals to get drugs of higher prices and those prescribed for longer duration. Thus, use of drugs of higher prices in primary facilities was reduced (Hsu and Lu, 2015). In the end, the policy did not achieve the intended goal of reducing pharmaceutical expenditure.

b. Positive list/Negative list

The cost-saving potential of positive lists could be enhanced depending on the reimbursement criteria selected. It is recommended that pharmaceuticals be included in the positive list after having assessed their added value via health-technology assessment to assert their cost effectiveness (Carone, G. et al., 2012). In addition, positive lists should be revised systematically and regularly in line with new pharmaceuticals that come into the market (ibid) and in line with new epidemiology of diseases and new treatment guidelines. On the other hand, cost containment effects of a negative list or excluding medicine from public reimbursement may be uncertain unless it is properly designed (Carone, G. et al., 2012). For example, if a medicine on a negative list has substitutes that are more expensive on the positive list this may push up costs.

NHIA in Taiwan has a category of medicines/medical devices, which it excludes from reimbursement (Hsu and Lu, 2015). Some categories of medicine for exclusion that could be of relevance to LICs in general and the case study countries in particular include: (1) medicines and commodities that are delivered as part of exempted services (e.g. TB and leprosy treatment, vaccination, inputs for delivery etc); (2) over-the-counter drugs and non-prescription drugs; (3) drugs for human-subject clinical trials; (4) medicines intended for the treatment of minor, self-limiting diseases (those intended for self-medication such as simple antacids and cough syrups); 5) products that have already been reported as unnecessary by medical publications or health professionals (WHO, 2003); and (6) finally, medicines that are taken off the market for safety reasons should all be excluded from the list.

c. Reimbursement schedule/Formulary

Having reimbursement schedule/list or formulary is one key tool to guide medicine purchasing. It is also crucial that the list be updated regularly to reflect changes in the pharmaceutical sector.
Experience from one large private medical scheme in South Africa shows that there is medicine formulary for benefit package of the scheme. Formularies are updated at the start of each year and enhanced once within the year. In Sweden, the Pharmaceutical Benefits Board (LFN) uses cost-effectiveness from societal perspective as its central principle to decide on reimbursement of medicine. The Board updates its reimbursement list on regular basis. The following criteria are applied in decisions about reimbursement:

- Human value principle – There will be no discrimination against people due to race, sex, age, etc. in making reimbursement decision
- Need and solidarity principle – people with more severe diseases are prioritized over those with less severe conditions
- Cost-effectiveness principle – cost of using a medicine should be reasonable from medical, humanitarian and social economic perspective.

In China, Formulary is the key tool to manage drugs for health insurance. The formulary has three categories of medicine; western medicine, traditional Chinese medicine, and Chinese herbal pieces. Positive list is developed for western medicine and traditional Chinese medicine. Negative list is applied for Chinese herbal pieces (Ngorsuraches et al., 2012). The positive reimbursement list is divided into class A and B based on drug characteristics, authorization level, reimbursement rates and usage limitation. Those in class A are essential and low cost, while those in class B are optional and have relatively high price. Medicine in class A are allowed to be reimbursed at specific rates with few limitations, while cost of drugs in class B must be shared as co-payment by the insured.

d. Health technology assessment

Experiences from developed countries show that there is shift towards policies that target paying for value, that is, those commodities with high cost benefit ratio, through the application of technology assessments including pharmacoeconomic analysis (Stabile et al., 2012). Hence, in order for new products to be included for reimbursement, there should be added value of a certain product (ibid; WHO, 2015). In rare cases, previously accepted medicine without cost effectiveness evidence is excluded (Stabile et al., 2012). Health technology assessment (HTA) is mostly used to evaluate pharmaceuticals, although medical devices, clinical procedures and public health interventions are increasingly becoming subject to HTA (Carone, G. et al., 2012).

As Carone, G. et al., (2012) show, HTA has been primarily used in the EU for coverage and reimbursement decisions, though sometimes also for pricing. Lately, however, more and more countries have resorted to HTA. In Germany and the UK, manufacturers have to show how they set their price based on the value the medicine brings to patients. Germany had free pricing of new medicines. However, according to a new policy, if a new product has no added therapeutic value, reimbursement price will be set similar to that of a comparable product, which is already in the market.

e. Tendering

Tendering can be used where there is strong purchasing power and where there are multiple sources of medicine. This can result in significant cost savings. Excellent example of a country implementing successful tendering is New Zealand where it conducts international competitive tendering for prescription medicine, which is distributed through private pharmaceutical supply system but
financed publicly (Nguyen et al., 2015). It brought about a 15% to 20% reduction to the already low price acquired through IRP (ibid).

4.3.4. Other measures

a. Promotion of generic medicine/generic substitution

Sweden reformed its medicine reimbursement system in 2002. In the 1990s, cost of reimbursed medicine increased rapidly. The country had a very generous reimbursement system, which covered all prescription drugs. The system had no way of knowing if it got value for money, that is, whether the increase in cost was balanced by added therapeutic value. Hence, various measures were introduced targeted at reducing pharmaceutical expenditure (LFN, 2007). Encouraging use of patent expired generics and generic substitution were among the major reform measures. Generics substitution became mandatory. Hence, the patient that demands the brand drug needs to pay the price difference between the generic and brand medicine. Because of a successful implementation of generic substitution policy, pharmaceutical prices have dropped by about 15%. Sweden made a cumulative saving of 700 million Euros between 2002 and 2005 (LFN, 2007). The Swedish Medical Products Agency prepares a list of therapeutically interchangeable products to guide the process of generic substitution (Hassali et al., 2014).

Experience from South Africa showed that it is essential to consider incentive for prescribers and dispensers to promote generic substitution. Because of lack of incentive, pharmacists are reluctant to prescribe lower cost medicines as it reduces their profit margins. On the other hand, pharmaceutical companies incentivize pharmacists to dispense certain product lines that are not the best priced in the industry (case study). Japanese experience, on the other hand, is testimony that incentive to health professionals will not guarantee the success of generic substitution policy ((Hassali et al., 2014). Since 2008, pharmacists were able to implement generic substitution unless the physicians prohibit it for medical reasons. It was estimated that generic substitution would result in a saving of about US$ 11.1 billion from the total annual medicine expenditure. To encourage generic uptake further, Japan introduced financial incentives for physicians, pharmacists and hospitals. Physicians were paid about US¢ 0.17 when they prescribe a generic medicine. Pharmacists were given US$ 1.45 if the proportion of generic medicines in their pharmacies was over 30% in a three-month period. In addition, pharmacists were paid US¢ 0.85 when they gave information about generic medicine to their clients. However, the policy did not bring about the intended effect because many prescribers had negative attitude towards generic medicine. Similarly, pharmacists rarely, if ever, recommend generic substitutes to their clients because of unavailability of generic medicine in their stock, patients’ objection on account of insignificant cost saving, opposition by physicians, doubts about its quality and inadequate information about generic medicines (Hassali et al., 2014).

In Netherlands, however, financial incentive has brought about the intended resulting effect which sustained well after abolishment of incentives. Netherlands allowed pharmacists to keep a third of the difference between the reference price and price of medicine they dispensed where the latter is lower. This helped to increase share of generic medicine in the market. However, even after abolishing the measure in 2005, share of generic medicine increased from 42% in 2005 to 56% in 2009 (Vogler, 2012). The study states that this trend is due to positive attitude developed by pharmacists over time.
In the US, patients are encouraged to use generic medicines by making them pay significantly less co-payment when selecting generic medicines. Most insurers use formularies with three tier co-payment (Hassali et al., 2014). In this system, patients pay the lowest co-payment for generic medicines (first tier), a middle co-payment for preferred brand name medicine (second tier) and the highest co-payment for the expensive non-preferred brand medicine (third tier). Another approach employed in the US to encourage generic medicine uptake is the so-called ‘step therapy concept’ which is to use a generic medicine or preferred brand medicine before using a more expensive brand medicine in treatment. In addition, pre-authorisation is required before prescribing expensive medicines when an equivalent generic version is available (Congress of the United States, 2010; Hassali et al., 2014). Evidence shows that promotion of generic medicines resulted in considerable savings of about US$ one trillion over a decade (ibid).

Generic prescription is quite common in the United Kingdom (UK). In 2008, more than 83% of prescriptions in general practices were written in generic names (Hassali et al., 2014). Some of the key factors behind this success are the following: Medical students are encouraged to prescribe generically in medical schools. Physicians are encouraged through financial and non-financial incentives. There is budgetary incentive whereby savings achieved by the physicians beyond the indicative budget can be used for other purposes such as training. On the other hand, physicians are empowered by provision of information through national and local cost-effective prescribing guidelines, prescribing monitoring and feedback, technology and decision support systems. In 2008, adoption of cost effective prescribing (prescribing cheaper generic medicine) led to cost saving of around US$ 600 million (Hassali et al., 2014).

One effective way of promoting generic medicine, implemented in the Netherlands, is to install an electronic prescribing system, which automatically changes the brand name on a prescription into a generic name (Zuidberg, 2010; Carone, G. et al., 2012).

b. Cost sharing

Sweden instituted a deductible of €200 per annum for medicine averaging around 21% of cost for outpatient medicine, which is deemed affordable to Swedes. However, insulin is fully reimbursed (LFN, 2007). No country has compared the impact of cost sharing on pharmaceutical expenditures against a no cost-sharing alternative (Espin and Rovira 2007; Carone, G., G. et al., 2012). However, trends show that it tends to increase the use of generic medicine thus leading to cost savings. Nonetheless, there are also studies, which show that it leads to reduction in the use of both needed and non-essential medicine. Thus, the lesson to draw is that cost sharing needs to be well designed to promote consumption of cost effective medicine without affecting access of the poor (Carone, G., G. et al., 2012).

c. Monitoring, information management and computerization

One of the largest private insurance schemes in South Africa has a database of prescriptions, which is used for risk management purposes. They also have a database of medicine retail prices to ensure alignment with prices in the South African Medicines Pricing Registry. This registry is updated regularly. The scheme has a system to monitor prescribing practices and expenditure on medicine.
In at least 22 EU Member States, physicians’ prescription patterns are monitored (Carone, G., G. et al., 2012). Third party payers may monitor individual physicians’ prescriptions and compare these with prescriptions from their colleagues of similar specialty in a certain region or country. A system is installed that enables electronic transfer of prescriptions. Third part payers could send feedback and visit physicians when the need arises. In cases where there are major discrepancies, physicians may be asked to explain and where there happens to be an unexplained departure a physician may be fined, undergo legal action and face action up to the extent of having his/her prescription rights waived.

**Computerization** has gone a long way in facilitating health insurance mechanisms monitoring. The health insurance system in South Africa adopted a coding system whereby each particular service is allocated a code so that the National Health Insurance would be able to reimburse for the service with a full understanding of the service has been delivered and goods supplied (Department of Health, n.a.). In addition, billing and reimbursement are made electronically which has led to a gain in efficiency, reduction in delay of reimbursement and cost reduction.
5. Recommendations to improve medicine pricing and reimbursement in AFRO in general and case countries in particular

5.1. Recommendations to address common challenges

1. **Reimbursement schedules or formularies**: This is one of the policies, which has been implemented in many African countries. Its comparative ease of implementation makes it popular. Experiences show that successful schedules should have clear and transparent inclusion objective and criteria. The list should be updated regularly in line with evidence-based standard treatment guidelines and unnecessary products should be delisted by applying the same criteria. Revising the reimbursement list in line with its epidemiological profile is a priority for Gabon. Ethiopia needs to design a reimbursement list while the rest of the countries should update their list regularly.

2. **National generic medicine policy** is essential which has an inbuilt system to incentivize prescribers, dispensers and patients. There is ample evidence from countries that it has huge cost saving potential. Key messages from positive experiences and failures are as follows:

   a. **Regulation**: generic medicines should be registered via a thorough scientific registration process to ensure quality, safety, efficacy and bioequivalence of generic medicines. In addition, there should be a post-marketing surveillance to detect any safety or quality issues that may arise after registration. Regulatory body should also control low quality and counterfeit medicine (Alrasheedy et al., 2013).

   b. **Information**: health professionals and consumers should be informed of the registration process and standards to build their confidence in generic medicine. In addition, a list of generic medicine that has passed the registration process should be disseminated widely among health professionals. Posting it online is a key means of making it widely accessible.

   c. **Promotion**: related with disseminating information, there is need to have a promotion plan, which addresses various aspects and issues related with generic medicine.

   d. **Incentive to health professionals**: simultaneously with other measures, it is important to consider incentive.
e. **Address misconception among professionals**: proactively address any negative perception or misconception that prescribers and dispensers may have. Providing information about registration process and the efficacy, quality, safety and bioequivalence of generic medicine is crucial in this regard. There should also be co-operation between healthcare professionals.

f. **Address misconception among consumers and provide incentives**: there is need to conduct media awareness, IEC through health professionals, etc. In addition, designing incentives targeted at consumers could be effective.

g. **Advocating generic prescription during medical trainings**

h. **Support through computerization**: the Netherlands experience of a system that automatically changes brand prescription into generic name

i. **Patients should be given the option** to get brand drug but on the condition that they pay the price difference with the generic equivalent/reference price.

j. **Its effect should be continually measured** such as the extent of availability of adequate generics, extent to which products are low priced, efficiency in the market, competitiveness of the market, etc.

3. Countries should use a combination of different **pharmaceutical pricing policies** that are selected based on the objective, country context and health system. Countries should employ a combination of pharmaceutical policies that address both supply and demand issues (WHO and HAI, 201) as well as pricing and the level of consumption (Nguyen et al., 2015).

Lesson from countries that have experience in **pricing policies is that no single method is full proof**. Countries need to try mixing different pricing techniques and reimbursement mechanisms depending on their situation. Below are some of the techniques that could be tested in African countries given their data management system, the level of skill and capacity available in countries and the cost saving potential of the pricing technique.

a. **ERP**: it is suggested that it should mainly be used for price negotiation and benchmarking (WHO, 2015). The main challenge to implement ERP in African countries as is the case in other LICs will be availability of reliable historic price data. Existing data options are from MSH and WHO/HAI. Countries should further explore possibility of setting up information exchange system/database through regional communities such as the East African Community, SADC, IGAD, ECOWAS, etc. The other challenge to be expected is market launch delays in countries with low prices and convergence in international prices thus pushing up the price levels for LICs. In addition, companies could reduce price transparency making it ineffective.

b. **IRP**: there are some challenges for LICs as PE analysis might be needed to identify therapeutic groups, which in turn requires advanced expertise and rigorous data. Purchasers should be monopsonic to push pharmaceutical companies to agree to a reference price. IRP could also push price up for those companies which have a lower price schedule than the reference price. Variation could be designed whereby pharmacists are incentivized by allowing them to keep the difference between the price of medicine they dispense and the reference price.
where the former is lower. However, this system should be backed by policy of allowing
generic substitution. Finally, reference prices should be updated regularly. Evidence from
Cochrane systematic review shows that reference pricing tends to reduce medicine price
and expenditure but there is no evidence of adverse effect on health care utilization or
outcomes (Nguyen et al., 2015).

c. **Fixed markup:** Mark-up cap could be set ex-factory level or on retail price. If cap is set at
wholesale level, retail mark-up needs to be regulated. However, if mark-up cap is set at
retail level then regulation further down the line might not be required. It is suggested that
regressive mark-up whereby mark-up percentage decreases when medicine price increases
might be a better alternative to test for LICs (WHO, 2015). The ease of implementation and
potential to reduce costs, especially in countries which have not implemented prior price
regulations, is a plus. There is no robust evidence on its effect. However, experiences show
that it should be designed together with adequate enforcement to increase its effectiveness
(Nguyen et al., 2015).

Strengthening capacity of MPDD in Rwanda, initiating pooled procurement in Ghana and
initiating tendering process is crucial. Ethiopia has a good experience in this regard whereby
PFSA is the central procurement agency, especially for the public sector and purchases through
international competitive bidding process. Over time, the agency has been expanding its capacity
to handle increasing share of medicine, medical devices and equipment procured for the country.
In all countries, it is important to improve the availability of quality, safe and efficacious medicine
in HFs.

4. **Limitedness of funds** would be addressed through multidimensional reform measures. First,
expanding insurance risk pool by addressing fragmentation would lead to increase in revenue
generation and decline in expenditure. Second, diversifying income sources for the insurance
fund such as deductible from various tax and non-tax government income sources such as VAT,
sin tax, mobile charges, etc. Investing insurance fund would be another revenue-generation
mechanism as the experience from Gabon and Rwanda shows. Third, there is need to implement
various cost containment strategies such as promotion of generics and applying pricing and
reimbursement measures (see above). Fourth, improving quality of care is crucial in its own right.
In addition, it could increase members’ willingness to pay. Fifth, governments should subsidize/
cover insurance premiums for the needy. There is good experience from Ethiopia and Rwanda
in this regard. Sixth, it is essential to design appropriate provider payment mechanisms such as
DRG and capitation while minimizing the negative effects of each. Good experience from South
Africa is the development of risk-adjusted formula, which considers population, age, gender,
epidemiological profile, etc.

5. In LICs, as is the case in the case study countries, **strengthening and enforcing the legal
system**, such as pharmaceutical sector regulation, promoting competitive generic market,
together with an integrated incentive mechanism for prescribers, dispensers and patients is
highly recommended. Regulation should encompass and reach out to the private health and
pharmaceutical sector.

In particular, the priority for Rwanda should be setting up a national medicine regulatory body,
quality control laboratory and strengthening of its capacity. Senegal needs to develop an up-to-
date regulatory framework and separate the regulatory body from provider and financer of health.
The other countries need to strengthen the regulator’s capacity to regularly monitor the quality of service and medicine in public as well as private HFs. Preparing explicit medicine pricing and cost containment policy is another important background task for case study countries. In this connection, EML and STGs need to be developed and regularly updated.

With regard to policy, countries should consider exempting essential medicines from taxation, something Rwanda has already implemented.

6. Availability of medicine and quality of service is key success factor for insurance. Reforming and strengthening the national pharmaceutical logistics system and infrastructure is of utmost importance. Sensitizing HFs and health workers about insurance mechanisms and quality of care is also required. A related matter is the need to establish a system to monitor appropriate medicine use and follow up on wastage, educate the community as well as train prescribers and dispensers on appropriate medicine use. Insurance funds should also enter into agreement with HFs with clear terms and conditions of service. Furthermore, capacity should be strengthened in monitoring and contract enforcement.

7. The case studies have not assessed appropriateness of medicines and equity in access to reimbursed medicines. Future studies should include these issues as they are important parameters in their own rights. In addition, these are important determinants of medicine spending apart from price and volume.

8. **Strengthening information management system and computerization** would support monitoring and evaluation of pricing and reimbursement undertakings. Setting up a database of prescriptions, medicine retail prices, utilization, electronic system for electronic transfer of prescription, and billing are some of the key lessons from other countries. However, in African countries the main concern will be building computer skills of health professionals and other relevant civil servants, developing software, which is user friendly and has a simple interface. Medicine experts should be closely engaged in the development of software. However, countries should simultaneously be strengthening their monitoring systems. It is crucial to set up system to monitor medicine utilization and spending.

### 5.2. Recommendations to address country-specific challenges

9. For Gabon in particular and for the other countries as well, there is need to put a ceiling on patient charges. Such charges have modest impact in reducing (irrational) utilization and possible adverse effect. Evidence from Cochrane review shows that it results in reduction in third-party medicine expenditure but also in substantial reduction of medicine use, which could have adverse health effects, especially for the poor and needy. Thus, cost-sharing policy should be complemented by effective exemption mechanisms for the poor and chronically ill.

10. Rwanda needs to invest in awareness raising among all potential users/stakeholders on the existing laws, regulations and guidelines. Various forums should be used to this effect – mass media, various government and community meetings/gatherings, etc.

11. Senegal requires a radical transformation of its insurance system. Key priority is expanding insurance risk pool by addressing fragmentation with a vision towards universal health coverage. Gradual pooling would be more practical. Initially, the country may start by defining a minimum
benefit package that all schemes should adopt. The Ghanaian experience is a good lesson in this regard. Next step could be pooling of risk among the different schemes, for example pooling diverse IPMs into one, the different mutual insurances under one umbrella, merging the SESAME plan with civil servant coverage, etc. and then incorporating exemption policy into the different schemes and so forth. Subsequently, insurance design features will need to be revisited in line with contribution rate, benefit package, level of subsidy, waiver mechanisms, financial sustainability, etc. Such reforms need to be supported with legal and regulatory mechanisms. It is also crucial to build capacity of insurance managing body in contracting, and monitoring. Although they are at different stages of maturity, all the case study insurance schemes could benefit from risk pooling measures.

5.3. General recommendation

12. Key drawback for most African countries is that governments do not yet have single purchaser (monopsonic) position, which would have enhanced their power to institute and enforce various pricing policies and improved their bargaining power with pharmaceutical companies. Moving towards UHC is key in bringing about this change.

13. Setting up pharmaceutical analytics unit in each country would be important. Such a unit would be responsible among others to (1) provide technical support in the development of STGs, formularies, etc., (2) lead the process of developing medicine reimbursement list, (3) monitor utilization by product type, value and volume (using different sources of data available in systems) to inform policy decisions, including, but not limited to, decisions about pricing, (4) bring different stakeholders together to pool efforts on pharmaceutical policy implementation.

14. It is worthwhile to explore the practicality of various reimbursement/purchasing mechanisms within the countries’ context. For example, HTA requires a high level of technical capacity and rigorous data thus it is not easy to start implementation in African countries immediately. However, countries should take a systematic approach to develop legislative, technical and data generation capacity over the long term. Starting such training in universities at the pre-service level, creating critical human resource pool, collaborating with universities, research centers, professional association, nurturing north-south collaborations for knowledge transfer, etc., to build core capacity in health/pharmaceutical economics, consider outsourcing until a time when such capacity is built within government. On the other hand, countries, especially those in the upper middle-income category, could explore the potential of price volume agreement to manage prices for expensive treatments such as cancer, cardiovascular diseases and so forth.
References


Countries cases studies
Ethiopia
Assessment of medicine pricing and reimbursement systems under the community-based health insurance scheme in Ethiopia
### Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>APTS</td>
<td>Auditable pharmaceuticals transaction system</td>
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<tr>
<td>CBHI</td>
<td>Community-based health insurance</td>
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<td>CSA</td>
<td>Central statistical agency</td>
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<tr>
<td>DACA</td>
<td>Drug administration and control authority</td>
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<tr>
<td>DHS</td>
<td>Demographic and health survey</td>
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<td>EFY</td>
<td>Ethiopian fiscal year</td>
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<tr>
<td>ETB</td>
<td>Ethiopian Birr</td>
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<tr>
<td>FDRE</td>
<td>Federal Democratic Republic of Ethiopia</td>
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<tr>
<td>FMHACA</td>
<td>Food, medicine and health care administration and control authority</td>
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<tr>
<td>FMOH</td>
<td>Federal Ministry of Health</td>
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<tr>
<td>GNI</td>
<td>Gross national income</td>
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<td>GOE</td>
<td>Government of Ethiopia</td>
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<td>GTP</td>
<td>Growth and Transformation Plan</td>
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<td>HEW</td>
<td>Health extension worker</td>
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<td>HSDP</td>
<td>Health sector development programme</td>
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<td>IMF</td>
<td>International Monetary Fund</td>
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<td>MDG</td>
<td>Millennium Development Goal</td>
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<td>MOFED</td>
<td>Ministry of Finance and Economic Development</td>
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<td>MRO</td>
<td>Medicine retail outlet</td>
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<td>NHA</td>
<td>National Health Accounts</td>
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<td>PFSA</td>
<td>Pharmaceutical fund and supply agency</td>
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<tr>
<td>PHC/U</td>
<td>Primary health care/unit</td>
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<tr>
<td>RMF</td>
<td>Revolving Medicine Fund</td>
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<tr>
<td>SNNPR</td>
<td>Southern Nations, Nationalities and People’s Regional States</td>
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<td>TGE</td>
<td>Transitional Government of Ethiopia</td>
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<td>USD</td>
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<td>WB</td>
<td>World Bank</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>

### Terms

*Woreda* – equivalent to a district

*Kebele* – equivalent to a village
1. Population and socio-economic status

Ethiopia is the second most populous country in sub-Saharan Africa, with a population of 94.1 million, although the latest estimate by the Government of Ethiopia (GOE) is 85.8 million. The population is growing at the rate of 2.6% per annum (website, World Bank, 2015). Ethiopia achieved rapid economic growth over the last decade. Growth averaged 10.8% per annum between 2002/03 and 2012/13 (World Bank, ibid). In 2012, the country had the twelfth fastest growing economy globally (World Bank, 2013). During most of this period, it faced double-digit inflation, which reached a peak of 34.2% in 2012, according to the Ministry of Finance and Economic Development (MOFED, 2014). Since 2013, however, inflation has dropped to 5.3% (ibid), and is projected to remain stable for the next two decades at an average of 9% (IMF, 2014).

The country is aspiring to attain middle-income status by 2025. The per capita income (GNI at current market prices) stood at US$ 629 in 2013/14 (MOFED, 2014), which is much lower than the sub-Saharan Africa average of US$ 1,657, and lower than that of other low-income countries which averaged US$ 709 in 2013 (World Bank, 2014). Despite impressive growth trends over the last decade, Ethiopia has a long way to go before reaching middle-income status.3 i.e., to have a GNI per capita of above US$ 1,045.

Broad-based growth that Ethiopia experienced has resulted in reduction of poverty. While 38.7% of Ethiopians lived below the poverty line in 2004/05, this proportion fell to 29.6% in 2009/10, with the national Growth and Transformation Plan (GTP) aiming to further reduce the proportion to 22.2% by 2014/15 (World Bank, 2015). Similarly, Ethiopia is one of the countries in sub-Saharan Africa that is on track to meet most of the MDGs (6 out of 8 goals) (ibid). The MDG for child mortality (cut by half) and water (population with access to clean water more than doubled) have been achieved. The country has also achieved universal primary education (enrolment quadrupled over the past two decades), attained gender parity in primary education, and succeeded in fighting against HIV and malaria (World Bank, 2015). The government is making concerted efforts to improve on progress in reducing maternal mortality and achieving gender equality – the two MDG goals that are lagging behind. Subsequent DHS reports have documented improvements in health and nutrition indicators over time. The total fertility rate declined from 5.5 to 4.1 between 2000 and 2014, according to records from the Federal Ministry of Health (FMOH) and the Central Statistical Agency (CSA and FMOH, 2014). Other achievements during the same period included an increase in contraceptive prevalence from 8% to 42%, an increase in ante-natal care provided by skilled professionals from 27% to 41%, an increase in deliveries attended by health professionals from 6% to 16%. Furthermore, there has been a decline in chronic malnutrition (stunting) from 58% to 40%, and in underweight children from 41% to 25%; an insignificant decline (between 12% to 9%) has been recorded in wasting cases (ibid).

To date, Ethiopia has not launched a national risk-pooling mechanism. The country developed a health insurance strategy to launch social health insurance for the formal sector, and a community-based

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3 According to updated income classifications by the World Bank, middle-income countries have a GNI per capita of US$ 1,045 to US$ 12,746.
health insurance scheme for the informal sector in 2008 (FMOH, 2008). Community-based health insurance (CBHI) was initially piloted in 13 woredas (districts) spread out in four regions. The pilot studies have been expanded and a scale-up plan has been designed. The launch of social health insurance has, however, taken time, although background tasks are in process. This report reviews the experience of medicine pricing and reimbursement under the Community-based health insurance (CBHI) pilot.

2. National health care services

Ethiopia follows a three-tier health service delivery system, classified under primary, secondary and tertiary levels. Primary health care (PHC) has three points of service: health posts (HPs), health centres (HCs) and primary hospitals. The HP is staffed by two health extension workers (HEW) who focus mostly on preventive and promotive health care. They serve 3,000 to 5,000 people. The HC has an average of 20 staff, and provides preventive and basic curative care, such as childhood disease management, basic emergency obstetric and newborn care (BEmONC), management of malnutrition, etc. Rural HCs serve up to 25,000 people, while urban HCs serve up to 40,000. Primary hospitals provide inpatient and ambulatory services to an average population of 100,000. In addition to what a HC can provide, a primary hospital provides emergency surgical services, including Caesarean sections, and delivers blood transfusion services. It also serves as a referral centre for HCs under its catchment area, and is a practical training centre for nurses and other paramedical health professionals. A primary hospital has an inpatient capacity of 35 beds.

The secondary level of care comprises general hospitals. A general hospital provides inpatient and ambulatory services to an average of 1,000,000 people. It serves as a referral centre for primary hospitals. General hospitals have an inpatient capacity of 50 beds and act as training centres for health officers, nurses and emergency surgeons, among other health professionals. The tertiary level of care is made up of federally-run, specialized and teaching hospitals. A specialized hospital serves an average of five million people. It serves as a referral point to general hospitals, and has an inpatient capacity of about 110 beds.

Over the last two decades, the Government has given high priority to expansion of the PHC system, and of services provided at this level of care. The health sector saw an unprecedented expansion of PHC/Us, with all kebeles having their own health posts, complete with health extension workers; PHC/Us also had more access to health centres. In addition, PHC/Us are getting stronger, with a linkage to primary hospitals. Primary health service coverage increased from 45% in 1996/97 (at the start of HSDP I) to 93.6% in 2012/13 (FMOH, 2011a; FMOH, 2012, FMOH, 2013). As of last year, there were 16,251 health posts, compared to only 76 in 1996/97. Over the same period, the number of health centres increased from 412 to 3,335. Of these, 3,315 (99.4%) were functional and additional 211 were under construction. At the same time, the number of hospitals increased from 87 to 156; 150 of them (96.2%) were functional, with 123 more under construction (FMOH, 2014b).

In line with this focus on accelerated expansion of health care, there has been massive training of low-to-mid-level health professionals as well as extensive training of general practitioners. Accordingly, the number of health extension workers per 100,000 population increased from null to 41.1 between 2004 (when the programme started) and 2013 (FMOH, 2005; FMOH, 2014b). Between 2000 and
2013, and per 100,000 population, the number of nurses (including midwives) increased from 10.5 to 53.6; the number of midwives increased from 1.3 to 6.8; and the number of physicians (including specialists) increased from 2 to 3.1.

Health services in Ethiopia are predominantly provided by the public sector. Nonetheless, the role of the private sector, especially the for-profit sector, has been increasing over time, particularly in major urban areas. Of the 194 hospitals that were available in 2010/11, the private for-profit sector owned 56, and 7 were owned by non-profit organizations (mainly NGOs) (FMOH, 2012). In addition, there were 4,088 private clinics of various levels (ibid). The private for-profit sector is a key player in the import, distribution and retail of pharmaceuticals. According to the 2010/11 household survey, conducted as input to the fifth round of national health accounts (NHA), private for-profit providers (including medicine retail outlets) accounted for close to 20% of all outpatient visits from households, while the NGO share was 1.4% (FMOH, 2014d). Similarly, private for-profit providers accounted for almost 21% of inpatient visits, while the NGO share was 5.52%. The survey also showed that urban residents and those from high-wealth quintile groups are highly likely to use private providers than public providers.

Despite achievements in service expansion, quality of service is a concern among all stakeholders, including the Government. HSDP IV (Health Sector Development Programme IV) has given due emphasis to quality of service. Overriding issues in quality include equipping and staffing newly constructed health facilities to standard, strengthening maintenance capacity, building the hands-on skills of staff, procuring required medicines and pharmaceuticals regularly, strengthening the referral system, reducing waiting times, improving patient safety, integrating services, and having the required operational budget.

3. The pharmaceuticals sector

Ethiopia developed the first national drug policy in November 1993. Since then, amendments have been made to the policy in order to address changes in national economic policy. The country has introduced a free market system, and initiated comprehensive care for HIV/AIDS, according to records at the Food, Medicine and Health Care Administration and Control Authority (FMHACA, 2015). Thus, the policy on the supply and use of anti-retroviral medicines was developed in July 2002. It complemented the National drug policy (ibid). The national drug policy itself aims to meet the country’s demand for essential medicines through organized and regulated supply, distribution and use of medicines. Other objectives of the policy include keeping medicine prices within people’s ability to pay; ensuring the safety, efficacy and quality of medicines; developing domestic medicine manufacturing capacity and future export; strengthening human resource training, research and development; and formulating strategies to integrate traditional medicine into formal health services after ensuring its safety and efficacy (Transitional Government of Ethiopia, 1993). The national drug policy is more than 20 years old, and needs to be revised to keep it abreast of new developments in the pharmaceuticals sector.

The pharmaceuticals sector had been regulated by pharmacy regulation 288/64 of 1964. In order to implement the provisions of the National drug policy and strengthen regulation, previous legislation was replaced with Drug Administration and Control proclamation 176/99 that also
established the Drug Administration and Control Authority (DACA). DACA is the pharmaceuticals regulatory body. Food, medicines and health care administration and control proclamation 661/2009, in turn, replaced the existing proclamation. The latest proclamation expanded the mandate of the regulatory body. Instead of regulating medicines only, it now included food, environmental health, health professionals, and health and health-related institutions (FDRE, 2010). Subsequently, the Food, medicines and health care administration and control authority (FMHACA) was established by regulation 189/2010. Details of proclamation 661/2009 have been provided in Food, medicines and health care administration control regulation 299/2013.

Apart from legislative documents, the pharmaceuticals sector has endorsed various medicine lists, formularies, and standard treatment guidelines that are deemed crucial for the effective running of the health sector in general, and the pharmaceuticals sector in particular. Some of the key documents are listed in Table 2 below.

Table 2: Key pharmaceuticals sector documents

<table>
<thead>
<tr>
<th>No.</th>
<th>Document title</th>
<th>Year of publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>List of medicines for Ethiopia, 6th edition</td>
<td>September 2010</td>
</tr>
<tr>
<td>4.</td>
<td>List of medicines for zonal hospitals</td>
<td>July 2002</td>
</tr>
<tr>
<td>5.</td>
<td>List of medicines for health centres</td>
<td>June 2012</td>
</tr>
<tr>
<td>10.</td>
<td>Standard treatment guidelines for primary hospitals</td>
<td>January 2010</td>
</tr>
<tr>
<td>11.</td>
<td>Standard treatment guidelines for general hospitals</td>
<td>2010</td>
</tr>
<tr>
<td>12.</td>
<td>Standard treatment guidelines for health centres</td>
<td>January 2010</td>
</tr>
</tbody>
</table>

4. The pharmaceuticals supply chain and logistics system

To solve the problem of pharmaceuticals in public health facilities, the Government of Ethiopia has evaluated the system and proposed the development of a Pharmaceutical logistics master plan. Accordingly, the master plan was prepared with the objective of ensuring that “vital and essential pharmaceuticals of approved quality will be readily available to public sector health facilities, for use in the prevention, diagnosis, and treatment of priority health problems, in adequate quantities and at the lowest possible cost” (PFSA, 2012). To achieve this objective, the Government established the Pharmaceuticals Fund and Supply Agency (PFSA) in 2007 through proclamation 553/2007.
There are four main reasons why PFSA came into existence. First, to streamline supply, as there had been duplication of efforts in the past. The second rationale was to reduce wastage through appropriate management of medicines and integration of the fund, if necessary. Third, to make supply in a pool system function according to customers’ needs. Fourth, to improve the physical distribution (transportation) system (FMOH, 2011b).

PFSA procures and distributes medicines, medical supplies, laboratory reagents, and medical instruments. Its procurement of medicines and medical supplies is classified under two categories: programme commodities and the revolving medicines fund (RMF). Programme commodities are those used for malaria, tuberculosis, HIV, family planning and vaccines; these consume around 70% of resources. RMF commodities, on the other hand, consume 30% of resources, and include all other generic medicines and supplies on the essential medicines list. PFSA encourages national manufacturers to enter international competitive bids by providing various incentives (FMOH, 2011b). It runs a revolving medicines fund, which was initially financed from Government, FMOH and donor resources; the Agency continues to receive support periodically. As of the 2013/14 fiscal year, the RMF managed approximately 2 billion Ethiopian Birr (FMOH, 2014c).

Operation of the PFSA is overseen by a management board, and the Agency is managed by a Director-General and two deputies who are responsible for the Operations department and the Human resources and general services department. The core activities of PFSA are managed at regional hubs or branches, which now number 17. The four newly opened branches will start operation this month (September 2015). The branches forecast needs in collaboration with health facilities. Branches also store and distribute medicines and other items.

Despite increased demand over time for the procurement and supply of health commodities, including medicines, PFSA has improved its capacity to cope more effectively. Accordingly, the number of complaints by health facilities regarding shortage of medicines and other supplies has dropped significantly (FMOH, 2014c). Nonetheless, there remain some challenges in the pharmaceutical logistics and supply chain (FMOH, 2014b; FMOH, 2014c). First, there continues to be interruption of supplies. Second, forecasting and quantification remain a major weakness in the supply chain cycle, due to limited capacity and a poor information system. Furthermore, quantification and forecasting of programme commodities is done centrally, without consulting RHBs; this causes a mismatch between demand and supply. Third, delays by health facilities in sending requests to the Pharmaceuticals Fund and Supply Agency (PFSA), and delays by PFSA in the delivery of requested supplies, remain a challenge. Fourth, there is a shortage or lack of standard protocols and treatment guidelines in many health facilities. Fifth, infrastructure for supply chain management is weak; there is a shortage of trucks and warehouses, and there is no cold chain. Sixth, a gap exists in inventory management and quantification skills within the system. Finally, there is pilferage of medicines and medical supplies along the supply chain.
5. Medicines financing and pricing

The health care system in Ethiopia is financed from four main sources: the Government, households, external assistance and the private sector. Findings from National Health Accounts (NHA) studies show that health financing has improved significantly over the years. Total per capita health spending almost quadrupled between NHA I and NHA V, from US$ 4.50 in 1995/96 to US$ 20.77 in 2010/11 (FMOH, 1996; FMOH, 2014a). However, financing remains low compared to global estimates of expenditure needed to meet essential health care needs. Accordingly, the Commission on macroeconomics and health (CMH), estimated that, by 2015, the per capita resource requirements in low-income countries to procure essential MDG-related services would total US$ 38.00 (expressed in 2002 dollars). On the other hand, the high-level task force (HLTF) on innovative financing put that figure at US$ 54.00 (expressed in 2005 dollars) if the country is to procure more comprehensive services included in its estimates. In 2012 dollars, the CMH estimate is equivalent to US$ 71.00, and that of the HLTF is US$ 86.00 (McIntyre & Meheus, 2014). Current results in the health sector in Ethiopia show that it has a low-cost service delivery model, and a comparative advantage in terms of purchasing power parity. Nonetheless, it is clear that total health expenditure in Ethiopia is quite low.

NHA findings also show that the contribution of Government to total health expenditure declined between NHA II and NHA IV, from 33% in 1999/2000 to 16% in 2010/11. Over the same period, out-of-pocket payments by households showed an insignificant decline, from 36% to 34%. The major driver of increased per capita spending in Ethiopia is external resources, the share of which more than doubled from 22% to 50% over the same period. Although government expenditure on health has been increasing in nominal terms, it is a challenge to note that its share of total health expenditure is declining, and government health expenditure as a percentage of GDP is a mere 0.8%. WHO recommends that countries should strive over time to achieve government health spending levels of at least 5% of GDP, supplemented by a minimum target of US$ 86.00 per capita government and donor funding in low-income countries, if basic PHC services are to be maintained (McIntyre & Meheus, 2014). In addition, the government has to cover health expenditure financed by external partners in the medium to long term, given Ethiopia’s ambition to become a middle-income country by 2025. Besides, given the country’s aim to achieve universal health coverage, the Government needs to cover part of the out-of-pocket (OOP) health spending.

In NHA studies, expenditures on medicines incurred within health facilities for outpatient or inpatient care are accounted for as part of expenditure on respective outpatient and inpatient services. Hence, it was not possible to disaggregate total expenditure on medicines in Ethiopia. The only available information is from the household survey which was conducted as input into NHA V (FMOH, 2014d). The survey shows that households spent US$ 387.2 million in 2010/11; this accounted for almost 63% of total out-of-pocket household health expenditure (ibid).

Most PFSA procurements are in bulk, and are usually shipped. Consequently, PFSA mostly considers FOB prices, which are negotiated to include the cost of the item, the cost of shipment, and other related costs, until the item reaches an agreed port of discharge. Where some items are transported by air, PFSA agrees on a CIF price, which covers the item cost, freight and insurance. For items imported based on the FOB price, additional costs, such as bank charges, insurance, freight, customs duty, etc., could amount to 20% of the FOB price.
Once items reach the PFSA headquarters, distribution costs are calculated based on a moving average cost principle. According to this principle, the agency considers different transportation costs to different parts of the country and averages them out, so that there is uniform pricing in all regions and localities in the country. After the cost of import and distribution has been considered, PFSA calculates its mark up. There are four categories of items where different mark-ups are estimated. First, for items manufactured locally, a reduced mark-up of 8%–10% is levied. Second, for items, that are considered very essential such as insulin, no mark-up is added. Third, expensive items considered essential, such as cancer medicines, are instead subsidized. Fourth, all other items, depending on the cost and need, a mark-up ranging from 25% to 40% is added. Details of costing procedures are documented in a costing manual, which has been approved by the PFSA management board.

6. Management of medicines within health insurance schemes

The Council of Ministers adopted the Health care and financing strategy in 1998. That strategy aimed to increase financial resources for the health sector, and improve efficiency in the utilization of the resources. The Strategy devised various mechanisms to meet its goal, one of which was establishing various private, community-based or social health insurance schemes. Following various pre-feasibility and feasibility assessments, the plan to pilot community-based health insurance in selected woredas was approved. The Federal Ministry of Health (FMOH) developed a health insurance strategy that proposed community-based health insurance (CBHI) for the informal sector, and social health insurance for the formal sector (2008). Subsequently, a CBHI directive was developed by the FMOH, and regional governments adapted it to their context. Based on the regional directive, each woreda CBHI scheme developed bylaws. CBHI was intended to pool risks and protect from the regressive effects of out-of pocket payments among people employed in the informal sector.

CBHI has been piloted since 2010/11 (2003 EFY) in 13 woredas in Amhara, Oromiya, Southern nations nationalities and peoples (SNNP), and Tigray national regional states. Each of the regions has three pilot woredas, with the exception of Oromiya Region which has four pilot woredas (see Table 3).

Table 3: List of initial CBHI pilot woredas

<table>
<thead>
<tr>
<th>Amhara</th>
<th>Oromiya</th>
<th>SNNP</th>
<th>Tigray</th>
</tr>
</thead>
<tbody>
<tr>
<td>South AcheferFogera</td>
<td>Gimbichu</td>
<td>Yirgalem City Demboya</td>
<td>KilteAwlaelo</td>
</tr>
<tr>
<td>Tehuledere</td>
<td>Kuyu</td>
<td>DamotWoyde</td>
<td>Aherom</td>
</tr>
<tr>
<td></td>
<td>Deder</td>
<td></td>
<td>TahtayAdiabo</td>
</tr>
<tr>
<td></td>
<td>LimuKossa</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The main sources of finance for CBHI schemes are premium payments and registration fees collected from members, general subsidies from the Federal Government (FMOH), and targeted subsidies from the regions and woredas covering the expenses of indigents that average 10% of total membership in each scheme. All the pilot regions have more or less similar design parameters. Some of the key features are summarized in Table 4.
### Table 4: Key design parameters of CBHI pilot schemes

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Amhara</th>
<th>Oromiya</th>
<th>SNNP</th>
<th>Tigray</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Membership unit</strong></td>
<td>Household-level (as opposed to individual-based)</td>
<td>Household-level</td>
<td>Household-level</td>
<td>Household-level</td>
</tr>
<tr>
<td></td>
<td>Household-size is limited to 5 members</td>
<td>Household-level</td>
<td>Household is limited to parents and children under 18</td>
<td></td>
</tr>
<tr>
<td><strong>Registration fee per household</strong></td>
<td>US$ 0.14</td>
<td>US$ 0.24</td>
<td>US$ 0.24</td>
<td>US$ 0.24</td>
</tr>
<tr>
<td><strong>Premium per annum for the core household</strong></td>
<td>US$ 6.83</td>
<td>US$ 5.98 (Extra charge of US$ 1.71 per additional household members (those beyond 5 members))</td>
<td>US$ 8.54</td>
<td>US$ 6.26 (Extra charge of US$ 1.42 per child above 18)</td>
</tr>
<tr>
<td><strong>Financing of indigents (targeted subsidy)</strong></td>
<td>90% of subsidy cost is covered by region and 10% by woreda</td>
<td>100% covered by woreda</td>
<td>100% covered by woreda</td>
<td>70% of subsidy financed by the region, and 30% by woreda</td>
</tr>
<tr>
<td><strong>General subsidy</strong></td>
<td>FMOH subsidizes the schemes by contributing 25% of premiums collected per year</td>
<td>FMOH subsidizes the schemes by contributing 25% of premiums collected per year</td>
<td>FMOH subsidizes the schemes by contributing 25% of premiums collected per year</td>
<td>FMOH subsidizes the schemes by contributing 25% of premiums collected per year</td>
</tr>
<tr>
<td><strong>Payments to providers</strong></td>
<td>Fee for service at health centres and hospitals</td>
<td>Fee for service at health centres and hospitals</td>
<td>Fee for service at health centres and hospitals</td>
<td>Fee for service at health centres and hospitals</td>
</tr>
<tr>
<td><strong>Benefits package</strong></td>
<td>All health services available in public health centres and hospitals, except for tooth implantation and eyeglasses</td>
<td>All health services available in public health centres and hospitals, except for tooth implantation and eyeglasses</td>
<td>All health services available in public health centres and hospitals, except for tooth implantation and eyeglasses</td>
<td>All health services available in public health centres and hospitals, except for tooth implantation and eyeglasses</td>
</tr>
<tr>
<td><strong>Housing of the CBHI scheme</strong></td>
<td>Within the woreda administration office</td>
<td>Within the woreda administration office</td>
<td>Within the woreda administration office</td>
<td>Within the woreda administration office</td>
</tr>
<tr>
<td><strong>Governance and management</strong></td>
<td>Woreda CBHI board4 oversees the initiative. The scheme staff are employed by the woreda administration</td>
<td>Woreda CBHI board oversees the initiative. The scheme staff are employed by woreda administration</td>
<td>Woreda CBHI board oversees the initiative. The scheme staff are employed by woreda administration</td>
<td>Woreda CBHI board oversees the initiative. The woreda health office assigns the curative core process owner as coordinator. Other CBHI executive staff are employed by the woreda administration.</td>
</tr>
</tbody>
</table>

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4 Woreda CBHI boards comprise the chief woreda administrator, the head of the woreda health office, the head of the woreda finance and economic development office, and seven representatives from each village (kebele) within the woreda.
Before the launch of CBHI pilots, the FMOH developed a prototype CBHI directive and shared it with the piloting regions to give them a general direction about governance, management, and the key design features of the pilots. However, given the decentralized system of governance in Ethiopia, each region has the latitude to adapt the federal directive to its specific context, hence, the differences in registration fees, premiums, and indigent financing options. Given that this is a pilot project, it is good to have such differences as it allows the scale-up stage to benefit from different experiences and best practices. However, once the pilot has been scaled up, it is advisable to propose different premium- and registration-fee levels, depending on the means available to members in different areas. For example, lessons from the pilot show that premiums need to be higher in urban than rural areas, to sustain the scheme. In addition, premiums in cash-crop producing districts could be higher than those in districts that only grow grain, or that have very high population density and smaller-scale average farm size. During scale-up, such differences in means should be considered when setting premiums, where data and practicality allow.

CBHI pilots are set up at the woreda level pool risks from the kebeles. There can only be one CBHI scheme per district. Each scheme has branches at kebele or village level. The higher governing body of CBHI schemes is the General assembly, with the Board managing its operations. The scheme also has permanent staff comprising a focal person, an accountant, and a data or IT clerk. In the current design, there is no regional or national risk-pooling between schemes.

The performance of the pilots was evaluated in 2014 (EHIA, 2015a) and a scale-up strategy designed (EHIA, 2015b). The strategy is being refined in consultation with a wider group of stakeholders. At the same time, the pilots are being expanded to close to 190 additional woredas within the same four pilot regions.

According to the latest available data (April, 2015), there were close to 755,000 members in the initial pilot woredas, and more than 4.7 million members in the newly expanded woredas, excluding new members in SNNPR and six expansion woredas in Tigray where data is not available (see Table 5). It was possible to raise a substantial amount of money from CBHI schemes. In fact, as of April 2015, a cumulative sum of US$ 1.96 million had been raised from the initial 13 woredas since the pilots started in 2010/11. A total of US$ 5.65 million was also raised from the 128 expanded woredas (see Table 5).
Table 5: CBHI membership and premiums collected in USD\(^5\) in initial and expanded woredas, cumulative as of April 2015

<table>
<thead>
<tr>
<th>Region</th>
<th>No. of woredas</th>
<th>Total No. of households Paying</th>
<th>No of member households</th>
<th>Total beneficiary</th>
<th>Average enrollment rate</th>
<th>Amount of premiums collected (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Indigent</td>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amhara</td>
<td>Initial</td>
<td>3</td>
<td>104,949</td>
<td>46,471</td>
<td>6,459</td>
<td>52,930</td>
</tr>
<tr>
<td></td>
<td>Expanded</td>
<td>64</td>
<td>1,963,917</td>
<td>527,531</td>
<td>84,255</td>
<td>611,786</td>
</tr>
<tr>
<td>Oromiya</td>
<td>Initial</td>
<td>4</td>
<td>135,599</td>
<td>43,231</td>
<td>11,811</td>
<td>55,042</td>
</tr>
<tr>
<td></td>
<td>Expanded</td>
<td>59</td>
<td>1,805,862</td>
<td>206,004</td>
<td>182,105</td>
<td>388,109</td>
</tr>
<tr>
<td>SNNPR</td>
<td>Initial</td>
<td></td>
<td>47,887</td>
<td>20,210</td>
<td>1,425</td>
<td>21,635</td>
</tr>
<tr>
<td></td>
<td>Expanded</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tigray</td>
<td>Initial</td>
<td>3</td>
<td>92,042</td>
<td>33,797</td>
<td>8,651</td>
<td>42,448</td>
</tr>
<tr>
<td></td>
<td>Expanded</td>
<td>15</td>
<td>3,951#</td>
<td>11,359#</td>
<td>15,310#</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>Initial</td>
<td></td>
<td>380,477</td>
<td>143,709</td>
<td>28,346</td>
<td>172,055</td>
</tr>
<tr>
<td></td>
<td>Expanded</td>
<td></td>
<td>3,769,779</td>
<td>737,486</td>
<td>277,719</td>
<td>1,015,205</td>
</tr>
</tbody>
</table>

Source: Adapted from HSFR/HFG, 2015

Note:
# It is a compilation of data from nine woredas out of the 15 that have expanded CBHI in the region.

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\(^5\) Exchange rate is estimated at US$ 1.00 = ETB 20.56 ([www.oanda.com](http://www.oanda.com)).
CBHI has brought about improvements in health service utilization. Data from pilot woredas show that per capita health service utilization per year was 0.7 in the pilot woredas, while the national average stood at 0.3 (HSFR/HFG, 2015; FMOH, 2013). In addition, empirical analysis shows that a CBHI member is 26.3% more likely than a non-member in a pilot district to visit a health facility in case of illness (EHIA, 2015a).

The CBHI scheme makes payments to contracted health facilities after they render service. As of January 2015, a cumulative total reimbursement of close to US$ 2.1 million was made to health centres and hospitals (Table 6). However, disaggregated data are not readily available to see how much is spent on different components of health care. CBHI schemes at woreda or kebele levels do not face operating costs resulting from such items as salaries, per diems, travel-related expenses, office equipment and supplies, utilities, etc. Such costs are covered by CBHI hosting institutions at woreda and kebele levels, i.e., the woreda administration office, and the kebele administration office respectively (FMOH, 2011c; EHIA, 2015a). Nonetheless, the schemes face budget shortages. This affects scheme effectiveness by limiting supervisory and monitoring visits to kebeles and health facilities. Budget shortages also cause delays not only in board and general assembly meetings, but also in the timely deposit by kebeles of collected premiums (EHIA, 2015a).

Table 6: Health service utilization and reimbursement of costs, cumulative as of January 2015

<table>
<thead>
<tr>
<th></th>
<th>No of woredas that have started rendering service to members</th>
<th>Number of service users</th>
<th>Total insurance expenditure* in USD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Health centre</td>
<td>Hospital</td>
</tr>
<tr>
<td>Amhara</td>
<td>Initial</td>
<td>3</td>
<td>528,892</td>
</tr>
<tr>
<td></td>
<td>Expanded</td>
<td>34</td>
<td>541,832</td>
</tr>
<tr>
<td>Oromiya</td>
<td>Initial</td>
<td>4</td>
<td>122,091</td>
</tr>
<tr>
<td></td>
<td>Expanded</td>
<td>10</td>
<td>32,321</td>
</tr>
<tr>
<td>SNNPR</td>
<td>Initial</td>
<td>3</td>
<td>212,505</td>
</tr>
<tr>
<td></td>
<td>Expanded</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tigray</td>
<td>Initial</td>
<td>3</td>
<td>190,455</td>
</tr>
<tr>
<td></td>
<td>Expanded</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total of Initial woredas</td>
<td></td>
<td>1,053,943</td>
<td>160,377</td>
</tr>
</tbody>
</table>

Source: Adapted from HSFR/HFG, 2015

Note:

*At the pilot stage, the only expense for the CBHI is medical expenses of members. Administrative costs are covered by the district government.*
7. Medicines coverage and their selection for reimbursement in health insurance schemes

Members of CBHI schemes can obtain services only from public health facilities, i.e. at health centres; they can also get referrals to the nearest hospital contracted by the CBHI scheme. In some regions, such as Tigray, members can get referrals up to the regional referral hospital. Within contracted health facilities, all care-related costs incurred by members, including consultations, diagnostics, procedures, inpatient services, and pharmaceuticals, are covered by the insurance scheme. Hence, patients do not pay for medicines, whether as inpatients or outpatients. When they come to the health facility, members present a renewed (premiums paid to date) membership identification card. They get the required service within the contracted health facility, including medicines, without paying anything out-of-pocket. There is no co-payment for medicines or services at the outpatient or inpatient level. Absence of co-payment at this stage is a more pragmatic design feature for various reasons.

First, the concept of health insurance is still new, and communities need to internalize the fact that the benefits to be gained from insurance membership far outweigh the premiums they pay before introducing additional charges. Second, CBHI members can only access public health facilities where long waiting-times and shortage of medicines largely check the potential for unnecessary visits. In addition, non-medical costs, such as travel, food, accommodation, etc. tend to be significant among hospital-care-seeking patients, hence discouraging irrational use. Third, per capita health service utilization is still very low. However, once CBHI is scaled up, SHI launched, and access to private health facilities included in the benefits package, co-payment may become necessary.

Where members ignore the referral system and visit a hospital without a referral note from a health centre, and where there is no emergency, the patient pays 50% of the cost as a bypass fee. This is a good measure, which has helped improve the referral system, thereby reducing an unnecessary burden at hospital level. Accordingly, about 87% of health service utilization by CBHI members is within health centres (see Table 6).

In cases where a medicine is not available within the contracted health facility, users are required to get evidence (a stamp, for example) from there indicating that the medicine is not available. They can then purchase the medicine at a private medicine retail outlet (MRO) by paying out of pocket. In Amhara and Tigray regions, members who buy unavailable medicines from private MROs are reimbursed. In Oromiya, on the other hand, the scheme contracts with certain private MROs, which are authorized to give service only when medicines are not available in public health facilities. The cost of the medicines is then reimbursed to the private MRO. In SNNPR, patients are not reimbursed for medicines they buy outside of contracted health facilities, even if a particular medicine is not available in the former.

With regard to a medicines list for reimbursements, CBHI has not yet developed one. CBHI benefits packages cover all health services available in public health centres and hospitals, except for tooth implantation and eyeglasses. Accordingly, all medicines prescribed for eligible services are good for reimbursement. Lists of medicines that can be prescribed in respective health facilities are widely known as they are shown in both Standard treatment guidelines and in the list of medicines, by level of health facility, developed by the Food, Medicine and Health Care Administration and Control.
Authority (FMHACA). The FMHACA list is drawn from essential medicines and is generic. Based on these standard documents, each health facility develops its own medicines list appropriate to its context.

8. Pricing of medicines and reimbursements by health insurance schemes

The primary source of medicines supply for government health facilities is the Pharmaceutical Fund and Supply Agency (PFSA). Public health facilities can procure medicines from private importers only where the items are not available at PFSA, or when they are in an emergency.

The CBHI scheme does not have a proper price-setting mechanism for medicines; importers such as PFSA, and private companies, set selling prices. Then the respective health facilities set the retail price of the medicines and supplies by adding a 15% to 25% mark-up to the cost of the medicines. CBHI schemes, for their part, simply assume the price based on user fees charged by health facilities. When a contract is signed between the scheme and the public health facility, the user fee for each service type, and the price of various medicines, are attached to the contract. When revisions in user fees or the price of medicines occur, the insurance scheme is informed. Consequently, after contracted health facilities have provided a service, they list the cost of each service provided and each medicine dispensed based on the regular fee that the health facility charges. The latter request reimbursements on a quarterly basis. It is stated in the CBHI directive (FMOH, 2011c) that when the health insurance scheme receives a request for cost reimbursement, it should automatically pay 75% of the requested amount. The remaining 25% is paid once the scheme has checked the report, and has monitored the contracted health facility by taking samples of patients that utilize services, and by checking through their medical as well as respective financial records.

In the initial pilot period, health facilities got reimbursement for their total costs on a fee-for-service basis. Following the expansion of pilots, and starting from the current fiscal year, the scheme has changed its provider payments modality at the health centre level. Of the total revenue collected by the scheme, 40% will be distributed among contracted health centres based on their catchment population. This is a strategy designed to protect the schemes from financial loss. However, such a financing mechanism could in turn transfer financial burdens to health centres.

In terms of timelines for reimbursement, health facilities are required to file a reimbursement request within seven to 15 days of the end of the quarter. If they do so, they will be reimbursed within two weeks of receipt of the request. However, in some woredas, especially those facing financial difficulty, delayed reimbursements are possible. For example, in Yirgalem City, the CBHI scheme has not reimbursed health centres for close to three quarters (EHIA, 2015a).

There are difficulties with reimbursing costs to members who have purchased medicines from private MROs. Reimbursements in such cases can take up to three months, or denied altogether. First, members need to get evidence or a stamp from the contracted health facility attesting that a particular medicine is not available. A record of the same stamp is transferred to the patient’s file. Second, members must have cash to pay out-of-pocket. Third, there are moral hazard problems within private MROs such as dispensing medicines that are not on the prescription, or selling higher
doses of the prescribed medicine, etc. Fourth, the reimbursement process is tedious. Reimbursements requested at kebele level are sent to the woreda. The woreda insurance scheme can call the client for explanations. The client also checks with the scheme whether reimbursement is ready or not, by going to the woreda. Finally, the client needs to travel to the woreda to collect the refund. All this entails travel costs, and have an opportunity cost as well.

9. System for managing and monitoring medicines in health insurance schemes

The scheme does not have a systematic mechanism for monitoring service delivery or medicines in contracted health facilities. The latter are monitored if and when inaccuracies are observed in the reimbursement requests, or when clients lodge complaints. In such cases, scheme staff go to the respective health facilities, hold discussions, and inspect relevant documentation such as patient cards, prescriptions, referral notes, fee levels, etc.

Recently, attempts have been made to strengthen the monitoring system; clinical audit guidelines have been developed, which give details of the steps to take; there is even a checklist. The clinical audit aims to ensure and maintain quality service, as well as reduce moral hazards and malpractice (EHIA, 2014). The scheme will conduct medical checks when health facilities request reimbursements. The audit also intends to minimize fraudulent and erroneous cost reporting. Schemes are encouraged to take a sample of patients who have used service during a particular quarter, and to check their documentation within the health facility. Reports will be prepared and documented after such visits. The monitoring team will also communicate their findings to the staff of the health facility.

With regard to medicines, clinical audits monitor prescribing practices in that they check if the prescription is as per the Standard treatment guidelines. The audits also check whether or not all prescribed medicines are dispensed within the contracted health facility. If not, they check whether referrals are justified. In addition, the audits check whether the fees recorded in the reimbursement report agree with the fee schedule of the health facility for the particular medicine. The scheme receives the prices of medicines and services during contract signing every year. However, it does not keep a database of prescriptions.

Recently in SNNPR, a health facility-community forum was started where the community meets every month to provide feedback on the quality of service in a particular health facility (EHIA, 2015a). A woreda chief administrator, or the head of a woreda health office typically chairs such forums; all health facility staff are usually present. Issues raised by the community are discussed and resolved, and action points set for the next forum. Service quality for CBHI members is one major discussion area during such forums.
10. Major challenges

10.1. Medicines selection, supply, expenditure, pricing, and reimbursements

There are various challenges that affect medicines in community-based health insurance schemes:

**Service quality, supply and reimbursement**

1. There is a shortage of medicines and supplies in public health facilities; consequently, patients are referred to private medicine retail outlets. This, in turn, causes various challenges to users. First, they need to have cash at hand to buy from private sources. Second, it entails time, travel, and related costs, as the client has to search for the retail outlet where the medicine is available. Third, users might face inappropriate dispensing practices (moral hazards) in private medicine retail outlets where they run the risk of being sold preparations that were not prescribed, or of the wrong dose or type. Finally, users also face inconvenience and delays in reimbursement. Members could be denied a refund in regions such as SNNPR, if there are missing documents, or where there has been inappropriate dispensing.

2. There are some issues with service quality for members of community-based health insurance schemes, as is common in other health facilities. In addition to shortages of medicines, some diagnostic facilities and services are not available, waiting times are long, and staff courtesy leaves something to be desired.

3. Health facilities complain of shortages, or of the non-availability of pharmaceutical supplies at the regional hubs of the Pharmaceuticals Fund and Supply Agency (PFSA). Public health facilities cannot buy from private wholesalers unless PFSA gives them evidence that the item is out of stock; and PFSA usually delays giving such evidence. PFSA is also known to signal cases of theft and mishandling of medicines, especially in hospitals, all of which causes shortages.

4. Health facilities sometimes send incomplete reports and documentation when requesting reimbursements for the cost of services, including medicines. Usually, the health insurance scheme and the health facility try to resolve the matter through dialogue. However, this leads to delays in reimbursement.

5. Community-based health insurance schemes have not yet developed lists of medicines that are eligible for reimbursement based on the benefits package. In the future, this could give room for provider moral hazards and lead to cost escalation.

**Financing**

6. The financial sustainability of some of the schemes is a huge challenge. Take the scheme in Yirgalem for instance. This is the only pilot in an urban setting among the Phase I pilots. The scheme has not been able to reimburse health facilities for close to three quarters (EHIA, 2015a). This has a direct effect on both the quality of service delivered and availability of medicines, as the health facilities lack the funds with which to re-stock.

7. Currently, there is no regional or national risk pooling among community-based health insurance schemes. This reduces the potential for minimizing adverse selection and increasing financial sustainability.
Access

8. Health facilities do not operate during weekends. Hence, in cases where members need to access service during this period, they are bound to visit a private health facility. Those who do not have cash to pay out of pocket face difficulty.

Data and monitoring

9. The schemes face difficulties in monitoring service quality and conducting medical audits at hospital level. The level of service, and of the professionals in hospitals, is very high; and health insurance schemes do not have professionals of such calibre. The medical audit guide suggests using high-level professionals from the Food, Medicine and Health Care Administration and Control Authority (FMHACA), EHIA and professional associations. However, this is often difficult to realize.

10. Schemes have inadequate administrative budgets, which affects their operations, including limitations in timely monitoring.

11. Even though information management was one dimension considered in the pilot design, there remain significant gaps in generating, sharing, and using data at all levels. Basic information, such as membership renewals, premium collection, details on reimbursements to health facilities, member service utilization, is often inconsistent, out of date, or not readily available at the level of the insurance scheme (EHIA, 2015).

10.2. Measures taken or planned to mitigate the challenges

The Ethiopian Health Insurance Agency (EHIA), together with the Federal Ministry of Health (FMOH), is taking various measures to address the challenges faced in community-based health insurance pilots. Some of the measures are already operational in woredas where pilots have been expanded. Other measures are being introduced in the CBHI scale-up strategy, and will be effective with the scale-up.

It may be well to cite some of the measures proposed for the scale-up stage (EHIA, 2015b). First, the EHIA quality assurance section (federal and regional branches) will conduct periodic quality assurance, and will control service provision at referral and specialized hospitals. Second, there is a plan to work closely with PFSA to ensure medicine availability. Accordingly, it is proposed to hold joint steering meetings with the EHIA, PFSA and FMOH every two months. Also, at the regional level, the PFSA regional manager will be part of the Regional health bureau management team. Third, efforts are being made to improve government ownership through discussion with different levels of government, and by conducting experience-sharing visits. Fourth, the insurance risk pool will be expanded through the introduction of pooling at woreda, regional and federal levels. Fifth, there is a plan for federal and regional states to cover the CBHI costs of members who fall below the poverty line. Sixth, to improve revenue generation, contributions will be strictly for core household members. For extended family members, additional payments will be made on a per capita basis. Furthermore, premium levels will be increased. Seventh, a management information system will be put in place; it is proposed that CBHI-related data be included in the national Health management information system (HMIS).
The EHIA has also held discussions with PFSA on how to improve availability of medicines at the local level. PFSA has started to take action. The EHIA believes that the medicines issue will be resolved. PFSA has started implementing the Auditable pharmaceuticals transaction system (APTS) initiative, which aims to improve the quality of pharmacy services and increase the availability of specialty and essential medicines, especially in hospitals. Implementation of the APTS initiative will have a number of advantages. Through APTS, hospitals have established evidence-based, transparent, and accountable pharmaceutical services and financial transactions, thereby minimizing wastage and the expiry of medicines (FMOH, 2014b). In addition, pharmaceutical services have become auditable, further reducing wastage and the expiry of medicines, and hence improving the quality of care. Besides, implementing hospitals have managed to easily produce monthly cost and consumption reports, and to utilize their budgets appropriately. As of last year, more than 30 hospitals in different regions were implementing APTS (ibid).

The health sector is taking encouraging measures that are intended to strengthen the health system, raise the quality of service and improve the performance of CBHI schemes. There are various measures proposed to address the issue of service quality in general, and shortages of medicines and supplies in particular. Some of the major undertakings in this regard include periodic quality assurance supervision by the EHIA; the introduction of APTS; stronger collaboration and partnership among the EHIA, the FMOH and PFSA, and efforts to strengthen government ownership at different levels. One major limitation of the proposed quality assurance supervision, the introduction of APTS, and the ongoing Ethiopian hospital reform implementation guidelines (EHRIG), which aims at strengthening hospital management to ensure high quality clinical care and patient satisfaction, is that they all focus on hospitals. Holding close discussions with PFSA, involving them in national steering committee deliberations, at the regional level, are all steps in the right direction. They will emphasize the urgency of improving medicines supply. The launch of Social health insurance will add to the urgency, as the stakes will be high and the size of the membership massive. However, such efforts (the efforts already begun) need to be followed through.

Regarding financial sustainability, proposed measures such as improving government ownership, expanding the risk pool, increasing premiums, charging additional fees for non-core household members, are excellent measures. Furthermore, the proposal to cover the insurance membership costs of people living below the poverty line will not only improve equity and facilitate the path towards universal health coverage, but will also increase the financial sustainability of the schemes.

The measures proposed to improve data management and monitoring are already enhancing government ownership and incorporating CBHI-related data and indicators into the Health management information system. Nonetheless, these measures will not be adequate to resolve the challenges faced in this regard.

The additional recommendations provided below are aimed at resolving pertinent challenges that have not been addressed by the above measures.
11. Recommendations

11.1. On quality, supply and reimbursement issues

1. Compile a list of private medicine retail outlets (MROs) and health facilities, and negotiate service delivery modalities and prices. Such pre-identified private MROs will dispense medicines and provide other services that are not found within the contracted (public) health facility. The insurance schemes should contract with such MROs or health facilities, and reimburse them when they provide service. In this way, patients should be able to get service without much difficulty, and without paying out of pocket. However, there is a need to institute an appropriate quality assurance and control system. The insurance scheme and the EHIA need to monitor and check for moral hazards and inaccurate dispensing practices. They must also ensure medicine safety and efficacy, control counterfeit medicines, and contain costs.

2. As CBHI data show, 87% of service utilization by members is within health centres. Thus, the ongoing good initiatives to strengthen service quality and increase patient satisfaction within hospitals need to be expanded to, and strengthened at, the health centre level. Shifting ongoing initiatives towards electronic patient data management would also help a great deal.

3. The EHIA and FMOH initiative to set up a steering committee, and to closely involve PFSA, is a good one. However, it should be followed through so that it does not stall. Furthermore, health facilities need support in strengthening their commodity forecasting and quantification capacity. PFSA should play a major role by providing technical support, and facilitating regular quantification and forecasting workshops for health facilities through its branches.

4. With the scale-up of community-based health insurance, and the possibility of expanding service access to private health facilities, developing lists of eligible medicines will become mandatory in order to ease reimbursement problems. In addition, insurance schemes will need to do their own service costing and medicine pricing before negotiating service delivery modalities and costs with health facilities.

11.2. On access

5. Emergency operations during weekends and off-work hours should be negotiated with health facilities when signing contracts.

11.3. On financial sustainability

6. It would be advisable to set different premiums for rural and urban areas, and for better-off and poorer areas, based on variations in access to health services, service utilization patterns, and economic potential, where practicable.

7. Once community-based health insurance is scaled up, social health insurance launched, and access to private health facilities included in the benefits packages of the insurance schemes, it would be advisable to introduce some form of co-payment to discourage irrational use.

8. There is a need to develop a financial administration and management system that will regularly analyze the financial status of the insurance schemes and take early action.

9. During CBHI scale-up, adequate budgets that will cover salaries and other operational expenses should be properly considered.
11.4. On data and monitoring issues

10. EHIA should prioritize the strengthening of monitoring and evaluation capacity within community-based health insurance schemes. Mobilizing regional and zonal expertise for periodic monitoring would be one mechanism for addressing the capacity issue. In addition, collaboration should be sought with professional associations to support monitoring and medical audits at hospital level. For example, EHIA could enter into multi-year arrangements, or sign outsourcing contracts, with professional associations. There is also a need to set aside a small fraction of the revenue collected. Such amount could be used for financing monitoring, evaluation and research activity.

11. Ongoing orientations for health facility staff on proper documentation and reporting of insurance member data is crucial. Such activities could be coordinated to hold at the same time as monitoring exercises. It would be helpful to design a data management system, and prepare a standard set of indicators to help schemes monitor activity and report at different levels of the administrative structure. In addition, there is a need to design simple data management software to ease data recording, analysis and reporting. This would resolve issues with availability of disaggregated data and incomplete reporting during requests for reimbursement.
References


Assessment of medicine pricing and reimbursement systems in Gabon
1. Population and socio-economic situation of Gabon

Gabon is located in central Africa; it is bordered to the northwest by Equatorial Guinea, to the north by Cameroon, to the east and south by the Republic of Congo, and to the west by the Atlantic Ocean. It has a surface area of 267,667 km², 85% of which is covered by forests. The population of Gabon was estimated to be 1,802,728 in 2015 (RGPH, 2015); it is predominantly female (52%). Life expectancy is 64 years for women and 62 years for men (World Health Statistics, 2014). Gabon’s political capital is Libreville, while Port-Gentil is its economic capital. Gabon has nine provinces, 52 administrative divisions (départements), 27 districts, 152 cantons, 50 councils and 3,304 villages and groups of villages.

Almost 84% of the population lives in urban areas, with 50% living in Libreville and Port-Gentil, and the rest spread along highways and river courses. Most of the roads in the country are not all-seasonal, while the river courses are only partially navigable. In 2014, UNDP placed Gabon 112th out of 187 countries, and assigned it a human development index (HDI) of 0.674. It has a Gross National Product (GNP) of US$ 16,977 per capita (UNDP 2014). Gabon is thus classified as an upper middle-income country with average human development. Close to 33% of the population lives below the poverty line.

Table 7: Summary of Gabon’s socio-economic data

<table>
<thead>
<tr>
<th>Heading</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>1,802,728 inhabitants</td>
</tr>
<tr>
<td>Life expectancy at birth</td>
<td>64 years for women</td>
</tr>
<tr>
<td></td>
<td>62 years for men</td>
</tr>
<tr>
<td>GDP per capita</td>
<td>US$ 16,977</td>
</tr>
<tr>
<td>Human development index (HDI)</td>
<td>0.674</td>
</tr>
<tr>
<td>HDI classification</td>
<td>112th out of 187 countries</td>
</tr>
<tr>
<td>Mortality rate 15-60 years m/w (for every 1000, 2013)</td>
<td>296/235</td>
</tr>
<tr>
<td>Total health expenditure per capita ($ int., 2013)</td>
<td>735</td>
</tr>
<tr>
<td>Total health expenditure as a % of GDP (2013)</td>
<td>3.8</td>
</tr>
</tbody>
</table>
2. The health system

Gabon is subdivided into 10 health regions and 52 health districts. The health system is based on three sectors: the civilian and military public sector, the semi-public sector and the private for-profit and private non-profit sector.

The civilian public sector is a pyramid-shaped organization consisting of three levels. The central or strategic level comprises all the central directorates, including the programmes, institutes and university teaching hospitals. The intermediate level essentially comprises the 10 regional health directorates and the nine regional hospitals located in the regional headquarters. The peripheral level, known as the health district, is the first level of the health pyramid, and comprises medical centres, dispensaries, district or urban health centres and health stands. The military public sector is directly managed by the Ministry of Defence. It comprises a referral hospital, military health centres, and a vast network of infirmaries. The semi-public sector, with the Caisse nationale de Sécurité sociale (CNSS) [National Social Security Fund], has two polyclinics and seven medico-social centres spread all over the country.

The private non-profit sector is represented by the Albert Schweitzer Hospital in Lambaréné, the Bongolo Evangelical Hospital in Lébamba, and Catholic and Protestant mission dispensaries. The private for-profit sector comprises polyclinics, clinics, doctors', dental and nursing practices, clinical laboratories, wholesale distributors of pharmaceutical products, pharmacies, pharmaceutical depots, and a rehabilitation and orthopaedic centre.

3. The pharmaceuticals sector

In Gabon, the management of medicines is the duty of the Department of Medicines and Pharmacy (DMP), which is responsible for regulating the pharmaceuticals sector. In that capacity, it is tasked with developing the national pharmaceuticals policy (PPN), drawing up the national Essential Medicines List (LNME), and issuing marketing authorizations (AMM). The regulatory architecture is completed by the General Inspectorate of Health, which comprises an inspectorate of pharmacies that is responsible for supervising pharmacies and other wholesalers. There is a central purchasing body (OPN) responsible for supplying, storing and distributing medicines to public health facilities. The private sector has two distributors: wholesalers and about one hundred pharmacies. Gabon adopted a national pharmaceuticals policy in 2010. The pharmaceuticals sector is regulated by Ordinance 001/PR/2011 to organize the pharmaceuticals sector in the Gabonese Republic. A national essential medicines and medical devices list [LNME], by level of health facility, was drawn up as early as 1998, and has been regularly revised every two years. The latest revision of the LNME was in 2013.
In 1998, the Ministry of Health, with the support of partners, developed Standardized Treatment Regimens [STR] for the management of common illnesses at the level of dispensaries. Certain disease control programmes such as programmes for the control of HIV/AIDS, tuberculosis and malaria, have drawn up individual STRs. In spite of several attempts, the Ministry of Health has neither revised the STR nor developed new ones.

According to the 2013 health accounts, pharmaceuticals spending made up the second largest health expenditure item at 27.7%, that is, about CFA 62 billion, after remuneration of employees (42.58%). Funding for medicines is provided by the Government (25.6%), public health insurance (15.4%), private health insurance (4.7%), household spending (54.2%) and donations (0.06%), as shown in Figure 2.

Government spending takes the form of State subsidies to health facilities for the purchase of medicines. Public and private health insurance spending essentially comprises reimbursements for medicines, in the form of third-party payments. Household spending comprises out-of-pocket payments and co-payments made by insured persons.

In health insurance, medicines represent 19.9% of the total spending of public and private insurance schemes, that is, the second expenditure item after hospitalizations.
Medicine pricing is regulated by Decree No. 504/MINECOFINPAR/CAB of the Ministry of the Economy, which sets the margin at 1.58% of the purchase price of the medicine in Libreville, and 1.7% for Port-Gentil and the other towns of Gabon. Following the devaluation of the CFA franc, that decree was drafted by the Association des pharmaciens du Gabon (APG) [Association of Pharmacists of Gabon], which established new pricing rules as from 2004. The decree is implemented by all pharmacies in the country. It serves as a tool to the various services of the Ministry of the Economy (General Directorate of Taxation, General Directorate for Consumption and Competition, and the General Inspectorate of Health) for supervising the activities of pharmacies.

4. Management of medicines in the health insurance system

In 2007, by Ordinance 0022/PR/2007, Gabon established a mandatory health insurance scheme, with the mission of providing coverage to all insured members against risks related to illness and maternal care, and to provide family services to low-income Gabonese citizens. The Caisse nationale d’Assurance-maladie et de Garantie sociale” (CNAMGS) [National Social Health Insurance Fund] is a public body that incorporates three funds: a fund for low-income Gabonese, another for civil servants, and the third one for employees of the private and semi-public sectors and self-employed persons. The Fund derives its funding from dual employer-employee contributions, whose rate is set at 6.6% (that is, 4.1% for employers, 2.5% for employees, and 1.5% for pensioners). The revenue comes from a tax on mobile telephones and money transfer operations [known as the mandatory health insurance levy (ROAM)], from State subsidies, and from gifts, bequests and other revenue generated by the Fund’s own activities.
In 2014, CNAMGS had about 900,000 members and claimants, representing 60% of the Gabonese population. Total spending (technical and operational expenses) for the same year came up to about CFA 39 billion.

In addition to the health and social insurance scheme, the country also has a number of private health insurance companies. These companies essentially provide coverage to employees and staff of major private sector groups, and of certain public institutions. The major ones include ASCOMA, AXA, OGAR, NSIA and Gras Savoye. Funding for these private insurance schemes comes from employer and employee contributions. Discussions are under way to transform these private insurance schemes into complementary components of the mandatory health insurance scheme, as provided for by Law No 0022/2007/PR to establish the health insurance scheme in Gabon. The ongoing discussions are extremely difficult, first on account of resistance from the insurance companies that are afraid of losing their market share, but second, because of the reticence of employees of the private sector, whose managerial category enjoys better coverage than coverage provided by CNAMGS.

In social and private insurance schemes, reimbursements for medicines cover outpatient care as well as hospitalizations. In the case of CNAMGS, the conditions for reimbursements for medicines are determined by decree, while for private schemes, they are established by their respective boards of directors, or by insurance policies. A list of cost-reimbursable medicines is drawn up by each health insurance company, with the exception of one insurance company (NSIA). CNAMGS has established a list of medicines for which reimbursements may be made. The list is revised after every two years. A technical committee comprising CNAMGS, the Department of Medicines and Pharmacy, the Inspectorate of Pharmacies, the Order of Pharmacists and Physicians, the Union of Pharmacists, various prescribers by specialty, learned societies and WHO, is responsible for updating the list of cost-reimbursable medicines.

Patient groups and other members of civil society are not involved in the process. Only expenses for medicines on the list are reimbursed at the rate of 80% for common illnesses, 90% for long-term health conditions (ALD) or chronic illnesses, 100% for maternal care, and 50% for expensive products. There is a specific procedure for making reimbursement for expenses incurred for long-term health conditions. The patient must be sent to CNAMGS by the attending physician, along with medical evidence of the chronicity of person’s illness. CNAMGS then issues a special card to the patient bearing the words ‘ALD’. The holder of the card is entitled to 90% coverage from CNAMGS for consultation fees for their condition and its sequelae, and 90% coverage for medicines specifically related to their chronic illness and its sequelae. Certain medicines that are not on the list of cost-reimbursable medicines (notably for evacuated patients), are subject to the prior approval of CNAMGS (the opinion of CNAMGS’s medical consultant), and are covered at the rate of 50%.

Each insurance scheme has a structure that manages reimbursements for pharmaceuticals. There is no specific mechanism for managing disputes between the reimbursement management structures and health facilities. Where a dispute between the health facility and the health insurance scheme is not settled amicably, the conventions specify that only the courts have jurisdiction to adjudicate. For social insurance, it is the specialized unit within Department of medical supervision and fraud control. For most of the insurance companies in Gabon, reimbursements are handled directly at pharmacies for medicines used in outpatient care, and in hospitals for medicines used by hospitalized patients. The insurance companies have specific forms for reimbursement in respect of medicines. Attending
physicians must indicate the products and quantity prescribed, and the pharmacy must state the cost of the products dispensed to the patient. The validity of the Medicines-prescription Form is 10 days. Some private insurance companies do not have specific medicines-prescription forms. Rather, they have a form that serves as confirmation that the attending physician has issued a prescription. Only prescribed medicines qualify for reimbursements at all health insurance schemes.

The establishment of the list of cost-reimbursable medicines takes into account the country’s epidemiological profile, the most common illnesses encountered by physicians, the national Essential Medicines List, the existence of a marketing authorization issued by the DMP, the cost-effectiveness and benefit of the medicine (where necessary), the prescription patterns of physicians, and the availability of effective generic products.

Medicines excluded from the list vary from one insurance scheme to another. In the case of CNAMGS, they are essentially medicines provided by certain programmes in the Ministry of Health (vaccines, ARVs, tuberculosis medicines), and medicines considered to be palliatives. Private schemes also exclude certain categories (therapeutic categories) of medicine. Generic medicines represent about 25% of products in CNAMGS’s latest list of cost-reimbursable medicines. While this figure is particularly low, it reflects the general situation in the country, which is marked by a low proportion of generic medicines in pharmacies and in practitioners’ prescriptions.

There is no reimbursement calculation in monetary terms for medicines dispensed to third-party payers. The insurance scheme covers (in accordance with the law or the insurance contract) a percentage of the cost of the medicine (80%, 90% or 50%), regardless of the amount in monetary terms. The remaining cost of the medicine is borne by the insured person in the form of a co-payment. There is no mechanism for a declining co-payment, or an upper limit for co-payments. Where the co-payment is high and the patient is unable to pay, there is a little known public structure called the National Social Assistance Fund (FNAS), which can underwrite the cost for destitute patients. As a general rule, the patient’s family bears the cost of the medicines, failing which the patient does not have access to them.

For payment for services, pharmacies and hospitals send their invoices to the insurance companies for reimbursement. The latter have a contractual time limit of one month within which to conduct checks and settle the bills. In third-party payer schemes, a claim form is filled, which is then signed by the physician.

Co-payment for medicines is valid for both outpatient services and hospitalized patients. In the case of CNAMGS, the co-payment rate is set by regulatory texts. The rate is 20% for common medicines, 10% for long-term health conditions, and 0% for maternity care. In private insurance schemes, the co-payment is determined by the board of directors, and by the contracts that bind these insurance schemes to the companies that use their services.

CNAMGS does not have a database on medicine pricing, nor does it have a system for monitoring the evolution of prices in relation to medicine supplies. However, it has set up a system for tracking mega-prescribers and mega-users. The system was set up as part of its computerization drive, and makes it possible to record all of the patients’ medical claim forms, which forms indicate the name of the attending physician as well as all the prescriptions that the particular physician has issued to the
insured person. Thus, the Fund can track the prescriptions of physicians who are bound by contract to it, and the expenses incurred by each insured person. Where there is suspicion of over-prescription or over-use, the Fund may resort to a number of measures, including a simple call to order, suspension of its agreement with the health facility, or withdrawal of the insured person's insurance card, and even initiation of legal proceedings.

There is inadequate information on the reaction of physicians. CNAMGS does not communicate regularly with prescribers and health facilities on prescription and medicines administration practices. The assessment of the system for making reimbursements for pharmaceuticals by health insurance schemes in Gabon has led to the finding that all insured persons are reimbursed, both for outpatient care and hospitalizations. The reimbursement procedures appear to be the same for social insurance and private insurance schemes (the existence of a list of cost-reimbursable medicines, the existence of reimbursement forms, and direct payments to health facilities [third-party payers]), but each system has its own tools. The rates of reimbursement in social insurance are the same, regardless of an insured person's category, and only their medical status (ALD) can change the rate of reimbursement. In private insurance schemes, the rate of reimbursement varies with the insured person's socio-professional category. The absence of a monetary ceiling for medicine-related reimbursements is an undeniable asset.

5. Main challenges to overcome

- The low proportion of generic medicines in the list of cost-reimbursable medicines is an obstacle to health care access for underprivileged families (as they have to provide their share of the co-payment), while increasing medicines-related spending by insurance schemes, notably social insurance schemes.

- Under-utilization by attending physicians of the list of cost-reimbursable medicines leads to an increase in the prescription of medicines not covered by insurance, and whose cost has to be borne by the patients.

- The absence of updated Standardized Treatment Regimens does not facilitate the supervision of medical prescriptions.

- The low level of participation of pharmacies in the health insurance system does not improve the population's access to medicines and, by extension, to care.

- The principle of using a single reimbursement claim form by the same pharmacy often creates bottlenecks when the pharmacy does not have in stock all the pharmaceuticals prescribed by the physician.

- The non-existence of a declining co-payment arrangement, or an upper limit for co-payments, constitutes an obstacle to health care access for the most vulnerable groups when the co-payment is high.

- The lack of a pharmaceuticals pricing database, and of a system for monitoring supplies and price evolution within CNAMGS, deprives the Fund of the means of controlling its pharmaceuticals spending, and robs it of the enhanced ability to supervise pharmacies.
• The absence of patient groups and other civil society stakeholders in the committee in charge of revising the list of cost-reimbursable medicines does not allow for proper articulation and consideration of the needs of the population.

• Lastly, at the level of management, the absence of remote transmission of invoices, of insurance claim forms, and an electronic database, causes lengthy payment delays for claimants, makes archiving deficient, and often overburdens the system.

6. Measures taken to address the challenges

CNAMGS has launched a programme to disseminate the list of cost-reimbursable medicines by distributing it to all approved attending physicians. A similar programme is under way to raise awareness among medical doctors, and to encourage them to prescribe medicines included in the list of cost-reimbursable medicines. Lastly, in the early stages of the establishment of the new list, CNAMGS opted for greater involvement of prescribers and learned societies, so as to take account of the most widely-used molecules for each specialty. During the latest revision of the medicines list in March 2015, CNAMGS set itself the target of raising the proportion of generic medicines on the list from 25% to 60%, so as to significantly reduce spending both by households and by the Fund.

7. Recommendations

Gabon’s system of reimbursements for pharmaceuticals by health insurance schemes guarantees some form of equity among patients, because coverage is identical, regardless of the patient’s status. The low proportion of generic medicines included in the list of cost-reimbursable medicines, the absence of standardized treatment regimens, the low level of participation of pharmacies in the health insurance system, inadequate data management, and the low level of civil society involvement, restrict access to pharmaceutical products for indigent persons, on account of the financial barrier inherent in the co-payment system, and the other challenges mentioned above.

We therefore recommend the following:

1. Raise to 80% the proportion of generic medicines in the list of medicines for which CNAMGS may make reimbursements.

2. Involve attending physicians and civil society, notably patient groups, in the establishment of the list of cost-reimbursable medicines; at the same time, dissemination of the list will encourage greater prescription of medicines that appear therein, for the benefit of members of the health insurance scheme.

3. Establish a single list for cost-reimbursable pharmaceuticals for all public and private health insurance schemes, and harmonize reimbursement procedures and rates; that would facilitate management by pharmacies of the system for making reimbursements for pharmaceuticals, and help reduce inequalities and disparities among beneficiaries of the various health insurance schemes.
4. Establish a declining co-payment arrangement, or an upper limit for co-payments, to enhance access to quality medicines by the most underprivileged groups. For instance, three categories could be established, namely, vital medicines, which would be covered at 100%, essential medicines at 90%, and non-essential medicines at 50%.

5. Set up a robust price monitoring system, but also a system of medicines prescription and use, in order to strengthen fraud control, and improve the system for making reimbursements for pharmaceuticals.

6. Strengthen the programme to supervise and control medicines pricing, through the establishment of a prices database, and the tracking of medicine prescriptions (mega-prescribers) and medicine use (mega-users); in like manner, the reactions of prescribers should be routinely collected so as to get them to improve their prescriptions.

7. Lastly, raise to 90% the proportion of pharmacies countrywide that participate in the mandatory health insurance scheme, and set up an invoices management system based on remote transmission, in order to reduce delays in payment or reimbursement of pharmacies’ bills, and thus encourage them to participate in the system and enhance access to medicines for insured persons.
References


Assessment of medicine pricing and reimbursement systems in Ghana
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<td>Artemisinin combination therapy</td>
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<td>CHAG</td>
<td>Christian Health Association of Ghana</td>
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<td>CHPS</td>
<td>Community-based health planning services</td>
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<td>DMHIS</td>
<td>District mutual health insurance scheme</td>
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<td>EML</td>
<td>Essential medicines list</td>
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<td>Gross Domestic Product</td>
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<td>Ghana diagnosis-related group</td>
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<td>Government of Ghana</td>
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<td>HAI</td>
<td>Health Action International</td>
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<td>HFAB</td>
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<td>INN</td>
<td>International Non-proprietary Name</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<td>NHA</td>
<td>National Health Accounts</td>
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<td>NHIA</td>
<td>National Health Insurance Authority</td>
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<td>NHIF</td>
<td>National Health Insurance Fund</td>
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<td>NHIS</td>
<td>National Health Insurance Scheme</td>
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<td>OOP</td>
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<td>Social Security and National Insurance Trust</td>
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<td>Standard Treatment Guidelines</td>
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<td>THE</td>
<td>Total health expenditure</td>
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<tr>
<td>VAT</td>
<td>Value added tax</td>
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<tr>
<td>VIP</td>
<td>Very important person</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</table>
1. Geography, population and economic context of Ghana

Ghana is centrally located on the west coast of Africa, sharing borders with three countries: 548 km with Burkina Faso to the north, 668 km with Cote d’Ivoire to the west, and 877 km with Togo to the east, as shown in Figure 3. Administratively, the country is divided into 10 regions and 216 decentralized districts, covering an estimated population of 25.9 million inhabitants in 2013. The last Population and Housing Census (PHC) was conducted in 2010. It estimated the population of Ghana to be 24.9 million inhabitants (Ghana Statistical Service, 2013).

![Figure 3: Map of Ghana](image)

Ghana’s population has a young and aging structure. In 2010, children under 15 represented 38% of the total population, compared to 41% in 2000 and 45% in 1984. Persons 65 years old and above represented 4.7% of the population in 2010, compared to 4% in 1984. The dependency ratio\(^6\) is now 76%, compared to 96% in 1984 (Ghana Statistical Service, 2013).

1.1. Economic context of Ghana

In relation to the economic context, Ghana faced significant macroeconomic challenges in 2014, as its fiscal and current account deficits remained very high. The high fiscal deficit, which reached 10.9% of GDP in 2013, remains the biggest source of vulnerability of the Ghanaian economy. The main drivers of the deficit in 2013 were the high wage bill, increased interest costs, the energy subsidy, and a shortfall in revenue collection. The government has taken some measures to reduce the fiscal

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\(^6\) Dependency ratio is the ratio of the population of persons under 15 and persons 65 years or older, compared to the 15–64 years old population.
deficit. These include a 2.5% increase in the rate of value added tax (VAT), a moratorium on the award of new contracts, and an adjustment in utility tariffs and the price of petroleum products. Concerns over depreciation of the currency and loss of reserves, led to strict regulation of transactions and holdings of foreign currency in Ghana, starting in February 2014. However, the deficit is projected to come down to approximately 10% of GDP. The large fiscal deficit was financed mostly domestically, through the government issue of a eurobond for US$ 1 billion in August 2013.

Nevertheless, Ghana’s growth prospects are positive in the long-term, as suggested by econometric models which predict average per capita growth rates of 4% to 6% for 2014–2024. However, the predictions are subject to uncertainties associated with the expected trends and volatility of the drivers of growth: investment, mineral and oil royalties, and macroeconomic factors such as inflation and government spending (IMF, 2014).

2. National health care services

Ghana’s health sector responsibilities are well defined and structured. The sector is divided into a policy-making arm (the Ministry of Health (MOH); a service delivery arm (the Ghana Health Service (GHS); and teaching hospitals (THs). The health care system itself is organized into four main categories of delivery systems: public (55%), private-not-for-profit (19%), private-for-profit (23%), and traditional (3%). The Ghana Health Service (GHS), faith-based institutions (including the Christian Health Association of Ghana (CHAG) and Islamic Health), quasi-government health institutions (including universities and security services), teaching hospitals, and the private sector, are responsible for health service delivery in the country (Ministry of Health, 2014).

Ghana’s health sector operates a decentralized system, and health service delivery is organized at three levels: national, regional and district. The district level is further divided into a number of sub-districts, and incorporates a community-level health delivery system. Public health services are delivered through a hierarchy of hospitals, health centers, maternity homes and clinics, and incorporate a community-based health planning and services (CHPS) strategy.

In 2012, total health expenditure (THE) was estimated at a little over US$ 1,933 billion. The health sector in Ghana is financed from the traditional sources: public funds (these are government funds that include contributions from the National Health Insurance levy – a form of value added tax on some selected goods and services, but excluding premiums paid by households), private funds (from companies and households), and international funds (from donors) (Ministry of Health, 2014). The breakdown of financing sources in 2005, 2010 and 2012 is shown in Figure 4.
In 2012, about 57% of total health expenditure came from Government domestic revenue, 34% from private funds, and 9% from international sources (National Health Insurance Authority, 2015).

The percentage change in financing sources for the years 2005, 2010 and 2012 is shown in Table 8. International funds (from donors) decreased from over US$ 360 million in 2005 to nearly US$ 179 in 2010, representing a decrease of more than 50%; there was a further decrease of nearly 2% in 2012. Private funds, on the one hand, remained relatively constant, with a change of only 3.51% between 2005 and 2010. The most significant change of over 437% was between 2010 and 2012. Public funds, on the other hand, increased from well over US$ 201 million in 2005 to nearly US$ 663 million in 2010, representing a change of a little more than 229%. But the change was marginal in 2012, when it represented over 65%.

In terms of expenditure per capita, health spending went from $13.60 in 2002 to $74.55 in 2012, representing a more than 5-fold increase.

Table 8: Percentage change in financing sources 2005, 2010 and 2012

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<tbody>
<tr>
<td>International Funds</td>
<td>360,479,692.54</td>
<td>178,932,270.64</td>
<td>-50.36%</td>
<td>175,432,002.15</td>
<td>-1.96%</td>
</tr>
<tr>
<td>Private Funds</td>
<td>118,661,796.53</td>
<td>122,831,726.54</td>
<td>3.51%</td>
<td>660,363,780.86</td>
<td>437.62%</td>
</tr>
<tr>
<td>Public Funds</td>
<td>201,408,758.71</td>
<td>662,918,655.69</td>
<td>229.14%</td>
<td>1,097,466,732.08</td>
<td>65.55%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>680,550,247.78</strong></td>
<td><strong>964,682,652.87</strong></td>
<td><strong>41.75%</strong></td>
<td><strong>1,933,262,515.09</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Source: NHA 2012
Per capita out-of-pocket payments (OOP) also recorded a marked increase from 4% in 2001 to 20% in 2008, and reaching up to 24% in 2012. This trend is unacceptable as it increases the risk of catastrophic health expenditure and impoverishment, quite against the objective for setting up the National Health Insurance Scheme (NHIS) in the first place.

Health sector financing is currently fraught with uncertainties. Although the budget of the Government of Ghana (GOG) increased progressively from 2005 to 2012, this was mainly due to a sharp increase in worker ‘compensation’ (salaries). In 2012, employee compensations were already 63% of the total health expenditure. The NHIS, which has assumed a central role in sector financing, has to deal with questions of sustainability, coupled with a growing demand for expansion of coverage. Donor funding is also currently dwindling, partly as a result of global economic constraints, and partly due to the recognition of Ghana as a lower middle-income country. The challenge is that financial protection for the poor is still weak, while funding for the sector continues to be inadequate. Another challenge is the untimely release of funds and the late payment of claims by the NHIS. The challenge is that financial protection for the poor is still weak, while funding for the sector continues to be inadequate. The challenge is that financial protection for the poor is still weak, while funding for the sector continues to be inadequate. The challenge is that financial protection for the poor is still weak, while funding for the sector continues to be inadequate. Another challenge is the untimely release of funds and the late payment of claims by the NHIS (HSMTDP 2014–2107). Finally, the degree of real fiscal decentralization is limited (IMF, 2014).

**Figure 5: Trends in per capita spending on health**

Source: NHA 2012

### 3. Pharmaceuticals sector information

#### 3.1. Medicines policy

Ghana adopted the World Health Organization Essential Medicines concept in 1988. Medicines policy for Ghana is defined in the Ghana National Drug Policy (Second edition, 2004), which is an element of the overall Ghana National Health Policy. A more recent document that sets specific goals for health, and also outlines Ghana's medicines policy is the Five-Year Programme of Work 2007–2011, issued by the Ministry of Health (MOH) in February 2008. It defines medicines policy objectives in the areas of access, improved supply management, quality assurance, and rational use of medicines. The Ghana National Drug Programme is an entity within the MOH; its role is to define medicines policy and coordinate its implementation within the pharmaceuticals sector, both public and private.

Ghana's public procurement of pharmaceuticals is done at tier levels as defined by public procurements Act 663. The law allows for decentralization, but the trade-off is loss of economies of scale, since service delivery points are permitted to procure their goods at the thresholds defined within Act 663.
The overall legal framework for the pharmaceuticals sector is set by the food and drug law of 1992, which was amended by Act 523 of 1996, and has currently been replaced by Public Health Act 851. The latter act defines the role of the Food and Drug Board as a separate entity under the control of the MOH, with responsibility for regulating the sector.

In 2013 Ghana performed an assessment of the Ghana National Drug Policy 2004 and identified a set of core policy directions to be considered for the next National Medicines Policy. This is what is currently work in progress. The assessment concludes that about half of 60 key policy components are on track, and one-third are at risk (Hogerzeil, et al., 2014).

In a small number of policy areas, no action has been taken at all. The most important achievement has been the establishment of the National Health Insurance Scheme. That and other positive indicators are sufficient to declare the National Drug Policy a success. As a consequence of the NHIS, and the related dramatic increase in government funding, the country is well on track to achieve universal access to essential medicines, with increased patient numbers and high levels of patient satisfaction. Table 9 shows that medicines availability indicators are pointing in the right direction.

<table>
<thead>
<tr>
<th>Table 9: Medicines availability indicators</th>
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<tbody>
<tr>
<td>Indicator</td>
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<tr>
<td>-------------------------------------------</td>
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<tr>
<td>Availability of key medicines (country list) in</td>
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<tr>
<td>public health facility dispensaries</td>
</tr>
<tr>
<td>private</td>
</tr>
<tr>
<td>warehouses supplying the public sector</td>
</tr>
<tr>
<td>% of prescribed medicines dispensed or administered to patients at public health facility dispensaries</td>
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<tr>
<td>Average stock-out duration in</td>
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<tr>
<td>public health facility dispensaries</td>
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<tr>
<td>warehouses supplying the public sector</td>
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<tr>
<td>Adequate record keeping in</td>
</tr>
<tr>
<td>public health facility dispensaries</td>
</tr>
<tr>
<td>warehouses supplying the public sector</td>
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The downside however is that the pharmaceuticals sector is inefficient and rather costly, mainly because of decentralized procurement, with loss of economies of scale and incomplete quality assurance, absence of a medicines pricing policy and regulations, and insufficient critical analysis of reimbursement by the NHIS, which allows for unbridled overprescribing and high medicine costs. Both inefficiencies need to be corrected, for the future sustainability of the NHIS to be guaranteed. There is a negative trend in medicine affordability as depicted in Table 10.
Table 10: Medicine affordability
Affordability > Days Wage (2008)

<table>
<thead>
<tr>
<th>Public</th>
<th>Mission</th>
<th>Private</th>
</tr>
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<tbody>
<tr>
<td>Ulcer using Omeprazole 20mg cap/tab (2.7 days wages)</td>
<td>Ulcer using Omeprazole 20mg cap/tab (2.7 days wages)</td>
<td>Ulcer using Omeprazole 20mg cap/tab (2.7 days wages)</td>
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<tr>
<td>Adult respiratory infection using Ceftriaxone 1 g/vial injection (2.1 days wages)</td>
<td>Arthritis which involves the use of Diclofenac 50mg cap/tab (2.7 days wages)</td>
<td>Asthma where Salbutamol 100 mcg/dose inhaler is used (21.9 days wages)</td>
</tr>
<tr>
<td>Asthma where Salbutamol 100 mcg/dose inhaler is used (1.9 days wages)</td>
<td>Adult respiratory infection using Ceftriaxone 1 g/vial injection (2.1 days wages)</td>
<td>Hypercholesterolaemia for which the medication Simvastatin 20 mg cap/tab was available in only that sector (private) at a cost of 10.1 days wages</td>
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A previous review of the MOH supply system in 2011 revealed the following systemic weaknesses and challenges (Ministry of Health, 2012):

- Indebtedness and delays in reimbursements between facilities and the ten regional medical stores (RMSs); between the RMSs and Central Medical Stores; and from the NHIA to facilities; these are major problems for the supply chain. The lack of cash has a negative impact on commodity availability in facilities, as higher levels do not have sufficient funds to procure commodities for future periods;

- The cost of out-of-pocket payments is up to 300% of international reference prices. This is largely due to the fact that all health facilities procure small volumes of product from local suppliers. But the main reason is the absence of regulation and a pricing policy;

- While the MOH has a ‘mark-up’ policy, in reality, facilities and others do not follow the policy, and mark-ups are highly variable, and do not always relate to procurement costs. Medicine and supply costs have risen from 15% to over 34% of NHIA claims expenditures in recent years. NHIA’s ability to continue with this cost structure is highly questionable;

- The Food and Drug Authority does not have adequate drug regulatory capacity, nor does the private sector adequately self-regulate. Collectively, the system is not ensuring that all medicines and medical supplies are of acceptable quality.

3.2. Standard treatment guidelines and the Essential medicines list

As a guidance document on the use of medicines by healthcare professionals, standard treatment guidelines (STG) are issued by the GNDP based on a work process that involves the Ghanaian medical and pharmaceutical professionals as well as WHO. The last edition was in 2010. Based on the STG, the Essential Medicines List (EML, 2010 edition) was issued. The list of essential medicines is selected for use in one or more health facilities for the public sector as a whole. In the latter case, the list usually indicates the level of the health care system where each medicine may be used, and also considered a supply list. Prescribing of medicines by generic name is mandatory in the public sector, and substitution with generics is permitted.
The EML serves as a basis for public procurement, and is also used in defining the medicines list of the National Health Insurance Authority (NHIA). The last version was published in January 2014. The NHIA medicines list defines medicines for which reimbursements may be made under the NHIS, and at what price. The reimbursement price is not regulated but defined by market survey: the median prices found in the local market for medicines on the NHIA medicines list are set as maximum reimbursement prices. This is negatively affected by inefficiencies in the local market as no reference is made to international reference prices. This is done annually using a combination of methods, including medicine pricing methods adopted by WHO and Health Action International (HAI).

The private sector is not necessarily obliged to comply with STGs and the EML, but those who are providers under the NHIS are compelled to do so through the Scheme’s system for making reimbursements for pharmaceuticals. In this way, NHIS is able to influence prescribing and dispensing practices in the private sector.

3.3. Medicine pricing and financing

Medicine prices are not regulated in the public or private sectors in Ghana. The system is supposed to be market-driven in an imperfect market such as the pharmaceuticals sector. Prices are determined by fixed costs such as manufacturers’ selling prices, and other variable costs at wholesale and retail points. Some of the variable costs for locally produced medicines are the manufacturer’s selling price plus the cost of transport to the purchasing entity; banking fees for foreign currency; inspection charges; port fees; customs clearance charges; import tariffs; importer mark-ups and profit margins; wholesaler expenses (for quality control, storage, handling, overheads, profit margins); retailer-related expenses (e.g., for storage, handling, overheads, and profit margins) (refer to Table 11).

In relation to financing, the bulk of public health care services rendered are financed through the NHIS. About 82% of all internally generated funds (IGF) of health facilities, mainly essential medicines, are financed from the NHIS. Private out-of-pocket payments and donations make up 18% (Ministry of Health, 2014). Per capita expenditure on essential medicines is US$ 3.0.

4. Management of medicines within national health insurance schemes

4.1. Brief introduction to existing health insurance schemes

Health care financing in Ghana has gone from free health care, with total costs borne by the Government, to the present era of a mixed government-funded and cost recovery systems, through a combination of health insurance and direct out-of-pocket payments. There are three types of health insurance scheme in Ghana, namely; district mutual schemes (DMHIS), private mutual schemes, and private commercial schemes.

All the schemes are regulated by the NHIA. Whatever the form of health insurance scheme one signs up for, one is entitled to some minimum outpatient and inpatient services. Outpatient services include general and specialist consultations and reviews; general and specialist diagnostic testing, including laboratory investigations, X-rays, ultrasound scanning; medicines on the NHIS medicines list; surgical operations such as operations for hernia repair; and physiotherapy. In-patient services include general and specialist inpatient care; diagnostic tests; medication prescribed from medicines
on the NHIS medicines list; blood and blood products; surgical operations; inpatient physiotherapy; accommodation in the general ward; and feeding (where available). Oral health comprises pain relief; tooth extractions; temporary incisions and drainage; and dental restoration (simple amalgam filling, and temporary dressing). Maternity care includes antenatal care; deliveries (normal and assisted); Caesarean sections; and post-natal care. Emergencies are included. These refer to crises in health situations that demand urgent attention.

The following health services are however excluded: appliances and prostheses, including optical aids, heart aids, orthopaedic aids, dentures, cosmetic surgeries and aesthetic treatment, antiretroviral drugs for HIV, assisted reproduction (e.g., artificial insemination), and gynaecological hormone replacement therapy. Also excluded are echocardiography, photography, angiography, dialysis for chronic renal (kidney) failure, organ transplants, all drugs that are not listed on the NHIS list, heart and brain surgery other than surgery resulting from accidents, cancer treatment other than breast and cervical cancer, mortuary services, diagnosis and treatment abroad, medical examinations for purposes other than treatment in accredited health facilities (e.g., visa applications, education, institutional driving licences, etc.), VIP ward accommodation.

4.2. Policy and legal framework related to medicines in health insurance schemes

Ghana’s National Health Insurance Scheme (district mutual) was established by National Health Insurance Act 650 of 2003, which has been replaced with National Health Insurance Act 852 of 2012. The Act is based on the national development plan, itself derived from the Ghana Poverty Reduction Strategy I & II (2000-2010) and the Ghana Shared Growth and Development Agenda (2010–2013) (NHIA, 2012).

The aim of the Scheme was to remove previous barriers created by the user-fee financing system, and ultimately provide equitable access to basic health care services for the entire population. The NHIS was subsequently implemented in 2005. It sought to reduce the catastrophic effects of out-of-pocket payments at the point of service delivery in both private and public facilities, and particularly among the lowest wealth quintiles.

Active membership of the National Health Insurance Scheme was 36.8% in 2013, an increase of 10% from 2012 to 2013 (but still below the 2012 target of 45%). Over 80% of all outpatients were insured, while only 36% of the population were active NHIS members – an indication of the increased utilization rate by active members (National Health Insurance Authority, 2015).

The sector does not currently have a good picture of the main drivers of the increased uptake of services, and there can be several explanations for the observed trend.

- Could this be a reflection of frivolous use of services by NHIS members (moral hazard), i.e., few insured patients consuming a lot of health services?
- Could it be a reflection of the high NHIS membership rate among those in need of services, i.e., persons only register when they fall sick, and refrain from renewing membership the following year if they are cured (adverse selection)?
• Could it be due to the policy of free enrolment of the poor, and of pregnant women and children, who are expected to have a greater need for health services (risk selection)?

Moral hazard, adverse selection and risk selection all provide financial risks to NHIS, and it has been recommended that these issues be further analyzed and addressed (National Health Insurance Authority, 2015).

### 4.3. Scope of medicines coverage in health insurance schemes

The National Health Insurance Act covers the management of medicines in health insurance schemes. Section 33 of Act 852 deals with the medicines list and medicine tariffs. The NHIA in collaboration with health care providers, and with the approval of the Minister, develops a National Health Insurance Scheme Medicines List and Medicine Tariffs derived from the Essential Medicines List. The Authority reviews the National Health Insurance medicines list and tariffs each year, in consultation with health care providers, and with the approval of the Minister.

### 4.4. Selection of cost-reimbursable medicines in health insurance schemes

The NHIS pharmaceutical reimbursement list covers more than 80% of medicines required to treat diseases of common occurrence in Ghana.

Selection of the NHIS pharmaceuticals reimbursement list is done by interdisciplinary groups using explicit analytical frameworks, and drawing from a variety of sources. This is an ad hoc committee whose membership is drawn from the Office of the Chief Pharmacist, the Ghana National Drug Programme, the Government and Hospital Pharmacists Association, the Pharmaceutical Society of Ghana, and the National Health Insurance Authority. The selection of the pharmaceuticals reimbursement list is based on the Essential Medicines List, which itself has been built on the basis of relevance to the pattern of prevalent diseases, proven efficacy and safety, adequate scientific data, evidence of performance in a variety of settings, adequate quality, favorable cost-benefit ratio, desirable pharmacokinetic properties, possibilities for local manufacture, and availability as single compounds.

The medicines are identified by their International Non-proprietary Names (INN), or their generic names. Other criteria to be considered in the future are whether or not the medicine or technology is likely to result in a significant health benefit, taken across the health sector as a whole, if given to all patients for whom it is indicated. Is the medicine or technology likely to result in a significant impact on other health-related government policies (e.g., a reduction in health inequalities)? Is the medicine or technology likely to have a significant impact on NHIS resources (financial or other) if given to all patients for whom it is indicated? For instance, artemisinin-based combination therapy (ACT) is highly effective at preventing post-treatment transmission of *Plasmodium falciparum*. It has specific activity against immature sequestered gametocytes, and has the capacity to minimize transmission of drug-resistant parasites. The MOH in 2005 replaced the use of monotherapies, such as artesunate, amodiaquine, sulphadoxine/pyrethromamine, etc. in the treatment of uncomplicated malaria with ACTs, although the cost of treatment was higher in the short term. This brought about enormous public health and economic benefits in the long term, to health care delivery in Ghana as the Global fund subsequently provided subsidies for the use of ACTs both in the public and private sectors, under the affordable medicine facility for malaria (AMFm).
4.5. Pricing and reimbursement for medicines in health insurance schemes

Figure 6: Revenue sources and allocation

Income Sources and Expenditure Outlets
Revenue Sources & Allocation (Act 852)

Source: NHIA

Figure 6 describes NHIS sources of revenue, and its allocation. The sources of funds are the National Health Insurance levy provided for under section 47 of Act 852; 2.5% of each person's contribution to the basic National Social Security Scheme; moneys that are approved for the Fund by Parliament; moneys that accrue to the Fund from investments made by the Authority; grants, donations, gifts and other voluntary contributions made to the Fund; fees charged by the Authority in the performance of its functions; contributions made by members of the Scheme; and moneys accruing to the Fund under section 198 of the Insurance Act, 2006 (Act 724). Only persons in the informal sector pay a premium based on their ability to pay. The premium to be paid ranges from GHS 7.20 to GHS 48.00. However, the average premium per person is GHS 22.00 per annum. The current premium rates are too low to cover the NHIS benefits package. Premiums, taxes and reinsurance payments for the NHIS and to DMHIS are not actuarially determined. The premiums for informal sector workers, who make up more than 70% of the labour force and 29% of NHIS membership, are low (GH¢ 7.2–GH¢ 48.0) depending on socioeconomic status, and regressive relative to the cost of care. As of 2009, revenue from these premiums accounted for just 3.8% of contributions to the NHIF.
In 2013, the NHIL constituted 72% of total income; Social Security and National Insurance Trust (SSNIT) funds accounted for 20%, returns on investment represented 4.7%, premiums collected from the informal sector was 3.4%, and other income, 0.1% (refer Figure 7).

In 2013, total expenditure on the NHIS, excluding staff costs, was US$ 445 million. This is further broken down into inpatient services, excluding medicines (17.49%); outpatient services, excluding medicines (23.34%); medicines (34.45%); investment on equipment (4.65%); running costs (16.45%); interest on loans (0.60%); and support for public health interventions (3.03%).

The categories of people exempted from the payment of contributions under the Scheme include (a) children under the age of 18; (b) persons in need of ante-natal, delivery and post-natal health care services; (c) persons with mental disorders; (d) persons classified by the minister responsible for social welfare as indigent; (e) differently-disabled persons as determined by the minister responsible for social welfare; (f) pensioners of the Social Security and National Insurance Trust; (g) contributors to the Social Security and National Insurance Trust; (h) persons above seventy years of age; and (i) other categories prescribed by the Minister (refer to Section 29 of Act 852).

**Figure 7: Revenue sources, 2005 to 2013**

![Graph showing revenue sources from 2005 to 2013](image_url)

*Source: NHIA*
Scheme subscribers may obtain their medications from pharmacies in public facilities, private facilities run by non-governmental and faith-based organizations, and private retail pharmacies.

Medicine pricing in the NHIS is done by survey of the market prices of generic medicines in both the public and private sectors. Median prices, and not the average prices, are used for making reimbursements since average prices are affected by extremes. The reimbursements list is reviewed annually. This approach is however negatively affected by the inefficiencies of the market, and threatens the sustainability of the Insurance Scheme, as shown in Table 11.

According to regulation 62 of the NHIS Act, claims are supposed to be settled after ninety days. The reality, however, is that sometimes it takes over one hundred and eighty days to settle a claim. A case in point is the recent threat by providers to discontinue service to subscribers on account of nonpayment of claims over a long period.

**Figure 8: Total expenditure on the NHIS, excluding staff costs in Ghana**

- **20%** Inpatient services excluding medicines
- **17%** Medicines
- **5%** Investment on equipment
- **35%** Outpatient services excluding medicines
- **23%** Running cost

*Source: NHIA*
Table 11: Ranges of contribution of various stages and sectors

<table>
<thead>
<tr>
<th>Stages</th>
<th>Urban Public Sector</th>
<th>Urban Private Sector</th>
<th>Rural Private Sector</th>
<th>Rural Public Sector</th>
<th>Rural Mission Sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSP</td>
<td>8.96 – 45.16</td>
<td>5.00 – 53.20</td>
<td>11.00 – 42.66</td>
<td>5.50 – 24.00</td>
<td>9.16 – 41.44</td>
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<tr>
<td>Insurance &amp; Freight</td>
<td>0.88 – 4.51</td>
<td>0.50 – 5.32</td>
<td>1.10 – 4.27</td>
<td>0.55 – 2.40</td>
<td>0.92 – 4.14</td>
</tr>
<tr>
<td>Wholesale Price Stage</td>
<td>10.50 – 39.32</td>
<td>17.67 – 77.72</td>
<td>14.10 – 54.15</td>
<td>17.20 – 55.42</td>
<td>15.50 – 47.32</td>
</tr>
<tr>
<td>Retail Pricing Stage</td>
<td>4.03 – 69.98</td>
<td>9.47 – 35.29</td>
<td>20.10 – 52.03</td>
<td>31.58 – 74.99</td>
<td>25.46 – 42.11</td>
</tr>
<tr>
<td>Markup</td>
<td>54.84 – 91.04</td>
<td>46.80 – 95.00</td>
<td>57.33 – 89.00</td>
<td>76.00 – 94.50</td>
<td>58.56 – 90.80</td>
</tr>
<tr>
<td>Cumulative Markup</td>
<td>221.43 – 1116.07</td>
<td>187.96 – 2000.19</td>
<td>234.37 – 909.28</td>
<td>416.67 – 1091.95</td>
<td>241.30 – 1091.95</td>
</tr>
</tbody>
</table>

Source: Medicine price components study in Ghana (2008) (WHO/HAI/MOH collaboration)

4.6. Fee for service

After a service provider has provided services to a member, that service provider completes a the health facility attendance book (HFAB), and ticks off the referral portion of the form where applicable. The service provider then compiles a schedule of the total cost of service, supplies and medicines, and attaches a copy of the referral to the HFAB (where applicable), including any other supporting documents. The service provider presents to the Scheme Office the schedule and original copies of the HFAB (with attachments, if any). It is at this office that reimbursements are made. All this is done manually at the various schemes. Needless to say the process is time consuming and fraught with irregularities, including fraud. Recently electronic centralized claim processing systems have been installed to address the challenges.

On average, pharmaceuticals account for some 35% of NHIS claims expenditure. The average number of medicines per prescription is currently 4.7, an indication of polypharmacy, supplier-induced demand, and over-utilization. Financing problems have led to situations in which providers sometimes refuse to dispense medicines to insured patients unless they pay in cash, even though co-payments are not allowed.

4.7. Cost containment strategies

A capitation pilot was undertaken in Ashanti Region and has been evaluated. The result indicated a 10% increase in NHIS active membership after an initial drop of 20% between 2011 and 2012, a reduction in outpatient attendance per capita for insured clients, and a reduction in claims under the Ghana Diagnosis Related Group (G-DRG). About 89% of clients rated services provided by providers as satisfactory (NHIA, 2011). Thanks to the successful pilot in Ashanti Region, three regions (Upper West Region, Upper East Region and Volta Region) have been earmarked for scale-up of capitation as a provider-payment mechanism. This will be part of an overall strategy to gradually scale up capitation to all the regions.
Clinical audits of claims have revealed challenges such as wrongful application of tariffs, irrational use of medicines by prescribers (polypharmacy), dispenser and patient inflation of the cost of medicines, and unauthorized co-payments.

Electronic claims processing was a strategy adopted by NHIS in 2013 to address logistical challenges associated with paper claims management, boost efficiency in claims processing, offer transparency to providers, and provide credible claims data for analysis. In April 2013, a pilot of e-claims processing was instituted in 47 health care facilities.

The establishment of clinical audits and the strengthening of internal audits in 2010 had resulted in huge cost savings to the NHIS. During the year under consideration, clinical audits alone recovered a total of GHS 2.7 million from 203 service providers audited. The exercise was also expected to help in ensuring quality service delivery to NHIS members. Through effective and efficient claims processing, the central e-claims processing center has been able to make appreciable cost savings of an average of 15% of claims submitted. Cumulative savings from claims in 2010 and 2011 stood at GHS 17.3 million. In 2011, a total of GHS 10 million was saved, representing 11% of claims submitted by service providers (NHIA, 2011).

Other cost containment strategies implemented, or that are being considered by the NHIS, include the consolidated premium account (which should facilitate the proper monitoring of premium collection in the over 145 schemes); uniform prescription forms with unique security features; prescriber identification (prescription forms are source documents for reimbursements under the NHIS, and therefore must be secured from abuse); linking diagnoses to treatment (to ensure monitoring of the rational use of medicines under the Scheme); support for disease prevention activities to reduce the disease burden on the Scheme; regular reviews of benefits packages; prescriptions by level of care; and a gatekeeper system.

4.8. Management information and monitoring system for medicines in health insurance schemes

A nationwide information, communication and technology (ICT) platform was implemented in 2005 to transform the operations of the NHIS. It provided the Scheme with a national network system. It had a central database that enabled the Scheme to distribute its services nationwide, and a single national identification card (ID) for all subscribers. The ICT platform also enabled subscribers to enjoy portability, and made it possible for health care facilities to verify the eligibility of subscribers.

The NHIA has also developed a database for prescriptions from which it conducts medicines utilization analyses, gets feedback, and conducts clinical audits. The database captures information such as patient bio-data, type of medicines dispensed, formulation and dosage forms, level of care, number of medicines per prescription, and cost of treatment. This has enabled the NHIA to link diagnosis to treatment, detect polypharmacy and patient-induced prescribing, and determine the cost drivers of claim reimbursements. It is however unable to perform a meaningful pharmaco-economic analysis to inform price-setting and decisions on reimbursements for pharmaceuticals, because of the absence of a price database. There is also no structured arrangement in place for the Scheme to monitor the availability and quality of medicines.
5. Major challenges

1. There are delays and indebtedness in reimbursements between facilities and the ten regional medical stores (RMSs); between the RMSs and Central Medical Stores; and between NHIA and facilities. These are major problems for the supply chain. The lack of cash has a negative impact on commodity availability in facilities, as higher levels do not have sufficient funds to procure commodities for future periods. Prices for out-of-pocket payments are up to 300% of international reference prices. This is largely due to the fact that all health facilities are procuring small volumes of product from local suppliers. And there is the absence of regulation and a pricing policy.

2. While the Ministry of Health has a ‘mark-up’ policy, in reality, facilities and others are not following the policy; the mark-ups themselves are highly variable, and do not reflect procurement costs. Medicine and supply costs have risen from 15% to well above 34% of NHIA claims expenditure in recent years. NHIA’s ability to continue with this cost structure is highly questionable.

3. The Food and Drug Authority lacks adequate drug regulatory capacity, and the private sector does not adequately self-regulate. Collectively, the system is not ensuring that all medicines and medical supplies are of acceptable quality.

4. Clinical audits of claims have revealed challenges such as wrongful application of tariffs, irrational use of medicines by prescribers (polypharmacy), inflation of the cost of medicines by dispensers and patients, and unauthorized co-payments.

5. The pharmaceuticals sector is inefficient and somewhat costly, mainly because of decentralized procurement, with loss of economies of scale and incomplete quality assurance, the absence of regulations and a medicines pricing policy, and an inadequate critical analysis of reimbursements by the NHIS – all of which generates unbridled overprescribing and high medicine costs.

Ghana developed a five-year health supply chain master plan in 2012 to address the above challenges, but there have been delays in its implementation.

6. Recommendations

In the short term, the NHIA must:

1. Analyze expenditure on medicines, using current local prescribing data and price information from suppliers;

2. Conduct actuary studies to determine the actual cost of providing services, and set realistic tariffs, including the use of co-payment mechanisms, to ensure the sustainability of the NHIS;

3. Consider the use of health technology assessment (HTA) as a tool to support decision-making on reimbursements, as well as price-setting and negotiation;

4. Quicken the scale-up of capitation in order to share financial risk among the schemes, providers and subscribers.

In the medium-to-long term, the Ministry of Health should accelerate the implementation of the supply chain master plan which has made the following recommendations:
1. Improve overall management of the supply chain:
   • By bringing together various important supply chain functions;
   • By providing a direct supervisory and organizational relationship between the central and middle levels of the supply chain;
   • By strengthening information systems;
   • By advancing data visibility and emphasizing transparency, accountability, efficiency, and cost-effectiveness;
   • By increasing the value of the supply chain for end-users.

2. Balance income and expenditure:
   • Guidelines, so that mark-ups at all levels directly reflect the actual cost of providing the commodity.

3. Ensure the viability of the NHIA:
   • By ensuring the financial sustainability of the NHIA, and the viability of revolving funds at all levels.

4. Realize cost savings in procurement:
   • By increasing the use of framework contracts and other procurement methods to realize cost savings, and by proposing a review of current laws and regulations that allow their use.

5. Improve the delivery of health commodities:
   • By implementing efficient and cost-effective direct delivery of health commodities nationwide.

Key components of the next national medicines policy should be rationalization of public procurements, and medicines pricing policy and regulatory regime. Active monitoring and correction of prescribing behavior by the NHIS in close collaboration with the Ministry of Health is essential. Support to the domestic pharmaceuticals industry within public health goals is also required.

In the medium-to-long term, the NHIA should consider regular reviews of insurance benefits packages, and of the policy on exemptions from payment of premiums by subscribers.
References

Anon., n.d. s.l.: s.n.


Assessment of medicine pricing and reimbursement systems in Rwanda: the case of the public servant Medical Insurance Scheme
### Acronyms and abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>Acquired immunodeficiency syndrome</td>
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<tr>
<td>CBHI</td>
<td>Community-based health insurance</td>
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<tr>
<td>CHW</td>
<td>Community health worker</td>
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<tr>
<td>EICV</td>
<td>Integrated household living conditions survey</td>
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<tr>
<td>EPI</td>
<td>Expanded programme on immunization</td>
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<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<tr>
<td>HSSP</td>
<td>Health Sector Strategic Plan</td>
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<tr>
<td>ICT</td>
<td>Information and communication technology</td>
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<tr>
<td>MIS</td>
<td>Medical insurance scheme</td>
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<tr>
<td>MMI</td>
<td>Medical Military Insurance</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<tr>
<td>MPDD</td>
<td>Medical procurement and distribution department</td>
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<tr>
<td>MSH</td>
<td>Management sciences for health</td>
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<tr>
<td>NEML</td>
<td>National essential medicines lists</td>
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<tr>
<td>PTF</td>
<td>Pharmacy Task Force</td>
</tr>
<tr>
<td>RAMA</td>
<td>Rwanda's Medical Insurance Agency (Rwandaise d'Assurance Maladie)</td>
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<tr>
<td>RNHA</td>
<td>Rwanda National Health Accounts</td>
</tr>
<tr>
<td>RSSB</td>
<td>Rwanda Social Security Board</td>
</tr>
<tr>
<td>RWF</td>
<td>Rwandan Francs</td>
</tr>
<tr>
<td>SPS</td>
<td>Strengthening pharmaceutical system</td>
</tr>
<tr>
<td>STI</td>
<td>Sexually transmitted infection</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>THE</td>
<td>Total health expenditure</td>
</tr>
<tr>
<td>USD</td>
<td>United States Dollar</td>
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<td>WHO</td>
<td>World Health Organization</td>
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1. Introduction

1.1. Demographic and socio-economic context

Rwanda is a landlocked country located in central East Africa, covering 26,338 square kilometres. The population was estimated to be over 11 million in 2015, with 62% of them below 25 years of age. The country has one of the highest population densities in Africa (445 inhabitants per square kilometre, with the great majority still living in rural areas). Fertility is still high (4.2 children per woman in 2015), making family planning information and services a major priority aimed at reducing population growth and poverty.

Since 1994, Rwanda has made significant developmental progress. Between 2001 and 2014, real GDP growth averaged 9% per annum. The poverty rate fell from 59% in 2001 to 45% in 2014. This has benefited most of the population since 2005 (the Gini coefficient also fell from 0.52 in 2005 to 0.45 in 2014). Remarkable improvements on key health indicators have also been observed, including reductions in under-five mortality from 196 deaths per 1,000 live births in 2000 to 50 deaths in 2015. Maternal mortality improved from 1071 maternal deaths per 100,000 live births in 2000 to 210 deaths in 2015. Life expectancy at birth increased as well from 29 in 1995 to 65.7 in 2015. The country is seeking to move from a low-income agriculture-based economy to a service-oriented economy with middle-income country status by 2020.

1.2. National health care services

Since decentralization and territorial reform in 2006, the organization of public administration has been simplified; this has affected the health system. The current decentralized structure (Figure 9) consists of 5 provinces, 30 districts, 416 sectors, 2,148 cells and 14,837 villages. The provinces are the de-concentrated structures of the central government, and serve as coordinating organs for central planning, implementation and supervision. Districts are decentralized structures that serve as the main organs for service delivery, while sectors are the planning and implementation units of the districts. Cells are the smallest political-administrative units.

The entire health care system is under the oversight of the Ministry of Health (MOH), and comprises public, faith-based and private health facilities. Faith-based health facilities are recognized by the MOH as part of the public health care system, and follow the norms, standards and programmes of the public sector. They represent approximately 40% of all facilities in Rwanda, most of these being health centres. The private sector is still relatively small, and is present mainly in urban areas. The public health care system is organized along the national administrative layout, with each level of care having a defined package of services. The levels coordinate to prevent overlaps in functions, and to improve the use of resources and services. The first line of service delivery is provided by community health workers (CHWs) at the village level (3 CHWs per village, for a total of about 44,551 CHWs). In addition, services are provided by a range of health facilities: 5 national referral hospitals, 42 district hospitals, 479 health centres and 44 health posts. Since 2006, public health and
faith-based health facilities have become autonomous entities responsible for managing financial and human resources for health. However, they are still required to follow national norms and standards on service quality and delivery.

1.3. Health financing

Rwanda, like many developing countries, still faces major challenges in providing quality health services at an affordable cost to all. Although real total health expenditure has increased from US$ 81.8 million in 1998 to US$ 420.3 million in 2009/10, health sector financing still relies heavily on external aid. In 2009/10, the major sources of financing were: donors (61%), followed by the private sector (20%), with households representing 18%, and the public sector 18%.

Due, in part, to the development of health insurance coverage, the country is relying less on out-of-pocket (OOP) payments as a source of health care financing (OOP expenditures as a percentage of total health expenditure (THE) has decreased from about 33% in 1998 to 11% in 2010). From about 1% of the population covered by pilot pre-payment schemes in three districts of the country in 2000, health insurance coverage has increased over the years. According to the last integrated household living conditions survey (EICV) in 2013/14, 70% of the population is currently covered by some form of health insurance. For instance:

- Community-based health insurance (CBHI), also commonly known as *Mutuelle de santé*, covers the great majority of the insured population (94%). Most of the beneficiaries are from the informal sector, and live in rural Rwanda. Before it moved to the Rwanda Social Security Board (RSSB) in July 2015, CBHI was under the oversight of the Ministry of Health;

- The Medical Insurance Scheme (MIS) of the RSSB (where this assessment was carried out) covers 4.4% of the insured population. The scheme is mandatory for all public servants, but reaches out also to private companies;
• Medical Military Insurance (MMI), covers 0.8% of the insured population, and provides compulsory health insurance coverage for the armed forces; and finally,

• Employers and private insurers, together, cover 0.9% of the insured population.

Insurance premiums for the poor and other vulnerable persons are fully subsidized by the Government under CBHI (~24% of the population). They are also exempted from co-payments and co-insurance at the point of care. The poor are identified based on a socioeconomic classification developed by the Ministry of Local Government in 2001. It is known as the *Ubudehe* classification (see Annex 1 for the criteria used for identifying destitute persons under the *Ubudehe* approach). *Ubudehe* is a process at the village-level for community decision-making. It is rooted in the Rwandan practice and culture of collective action and mutual support to solve problems in the community. It incorporates what is essentially a ‘poverty-mapping’ process; it also follows a systematic method, and allocates each household to one of six ordinal income and poverty-related categories, differentiated by well-defined qualitative criteria. This classification is used in all social protection programmes, including health.

Based on *Ubudehe* categories, the MOH defined CBHI member categories by aggregating the six *Ubudehe* categories into three CBHI broad categories (Category 1 = people living in abject poverty and the very poor; Category 2 = poor and resourceful poor persons; and Category 3 = food rich and money rich persons). Early this year, four new *Ubudehe* categories were created, and their categorization is ongoing.

Health insurance beneficiaries are entitled to medical services provided by public, faith-based and private health care facilities, depending on the contract with the insurance.

## 2. Methods

This study is part of a multi-country assessment of pharmaceuticals pricing and reimbursement systems in health insurance schemes in the African Region. In Rwanda, the assessment was conducted in the Rwanda Social Security Board Medical Insurance Scheme (formerly RAMA) in July 2015. It used a combination of different methods:

1) A desk review of key documents such as laws, national policy and strategic documents, guidelines, and other relevant materials;11.5

2) Key informant interviews within the Medical Services Department of the Rwanda Social Security Board Medical Insurance Scheme.

## 3. Pharmaceuticals sector information

### 3.1. Organization of the sector

The pharmaceuticals sector in Rwanda comprises several institutions. The Pharmacy task force (PTF) within the Ministry of Health is responsible for both the public and private pharmaceuticals sector. The PTF currently combines the responsibilities of a policy formulation, implementation and regulation agency with those of provider of minimum services related to product licensing, quality assessment, and supply channel monitoring.
The Medical procurement and distribution department (MPDD) (formerly CAMERWA) of the Rwanda Biomedical Center is the primary supplier of pharmaceutical commodities, including generic essential medicines, medical supplies, and laboratory test kits and reagents. It operates as an autonomous entity, under the supervision of the MOH. In principle, the MPDD mandate is to supply pharmaceutical commodities to all public institutions (health facilities, including referral hospitals, the national reference laboratory, etc.).

In each of the 30 districts of the country, there is a district pharmacy that distributes pharmaceutical commodities, procured at MPDD, to district hospitals and health centres. In practice, referral hospitals procure some pharmaceutical commodities from MPDD. But these hospitals also rely heavily on private suppliers, such as the Office for not-for-profit medical facilities in Rwanda (BUFMAR). Similarly, district hospitals and health centres can access the private outlets for any commodities that they are not able to procure from MPDD or BUFMAR through their respective district pharmacies. About 85% of the requests from health facilities are met by the MPDD, the remaining supply being covered by other supply agencies. The MPDD also manages all procurements funded by donors; medicines and supplies for HIV/AIDS and malaria are examples. The US Government is, however, an exception. Its payments are made by a US Government implementing partner, Supply Chain Management Systems).

3.2. Policy and legal framework related to medicines

The entire health sector is currently guided by the Third Health Sector Strategic Plan (HSSP, 2012–2018). This plan was inspired by the country’s long-term development goals as embedded in its ambitious Vision 2020, the Health Sector Policy of 2004, and the priorities identified in the Economic Development and Poverty Reduction Strategy (2008–2012). To achieve the overall objective of HSSP III — ‘Ensure universal accessibility (in geographical and financial terms) of quality health services for all Rwandans’ — a conceptual framework was developed. The framework linked the various programmes that provide preventive, promotive, curative and rehabilitative care, with the support systems needed to deliver the expected results (including a national medicines policy), and improve good governance in the health sector. HSSP III, among other things, identifies as priority areas of intervention, the establishment of a legal framework, strengthening of the national health commodities supply chain, institutionalization of pharmaceutical quality assurance, and improvement of human and institutional capacity. Based on information reported in the MOH annual report for 2013/14 and the 2015 preliminary report of the mid-term review of HSSP III, we present hereunder the main activities implemented by priority area of intervention.

(a) Establishment of a legal framework. Several laws were passed, including Law No. 45/2012 of 14 January 2013 on the organization, functioning and competence of the Council of Pharmacists; Law No. 46/2012 of 14 January 2013 establishing the Rwanda Allied health professions council, and determining its organization, functioning and competence; and Law No. 47/2012 of 14 January 2013 relating to the regulation and inspection of food and pharmaceutical products. Although a law had been passed to establish the Rwanda Food and Medicines Authority (Law No. 74/2013 of 11 September 2013), the Government decided to create one as part of the East African Community (EAC) Medicines regulatory harmonization project. Several guidelines have also been developed to promote regional integration, including guidelines on good manufacturing practices, quality management systems, medicine evaluation and registration, information management systems, and other quality and regulatory systems. The Rwanda inspectorate and
competition authority (RICA) is also being set up, and will serve as a single quality inspectorate for the ministries of trade and industry, and health and agriculture, to ensure proper coordination. Currently, the bill is awaiting parliament’s approval.

(b) **Strengthening of the national health commodities supply chain**

- Construction of a modern warehouse of 2,673 square meters at the MPDD, and of two stores at the Kigali Economic Free Trade Zone will ensure the supply of pharmaceutical commodities to public health facilities, including referral hospitals, district pharmacies, and other public sector institutions, such as the National Reference Laboratory. As a result, storage capacity has been increased by two-thirds.

- Roll out of a computer-based logistic management information system (eLMIS) in 80% of structures (including district pharmacies, district hospitals, referral hospitals and health centres) will ensure efficient quantification of commodities at health facility level. The system will enable them to predict and procure adequate supplies in a timely manner. It has the advantage of improving stock visibility at each level of the pharmaceutical supply chain, improves the accuracy of forecasts, and enhances the rational distribution of medicines and health commodities. The system monitors monthly stock-outs for 250 tracer products. Previously, there were commodity stock-outs, but measures have been put in place to increase stock availability. Using locally generated funds, district pharmacies have been rehabilitated, and their storage capacity expanded. As a consequence, district pharmacies have increased their stocks and assets. In 2015, there were no stock-outs for tracer drugs in 98% of health facilities, compared to 55% in 2011.

(c) **Institutionalization of pharmaceutical quality assurance.** Drug therapeutic committees have been instituted in all hospitals, and are functional. A pharmaco-vigilance system is in place. The National Quality Control Laboratory has been constructed, but is not yet fully operational. It will be used for testing and analyzing samples and pharmaceutical products on the market.

(d) **Improvement of human capacity.** The MOH holds quarterly meetings, known as monitoring, training and planning meetings, with district pharmacies to review issues related to the availability and distribution of medical supplies; the meetings also adopt strategies to improve performance.

3.3. National medicines policy

Although the draft national medicines policy is still in its final stage of approval, several aspects of the basic components of a national medicines policy are being implemented, including:

- Developing comprehensive legislation for the pharmaceuticals sector – in recent years, several laws, regulations and guidelines have either been reviewed or developed;

- Adoption of, and political commitment to, the essential medicines concept – this is evidenced by the regular update of treatment guidelines and the national list of essentials medicines; both documents serve as reference sources for the availability of essential health products in public institutions and facilities;

- Putting in place a public pharmaceuticals supply system strategy that procures and distributes essential medicines, supplemented by the private sector (not-for-profit and for-profit);

- Increasing access to medicines through the health insurance mechanism.
However, there are still challenges that need to be addressed, including the importance of raising awareness, among both health providers and insurance companies, about existing pharmaceuticals legislation. This will strengthen monitoring of its enforcement, and effectively enhance compliance on the national territory. This challenge is, in part, due to the lack of a national medicines regulatory authority. As mentioned above, the PTF provides only minimum services related to product licensing, quality assessment and medicines registration, inspection of manufacturing facilities, monitoring of supply channels, laboratory quality control, post-marketing surveillance, advertisement of pharmaceuticals, and promotion. With regard to the quality of pharmaceuticals, the country also lacks a national medicines quality control laboratory which, together with the medicines regulatory authority, ought to ensure the quality, safety, and efficacy of medicines.

Another important challenge is that the MPDD still does not have adequate capacity to provide for all the needs of the public sector, especially non-programme products. Factors that contribute to stock-outs include slow responsiveness by suppliers, and lengthy administrative processes. Although quarterly meetings and the use of LMIS linked to the central MPDD systems have improved the situation, there are still some difficulties with matching needs at the district level with those at the central level.

Other challenges relate to human resources capacity. Most staff of the MPDD do not have formal training; they learn on the job. Staffs at district pharmacies still do not have a career growth plan. At lower levels, the utilization of e-LMIS has become challenging due to lack of computer skills among some staff.

### 3.4. National medicine pricing policy

No medicine pricing policy is currently available in Rwanda. In the public sector, there is ministerial instruction No. 20/1658/PTF/2007 of 15 June 2007 on the procurement and distribution of medicines and other medical supplies on the national territory. The instruction sets a maximum of 20% of total cost as the profit margin for MPDD sales to district pharmacies and public health facilities. MPDD uses cost and freight as the basis for pricing, while BUFMAR uses cost, insurance and freight. In the private sector, there is no regulation that determines the maximum profit margin. In practice, most retail pharmacies tend to apply a 40% profit margin.

An assessment of the availability and accessibility of selected medicines for children conducted in Rwanda in 2012 showed that final prices to patients were 23.4% higher than procurement prices for generic equivalents in the public sector; in the private sector, however, they were 89.2% higher than in the public sector. Although the add-on costs in the public sector distribution chain indicated reasonable mark-ups, it is important to make sure that generic medicines are available. It is equally important to regulate prices, especially in the private sector. Otherwise, patients will be forced to purchase medicines at a higher price in the private sector.

### 3.5. Standard treatment guidelines

Standard treatment guidelines and protocols are designed to provide a useful resource for health care providers involved in clinical case management in Rwanda. They are intended to standardize care at both the secondary and tertiary levels of service delivery across different socio-economic strata of the
society. These guidelines, when applied, are relevant to health insurance schemes, as they encourage health providers to prescribe the most efficacious, safe and cost-effective medicines for the priority conditions identified. In addition, given that in Rwanda, health providers are paid on a fee-for-service basis, it would be helpful to reduce the number of unnecessary services provided to the patient. Providers can actually improve diagnosis, and therefore, the management and treatment of patients. It is therefore important not only to train health professionals on how to use the guidelines, but also to monitor their use.

The first edition of *Standard treatment guidelines* was published in October 2007. Subsequently in September 2012, the following guidelines were developed: Paediatric clinical treatment guidelines, Paediatric emergencies clinical treatment guidelines, Neonatology clinical treatment guidelines, Gynaecology and obstetrics clinical protocols and treatment guidelines, Internal medicine clinical treatment guidelines, Ear nose and throat clinical treatment guidelines, Surgical clinical treatment guidelines, Pain management guidelines, Dermatology clinical treatment guidelines, and Oral conditions clinical treatment guidelines.

### 3.6. National essential medicines lists and medicines formulary

The latest versions of the National Essential Medicines Lists (NEMLs) were published as recently as September 2015. These lists take into account the hierarchical levels of the health care delivery system. The NEMLs are the result of the work of a technical committee composed of clinicians, public health programme specialists, laboratory specialists, and public pharmaceutical procurement specialists, under the coordination of Ministry of Health. For the first time, there is a paediatric edition that has been developed based on the 2013 indicative list of WHO for paediatrics, 4th edition; the 2013 National Standard Treatment Guidelines, 2nd edition; and treatment protocols from different public health programmes. The 2015 National Essential Medicines Lists for adults is the 6th edition. This edition was based on the previous 2010 edition; the 2013 Standard Treatment Guidelines, 2nd edition; the 2013 and 2015 Model list of WHO, 18th and 19th edition, to ensure harmony in treatment, procurement and re-imbursements.

The selection of these essential medicines took into account different criteria, including the results of clinical and epidemiological criteria, and comparison of the cost of medicines, products and treatment. For equivalent medicines, the choice was based on the studies done, the pharmacokinetics of the medicines, adaptability to local conditions of storage, and the assurance that the product will enhance adherence and compliance to treatment better. In Rwanda, the list of essential medicines is used to guide the selection of medicines for procurement and good prescribing and dispensing practices, mostly in the public sector.

The latest National Medicines Formulary was published in 2007. It was developed based on the 2005 NEML. It was also designed to improve the management of priority conditions, and to contribute to the rational use of medicines. Given that new treatment guidelines were developed, followed by the NEML, it would be advisable to revise this version so that there is a link between the two documents.
4. National medicine financing

User charges in Rwanda apply to outpatient care, inpatient care, and pharmaceuticals. Co-payments or co-insurance are different, depending on the type of health insurance scheme a member is registered in. For beneficiaries of the main health insurance scheme (CBHI), there is a flat co-payment of US$ 0.30 at the health centre (this includes medicines) and 10% co-insurance at hospital level (this also includes medicines). The poor and other vulnerable persons are exempted from co-payments and co-insurance at the point of service.

HIV/AIDS, malaria, immunization and tuberculosis services and products are subsidized and provided for free in the public health care system. In addition, Rwanda has exempted medicines and medical products of national priority importance from all taxes, including value-added tax (VAT).

Table 12 shows estimated expenditure on pharmaceuticals in Financial Year 2009/10 (latest National Health Account available). However, caution should be exercised when interpreting these figures as they refer only to expenditures related to the provision of pharmaceuticals from private pharmacies (outside a health facility). The expenditures were reported under ‘Medical goods dispensed to outpatients’ in the Rwanda National Health Accounts (RNHA) for the Financial Year 2009/10. It is important to note that expenditures on medicines included in this category only account for a fraction of overall expenditure on medicines in Rwanda’s health sector. In the RNHA for Financial Year 2009/10, expenditure related to medicines and medical supplies is generally included in the category of outpatient and inpatient care. Services for curative care (outpatient as well as inpatient) represented 44% of total health expenditure.

Table 12: Expenditure on pharmaceuticals–RNHA Financial Year 2009/10

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total population in 2009/10</td>
<td>10,412,820</td>
</tr>
<tr>
<td>Total health expenditure (in USD)</td>
<td>420,325,340</td>
</tr>
<tr>
<td>Percentage out-of-pocket expenditure on health</td>
<td>10.5%</td>
</tr>
<tr>
<td>Expenditure on medicines (in USD)*</td>
<td>31,867,051</td>
</tr>
<tr>
<td>Expenditure on medicines in health insurance schemes</td>
<td>4,816,687</td>
</tr>
<tr>
<td>Out-of-pocket % on medicines as a fraction of expenditure on medicines</td>
<td>82.1%</td>
</tr>
<tr>
<td>Per capita expenditure on medicines (in USD)</td>
<td>3.1</td>
</tr>
</tbody>
</table>

Note: *Refers only to expenditures related to the provision of pharmaceuticals from private pharmacies.

Source: Rwanda National Health Accounts Report, Financial Year 2009/1
5. Management of medicines within the Medical Insurance Scheme

5.1. Organizational overview

Rwanda Social Security Board’s Medical Insurance Scheme (formerly RAMA) was created in 2001 by Law No. 24/2001 of 17 April 2001. Initially, RAMA was under the oversight of the ministry in charge of public administration, but in 2007 it was placed under the authority of the Ministry of Finance and Economic Planning, and supervised by the National Bank of Rwanda as a financial institution. As of 14 December 2010, the scheme was merged with the Social Security Fund, and placed under the Rwanda Social Security Board (RSSB). The Rwanda SSB is a parastatal organization with administrative and financial autonomy.

Membership of (affiliation with) the Scheme is compulsory for all civil servants and staff of public or parastatal organizations, including the staff of development projects (but excluding military forces and the police). Spouses and legal dependents are covered for the same benefits as affiliates. The Scheme also covers the majority of people in the formal private sector and their dependants. Affiliation for private companies is voluntary, and is conditional on prior approval by the Board of Directors, following a formal request. Candidates for affiliation need to have been contributing members of the former Social Security Fund of Rwanda. Individual registration is not possible, and a minimum of seven employees is required in order to lodge a request. In January 2015, private companies represented only about 16% of their affiliates. Also, pensioners who previously contributed towards the Medical Insurance Scheme before retirement are included. A 7.5% contribution is deducted from their monthly pension. As of 10 July 2015, the Scheme had enrolled 221,021 affiliates and 395,503 dependents. In total, there are currently 616,524 beneficiaries representing about 5% of the total population.

Members’ contributions are the primary source of financing, followed by return on investments. The total contribution rate for members is 15% of the base salary, with the contribution shared equally between employer and employee. Employee contributions are deducted directly at source, and paid to the Scheme by employers not later than the tenth day of the following month. There is no medical examination or excluding precondition for candidates.

Figure 10 illustrates the organizational structure of RSSB. The RSSB Medical Insurance Scheme (RSSB-MIS) in particular refers in the chart to the Medical Services Department. The Medical Services Department is led by a head of department who is assisted by an administrative assistant. The Department is divided into two Divisions: the Medical Benefits Division and the Pharmacies Division.

- The Medical Benefits Division oversees the Medical Access Unit and the Medical Invoices Verification Unit. The Division supervises all activities pertaining to members’ registration, membership management, beneficiaries’ access to health care services (including verification of membership in real time), and related invoice verifications. RSSB-MIS works with all public and faith-based health facilities, and with 64 private health facilities. The number of partner health facilities changes often, based on new partnership agreements.

- The Medical Access Unit is headed by a director, assisted by three medical access officers at the central level. At the district level, there are 100 medical benefits access facilitators. They are based in the different health facilities, and work in partnership with RSSB-MIS. The presence and number of facilitators depend on the volume of the health facility’s activities.
• The Medical Invoices Verification Unit is also headed by a director, who is assisted by five verification officers at the central level. They are in charge of consolidating invoices by district, and for counter-verification activities. There is also at least one verification officer per district.

• The Pharmacies Division oversees all activities pertaining to access to services provided by private pharmacies, and related invoice verification. The Division, supervised also by a division manager, is divided into two different units, each headed by a director:
  - The Pharmaceutical Operations Unit comprises a director and three pharmaceutical operations officers;
  - The Pharmaceutical Invoices Verification Unit comprises five pharmaceutical invoices verification officers.

All staff are based at the central level. Until recently, the Pharmacies Division made medicine reimbursement decisions, including revision of the content and prices of medicines to be included in the list of cost-reimbursable medicines. For revision of the content of the list of cost-reimbursable medicines, RSSB used to request suggestions from partners' pharmacies and clinics. The Pharmacies Division then reviewed the suggestions and proposed decisions based on the principle of quality, cost-effectiveness, added value, and the needs of prescribers and patients. After that, a validation meeting was organized with partners, who provided suggestions.

Revision of medicine prices was done by a committee within the Pharmacies Division composed of the Division Manager, all staff of the Pharmaceutical Operations Unit, and five representatives from the private pharmacies of RSSB partners. This committee discussed medicine prices obtained during a comparative market survey conducted among major wholesalers, and proposed new prices that would be communicated to the top management of RSSB for approval and onward transmission to partner pharmacies and clinics. But recently, it was decided that the activity of updating the list of cost-reimbursable medicines will be performed by the Office of the Executive Secretary of the Rwanda Health Insurance Association (RHIA). Every health insurer who is a member of the RHIA will send a representative for that activity.

The Branch Coordination Unit (see chart) is based at the central level. This unit serves as a link between the head office and the 30 district branches, and coordinates all technical activities undertaken at the district level.

5.2. National legislation and legislation on insurance and pharmaceuticals

RSSB-MIS has reported that there is a link between national policies, strategies and legislation on the one hand, and insurance policies, strategies and legislation on the other. But this link is still weak. By providing coverage to its beneficiaries, RSSB-MIS collaborate with health service providers under Ministry of Health regulation. RSSB-MIS expect more regulation of health care in general by the Ministry, and more regulation on the use of medicines. A national pricing policy would guide both health providers and insurance organizations. In addition, there is a national policy on health insurance in Rwanda that was adopted in 2010, but the management of medicines by health insurance organizations is not clearly outlined.
Figure 10: The RSSB organizational chart in 2015

Source: Adapted from a Special Issue of the Official Gazette published on 25/02/2015 and Prime Minister’s Order No. 27/03 of 24/02/2015.
5.3. Selection, pricing and reimbursements for medicines

RSSB-MIS has a medicine pricing system that is mainly based on market survey results from main wholesale pharmacies, with the inconvenience that sometimes wholesale pharmacies determine prices based on the availability of the medicines among them. To determine the price for each medicine on the list, for the private sector, RSSB-MIS uses prices obtained from survey results and apply a maximum of 40% as a profit margin. The lowest price is used for reimbursements, except when that price is so low that it gives cause to question the quality of the product. For the public sector, prices in health facilities follow Ministry of Health instructions (maximum of 20% of total cost as profit margin).

The RSSB-MIS issues the list of cost-reimbursable medicines in private health facilities and private pharmacies. Preference is given to generic medicines where they are readily available. RSSB-MIS covers medicines for both outpatients and inpatients, in accordance with approved lists of cost-reimbursable medicines. All types of medicines included in the list are covered. Reimbursements are however not made for some branded products for which equivalent generics are readily available. Reimbursements may also be made for some medicines on approved lists if authorized by a medical advisor. Such advisor may, before authorization, discuss with the prescriber, or verify the patient’s file. In addition, prescriptions with a total value of more than 40,000 Rwandan francs require a medical advisor’s authorization.

There is an approved standard list of medicines for private health facilities and private pharmacies (for outpatient care). For public facilities, the Scheme uses mainly the list of essential medicines as the basis for reimbursements. The same applies to the list used for private health facilities; especially for public referral hospitals (see Annex for a copy of each of the three lists). These lists are not necessarily mutually exclusive. Medicines that are fully subsidized through vertical programmes (such as for HIV/AIDS, tuberculosis, sexually-transmitted infections, vaccines for children, and the Expanded Programme on Immunization (EPI), etc.) are excluded from the reimbursement system.

RSSB-MIS makes reimbursements for medicines following the list of cost-reimbursable medicines, or the authorization of the RSSB medical advisor, where a particular medicine is not included in the list. Furthermore, prescriptions with a total value of more than 40,000 Rwandan francs are also subject to the approval of the medical advisor, to limit abuse. For every such case, the medical advisor analyzes the patient file, discusses all the treatment alternatives with the clinician, and selects the most cost-effective option. For patients who cannot pay co-insurance, there is a social affairs committee that studies each case and decides accordingly.

The list of cost-reimbursable medicines is updated annually for content, and every six months for prices. There are no approved guidelines on the selection of cost-reimbursable medicines. As mentioned above, the principle of quality, cost effectiveness, added value, and the needs of prescribers and patients, is taken into consideration during an update. The price revision is made in collaboration with a team of representative of partner pharmacies.

The current system for reimbursements is determined by Law No. 24/2001 on the establishment, organization and functioning of a health insurance scheme for government employees (formerly RAMA). But, it is too general. For instance, reimbursements for medicines are not made by
pharmaceutical class, by exclusion of over-the-counter medicines, or by percentage differentiation, depending on the class of the pharmaceutical, etc.

Co-insurance was determined by law after an actuarial study. To date, four actuarial studies (in 2000, 2004, 2010 and 2012) have been conducted. Affiliates pay 15% of the total cost (consultation, laboratory tests, medicines, etc.) for outpatient and inpatient services. RSSB-MIS reimburse 85% of the cost of medicines on the list of cost-reimbursable medicines. Patients get their prescribed medicines either from all pharmacies run by public health facilities, or from partner private pharmacies. The prescription of medicines by generic name is not mandatory either in the public sector or in the private sector. Pharmacists are allowed to substitute with generic medicines.

The process of submission and processing of claims for reimbursement is described as follows: the patient pays 15% of the total cost of prescribed medicines directly to the provider (in this case, the retail pharmacy). Thereafter, providers submit their monthly claim to RSSB-MIS for reimbursement of the remaining 85%. It takes on average 30 days to process claims in respect of reimbursements for medicines.

The Medical Insurance Scheme does not have a written cost containment policy. In practice, the cost of medicines is subject to review twice a year in consensus between RSSB and representative of partner pharmacies. However, as mentioned above, revision of the list of cost-reimbursable medicines will now be done at the Office of the Executive Secretary of RHIA.

5.4. Estimates of RSSB-MIS expenditure in Financial Year 2013/14

The total expenditure of RSSB-MIS for the Financial Year 2013/14 is estimated at US$ 65,973,193. Of this amount, reimbursements for medicines represented about 11%. Outpatient and inpatient expenditures, together, represent more than one-fifth of all expenses.

Table 13: Estimates of RSSB-MIS expenditure for July 2013–June 2014*

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount in RWF</th>
<th>Amount in USD</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatients, including accommodation and excluding medicines</td>
<td>380,800,000</td>
<td>570,867</td>
<td>0.9</td>
</tr>
<tr>
<td>Outpatients, excluding medicines</td>
<td>9,139,200,000</td>
<td>13,700,803</td>
<td>20.8</td>
</tr>
<tr>
<td>Reimbursements for medicines, including medical products</td>
<td>5,000,000,000</td>
<td>7,495,625</td>
<td>11.4</td>
</tr>
<tr>
<td>Staff salaries</td>
<td>2,610,000,000</td>
<td>3,912,716</td>
<td>5.9</td>
</tr>
<tr>
<td>Equipment and investments, excluding medical products</td>
<td>23,736,000,000</td>
<td>35,583,231</td>
<td>53.9</td>
</tr>
<tr>
<td>Running costs</td>
<td>1,375,500,000</td>
<td>2,062,046</td>
<td>3.1</td>
</tr>
<tr>
<td>Other</td>
<td>1,766,300,000</td>
<td>2,647,904</td>
<td>4.0</td>
</tr>
<tr>
<td>Total</td>
<td>44,007,800,000</td>
<td>65,973,193</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: Rwanda Social Security Board

*Note: From 2011 the fiscal year of Rwanda, which started in January and ended in December, changed. It now starts in July and ends in June, to match the fiscal year followed in the East African Community.
As Figure 11 illustrates, RSSB-MIS insures a relatively wealthy part of the population. About 85% of households reportedly being insured through RAMA are in the richest quintile. Its members have access to virtually all services provided in public and private facilities, and contribution rates of the Scheme seem to be high enough to generate savings for reinvestment in the national economy. Engaging in investment is one of RSSB’s missions as defined by Law No. 45/2010 of 14 December 2010 establishing RSSB. In 2013/14, more than 50% of its budget was spent on equipment and investment.

**Figure 11: Distribution of the population insured by RAMA by expenditure quintile, EICV 2010**

The Scheme invests in different types of area, such as long-term deposits, and shares in national and international banks and companies. In the same period, the Scheme built a modern medical laboratory and two administrative blocks (one serves as the Scheme’s head office).

### 5.5. Management information and monitoring system

RSSB-MIS archives hard copies of all prescriptions, as they are currently not recorded in an electronic system. These archived prescriptions are used for further studies, research on a particular disease, or for investigations involving fraudulent cases.

The Scheme also archives all versions of price lists of cost-reimbursable medicines. The retail price is the type of prices recorded. Medicine prices are recorded to inform the discussion on the content of the list of medicines and prices between partners and RSSB, but also for the purpose of audits conducted by the National Bank of Rwanda.

RSSB-MIS uses the results of the Rwanda market survey conducted among wholesaler pharmacies (comparative list of prices) to monitor the prices of medicines.

The Scheme does not have a system for monitoring the availability of quality medicines from service providers. This should normally be done at the national level, but the country does not currently have a functioning National Medicines Quality Control Laboratory.

RSSB-MIS does not have a system for monitoring medicine prescribing practices per se, but during the process of verifying claims, a kind of monitoring is done. For example, there cannot be more than four products on any medical prescription. Only prescribers who are found guilty of malpractice receive feedback.

Currently, the Scheme has a system for monitoring expenditure on medicines. The pharmaceuticals verification unit in the Pharmacies Division (in charge of verifying invoices from partner pharmacies) and the medical verifications unit in the Medical Benefits Division (in charge of verifying invoices from health facilities for services and medicines provided to RSSB beneficiaries) report regularly on real expenses incurred. But an ICT application system is needed to improve the system.

6. Challenges

The major challenges observed in the system for making reimbursements for medicines are organized here into general challenges and challenges specific to RSSB-MIS. We take them in turn.

6.1. General challenges

1. Although comprehensive pharmaceuticals legislation exists (laws, regulations, guidelines), there is a need to increase awareness about them among all potential users, including health providers and insurance companies. Monitoring of their use also needs strengthening, along with their effective enforcement and compliance on the national territory.

2. A national medicines regulatory authority is yet to be established. In addition, the National Medicine Quality Control Laboratory is not yet fully operational. Yet, these two institutions are critical to ensuring the quality, safety, and efficacy of medicines.

3. The supply of enough medical commodities to cover the national territory is still an issue. MPDD does not have adequate capacity to supply medicines and other health products to the public sector, especially for non-programme products.

4. There is no national medicine pricing policy that can help regulate medicine prices, especially in the private sector.

5. The prescription of medicines by generic name needs to become mandatory in both the public sector and the private sector.

6. The link between national policies, strategies and legislation and insurance policies, strategies and legislation is still weak.
6.2. Challenges specific to RSSB-MIS

1. Although RSSB-MIS use the principle of quality, cost effectiveness, added value and the needs of prescribers and patients when revising the content of the list of cost-reimbursable medicines, there is a need to develop written guidelines on the selection of medicines the cost of which can be approved for reimbursement.

2. RSSB-MIS archives all prescriptions in hard copy. There is a need for an electronic system to improve the management of archived information.

3. The Pharmaceuticals Verifications Unit and the Medical Verifications Unit of RSSB-MIS report regularly on real expenses made. However, an ICT application is needed to improve the monitoring of medicine expenses.

7. Measures planned to mitigate the challenges

It is important to note that most of the general challenges reported above are highlighted in the medium-term report of HSSP III, and actions recommended include enforcement of laws, improvement of forecasts, quantification of pharmaceuticals at all levels, development of a pricing policy to regulate the private sector, advocacy for an autonomous regulatory agency, and institution of an accreditation system for the quality control laboratory once it is operational.

With regard to challenges specific to RSSB-MIS, the Rwanda Social Security Board is planning to strengthen its IT system in order to reduce fraud. It will computerize all medical acts and medicines, and introduce bar-codes. The Board is also planning to use fingerprints at points of care or pharmacies.

7.1. Priority areas of action and recommendations

Given the above challenges, we recommend the following priority actions to improve reimbursements for medicines in health insurance schemes in Rwanda:

1. The regulatory system for medicines needs to be strengthened by continuing to advocate for the establishment of a national regulatory agency. This will ensure the quality, safety, and efficacy of medicines that enter the national territory. The PTF, which serves as a transitional alternative to a regulatory agency, should continue to provide minimum services related to medicines registration, quality assessment, monitoring of supply channels, and rational use of medicines.

2. Availability of quality generics on the national territory should be ensured. This will foster the prescription of medicines by generic name. It will also be more cost-effective for users and health insurance organizations.

3. The existing link between national policies, strategies and legislation and insurance policies, strategies and legislation should be strengthened, mainly by increasing awareness about the link, and by enforcing existing national pharmaceuticals legislation.

4. A medicines pricing policy needs to be formulated to help regulate the private sector in particular. Health insurance schemes in the country, such as RSSB-MIS, will certainly benefit from such a policy, as they often partner with private pharmacies and health facilities.
References


### Annex: Household classification criteria

Using the *Ubudehe* approach, the following criteria were used for identifying destitute persons:

<table>
<thead>
<tr>
<th>Population group</th>
<th>Characteristics</th>
</tr>
</thead>
</table>
| Abatindinyakujya ‘people living in abject poverty’  
*Category I* | This group of persons own no property, live out of begging and assistance from other people, and consider that death would be a relief. |
| Abatindi ‘very poor people’  
*Category II* | These people are homeless and lack food. Access to food is not easy but they can work for other people to survive. They are poorly clothed and own no land or livestock. |
| Abakene The Poor  
*Category III* | These people depend on food that is deficient in nutrients, own a small piece of land, have a low yield from farming, and their children cannot afford secondary education. |
| Abakenebifashije ‘The less poor’  
*Category IV* | These people own a piece of land, some livestock, a bicycle, and produce an average quantity of food; their children can attend secondary school, and they face fewer difficulties accessing health care. |
| Abakungu – Jumba ‘Rich people, because they have food’  
*Category V* | This group of persons own large areas of land, can afford balanced meals, and live in decent homes. They employ other people, own livestock, and their children can easily attend university. |
| Abakire ‘Rich people, because they have money’  
*Category VI* | This group comprises persons who own a bank account, can access bank loans, own a beautiful house, a car, livestock, fertile land, sufficient food, and have permanent employees. |

*Source: Ministry of Public Administration and Social Protection, Ubudehe Programme, Kigali, Rwanda*
Assessment of medicine pricing and reimbursement systems within health insurance schemes in Senegal
1. Introduction

Access to health care has to date remained a priority in Senegal. In fact, developments in the health system, even with improvements in health coverage, have not been spread evenly throughout the country. And access to health care is still not commensurate with the targets set by the State. Proof is that, in a population of about 14,000,000 inhabitants, only 20% have health insurance coverage. Nevertheless, several reforms have been undertaken that have brought about some improvement in the running of health facilities in terms of availability of medicines and financial viability. It should also be noted that health insurance has of recent reached an expansion phase in Senegal. Much as such expansion remains generally sluggish and inadequate, the trend is for real, and seems to be irreversible.

Extensive work has been carried out on health insurance, in a bid to establish types of insurance, and to critically examine them. Prominent among the difficulties generally emphasized are constraints in the system of reimbursements for pharmaceutical products, this, in the context of low funding for health care, and recourse to community funding in the form of mutual health insurance schemes. The objective of the present study is essentially to examine the relevance and limits of the system that health insurance schemes follow in making reimbursements for pharmaceutical products in Senegal. Closely linked to this, the study will analyse how different health insurance schemes are funded. It will define the limits of health insurance and identify the challenges that need to be met in order to make the system more efficient.

For the study, we reviewed:

- Existing documentation on the social coverage system in Senegal;
- Reports written on social protection;
- In-house documents produced by institutional stakeholders associated with the expansion of health insurance schemes.

Additional qualitative discussions yielded more information for analysis. These discussions were held with stakeholders, finance ministry workers, managers of health insurance institutions (IPM), mutual insurance companies, employees of the social security fund and the motor vehicle guarantee fund, officials of the universal health coverage agency, and medical advisers of private insurance companies. The study was carried out based on verified and validated information, and on data made available by the various persons and entities mentioned above.

Ultimately, study will focus on three things: (a) an appraisal of the situation of health insurance in Senegal; (b) identification of the obstacles that generally hamper the efficacy and effectiveness of the system for making reimbursements for pharmaceutical products; and (c) proposals for a more effective organizational model adapted to the context of the country.
2. Types of health insurance plan in Senegal

The health insurance system in Senegal comprises the three plans shown in Box 1.

Box 1: Types of health insurance plan in Senegal

1. Non-contributory plans
   These comprise:
   - National health insurance schemes that cover mainly the public sector; they are pegged to the status of eligible persons (civil servants, military personnel and students);
   - Health insurance schemes for free treatment; they provide exemptions and assistance for some special social strata. Beneficiaries get:
     - Free treatment if they are 60 years of age or older (the SESAME plan);
     - Free childbirth and Caesarean sections;
     - Free treatment if they are children aged 0 to 5 years;
     - Free coverage if they qualify as destitute persons;
     - Free access to antiretroviral medicines, medicines for tuberculosis, and simple antimalarial preparations

2. Compulsory contributory insurance plans
   The following fall under this category:
   - Health insurance institutions (IPMs);
   - The Social Security Fund;
   - The Motor Vehicle Guarantee Fund.

3. Voluntary contributory plans
   These are:
   - Mutual health insurance companies;
   - Private insurance companies.

3. System for making reimbursements for pharmaceutical products

At the institutional level, the Directorate of Pharmacy and Medicines (DPM) was created as a national regulatory authority. It is the sole guarantor of pharmaceuticals policy. It is also charged, under Decree No. 2004/1404 of 4 November 2004 organizing the Ministry of Health and Prevention, with the initiation and implementation of pharmaceuticals policy, and the inspection and registration of medicines. The key duties of this Directorate are (a) to initiate legislative and regulatory instruments relating to pharmacies, medicines, harmful substances, alcohol, and medical devices, and monitor
their implementation; (b) to regulate the exercise of pharmaceutical professions; and (c) to regulate and promote traditional pharmacopoeia.

Various laws, decrees and orders lay down the conditions for granting permits for the marketing of medicines (AMM), for administering prices, substituting medicines, opening pharmaceutical establishments, and for inspections. It should be noted that the regulatory and legislative framework, which was largely inspired by French regulations, is made up of a collection of mostly old texts, not often adapted to market specifics, and unefforceable because of weak institutions and inadequate human, technical and financial resources at the Directorate of Pharmacy and Medicines (DPM) that is responsible for administering the sector.

3.1. Non-contributory plans

**National health insurance**

For this non-contributory insurance plan associated with the public service, funding is by the State through the national budget. The State, as employer, ensures the health risk coverage of its employees (civil servants and non-civil servants) in active service and their next of kin (spouses and children). Law No. 61/33 of 15 June 1961, relating to general rules and regulations governing civil servants, instituted the social security scheme. Through the system of budgetary charges, the State covers 80% of medical costs. Pharmaceutical products are not part of the coverage. This is how coverage works:

- A letter of guarantee, containing a *Budgetary Vote*, is issued by the Ministry of Finance; this directly credits the invoice. The budgetary vote is valid for the month of issue, and for a given facility;
- Civil servants on secondment to local councils have the same medical coverage as any other State employee;
- In the case of students, university welfare centres cover them on behalf of the State. Students can get medical care from any recognized public and private health facility. The scheme covers routine care comprising consultations, medicines, laboratory work, dental care and hospitalization. A digital student identification card entitles the bearer to various health services and treatment.

Funding of the university welfare centres is by the State, but some of the funds come from registration fees charged to students. In case of hospitalization, university welfare centres cover the total cost of pharmaceutical products used. These must be products from recognized public or private facilities, and must have been used during hospitalization. For outpatient treatment, the cost of prescription medicines available in health centres is covered at 100% by university welfare centres. These are mostly generic products found on a list drawn up by the Directorate of Pharmacy and Medicines. The list is updated every two years. The products are also obtained from the national supply pharmacy. The choice of product depends on their therapeutic effectiveness and their affordability. Invoices issued by health facilities are sent to university welfare centres, and are settled by a payments officer on the recommendation of the student’s doctor.

**Exemptions and assistance for special social strata (the SESAME plan)**

In 2006, Senegal introduced a mechanism for funding treatment for elderly persons. It was known as the SESAME Plan. This initiative is part of the strategy to expand health coverage for Senegalese,
and concerns persons aged 60 years and above. Beneficiaries in this population group are divided into two categories. On the one side are elderly persons who pay for their own health care (PAF), and do not have a retirement pension. This category of persons does not benefit from any formal health protection, and represents 70% of elderly persons. It comprises mostly farmers, workers in agriculture and fishermen who do not have any social protection. On the other side are elderly persons who benefit from social protection.

Coverage under the SESAME Plan is at three levels: at health posts, at health centres and in hospitals. Coverage is on an individual basis, and is conditional on showing the electronic national identity card of Senegal. Persons who receive care must be referred from the lower level, except in cases of emergency. To consult at a hospital, compulsory proof from a district health office, in the form of a referral card, is required. The SESAME package provides 100% coverage for pharmaceutical products available in public health facilities, and covers outpatient treatment and hospitalization in approved public and private health facilities. It must be noted that the only products covered are those available.

The district health office collects all requests for reimbursement from health posts and health centres; a medical region pool all requests for reimbursement from their respective districts and public health establishments, and forwards them to the SESAME Plan office. SESAME Plan offices are at the Directorate of Health in the Ministry of Health. Here, payments are made according to the same reimbursement plan as in MSAS, upon approval by the coordinator and the Director of Health. Reimbursements for medicines at the district level are made in kind by providing the districts with medicines up to the amount owed them, and in accordance with the Plan. Advances of funds are made in conformity with the Plan as well.

With regard to sources of funding, the SESAME Plan is entirely financed from the national budget. Financial support by the State to health facilities, under the SESAME Plan, is in the form of current transfer expenditure charged to the general State budget. The SESAME Plan does not have any support from external partners. The State subsidy is usually disbursed in amounts proportional to requests for reimbursement made by public health establishments.

**Free childbirth and Caesarean sections**

The policy of free childbirth and free Caesarean sections was introduced in early 2005 in five regions of Senegal. These regions were chosen because they were the poorest. The policy was aimed at reducing the financial barriers that hindered the use of obstetric services, and at increasing safe deliveries in health facilities. The expected outcome was a reduction in maternal and perinatal mortality.

The treatment package comprised normal deliveries in health posts (PS) and health centres (CS), and Caesarean sections in levels 1, 2 and 3 public health establishments (EPS1, EPS2, EPS3). All pregnant women are covered. The funding mechanism for normal deliveries took the form of kits containing basic pharmaceutical products distributed via the National Supply Pharmacy (PNA). These kits replaced payments which users had to make at the place of childbirth, at least in theory. For regional hospitals, 55,000 CFA francs was paid in advance to the hospital for each Caesarean section, depending on the number of C-sections expected; but if the estimates were exceeded, the additional costs were reimbursed at the regional hospital. For EPS 1, there was no transfer of money, and the subsidy was made in the form of kits.
Establishments which participated in the mechanism put in place were all public establishments. Health units, which were structures at the community level where matrons carried out deliveries, were excluded. The private sector and not-for-profit associations were also not part of the mechanism. Districts and hospitals were expected to write monthly reports and submit partographs (labour progress charts) as proof of services provided.

**Free treatment for children aged 0 to 5 years**

The initiative to provide free treatment for new-born children and children aged less than five years, is part of the determination by the State to make universal health coverage a reality, and in order to contribute to attaining Millennium Development Goals 4 and 6. It constitutes one of the strategic pillars of the 2013–2017 development plan for universal health coverage.

Reimbursements for services rendered under free treatment are by treasury cheque, issued through medical regions and public health establishments. With the help of Universal health coverage (CMU) workers, a fixed amount is pre-determined in each health region, pro-rated to the number of cases expected. The chief medical officer of the region and administrator-delegate is required to appoint a manager-delegate beforehand, and to open a special CMU account at the regional treasury.

**Box 2: Package offered for free medical treatment**

<table>
<thead>
<tr>
<th>Elements of the package offered for free medical treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>• At health posts: consultations, available curative care (pharmaceutical products) for routine infections covered by the package for the health post, preventive care, and follow-up of children;</td>
</tr>
<tr>
<td>• At health centres: consultations, available curative care for all the infections covered by the package for health centres, preventive care, and follow-up of children;</td>
</tr>
<tr>
<td>• In hospitals: referrals and emergency consultations.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pharmaceutical products routinely offered free to children</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Simple malaria: TDR and ACT;</td>
</tr>
<tr>
<td>• Vaccines (BCG, PENTA 1, 2 and 3, VPO, measles and yellow fever);</td>
</tr>
<tr>
<td>• Acute and severe malnutrition: therapeutic foods and milk, amoxicillin, vit. A, mebendazol, Resomal;</td>
</tr>
<tr>
<td>• HIV/AIDS: Antiretroviral medicines;</td>
</tr>
<tr>
<td>• Tuberculosis: Curative tuberculosis treatment and chemoprophylaxis;</td>
</tr>
<tr>
<td>• Diarrhoea: ORS and zinc.</td>
</tr>
</tbody>
</table>

At the end of each month, the health facility (unit, post or health centre) sends a monthly report to the district health office, accompanied by a request for reimbursement. Supporting documents must be attached. Within 10 days of filing these documents, the district health office verifies and summarizes all the documents, then forwards a report, accompanied by a request for reimbursement, to the medical region.
Public health establishments (EPS) also send their monthly reports to the medical region after verification by the hospital supervisory bodies. The medical region in turn reviews all the reports from the districts and public health establishments. It summarizes the reports and submits them with supporting documents to the regional technical committee for their validation, then requests for reimbursement. A copy of the request for reimbursement is sent to the national technical follow-up committee composed of the CMU Branch, the DGS/DSRSE, the DGAS and the DAGE. Reimbursements are made after service has been rendered, and after validation of the supporting documents and the request for reimbursement (detailed invoices). Reimbursement for the treatment provided is made in the following manner:

- Initially, the district medical officers and directors of public health establishments forward to the medical region a request for payment, together with all the invoices;
- After checking through them, the medical region makes payment by bank transfer to its districts and public health establishments;
- Each health district pays in the amount due to the health committees, and this is signed for;
- Five days after payment, the medical region sends to the central office invoices from the health facilities, requests for payment, payment orders, and receipts from beneficiary facilities.

The national follow-up committee makes regular verification checks, sends written reports to the medical region, and transmits the supporting documents to the CMU branch. Reimbursements are made every two months, on submission of a request for reimbursement (invoices) by district chief medical officers and directors of public health establishments. Requests must be validated by the chief regional medical officers.

**The destitute**

There are at least five public health facilities that, in theory, provide coverage for the destitute. Law No. 62/29 of 26 March 1962 relating to certificates of indigence enables persons holding such certificates to have free health care in public health facilities. If the certificate of indigence is issued by an administrative authority (the *Préfet* (divisional officer) or *Sous-Préfet* (sub-divisional officer)), the service is billed to the Ministry of Finance. If it is issued by a mayor, it is in his council office that the bill must be settled. (4) Hence, Law No. 96/07 on decentralization empowers local councils to handle whatever pertains to the organization and management of help for needy persons. Accordingly, each local council has a budget line for this purpose, but it does not deal only with health issues.

Social services departments in hospitals have a budget which enables them to cover all or part of the expenditure for services provided to patients identified as social cases. For health centres and health posts, Service Note No. 006058/MSPM/DS/DSSP of 6 September 2005 refers to the provisions of the *National Health Committee Guide* which stipulate that 10% of revenue from health services be allocated to social cases, and that 5% of the profits realized from the sale of medicines be assigned to a solidarity fund.

The Directorate of Social Action grants aid for medical costs to persons in need. For this purpose, the Directorate entered into signed service agreements with certain hospitals. A hand-written application for aid, accompanied by the applicant’s identity card, is enough to give the applicant access to this facility. In such a case, the pharmaceutical products referred to in the coverage are those on the list
of essential products, either as generic or brand-name products, and available in public outpatient or inpatient health facilities.

**Free antiretroviral, tuberculosis medicines and simple antimalarials**

Free access to antiretroviral medicines and medicines for tuberculosis and malaria is policy in Senegal. It is managed by specific programmes (PNLS, PNILT, and PNLP), with a short list of cost-reimbursable products (see Box 2). Funding is provided by the State and by donors. The National Supply Pharmacy makes products available to public health facilities following manuals of procedure, and product management guidelines designed by the various programmes. All persons affected by these ailments are entitled to free medicines.

### 3.2. Compulsory contributory insurance plans

**Health insurance institutions (IPM)**

These institutions were set up by Law No. 75/50 of 3 April 1975 for the benefit of workers of the private sector and members of their family. The opening of an IPM is compulsory for all enterprises employing more than 100 persons. Businesses employing fewer workers come together and form an inter-company IPM, or take out membership in an authorized IPM. The rules governing the operation of IPMs are defined by Decree No. 75/895 of 14 August 1975.

As regards the funding of IPMs, only partial coverage of medical costs (for consultations, medicines, hospitalization, medical certificates, etc.) is guaranteed, and at rates that vary from one IPM to another (40% to 80% coverage). Contributions are fixed at 6% of earnings, up to a ceiling of 60,000 CFA francs. Employer’s contribute at least the equivalent of what the wage-earner makes. However, most IPMs no longer observe these parameters because they are ill-adapted to the present context.

It should be noted that the list of cost-reimbursable products is often updated on an individual basis by the IPMs, more specifically the part concerning pharmaceutical products. Excluded products vary from one IPM to another, and the products often approved are those which are used for curative treatment. The system of reimbursements for pharmaceutical products by approved providers is mixed (payments agent and third-party guarantor).

Co-payments may be made directly to the provider, or settled by the IPM with the provider. When the business undertaking reimburses the IPM ahead of time, it debits the amount of the co-payment to the participant’s salary.

The letter of guarantee signed by the IPM manager, the prescription signed by a medical doctor, and the IPM membership card entitle the bearer of the card to the services of approved private clinics, following signature of a partnership agreement. For hospitalization, the letter of guarantee and the membership card are sufficient.

**The social security fund for enrolled employees**

The social security fund for enrolled employees covers industrial accidents and occupational diseases to which workers may be exposed. Following an industrial accident, the consultations, medicines, analyses, surgical operations and other necessary intervention are covered at 100%.
The Fund was created on 1 January 1956 by Law No. 91/33 of 26 June 1991. Today, Fund has become an organization under private law, entrusted with a public service mission. The financial resources of the Social Security Fund are derived exclusively from contributions by employers. Coverage includes full reimbursement (100%) of the cost of pharmaceutical products for both hospitalization and outpatient treatment, in case of an industrial accident.

The social security card and the letter of guarantee issued by the Fund entitle the bearer to services provided by approved service providers. Reimbursements are by a payments agent, and there is no limit to coverage. There list of pharmaceutical products is not exhaustive either. The only products that are excluded are those that are of no therapeutic interest in the treatment sought.

**Motor Vehicle Guarantee Fund**

The Motor Vehicle Guarantee Fund covers bodily injuries resulting from accidents caused in Senegal by motor vehicles on land, the operators of which are unknown, uninsured, or totally or partially insolvent.

The Motor Vehicle Guarantee Fund (also) covers pharmaceutical products used in connection with motor vehicle accidents on land where the perpetrator is unknown (hit and run), and when the perpetrator is known but is uninsured or insolvent.

However, the Fund does not cover the driver who caused the accident, the owner or person who had custody of the vehicle at the time of the accident, and victims in a stolen vehicle.

Coverage for pharmaceutical products is provided at 100% for hospitalization and outpatient treatment. But reimbursements are made only for pharmaceutical products that are covered for bodily injuries reported. Pharmaceutical products that are indispensable for maintaining the victim's health after recovery are evaluated at a flat rate, following the recommendation of the medical advisor.

The accident declaration form, national identity card, and medical certificate, issued by a medical doctor are sufficient for coverage. Reimbursements follow a system of lump sum payments with approved service providers, or through a system of third-party guarantors.

### 3.3. Voluntary contributory plans

**Mutual health insurance companies**

The emergence of mutual health insurance companies in Senegal has gone through several phases, but three of them are prominent. These include: (a) the birth phase of initial mutual benefits experiments before 1994; (b) an expansion phase between 1994 and 1998; and (c) a commitment phase since 1998, that saw the involvement of an increasing number of stakeholders at both local and national levels.

Local mutual insurance company stakeholders in Senegal use several criteria to identify the different types of mutual health insurance company: the so-called complementary mutual insurance companies which provide full coverage; socio-professional mutual insurance companies; and
community mutual insurance companies. Complementary mutual insurance companies were created to provide coverage for services not covered by specific obligatory plans. Examples are the general mutual insurance scheme for the Armed Forces, and the mutual insurance scheme for teachers in Senegal.

Community health insurance schemes (or community mutual health insurance companies) are more and more popular with the state and donors, as a precondition for universal health coverage (CMU). These voluntary and not-for-profit plans are organized at the community level and specifically target people outside the formal sector. Some non-governmental organizations see this approach as a means of increasing the participation of the community in decision-making on health issues. Although community health insurance plans can serve as a hedge against financial risks, their potential for expansion to embrace CMUs remains limited. Guarantees provided vary according to the types of mutual insurance company, even though community mutual insurance companies generally prioritize basic treatment. However, Law No. 2003/14 of 4 June 2003 on mutual health insurance provides the legal framework.

**Funding and conditions of coverage**

The funds of mutual insurance companies are mainly generated from the subscriptions of registered members. Sometimes the funds come from the State (in the case of community mutual insurance companies), and sometimes from donors as initial capital. The rate of contributions varies from one company to the other, but also within the same company, as rates may depend on the member’s income.

The guarantees offered are for partial coverage, at variable rates, from one company to the other (coverage ranges from 40% to 80%). The variations are reflected in medical bills, including pharmaceuticals. Some companies provide 100% coverage for pharmaceutical products in cases of hospitalization; such is the case of the general mutual insurance for teachers in Senegal. There is a restricted list of pharmaceutical products for which reimbursements may be made by mutual companies. The list of medicines for which reimbursements are not possible varies, depending on the mutual insurance company; the lists can be updated.

The letter of guarantee signed by the manager of the mutual company, the endorsed prescription, and a membership card, entitle the member to the services offered. Some mutual insurance companies do not issue cards to their subscribers; however, such schemes often submit the list of their members to directly service providers.

The subscriber’s co-payment is collected in person by the service provider. Such co-payments are made to service providers following a mixed system of payments agents and third-party guarantors. Certain mutual insurance companies have limited ceilings for reimbursements made in respect of pharmaceutical products occasioned by hospitalization and outpatient treatment.

**Private insurance companies**

Private insurance companies are governed by the CIMA (Inter African Conference on Insurance Markets) Code. As a general rule, they cover individuals whose level of income allows them to subscribe to this type of scheme, such as members of the liberal professions, industry officials,
high-level executives of business firms, traders and businessmen. The health risks covered are either full or supplementary.

The funds of private insurers are generated from contributions paid in by insured members, and from dividends from investments. The amounts of contributions paid vary according to the policy. Similarly, the health risks covered also vary from 50% to 100% of medical expenses, including expenses for pharmaceutical products. Whatever limits exist for reimbursements for pharmaceutical products are stipulated in the insurance policy.

Private insurers do not pay for certain pharmaceutical products that are not used for the curative treatment of an illness. In private insurance companies, the only way to receive reimbursement for a given medicine is to show proof of its use for approved treatment. This judgment is reserved for medical advisors, who work for all private insurance companies. The list of the medicines is updated every six months, and the basic criterion is the therapeutic effect of the pharmaceutical product in question.

The endorsed patient card, the prescription signed by a doctor, and the member's insurance card, entitle the beneficiary to services in approved public and private health facilities.

Service providers raise invoices for pharmaceutical products, attach them to the patient's card and the original prescription, and submit them to private insurers. The reimbursement system is again a mixture comprising (a) a simplified payments component where the insurer pays up to the full rate of the guarantee; (b) a full payments component where the insurer pays the full bill and recovers the subscriber’s co-payment, if available, from the insured person; and (c) a third-party guarantor where the insurer reimburses the insured person who has prepaid the bill for pharmaceutical products.

4. Constraints and challenges in the system for making reimbursements for pharmaceutical products

The constraints observed in the system for making reimbursements for medicines fall within the general framework of difficulties encountered in the system for making reimbursements for medical costs as part of health insurance in general. Table 14 summarizes the constraints.
<table>
<thead>
<tr>
<th>Type of insurance</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health insurance for State employees</td>
<td>Health risk coverage for State employees is through a budgetary allocation, and coverage is partial: 80% coverage for cases, and exclusion of pharmaceutical products. However, medicines constitute a greater part (60%) of the cost of one episode of illness. This state health insurance scheme does not substantially reduce the health expenses of civil servants and state employees.</td>
</tr>
<tr>
<td>Free treatment initiatives</td>
<td>Existing management modes channel subsidies through treatment, thus making the service provider judge and party at the same time. Supporting documents are not systematically checked either in a medical sense, or for the authenticity of the documents issued. This largely administrative process has proven to be limited, especially as these initiatives are not merged into the functioning of the health system. Our evaluation has shown clearly that the setting up of these initiatives suffered from weak social and institutional engineering at the time they took root. Free treatment pervades the entire service chain, from consultation and childbirth to medicines. But only the costs of medicines (including kits) are reimbursed under these initiatives. The non-payment of these charges constitutes a huge loss of revenue for health committees (especially for childbirth), considering that these committees in fact take part in the funding of these initiatives.</td>
</tr>
<tr>
<td>The destitute</td>
<td>The numerous facilities covering health care for the destitute face many difficulties, owing to insufficient budgets. Administrative bottlenecks, the absence of clear allocation criteria, ignorance of the destitute about these facilities, and the absence of coordination of interventions, constitute major constraints in the system for making reimbursements for pharmaceutical products.</td>
</tr>
<tr>
<td>Health insurance institutions (IPM)</td>
<td>These health insurance management organizations constitute a major source of funding for health facilities, especially private health facilities. They, however, face some difficulties relating to the system of settling claims in respect of pharmaceutical products. These difficulties include:</td>
</tr>
<tr>
<td></td>
<td>• An outdated legal and regulatory framework for IPMs; • The absence of an accounting and financial benchmark, and a procedures manual; • The absence of prudential rules; • The absence of financial solidarity between IPMs; • Weak management skills among managers; • Inadequate technical parameters (rates and the bases of contributions); these generate inequities and financial difficulties; • The absence of medical controls, especially with regard to medical advisors; • The absence of cooperation agreements between health service providers and IPMs; • Weak supervisory authority, and the absence of regulations; • Delays in the validation of the new nomenclature of professional acts.</td>
</tr>
<tr>
<td>Type of insurance</td>
<td>Constraints</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Mutual insurance</td>
<td>The shortcomings of mutual insurance companies are summarized in terms of strategic, technical and operational weaknesses; they all have an impact on reimbursements for medicines.</td>
</tr>
<tr>
<td>companies</td>
<td>Stratégic and technical weaknesses</td>
</tr>
<tr>
<td></td>
<td>• Insufficient State support for the development of mutual health insurance;</td>
</tr>
<tr>
<td></td>
<td>• Low contributory capacity of households, especially in community mutual insurance schemes, and the absence of subsidy mechanisms by the State and its components;</td>
</tr>
<tr>
<td></td>
<td>• An inadequate legal environment for the development of mutual health insurance companies; a law was passed, but has not been followed by an enabling decree;</td>
</tr>
<tr>
<td></td>
<td>• The absence of a specific contracts policy to facilitate relations between mutual health insurance schemes and treatment providers;</td>
</tr>
<tr>
<td></td>
<td>• Weak coordination of support interventions for mutual insurance schemes (from both support structures and the Ministry);</td>
</tr>
<tr>
<td></td>
<td>• Weak documentation and inability to capitalize on experiences.</td>
</tr>
<tr>
<td></td>
<td>Operational weaknesses</td>
</tr>
<tr>
<td></td>
<td>• Weak risk management measures, which are linked to inadequacies in the concept of mutual health insurance scheme;</td>
</tr>
<tr>
<td></td>
<td>• Voluntary work by members of management bodies, and irregular meetings of the said bodies;</td>
</tr>
<tr>
<td></td>
<td>• Insufficient training of administrators in administrative and financial management.</td>
</tr>
</tbody>
</table>
5. Measures taken to attenuate the constraints and challenges of the health insurance system in Senegal

Table 15 summarizes the proposals made by the different stakeholders (MSAS, health insurance institutions, civil society, and authors) to attenuate the identified constraints.

**Table 15: Measures taken to attenuate the constraints and challenges, by type of insurance**

<table>
<thead>
<tr>
<th>Type of insurance</th>
<th>Proposals, recommendations and suggestions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health insurance for State employees</td>
<td>Review the coverage: This will entail taking into account medicines, defining the system concerned and, in order to avoid lapses, instituting a system of co-payments for treatment by all insured persons.</td>
</tr>
<tr>
<td>Free treatment initiatives</td>
<td>Current policies for free treatment initiatives subsidize requests by offering treatment in the face of all the organizational and management difficulties mentioned in the constraints.</td>
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<td></td>
<td>An evaluation of these free treatment policies by experts, social partners and stakeholders involved in the management of the policies, has underscored the need to create a procurement fund. For this fund to function properly:</td>
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<td></td>
<td>• The function of service provider must be separated from that of financier;</td>
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<td></td>
<td>• There must be a costumer-supplier relationship between the health facility and the organizations implementing the free treatment policy;</td>
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<td>• Health facilities must be paid for the services chosen by health authorities, in line with the national health policy;</td>
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<td></td>
<td>• Invoices must be monitored using accounting, and especially, medical audits (notably with regard to medical advisors);</td>
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<td></td>
<td>• Risk must be properly managed: use of medical services, frequency of risks, medical and financial readiness, must be monitored.</td>
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<td>Free treatment initiatives are currently financed by the State at 100%, through the Ministry of Health and Social Action. But the institution of a procurement fund, and the transparent use of the resources derived from it, will attract other financial partners.</td>
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<td>The destitute</td>
<td>Increasing the budget allocated to coverage of the destitute, in association with reducing administrative bottlenecks, introducing clear allocation criteria, and a good communication strategy, should make this health insurance scheme for the destitute more efficient.</td>
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<td>Health insurance institutions (IPM)</td>
<td>The shortcomings observed in IPMs call for the institution of a central structure to harness available resources. The functions of this central structure would include:</td>
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<td>• Instituting a new legislative and regulatory framework, taking into account all IPM determinants;</td>
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<td>• Training the staff and members of the decision-making organs of IPMs;</td>
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<td></td>
<td>• Providing legal, administrative, financial and accounting support;</td>
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<td></td>
<td>• Providing consultancy and risk management services;</td>
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<td></td>
<td>• Managing and settling disputes;</td>
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<td>• Concluding agreements between health professionals and IPMs;</td>
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<td>• Managing the instruments for safeguarding the finances of IPMs;</td>
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<td>• Facilitating the collection of contributions, and more generally, any monies owed to IPMs;</td>
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<td></td>
<td>• Providing medical control services to IPMs through a medical advisor.</td>
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</tbody>
</table>
Mutual health insurance companies have succeeded in occupying a prominent place in the current landscape of health insurance schemes in Senegal. This has been as a result of the social functions they carry out for the communities, and which they have built through solidarity and self-help values deeply entrenched in the traditions of Senegal. For their activities to be more effective, the following challenges must be tackled squarely:

**Strategic and technical measures**
- Setting up a new legislative and regulatory framework that provides follow-up of mutual insurance companies, so that they can professionalize their management system and better coordinate State inputs for the benefit of IPMs;
- Upgrading the contributory bases of households to reflect the real cost of services provided;
- Formalizing procedures for targeting and following up beneficiaries;
- Following up mutual insurance companies with a view to providing them with proper strategies, including the possibility of partnerships with several stakeholders.

**Measures at the operational level**
- Setting up risk management mechanisms through accounting and medical audits;
- Limiting voluntary work for occupants of certain strategic posts;
- Training managerial staff and the staff of decision-making organs in administrative and financial management.

### 6. Conclusion

The system for making reimbursements for medicines in Senegal is intimately linked to the health insurance situation in the country, particularly in financial terms. This system is plagued by inadequacies linked to the fact that the State has not yet set up a framework for managing health insurance schemes.

A general framework would pave the way for a harmonized standard method of making reimbursements for pharmaceutical products for all types of health insurance scheme, by taking into account all their respective specificities. It would equally help to define a process for making reimbursements for medicines, as well as the types of medicine to be covered or excluded.

Officials must heed the need to prioritize the four key principles adopted by the World Health Organization (WHO) for financing health: reducing direct payments; maximizing pre-payments; insuring risk on a large scale; and using State budgets to cover the majority of the population. Only this approach stands the best chance of succeeding.
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