Assessment of the regulation of the pharmaceutical sector in Guinea

Mission from July to September 2012
SIAPS Guinea

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ACRONYMS AND ABBREVIATIONS

ACT	artemisinin-based combination therapy
AMM	Marketing Authorization
NUMBER	antiretrovirals
ASBL	Non-profit organization
CCM	thin-layer chromotography
CNM	National Medicines Commission
CNT	National Transitional Council
DEAF	Administrative and Financial Affairs Division
DNEHS	National Directorate of Hospitals and Care Establishments
DNPL	National Directorate of Pharmacy and Laboratories
DNPSC	National Directorate of Prevention and Community Health
DPAV	deposit payable after sale
DPS	Prefectural Health Directorate
DRS	Regional Health Directorate
EPA	Public establishment of an administrative nature
EPIC	Public establishment of an industrial and commercial nature
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GIZ	Society for International Cooperation
GNF	Guinean franc
GTZ	Society for Technical Cooperation
IGS	General Health Inspection
INSP	National Institute of Public Health
LNCQM	National Laboratory for Quality Control of Medicines
MSH	Management Science for Health
MSHP	Ministry of Health and Public Hygiene
OICS	International Narcotics Control Board
OOAS	West African Health Organization
OMS	World Health Organization
NGO	non-governmental organization
PCG	Central Pharmacy of Guinea
PEV	Expanded Vaccination Program
PMI	Presidential Initiative to Fight Malaria
PNLP	National Malaria Control Program
PNLT	National Tuberculosis Control Program
PNPCSP	National Program for the Management and Prevention of IS/VIH/SIDA
PTF	technical and financial partners
Hourly	Systems for Improved Access to Pharmaceuticals and Services
HOW	acquired immunodeficiency syndrome
SSP	Primary Health Care
UE	European Union
UMC	Uppsala Monitoring Centre
ÿÿÿÿÿÿ	National Union of Pharmacists of Guinea
UNFPA	United Nations Populations Fund
UNICEF	UNICEF
USAID	United States Agency for International Development
HIV	Human immunodeficiency virus

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This systemic assessment mission of the pharmaceutical sector in Guinea and its regulation carried out by Management Sciences for Health (MSH) and the United States Agency for International Development (USAID) was only possible thanks to the kind welcome, open-mindedness and unrestricted provision by all of the Guinean authorities and their partners of all information necessary for experts to carry out their mission.

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The constructive welcome given by the heads of international organizations and technical and financial partners met showed the marked interest brought by these organizations to the proper functioning of the Guinean pharmaceutical sector.

The constant support of USAID staff and the MSH post in Conakry was a major factor in the success of the mission.

INTRODUCTION

This mission is the fruit of both the will of the United States Agency for International Development (USAID) – and more specifically, via the Presidential Malaria Initiative (PMI) and the Systems for Improved Access to Pharmaceuticals and Services Program ; SIAPS) implemented by Management Sciences for Health (MSH) – to invest particularly in the pharmaceutical sector in Guinea, and the request expressed by the Ministry of Health to strengthen its National Directorate of Medicines and Laboratories (DNPL).

The aim of this mission is to evaluate the regulatory function of the pharmaceutical sector, in several stages: first by describing the current situation of the sector, then by evaluating the regulatory function exercised mainly by the DNPL, finally by proposing recommendations which will make it possible, over time and in successive stages, to improve this essential function of the State, taking into account the entire supply circuit.
This regulatory role, specific to the State, is an essential key to good governance: The State is the guarantor, the driving force and the main actor.

The context

This mission follows the recommendations of the round table organized by SIAPS/PMI in April 2012.

The conclusions of the round table indicate in particular that “the success of priority actions will be closely dependent on the regular monitoring of recommendations” and that “the realization of these commitments requires strong leadership from the authorities of the Ministry of Health in general and the DNPL in particular. particular. This round table marks the beginning of a process.”

The round table aimed to “improve the coordination of technical and financial partners (PTF) operating in the medicines sector through a medicines regulation and management structure (the PCG and the DNPL)”.

In order to move forward in the process thus initiated, it was necessary to carry out a systemic technical evaluation, both functional and institutional, of the pharmaceutical sector and its regulatory function:

- Systemic: because it involves evaluating the regulatory function in relation to and its articulation with the other components and functions of the system;
- Functional: because the goal of the entire process is the proper functioning of the sector and public and private sub-sectors, which requires an inventory, a description of the sector as well as governance and efficiency of the work of Ministry of Health and more particularly of the DNPL;
- Institutional: because the health of populations is the responsibility of the State, which sets up institutions and standards to guarantee it;

- Regulation: the mission emphasizes the exercise and organization of this normative and control function by the State and especially by the DNPL, within the limits of its powers.

The mission

The mission includes several phases: an analysis of the sector and the functioning of the Ministry of Health in the field of medicines (Inspection, DNPL, Pharmacie Centrale de Guinée), followed by a workshop allowing a fairly broad debate on the findings and recommendations of the mission with a view to reaching consensus on prospects for improvement, and finally a final report.

The first part of the mission therefore has the following content: the study of the functioning of the sector, its institutional organization, its legal and regulatory environment, with particular emphasis on the institution most particularly responsible, within the State , the control function: the DNPL of the Ministry of Health. Practically, the mission carried out interviews in particular within the DNPL, the Ministry of Health, the Central Pharmacy of Guinea (PCG), the PTF, the Order of Pharmacists, by collecting data and legal texts and regulatory; she then proposed a restitution of her work and opened the debate.

The second part of the mission aims to:

- interviewing people or institutions who could not be met during the first phase and collecting missing data;

- a consensus workshop allowing an open debate on the findings, conclusions and recommendations of the mission and conclusions on the measures to be taken.

The third part of the mission is this final report integrating the content of the first two phases.

The workshop and the final report of the mission should lead to conclusions which will determine, in consensus:

- findings, recommendations, perspectives and strategies;
- the order of priorities of the measures to be taken;
- the chronology of the stages and successive objectives;
- the different organizations and/or people who will be responsible.

This process must keep as a common thread the desire to achieve, in the medium term, better functioning of the regulation function, as well as a precise definition of the means necessary to achieve this.

DESCRIPTION OF THE PHARMACEUTICAL SECTOR

The pharmaceutical sector is complex; it is made up of four major sectors, most of which are subdivided into sub-sectors:

- the public sector;
- the parapublic sector;
- the private sector;
- the informal sector.

The public sector

The first mission of the public pharmaceutical sector is to provide populations with quality medicines in sufficient quantities and, unlike the private sector, while ensuring its viability, at the lowest possible price.

Cost recovery is applied: all patients must purchase their prescribed medications and medical-surgical equipment. Only certain pathologies or medical cases (caesarean sections, childbirth, induced pathologies and indigents) benefit from free treatment, as do medicines delivered by national vertical programs supported by donors or by international institutions: combined treatment based on artemisinin (ACT) for malaria by the National Malaria Control Program (PNLP), antiretrovirals (ARV) for AIDS and the treatment of associated infections by the National Program for the Management and Prevention of STIs/HIV/AIDS (PNPCSP) and anti-tuberculosis drugs by the National Tuberculosis Control Program (PNLT), as well as drugs provided free of charge by a few non-governmental organizations (NGOs) and faith-based organizations.

The entire public sector is organized by the Ministry of Health and Hygiene Public (MSHP) which carries out different tasks as:

- organizer,
- importer,
- wholesaler-distributor,
- user,
- seller.

The Ministry, and particularly the DNPL, is helped in this by the National Medicines Commission (CNM), the National Medicines Quality Control Laboratory (LNCQM), the General Health Inspectorate (IGS) and the PCG.

MSHP as a procurement structure

The PCG

This structure, essential to the public system, is the subject of development later in the report.

DPS pharmacists

The head pharmacists of the “pharmacy and medical biology laboratory” sections of the Prefectural Health Directorates (DPS) have a supply, control and training role.

In this context they:

- centralize and control medication orders from health centers;
- grouping and placing these orders with the PCG;
- distribute deliveries to health centers;
- supervise the pharmaceutical activities of hospital pharmacies in regional hospitals, health centers and private pharmacies in their region;
- participate in staff training; And
- collect pharmaceutical training and write activity reports.

Pharmaceutical information is transmitted by the provincial health director to the Regional Health Directorate (DRS) then to the PCG which decentralizes.

DPS pharmacists have no organic or functional subordination with the DNPL or with the IGS. They accompany DRS pharmacists in their inspections.

MSHP as importer/ distributor

The Directorate of Administrative and Financial Affairs (DAAF) of the MSHP has a specific budget for the purchase of medicines (52 billion GNF in 2011 of which 42 billion have been committed and 30 billion GNF foreseeable for 2012), grouped over two main budget lines:

1. “Purchase of supplies and specific goods” (30.38 billion GNF in 2012) which allows the direct purchase of medicines with three priorities: medicines against tuberculosis (PNLT), products and devices for hemodialysis and payment of free care and medicines as decided by the government, such as cesarean sections and childbirth care.

2. “Vaccines” purchased for the Expanded Immunization Program (EPI) according to agreements spent with UNICEF (United Nations Children's Fund).

But other drug purchases are sometimes made. These direct purchases, carried out with the assistance of the DNPL, make the MSHP a major importer of medicines in Guinea. These purchases are made concurrently with the PCG. In this context, the PCG is placed in competition with national and international private suppliers to respond to calls for tenders carried out by its supervisory ministry within the framework of the public procurement code.

This mode of supply parallel to that, in principle exclusive[1] of the PCG, of which it is the mission, constitutes an additional destabilizing factor for the national state supply center.

[1] See State/PCG convention of 2011.

The MSHP as a client

Several branches of the MSHP are consumers and resellers of medicines:

- the National Directorate of Hospital and Care Establishments (DNEHS) which is the main user of health products with 42 public hospital pharmacies and 410 health centers or points of sale which do not come under the authority of the DNPL;
- the National Directorate of Prevention and Community Health (DNPSC);
- the National Directorate of Family Health and Reproduction.

Patients buy their medicines at the hospital pharmacy or health center at the public price set, in principle, by the government, and “according to the principle of split prescription” by purchasing, in the private sector, missing or out of stock medications. In this case, the purchase is also very often made in the illicit informal sector (at the nearest market) with, as a general rule, a lower price, unguaranteed quality and a degraded or counterfeit or even devoid of active ingredient medicine. or dangerous.

In practice, transfers are made at variable prices, depending on the purchase prices and therefore the fluctuation of the GNF.

Faced with dysfunctions in the public supply chain, health structures had acquired de facto functional and financial autonomy until 2011 and had become accustomed to sourcing their supplies locally from the private sector.

The parapublic sector

This sector is made up of national programs that have taken on a certain autonomy from the authority of the MSHP as well as programs led by international organizations.

Vertical programs

Certain vertical programs such as the PNLP or the PNPCSP de facto escape the control of the MSHP. These programs, supported by international organizations or supranational funds, have their own supply, storage (malaria) and distribution structures which largely escape the control of the DNPL.

International organisations

These are international organizations (UNFPA, UNICEF, Global Fund to Fight AIDS, Tuberculosis and Malaria) which are held to objectives and results obligations with internal audits. They have set up, out of necessity and to meet the needs of the populations, their own supply circuit in parallel with state circuits.

UNFPA (United Nations Population Fund) has become a direct operator of Guinean public health with its program for Securing Reproductive Health Products, whose activities focus on pharmaceutical supply and

equipping health structures with IT, software and heavy equipment (cold rooms, vehicles, etc.).

Imports made by these programs are carried out with simple formal control by the DNPL to the extent that the imported medicines are included on the list of essential medicines.
But, with the exception of the EPI, none of these programs have storage structures that meet “good practice” standards and each of them generally has its own independent distribution circuit.

These parallel supply circuits, which are one of the consequences of the dysfunctions of the official drug distribution circuit which have led certain donors to take its place, largely contribute to destabilizing the official drug circuit.

In addition, the free distribution of medicines no longer allows financial income for health centers, which strains their resources and reduces their purchasing capacity in the official circuit thus aggravating, in a self-sustaining mechanism, the functional structural deficit of the public sector.

It should however be noted that certain rapprochements of these structures with the official circuit have been underway since 2011 within the framework of “integrated logistics” (UNFPA in particular) unlike the EPI, supported by UNICEF, which remains, for the moment, completely independent.

The private sector

The private sector is divided into three subsectors:

- the official private sector,
- the para-formal private sector,
- the informal/illegal sector.

The last two sectors are outside the control of the MSHP and the DNPL. The informal/illegal private sector constitutes the largest part of the pharmaceutical sector in Guinea.

The formal private sector

This sector is made up of approved health structures which benefit from registration and an operating order complying with their operating conditions. But this sector nevertheless contains a certain number of uncertainties due to the limited means of the DNPL and the IGS to supervise and control compliance with “operating standards” and “good practices”.

Private pharmacies

The sector is made up of 408 pharmacies having obtained approval and having benefited from an operating order; 281 are located in the Conakry region and 127 in regions in the rest of the country.

A policy of encouraging young pharmacists to settle within the country is carried out by the Council of the Order. To do this, the National Council of the Order of Pharmacists is making a plea:

- with the DNPL to facilitate the granting of approval,
- with the prefectural authorities for a moratorium on taxes for the first year of installation, and
- with wholesale distributors to facilitate the initial establishment of a stock initial medication.

Medicines are supplied to private pharmacies by acquisition from wholesale distributors of medicines on the basis of the national nomenclature of pharmaceutical specialties and generics.

Pharmacies have the possibility of acquiring essential generic medicines (MEG) from the PCG.

In practice, wholesalers themselves determine their sales prices for medicines to pharmacies and include on the delivery invoice the prices that pharmacies must charge at the pharmacy. resale.

Wholesale distributor/ importer companies

Since 1985, 49 companies have been registered by the DNPL, including 26 in the last five years, 6 of which only benefit from approval but no operating order. All are located in Conakry, but some plan to set up depots in the region, which poses a regulatory problem, and only around ten of them actually carry out an official activity as wholesale distributors and make requests for authorizations to sell. import.

A large but unverifiable number of these wholesalers are suspected of contributing to the supply of the illicit drug market by selling off their excess stocks, unsold items and expired items. A significant number of them seem to have the sole activity of using their approval to facilitate the importation of fraudulent medicines intended for the parallel market. In addition, the management of the DNPL estimates, after contact with the customs service, that 30% of official imports escape its control.

However, a certain number of wholesale distributors actively participate in a public health mission by supplying – sometimes on credit – essential medicines to the public sector (hospital pharmacies, health centers) and the MSHP for its calls for tenders. Five of them provide support to the PCG through the delivery of medicines in DPAV (deposit payable after sale) carried out within the framework of specific agreements.

Local production

A single company, SODONGPHARMAGUI, of Chinese origin, produces locally around 40 formulations only in tablet form. This company is exempt from certain taxes and itself provides the DNPL with analysis and quality control bulletins for its production which, due to the lack of an operational LNCQM, cannot control this analytical data.

SODONGPHARMAGUI directly supplies the Guinean private market and the public market by responding to calls for tenders from the MSHP and the PCG. An agreement was recently signed between SODONGPHARMAGUI and the PCG.

Currently this industry cannot meet all the demands due to disruptions in the supply of raw materials.

There is no active policy in Guinea to encourage the establishment of a local industry.

The para-formal private sector

The para-formal private sector does not fully follow official procedures or comply with all regulations. It is made up of organizations partially or totally outside the authority of the MSHP due to:

- their particular status,
- their dependence on another guardianship and the absence of a framework agreement between their guardianship and the MSHP, and
- their exit from the formal sector of which they were a part.

There is no framework partnership agreement between private medicine, private clinics and the MSHP; there is therefore no effective control of prices, materials and best practices.
The quality of services provided to the national health system therefore varies extremely between the public sector and the different components of the private sector.

NGOs and faith-based organizations

They are not subject to the rules applicable to the public or private sector and, in fact, escape the control of the DNPL.

Medical structures in the mining sector

They are well endowed and report to the Ministry of Mines, thus escaping the authority of the MSHP.
Some have, in the past, been able to directly import medicines without DNPL control. However, certain legal provisions are provided for pharmacies of mixed economy companies (articles 62 s of the Pharmaceutical Law).

Other pharmacies and wholesale distributors/ importers

Some who had benefited from an approval and an operating order, but whose operating conditions have evolved, no longer meet the criteria established as part of their registration (disappearance or change of responsible pharmacist, expansion, change of premises or location for example…). In the absence of effective means of controlling the DNPL and the IGS, it is not possible to assess the importance of this sector which is neither totally outside the law nor strictly within the framework MSHP procedures (although 6 of the 49 officially approved wholesalers only have an approval but no operating order).

The informal sector

The informal sector is divided into two subsectors:

- The sector of traditional medicine and pharmacy, little or not formalized, but legal although not controlled, which is generally used first by patients from less well-off backgrounds before turning, if necessary, to others sectors;

- The illicit/illegal sector of counterfeit modern medicines which represents between 60% (DNPL-IGS) and 80% of the national medicine market (UNAPHAR – National Union of Private Pharmacists of Guinea).

The development of this particularly important sector is directly linked to the deficiencies of the state distribution circuit and the control of the MSHP, to the destructuring of the market, to the immediate availability of the drug "on the ground", to the attractive prices practiced in this sector, to the proximity to markets and the tolerance exercised in this area for several years by all authorities.

Although illegal, the sale of medicine on the ground has an official place in all markets across the country. In Madina, which is the largest market in Conakry, it occupies several bays and several aisles of adjoining shops located on the street and which are sometimes as well established as the official pharmacies.

A certain spread of these counterfeit medicine shops is currently observed outside traditional markets. This subject constitutes one of the concerns of the National Order of Pharmacists.

Although it has been the subject of numerous regulatory measures and taxes are paid to the Ministry of Commerce, this sector is officially ignored by the DNPL which is currently only concerned with their legal sector. It is also tolerated by all national authorities despite the following actions:

- The creation in 1999 of an Intersectoral Committee for the Fight against Parallel Markets bringing together representatives of the ministries of justice, the interior, the gendarmerie and the government administrations concerned. But this intersectoral committee was created without a budget or specific resources.

- The meeting, in 2007, of a special Council of Ministers dedicated to the development of strategies to combat parallel markets in illicit medicines.

- The cancellation order, in 2007, of the AGUIPHAR association (Guinean Association for the Dynamization of Parallel and Popular Pharmacies) recognized four years earlier by the Ministry of the Interior with the status of NGO and bringing together traders of “medicine on the ground” in defense association.

- The support provided by the Minister of Health in the fight against illicit markets of drugs :
    - o to governors, prefects, sub-prefects, security chiefs, central commissioners (note from March 2008);

- o to the chief of staff of the national gendarmerie (letter of March 2008);
- o by a letter to the Ambassador of the People's Republic of China (March 2008); And
- o with the authoritarian closure, in 2010, of parallel markets in the regions and then in Conakry. But these authoritarian closures caused a serious shortage of medicines which could not be compensated by the public and private sectors. They led to popular revolts, notably in Nzérékoré.

- The signing in June 2011 by the President of the Republic of Guinea of the Cotonou appeal for the fight against illicit medicines.

- Participation with 15 WAHO (West African Health Organization) countries in the creation in 2011 of a "Committee to combat drug counterfeiting and illicit trade".

- Collaboration with Interpol and six countries in the sub-region for the preparation of a coordinated control operation called COBRA.

The illicit medicine sector has been the subject of more than 62 theses defended at the Faculty of Pharmacy of Conakry (plus a certain number in progress since 2011) but its extent and its realities remain largely unknown.

It is important to understand that the rapid development of the illicit sector is a symptom and therefore a consequence rather than a cause of the poor functioning of the public supply circuit.

Sources of supply

The sources of supply are multiple and generally involve multiple dysfunctions:

- Poorly controlled entries at the borders of the port and airport of Conakry:
  - o fraudulent imports of medicines taxed as goods ordinary and
  - o fraudulent imports by approved but non-operational wholesale distributors.

- Permeability of certain uncontrolled borders in particular:
  - o with Sierra Leone for sutures or x-ray films,
  - o with Liberia the gateway to many drugs of Nigerian origin and Indian,
  - o with Côte d'Ivoire and areas of displaced populations and refugees,
  - o with Senegal and trade with the Touba market.

- Derived from the official market:
  - o sale of donations, particularly in the markets of Madina (Conakry) and Nzérékoré (assistance zone linked to the presence of refugees),
  - o sale of surplus, unsold and expired items from certain wholesalers.

Prices charged

The prices practiced in this sector are completely free according to the law of the market.

- Medicines with packaging that suggests that the contents comes from Western European countries or the United States are available at a lower price which can reach 50% of that charged in pharmacies[2] without being able to prejudge the authenticity of the content[3] .

- Generic medicines of poorly defined origin, often coming from Nigeria or India, are marketed with an average value 80% lower than that of equivalent generic products with a Marketing Authorization (AMM), an import authorization and sold in pharmacies.

- Conversely, certain medicines or medical devices are out of stock supplies on the official national market are sold at prices two to three times higher than those charged by the PCG or by wholesalers[4] .

Quality

- In the absence of a functional LNCQM, only the figures published in theses can be taken into consideration and indicate a rate of fraudulent molecules greater than 70% on parallel markets.

- In the absence of an operational pharmacovigilance and equipment vigilance alert system, only a few major accidents are occasionally reported[5] .

Conclusion

The pharmaceutical sector is very fragmented and polymorphous and only a very small part of it is subject to the authority of the DNPL and the MSHP.

The public and parapublic sector lacks coherence and the proliferation of alternative solutions does not allow it to fully fulfill its missions of supplying quality medicines at the best price.

The formal and para-formal private sector has developed in a context of uncertain implementation of the legislative and regulatory framework:

[2] Amoxicillin, Gynomax at 18,000 GNF instead of 23,500 GNF price of the survey carried out for the European Union in 2011).

[3] A parallel market for empty packaging exists with countries producing low-cost medicines.

[4] Catheters priced at 14,500 GNF at the PCG were sold at 25,000 GNF at the Madina market in Conakry due to stock shortages (survey carried out for the European Union in 2011).

[5] Povidone iodine imported by an approved wholesaler whose active ingredient did not correspond to the announced formula; a Betadine produced in the People's Republic of China whose stripping properties were responsible for the destruction of patients' dermis; amoxicillin replaced by cassava powder.

- The increase in the number of pharmacies and the recent creation of a certain number of private pharmacies by pharmacists belonging to the public service confirms the viability of this sector.

- The wholesale distributor sector seems to be flourishing in Guinea in the absence of active competition from the PCG, efficient control from the DNPL or the IGS, but part of this sector operates outside the legislative and regulatory framework.

The informal sector represents the largest part of the sector:

- The traditional pharmacopoeia sector remains, as in many countries, explore before being regulated.

- Although Guinea has joined the international certification system of the World Health Organization (WHO) in terms of quality assurance of medicines, the illicit sector of counterfeit medicines constitutes a state of affairs which responds to unmet needs.

- This illegal counterfeiting sector has become an essential and essential player uncontrolled public health in Guinea.

THE FUNCTIONS OF THE SYSTEM AND THE ROLE OF THE STATE

The entire pharmaceutical sector, in its diversity, should constitute a supply system with multiple faces, but regulated in its entirety by the State, guarantor of the health of its populations.

The different functions that make up a drug supply system can be defined as follows.

Distinction of functions

Distinguishing functions does not mean separating them: they must be articulated and interact to function as a system. We traditionally distinguish between the normative role and the delivery role. and the role of control. Regulation includes the normative role and that of control.

The normative function

The normative role is specific to the State. Only the State can define the standards and rules which will condition any activity relating to medicine, from its manufacture to its dispensation, from the conditions set for the exercise of the profession of pharmacist, to the marketing of a medicine, etc.

The state makes the rules, but the standards have several levels and emanate from different levels of power within the state.

In the pharmaceutical sector, the legal and regulatory framework escapes the Ministry of Health and therefore the DNPL when the standard comes directly from the Head of State by Decree. It also partly escapes it to the extent that the Law emanates from the National Transitional Council (CNT) or Parliament. Only in part, because it is the Ministry concerned by the Law which prepares it for submission to the CNT, or to Parliament.

We are therefore far from a situation where the DNPL would control the definition of standards. Let us remember again that only a Minister can commit the government: the DNPL has no autonomy and cannot decide anything alone and directly: it must, for the establishment of standards, respect the hierarchical circuit, go through the Minister or be “covered” by him.

The delivery function

The delivery role includes the organization and day-to-day operation of medicine supply chain activities: manufacturing, import, distribution, storage, distribution, sale-dispensing.

This role is not specific to the State: the State (the Ministry of Health is responsible for this) organizes the public drug supply system, but for their part, private actors freely develop their activities, provided they respect the legal and regulatory framework defined by the State and the Order of Pharmacists.

The introduction of cost recovery (Bamako initiative) and the obligation to recover the money invested to replace sold stocks and therefore to repurchase new drugs has caused an essential change for the state circuit: the purchase and sales, management, in a word a commercial character, even if its goal remains social.

This fundamental modification of the service affects both the know-how of service providers, commercial and financial issues as well as the governance of the state circuit.

The control function

This function, a logical continuation of the first two (standards, services, then verification of compliance with standards in the service) is the exclusive responsibility of the State.

Control involves sanctions for non-compliance with standards. If the control is faulty or insufficient, the sanction will not be applied. The result of this process is the appearance of a feeling of impunity.

The control role is essential for compliance with standards and, at each level of issuing these rules, it is essential for good governance. If the application of the norm is not controlled, if there is no sanction, the norm actually disappears over time.

Sovereign functions and the contractual approach

Regal functions

The word regalian is often used, but not always well understood. It is closely associated with the functions of a system and state representatives often claim to act according to the sovereign powers of the state.

The literal translation of the word regalian is: “which belongs to royalty”. At the time of royalty in France, the powers which belonged only to the King were described as regal. We will now say “to the State”. By extension, the adjective regalian designates that which is attached to sovereignty, the exclusive jurisdiction of the State. It is most often used in the expressions “regalian functions” and “regalian powers”, which have a very similar meaning.

The sovereign functions are limited to the major sovereign functions which underpin the very existence of the State and from which the State cannot exempt itself, of which it remains the holder. There are at least three:

- Ensure external security through diplomacy and territorial defense ;
- Ensure internal security, including health security or public health, and maintaining public order;
- Define the law and deliver justice.

Public health and therefore medicines are areas under the exclusive jurisdiction of the State. The law and the enactment of standards, and especially pharmaceutical regulation, is a sovereign function.

The contractual approach

We can define this approach, advocated by the WHO, as “the government's strategic option to integrate and organize by contract the participation of private actors in the implementation of the National Health Policy[6]”

The participation of private law actors is only possible for a non-sovereign function, that is to say the service, to the exclusion of normative and control functions.

The service is the activity of supplying medicines, from manufacturing or importation to sale. The State is ultimately responsible as guarantor of the health of the population, but it is not necessary for it to provide the service itself.
The provider can be public or private.

The normative and controlling State can thus entrust the service function to a structure or a set of autonomous structures, of a private, but non-profit type. The State entrusts them by agreement with a public service mission (this is a “devolution of public service”). The agreement contains the definition of the mission, the conditions for carrying out it (the “specifications”) and the obligations of both the service provider and the State. The State must provide, through the same agreement, compensation for the difficulties it involves. The service provider acts under the control of the Ministry of Health and more particularly, the DNPL (or, in other countries, the National Medicines Regulatory Authority).

The State must strengthen its essential roles: its (a) normative and (b) control functions, and to do this entrust that of service provider to an autonomous entity, which will carry out a difficult service better than it, a profession in its own right, with social aspects but also important commercial and financial aspects. A service provider with a private type of operation and organization, even if its mission is of public service, will be better equipped than the State, whose tools are not adapted (decision-making mechanisms, accounting, public procurement code , etc.), to create real competition with the private sector and to fight effectively against professionals in the illicit market. The State has an obligation to help public sector providers carry out their mission of general interest.

This delegation of function and mission does not mean for the State (the Ministry of Health):

- nor disengagement: it organizes (externally) the autonomy of the public supply system and strengthens its regulatory role;

[6] J. Perrot, “The role of contractualization in improving the performance of health systems”, WHO, Discussion Paper No. 1 (2004); “The challenges of contractualization” Contractual Approach t.2, CIDR, ASI, MMI (2003); J. Perrot, G. Carrin and F. Sergent, “The contractual approach: new partnerships for developing countries”, WHO (June 1997); J. Perrot, “The contractual approach as a tool for implementing national health policies in developing countries”, WHO (September 1999); J. Perrot and R. Fonteneau, “Contracting, a strategic option for improving health systems”, *Journal d'Economie Médicale* 21(4): 203–223.

- nor privatization: the State is one of the founders and administrators of the PCG and it is entrusted, by agreement, with a service mission by the State and the Ministry of Health remains responsible and guarantor. Private status does not mean the search for profit for service providers.

In the contractual approach, the State cannot do everything alone, but nothing will be done without the State.

The Agency or Regulatory Authority

In many Western countries, and especially for “sensitive” or evolving areas, the normative and regulatory functions are grouped within an “Agency” or “National Regulatory Authority”.

The agency is not a legal form, but a simple name. It is generally a public establishment benefiting from a status of autonomy in relation to the various ministries on which it may depend while remaining within a strictly administrative framework. Indeed, the objective is to entrust this state body with all the skills relating to the area concerned, by transferring them from several ministries. The areas concerned are, in particular, medicines, financial markets, public markets and telecommunications.

For medicine, skills concern the entire journey of the medicine, from its manufacture to its ingestion by the patient, or its destruction. They relate to the broadest normative (enactment of rules) and control functions (control, inspection, expertise, analyses, health police, sanctions).

In Africa, the use of regulatory authorities is more developed in English-speaking countries. In French-speaking Africa, Madagascar and Morocco have their medicines agencies. Other countries have adopted this type of national regulatory authority, particularly for telecommunications (Guinea), or public markets (DRC), in the interests of good governance.

Le leadership

The different functions will create interrelationships and thus function as a system thanks to their complementarity. This will not be possible without real leadership from the state, and particularly from the MSHP/DNPL. Exercising leadership means, as the WHO specifies, be the driving force, initiator and coordinator of actions.

If the “service” function is entrusted to a private structure, it will be at the initiative of the State, which will propose to potential partners and associates to initiate negotiations and which will set the framework.

Leadership and governance are part of the six pillars of public health identified by the WHO. State leadership is essential both for the functioning of the public supply circuit and for the development of a real regulatory authority. It is only under these conditions that the State will be able to fight effectively against the illicit sector.

Conclusion

Remember that regulation can be defined as the action of determining, controlling or supervising the rules of conduct in a given area.

When we consider the action of the State within the pharmaceutical sector from the strict point of view of regulation, we note that the exercise of its essential functions, normative and control, are quite dispersed: Head of the State, CNT or future Parliament, government, Minister of Health, IGS, DNPL and Regional Health Delegations, Prefectural Health Delegations, not to mention decentralization giving increased power to Governors and Prefects.

In Guinea, as in many other countries, especially in Africa, we operate within an administrative system.

However, in Western countries, since the 1980s, the regulatory function has generally been associated with a regulatory authority in the form of a state institution, independent of the Ministries, responsible for ensuring the regulation of a sector. This is the case in problematic sectors: public procurement, medicine, telecommunications, financial markets. In Guinea, the regulation of the Post and Telecommunications sector was recently entrusted to a Post and Telecommunications Regulatory Authority.

This type of administrative authority is state and has a public status, but is not subject to the hierarchical authority of a supervisory Minister; it depends neither on the controlled sector nor on the ministries or the government. It is often called an “Agency”.

The term “Agency” corresponds to the role and function assigned to the organizations thus named. For the most part, these organizations are responsible for carrying out a mission. On the other hand, their legal form is variable and can change: generally public establishments, they are sometimes associations, limited companies or even public interest groups.

The use of an independent administrative authority is the expression of the transition from administrative management to regulated management. It makes it possible to avoid the dispersion of responsibilities, the heaviness of the pyramid hierarchy, and to group all the necessary skills around an institution created for this specific purpose. We can cite notably :

- regulatory power,
- the power of sanction,
- special inspection,
- health police,
- prices,
- approvals, AMM, authorizations, registration,
- pharmacovigilance,
- the pharmacopoeia,
- health safety, traceability,
- research,
- narcotics.

The DNPL, Directorate of the MSHP, does not possess these skills and powers on its own. It is therefore statutorily less well equipped to ensure a real regulatory role.

It is necessary to refocus the missions of the DNPL, with a view to evolving towards an Agency, through a strengthening of the normative and control functions, including on the PCG, while fully delegating the service function.

LEGAL AND REGULATORY TEXTS

General

The legal and regulatory framework governing the pharmaceutical sector in Guinea essentially consists of the following texts:

- Law n°94/012/CTRN/ of March 22, 1994 relating to Pharmaceutical Legislation;
- Decree No. 94/043/PRG/SGG of March 22, 1994 relating to the regulatory provisions of Pharmaceutical Activities;
- Decree D/2011/061/PRG/SGG of March 2, 2011 relating to the responsibilities and organization of Ministry of Health and Public Hygiene: this text defines the composition of the Ministry as follows:
  - o A general secretary;
  - or A cabinet;
  - o Support services;
  - o National directorates;
  - o Related services;
  - o Public establishments;
  - o A public company;
  - o Public programs and projects;
  - o Advisory bodies;
  - o Decentralized services;
- Ministerial Order relating to the Missions and Responsibilities of the DNPL.

The Minister of Health is regularly charged by law or decree with providing implementing texts in different matters of which they only outline the main principles: this is particularly the case for the different components of the Ministry of Health, including the Directions and public establishments. The organization, definition of roles and organizational chart of the DNPL are defined by order of the Minister.

The law also creates organizations which themselves generate specific regulations, such as the Order of Pharmacists.

The texts in force in Guinea are complete and well written. They take up the classic subjects quite similar to those found in other legislations of African countries, when they have complete legislation: standards relating to medicines and pharmaceutical establishments, as well as biomedical analyzes . But this is not enough to ensure the proper functioning of the sector and its regulation.

Limits of regulations and legal texts

The power to develop standards, although it respects a strict hierarchy ranging from the most general to the most precise, from the Constitution to the ministerial circular, is relatively dispersed, in the sense that the DNPL does not bring together all the normative skills in matters pharmacy.

Standards are issued by the State but also by organizations created by it: the Order of Pharmacists, various commissions.

On the other hand, all legislation has its limits:

- firstly the difficult adequacy between the texts and a constantly evolving reality: this is particularly the case in Guinea for the pharmaceutical sector;

- then, the means of carrying out the planned arrangements.

This dual adequacy is difficult, but nevertheless necessary to achieve the desired objectives.

We need the political will to advance the legal framework by regularly innovating and enriching the country's legal arsenal. It is also necessary to distinguish the ideal, the objective targeted and the progressive measures to be adopted to get there in stages. This is a salutary realism, not a renunciation. This realism today requires flexibility and a lot of inventiveness and reactivity.

Regulations and the current situation

The Guinean legal framework is quite classic and complete, but not sufficiently adapted and applicable to the current reality of the sector. The necessary financial and human resources are not available.

The fight against the illicit market must use means other than those available to the State through the texts, even if it managed to find the financial and human resources necessary for their implementation, because the entire sector is in crisis. mutation. The State must be able to fight using structures as flexible and efficient as those used by the private sector.
The administrative nature of state action cannot compete with the generalized commercial aspect of the sector, including for the public part.

The current situation sees the coexistence of an administrative and regulatory world and a deregulated commercial world.

The pricing policy put in place after the devaluation of the CFA franc in 1994 could not be implemented, given the fluctuating political situation, the constant increase in drug prices on the international market and the significant deterioration of the GNF terms of trade (see annex).

Revision of texts in progress

A revision of the Law on Pharmaceutical Legislation and the Decree on Regulatory Provisions for Pharmaceutical Activities is currently underway.

The changes made mainly relate to:

- The Medicines Commission: more precisely the composition and method of operation of its subcommittees (revised draft Decree, art R6): it is no longer the Decree itself which determines them, but the Minister of Health, by Orders to be taken subsequently.

- The creation, in addition to the IGS, of a Pharmacy Inspection; the revised text also determines sanctions (Revised Draft Law, art 147 et seq.).

- This new inspection would no longer depend exclusively on the Minister of Health, but also on the DNPL and the Order of Pharmacists7 .

Conclusions

The planned changes are too timid, not profound enough to hope to evolve towards a real change in the sector.

For the Medicines Commission, which will be discussed more fully below, this is a missed opportunity. These modifications do not concern the General Assembly of the Commission. However, this General Assembly, made up of 42 members, only met once, and it is difficult to see the effectiveness of the work it would produce with more than forty participants.
Unfortunately, the new project maintains its composition and mission unchanged.

On the other hand, the fact of moving the composition and functioning of the sub-committees from the competence of the Head of State to that of the Minister of Health is a positive point, because this will allow the latter, assisted in this by the DNPL, to provide for simpler, more efficient, autonomous and functional subcommittees than those provided for in the current Decree. Furthermore, this competence falling to the DNPL goes in the direction of a grouping of normative powers within the DNPL, which strengthens it and allows us to hope for provisions more in line with needs and reality and closer to the competence of a regulatory authority. But the decisions have not been made and the real work of revising the subcommittees remains to be done.

Biology laboratories deserve a separate division within the DNPL given the importance of this sector which is currently very underestimated due to its largely informal nature.

The assignment of pharmacist inspectors to the DNPL seems to us to be a reform bringing real change. This is certainly a step in the right direction, that is to say the grouping of skills (in this case control and inspection) within the DNPL and the greater proximity of specialized inspectors.

It remains to be seen whether this isolated step will bear fruit if we consider

- the immensity of the task to be accomplished vis-à-vis the illicit sector

[7] It is also difficult to understand why the Order of Pharmacists is vested with power over the Inspection, which is a state institution.

- and above all the fact that control and repression will be difficult as long as the state drug supply circuit does not offer a real response to the needs of the population.

The legal form and statutes of the LNCQM are currently under discussion. Even if Decree D/2011/061/PRG/SGG relating to the responsibilities and organization of the MSHP of March 2, 2011 mentions in its article 7 the LNCQM as a public establishment, this is not currently the case. The problem of its operation also arises in an important way.

Nothing is planned either for a new legal form of the PCG, even if several of our interlocutors at the ministry told us of a project to see the PCG transformed into a non-profit association (ASBL), with a mission public service which would be entrusted to it by agreement. The PTF, although expected founding members of this association alongside the State, have not yet been invited to negotiate, it seems.

It would therefore be useful to continue and deepen the revision of the texts already in progress. The revision projects having been withdrawn from the general secretariat of the government to make modifications, we must take the opportunity to deepen the reforms in the different areas detailed below (LNCQM, ISG, PCG, CNM, Additional Division to the DNPL) and transmit innovative projects to the Minister and then to the government.

For the recommendations relating to each institution, we will refer to the examination, below, of their specific problems.

LA DNPL

If we consider the pharmaceutical sector from the point of view of the regulatory function, what is the place of DNPL within the State and the system?

The place of the DNPL in the administration

The DNPL is not an autonomous institution, it is a simple ministry department, placed under the authority of the Minister who himself is part of the government. There is of course a hierarchy within the Ministry of Health, but the only person who can commit the State and the government is the Minister himself. Any decision of the DNPL, even of its Director, is subject to the responsibility and decision of the Minister.

Likewise, the DNPL does not have direct power over the PCG, which is a Public Industrial and Commercial Establishment (EPIC) placed under the supervision of the Minister, and DNPL-PCG relations are not clearly organized. For the public sector, it is the PCG which has a direct relationship with the pharmacies of healthcare establishments and the pharmacists who are section heads of the DPS, who report to another Directorate.

The same applies to the IGS, which reports directly to the Minister and receives its mission orders from him. Furthermore, the competence of the Inspectorate is not limited to medicines.

Finally, the LNCQM depends directly on the National Institute of Public Health (INSP), which is a service attached to the Ministry of Health.

The DNPL's skills are therefore quite dispersed and it cannot control the regulation of the sector. We are, in any case, far from the powers of an independent regulatory authority.

Scope of DNPL skills

The DNPL must be able to organize and control the public supply system, the activity of the PCG and the LNCQM, the private sector (legal or not), and the activities of the PTFs and vertical programs.

According to the latest text of the MSHP determining the “missions, attributions and organization” of the DNPL (see appendix), its main tasks, classified according to roles, are as follows:

- Normative role
    - o “Develop regulatory texts” (and propose them to the Minister, and/or the government or the Head of State), organize and issue approvals, registrations and various authorizations.

- Role of provider
    - o “Organize a reliable and rational system for supplying Essential Medicines (EM) for public health facilities”. We

is here somewhat in the normative function, and especially in the service function.

- Control role
  - o Monitor compliance with standards: medicines, biological products, pharmaceutical establishments and laboratories.
  - o Organize quality control of medicines and biological products.
  - o Organize and supervise pharmacovigilance and traceability of medicines.
  - o Coordinate, monitor and evaluate the programs under its management.

The areas in which his skills are exercised are as follows:

- The public sector:
  - o the PCG (EPIC) and its regional repositories
  - o the LNCQM (dependent on the INSP)
  - o the following vertical programs: PNLP, PNLT, PNPSCP, PEV

- The private sector:
  - o wholesalers-importers o pharmacies o biomedical establishments
  - o associative importers (religious and NGOs)
  - o PTFs and international organizations
  - o the informal sector

In reality, the DNPL only exercises its powers over a minimal part of the private sector. Pharmacies in healthcare establishments (ministry services) depend from the technical and administrative points of view on the DNEHS and not on the DNPL, and their inspection is the responsibility of the pharmacist inspectors assigned to the DRS.

Operation and activities

The very extensive missions and sovereign functions of the DNPL are subject to adaptation in their execution depending on the means available, the extremely limited operational capacities at its disposal and the interpretation of these texts according to the local context and recent events at the national level.

In the appendix you will find a detailed description of the missions and operation of the DNPL. Here we focus on the elements which, for various reasons, pose problems for the DNPL in carrying out its missions.

The guarantee of having quality medicines on the national territory is subject to the effectiveness of:

- conditions for issuing marketing authorizations,
- quality control,
- import control,
- the proper functioning of public and private supply circuits, distribution and dispensing of medicines, and

- the security of these circuits, the traceability of medicines and vigilance related to their side effects.

The achievement of these conditions associated with a supply of legal medicines in sufficient quantities to meet national needs constitutes the main barrier to the entry of counterfeits into the national territory. These conditions are not currently met due to:

- lack of human and especially material resources,
- the absence of support structures, and
- the current limits of the DNPL's field of activities.

However, the environment in which the DNPL operates does not necessarily facilitate easy achievement of quality assurance of the supply of medicines:

1° The DNPL lacks the material resources essential to carrying out its missions:

- obsolete computer hardware, unprofessional and non-functional software
- absence of internal network,
- absence of data security, backup and archiving system
- lack of Internet access,
- lack of means of travel to carry out checks and inspections.

2° The questions falling within its competence are handled by a limited number of people who have full responsibility for all stages of the files, from the study to the final decision.

3° External technical opinions are lacking:

- The CNM is not sufficiently functional.
- The LNCQM is not sufficiently functional, and the structures which should do so too few call on him.
- The members of the “restricted technical subcommittees” belong to the essentials at the DNPL.

4° The MSHP calls for tenders managed by the DNPL are awarded by a review committee which includes members of the PCG which is itself the bidder and potential winner of these contracts!

5° There is a lack of resources for monitoring and verifying the application of laws and regulations, compliance with approvals, operating authorizations, etc.

6° The absence of real border control: it is random. Checks at the exit of customs areas of the port and airport have not been carried out for many years.

7°The inspection resources that can be mobilized by the DNPL are limited and ad hoc.

8° Quality control of medicines and biological products, and security of supply circuits and traceability of medicines is absent.

9° Pharmacovigilance is neither structured nor operational. Although the deputy director and two other members of the DNPL have benefited from pharmacovigilance training in Morocco, the pharmacovigilance and narcotics section sees its various functions shared between the other sections of the DNPL.

Recommendations

From a technical point of view

1° Strengthen its current capacities for controlling the conditions of registration, issuance of marketing authorizations, approvals and operating authorizations:

- Harmonize registration procedures and fees with those of the Community Economics of West African States.
- Systematically use WHO approvals and pre-certifications.
- Put the SIAMED software back into service and train staff in its maintenance[8] .
- Establish a list of reference countries whose assessments are recognized and for which MA application files can follow a simplified acceptance procedure after certification of the conformity of the file with that filed in the country of origin.

2° Provide controllers/inspectors to verify the application of laws, regulations and good pharmaceutical practices.

3° Carry out systematic quality controls on health products in laboratories approved by the WHO by charging analytical costs to laboratories, wholesalers or agencies requesting registration or importation on the basis of analysis fees officially defined, and resort to international cooperation as necessary.

The use, initially, of the LNCQM as a focal point for requests for quality analyzes formulated in Guinea and on the other hand of the results returned by external quality control laboratories should allow this national laboratory to gradually take its place. place in the regulation system in general and quality in particular.

4° Have the assessments essential for the granting of marketing authorizations carried out by approved and remunerated experts on the basis of officially agreed rates.

5° Ensure control over the determination and control of prices of health products both for importation and distribution, taking as a reference the prices charged by major international centers (Central Purchase of Essential Generic Medicines,
Essential Medicines Program, IDA – International Dispensary Association, UNICEF…).

[8] Training course and software configuration to be planned in Tunisia under the aegis of the WHO.

6° Implement the national medical biology policy.

From a functional point of view

1° Set up an efficient, coherent, interactive and secure IT system from the point of view of hardware, software, connections and backup system.

- Commission an internal network.
- Create a website.
- Implement data backup procedures.
- Collaborate with UNFPA in the implementation of CHANEL software.
- Equip yourself with a minimum of competent IT staff.

2° Carry out a complete census of approved and non-approved structures in the pharmaceutical and medical biology system:

- wholesalers/importers/distributors,
- pharmaceutical agencies,
- pharmacies and possible depots,
- pharmacy of clinics, NGOs and faith-based structures,
- hospital pharmacies and health centers,
- public and private laboratories.

Evaluate the informal part of the medicine and identify or have it identified by the most appropriate authorities (police, customs, tax administration and through the payment of fees to the authorities of the Ministry of Commerce, etc.) its different actors.

3° Record and codify information on databases according to WHO recommendations.

4° Disseminate and secure information by appropriate means, including the establishment of a documentation and information system with a website allowing you to know, in particular:

- all approved health structures, of all levels,
- medicines which benefit from marketing authorization,
- the composition of the different files to be submitted for registration, approvals, operating authorization…,
- national forms (list of essential medicines, form, etc.),
- drug prices.

5° Secure the drug circuit with the requirement of traceability throughout the territory and more particularly for importers/wholesaler distributors.

6° Establish an operational vigilance capacity and consolidate pharmaco, equipment and reaction vigilance activities.

7° Support the progress of the LNCQM by designating it as a focal point and approved expert for quality controls of medicines carried out at the national or international level to enable it to reach WHO level 2 technicality

8° Create or reactivate control over the exit of health products from bonded areas of the capital.

- Set up, if necessary, “customs clearance authorizations” issued after checking invoices, packing statements and certificates of analysis.
- Install SIAMED complementary software for import control.

9° Write guides to good distribution practices.

10° Update the conditions of practice and the curriculum necessary for the exercise of their profession and organize the essential training for:

- the pharmacists responsible for the agencies,
- pharmacists responsible for importing wholesale companies,
- medical representatives,
- regulatory enforcement and management of poisonous substances, narcotics and psychotropic drugs.

11° Redefine the functions and responsibilities of the two sections “drug economics” and “pharmaco vigilance, narcotics and quality controls”:

- Redefine the functions and responsibilities of staff (job descriptions, job descriptions) tasks).
- Define the function of “pharmacist responsible for information/pharmaco vigilance”.
- Formalize DNPL's relations with the Uppsala Monitoring Center (UMC).
- Officialize the statuses assigned personally by the UMC to the pharmacist in charge of the mission “responsible for information”.

12° Create job descriptions, task sheets and training plans for all DNPL staff.

13° Make a coherent and documented equipment plan, particularly in terms of computer equipment, means of inspection and communication (means of printing and dissemination of nomenclatures, list of essential medicines in particular) to be submitted to the authorities and possibly to the PTF.

From an institutional point of view

It would be important, to be more effective and move forward in the direction of a grouping of regulatory powers, to apply the contractual approach by making the service function (PCG) autonomous by modifying its legal form and concluding a new public service devolution agreement to the new legal entity. The DNPL would obviously remain guarantor of the proper functioning of this public circuit. It must ensure the proper execution of the agreement and the achievement of the public service mission entrusted to the PCG.

It is difficult for the Ministry of Health to organize real control over itself: we come back to the distinction of functions and the importance of the public service delegation of the “public supply” component. This will very naturally allow the DNPL to exercise its regular control over the PCG, charged by agreement with the service independently when the PCG-ASBL will no longer be a state body as currently, but an autonomous private law structure. At the same time, the DNPL will have to strengthen its normative and control roles.

Normative role

The DNPL must be closely associated with all modifications to legislative and regulatory texts. It already is, but it could play a greater and more systematic role of initiative and reflection.

A real reform of the Medicines Commission, which would make it both firstly functional, but above all effective and anchored in the real needs of the sector would be a first step.

It would be urgent to develop and propose an active pricing policy allowing better accessibility to medicines and the development of a national industry.

Control role

Here are institutional measures that can be taken in the short and medium term:

- Revise the DNPL organization chart as follows: o Create a
  Laboratories division with sovereign regulatory and control missions which could be oriented towards:
  ÿ analytical techniques and reagents, ÿ
  materials, metrology and maintenance, ÿ good
  practices, quality control and staff training.

  o Redefine, as part of the creation of this division, the hierarchical and functional relationships of the DNPL with:
  ÿ the LNCQM, which was successively attached to the INSP and the DNPL, and which must strive towards autonomy,
  ÿ the INSP on which the analytical laboratory activities depend directly from the MSHP without direct technical links with the DNPL and its laboratory section/division.

  o Merge the pharmaco, equipment and reaction vigilance sections into one section “vigilance” which could also ensure the traceability of health products.

  o Provide in the organization chart the person or service responsible for controlling the PCG and the public supply system (task of the Deputy Director?).

- Measure the importance of quality control and the necessary recourse to the expertise of a laboratory, even if it is foreign while waiting for a functional LNCQM on an analytical level.

- Gradually recreate formal links with NGOs, vertical programs, faith-based organizations and TFPs, through regular coordination meetings, for example. The aim is to establish a real partnership in the

framework of integrated logistics. Provide a driving force for national organizations and commissions involved in controlling counterfeiting and the illicit market in medicines.

- Conclude partnership agreements aimed at integrating the activities of stakeholders parapublic and private paraformal sectors.
- Participate in all PCG technical committees.
- Ensure the application of the agreement between the MSHP and the PCG.
- Establish a strategy for gradually regaining control of the informal sector, in starting for example by not tolerating its expansion outside of current markets, by prohibiting them from avenues and new spaces that it would attempt to invest, as has already been done in the past.
- Develop and propose to the government an active pricing policy allowing better accessibility of medicines and the development of a national industry.
- Make every effort to have a laboratory available as soon as possible good level control, functional and open to other stakeholders or clients; its legal form should evolve as soon as possible towards autonomy, also desired by the TFPs, and an important element of good governance in this area.

In general, develop the exercise of active control and initiative. We have the impression that the DNPL only submits to its control the structures which request it. It is the sovereign regulatory function of the State which is at stake: the leadership of the State, and particularly of the MSHP/ DNPL which is essential as the engine of the system.

THE NATIONAL MEDICINES COMMISSION

Institutional aspects

Text

The part of the Decree relating to the National Medicines Commission (CNM) is a perfect illustration of legal texts apparently well written, but inapplicable. The General Assembly includes 42 members from around twenty different ministries and organizations: it is heavy, expensive, unmanageable, unproductive and non-functional. It only met once and never really worked. Furthermore, she does not have the means. The composition of both the General Assembly and the five sub-committees is unsuitable for the missions entrusted to it.

Role

It is an advisory body. Its mission is to provide the Ministry of Health with reasoned technical advice necessary for its decision-making in the areas of medicine, notably marketing authorizations, imports (quality, conformity, price, regulations), laboratories and operators (wholesalers-importers, pharmacies, etc.), and vigilance.

It plays a role of external expertise more generally in terms of “development and implementation of the “National Pharmaceutical Policy”.

It is also responsible for making “recommendations on the socio-economic, political and regulatory aspects” of the drug.

It is therefore very broad, but the Commission does not decide: the decision rests with the Minister, via the Medicines Directorate of the MSHP.

Composition

Its composition is as follows:

- General Assembly and Permanent Secretariat;
- Five subcommittees:
  - Registration subcommittee: more or less functional, but three to five approximately members,
  - Approval subcommittee: more or less functional, but three to five approximately members,
  - Pharmacovigilance sub-committee: non-functional
  - Sub-committee national list MEG/vaccines/forms: not functional
  - Prices subcommittee: non-functional.

Its operation is provided for by the Decree:

- General Assembly: 60 members

- Five subcommittees each composed of 20 members, only two sometimes bring together a few members.

Functioning

Given its composition as well as the absence of material resources necessary for its operation, this commission only met once in a General Assembly.

Only the subcommittees for the registration of medicines and the approval of pharmaceutical companies and pharmacies have periodic activity in a restricted form and in a degraded mode of operation which does not correspond to the texts. The other subcommittees are dormant.

The registration subcommittee

The “technical registration subcommittee” generally meets twice a year to study the applications for marketing authorization for medicines and health products transmitted by the “standing committee” of the DNPL.

It is made up of only three members: a president (generally the Inspector General of Health) and two members (the head of the medicines division of the DNPL and the head of the medicine economics section of the DNPL).

It studies around 50 files per year and has the possibility of issuing three types of opinions:

- favorable opinion,
- pending with request for clarification,
- rejection.

These opinions are generally taken into account by the DNPL given the composition of this subcommittee. Two out of three members come from the DNPL: they give an opinion, then it is almost the same people who decide. In the event of a rejection notice (around 20% of cases) the applicant (laboratory or importer) is informed directly by the DNPL.

The accreditation subcommittee

After the admissibility study of requests for approval from pharmaceutical establishments by the DNPL, the file is studied by the “approval subcommittee”. This subcommittee made up of a few members is, in principle, chaired by the president of the National Council of the Order of Pharmacists. Although the mandate of the various members of the council of the order has lapsed for several years due to lack of re-election, the order thereby gives an opinion in principle for the creation of pharmacies, medical agencies, wholesalers, importers and industrial.

In the past, a certain number of unfavorable opinions from this subcommittee were not followed by the DNPL.

Recommendations

From a functional point of view

The technical opinion of the CNM is essential for the study of MA applications, their renewal and the validation of the criteria for the creation and commissioning of all pharmaceutical structures. This key element of health safety and a medicine quality policy is, however, not functional.

The implementation of autonomous advisory structures at the DNPL is an essential component which must be taken into account as part of an overall reorganization of regulation.

From an institutional point of view

The modification of the texts currently in progress is an opportunity which has not been taken to modify this state of affairs: the text of the Decree relating to the CNM has not been modified in any way in the Project.

Also, it is recommended, as part of the current modification, to modify Decree No. D 94/043/PRG/SGG defining the organization and composition of the bodies of the CNM and:

- Simply abolish the General Assembly, which is useless.
- Reduce the number of subcommittees (from five to two?).
- Simplify their composition o With
  the main concern of making the CNM operational and fulfilling its missions,
  o The number of 20 members per subcommittee
  ÿ is not realistic ÿ does
  not allow for effective and “reactive” work.
- Reduce the number of members to five or six, depending on the needs expressed by the DNPL.
- Provide independent experts as members (from various health services, the Order of Pharmacists, the University, the private sector, etc.), who give an opinion to the DNPL which decides.
- Avoid including members with skills and concerns that are far removed from the missions of the CNM (for example: a representative of the Central Bank, a representative of the Ministry of Justice, a representative of insurance companies, etc.).

THE NATIONAL DRUG QUALITY CONTROL LABORATORY

This reference laboratory is responsible for the external technical expertise necessary for the decisions of the MSHP in general and more specifically of the DNPL and must respond to requests for expertise and controls formulated by the IGS. The laboratory is more particularly responsible for controlling the quality and conformity of medicines, health products and medical devices.

Institutional aspects

The LNCQM is part of the INSP, itself being a service attached to the MSHP. However, in the Decree of March 2, 2011, it is listed as a Public Establishment, but this status did not materialize.

This status (EPIC) would suit its need for autonomy, openness towards other actors and an independence which guarantees its objectivity and good governance. This aspect is also a request from the PTFs. This EPIC could be placed under the direct responsibility of the Minister, with contractual agreements to be made with the INSP[9] , for a necessary collaboration.

Role

The LNCQM must provide independent technical and scientific expertise relating to the quality of health products, their compliance with the technical specifications necessary to obtain marketing authorization and their safety of use. This expertise is necessary for the DNPL, the CNM and the PCG to exercise their quality control functions as well as the IGS.

One of the particularities of the drug is that it is subject to an MA and then throughout its entire journey (manufacturing, importation, storage, distribution, dispensing) an evaluation aimed at guaranteeing a benefit/risk ratio that is always favorable.

Compliance checks carried out in laboratories must concern all health products: chemical and biological medicines, blood products, cosmetic products, medical devices as well as illicit and counterfeit products.

These determinations must be able to follow national and international regulatory developments to be able to validate compliance with international quality standards of the products studied and allow mutual recognition of controls between the different authorities. These controls use diverse and often sophisticated techniques: biochemical, immunological, physicochemical, biological, immunohematology, molecular biology requiring complex equipment and specific technical skills of laboratory staff.

[9] The INSP is a reference structure whose missions and functions are being redefined to play a role in the field of standardization of methods and quality control. The position of the INSP could be similar to that of the LNCQM: functional autonomy guaranteeing the independence and impartiality of the opinions given and direct reporting to the Minister.

The assessments are intended for the exercise of control for:

- confirm the quality of the products,
- provide assistance with marketing authorization and import decisions,
- provide technical arguments for the revision of MA files or to detect the arrival on the market of batches of imperfect quality to initiate corrective or preventive actions (withdrawal of batches, modification of MA, inspections, etc.),
- release batches of medicines placed in quarantine,
- carry out inventory quality monitoring (PCG),
- validate the quality of samples transmitted as part of public procurement,
- monitor markets and be able to trigger health police measures,
- detect falsified health products,
- process pharmacovigilance alerts.

The LNCQM is the necessary tool for a “quality approach” essential to improving health safety with control of all medicines and health products. Quality control is an essential link in the quality chain, from purchase to provision, knowing that a counterfeit or degraded medicine has a high cost for public health.

Functioning

The LNCQM saw its premises renovated in September 2009 thanks to funding from the African Development Bank which also enabled the supply of reagents and a certain number of technical materials which supplemented an old grant from GTZ/GIZ and a support in 2006 in reagents and training from the Pierre Fabre foundation (France).

But most of the materials made available to the LNCQM were either unsuitable or unusable because they were incomplete or accompanied by instructions in foreign languages. In addition, neither the equipment was commissioned on site nor the laboratory staff trained in these analytical areas.

Consequently, the only determinations made in pharmacology are the dissolution rate of tablets and the qualitative analysis of a limited number of drugs by the characterization of the active ingredients by thin layer chromatography (TLC) with a semi-quantitative evaluation of their concentration. by successive dilutions. The total absence of written techniques, reference documents, standards, internal and external quality control, and the extremely limited number of reference substances of undetermined origin make the few results provided hardly credible. Only the water analysis department was able to carry out basic analyzes using obsolete but valid manual techniques (titrimetry).

This situation was aggravated by:

- the almost permanent absence of electricity for most of the time of work and the absence of a generator,
- lack of water due to absence of booster (and electricity),
- sealing problems with laboratory windows preventing reliable bacteriology analyzes from being carried out.

The training which had been reserved for the laboratory director was supplemented by occasional support, provided on site, from the Pierre Fabre foundation (France) and by the visit for two years of five Chinese consultants with whom communications were limited by the lack of common language.

Following the change of ministerial team in July 2011:

- A new director has been appointed.
- Two pharmacists and nine engineers were recruited.
- An audit of the laboratory financed by the Global Fund was launched by WHO to October 2012 to be able to re-equip this laboratory thanks to an allocation from the Global Fund (RSS) estimated at $400,000 and bring it to WHO level 2.
- Discussions on laboratory equipment have been initiated with the French cooperation services.

Guinea's current membership of the West African Network of Laboratories (Burkina Faso, Senegal, Mali), supported by the Mérieux foundation, and whose objective is to strengthen biomedical analysis laboratories in West Africa should allow the LNCQM to benefit from support in the areas of staff training, quality assurance and external quality control, particularly in microbiology.

The objective of the current laboratory management is to obtain WHO prequalification as a level 2 quality control laboratory and, in the long term, to be included on the list of official WHO laboratories.

A repositioning of the supervisory authorities and in particular the DNPL could provide the beginnings of a response to the more worrying problem of the absence of recourse to the laboratory, which shows that the importance of quality control is underestimated.

Recommendations

From a functional point of view

The LNCQM is an organization essential to the quality of medicines and health products in Guinea through its support functions to the various structures of the MSHP: DNPL, IGS and PCG. But it does not currently have the technical and human capacities (personnel training) necessary to play this role.

Its commissioning requires to make it operational:

- total re-equipment in technical equipment, office automation, reagents and reference substances,
- complete training of its staff in reference techniques,
- the establishment of a documentation and repository system,
- integration into a network of operational laboratories.

The developments observed since the change of management and the prospects for renovation of buildings and acquisition of equipment by the Global Fund are favorable elements.
But support from the WHO and the Global Fund must be supplemented to:

- securing the supply of electrical energy and water;
- the provision of Internet access allowing the use of documentation essential techniques;
- practical and theoretical training (basic and specialized) for technical and management staff;
- the creation of partnerships with foreign laboratories and the sub-region referents in this field;
- integration into a technical network for quality control and scientific exchange and techniques and validation of analytical methodologies.

The LNCQM must initially position itself as a focal point and essential partner for quality vis-à-vis the PCG and the DNPL. It will initially have to subcontract most of the analytical determinations to external reference laboratories. This subcontracting will allow it to integrate into an international network of partner laboratories. The conditions for the success of this integration are linked to the partnership into which the PCG and especially the DNPL must integrate.

From an institutional point of view

As is apparently planned, giving the LNCQM the status of EPIC placed under the supervision of the MSHP:

- An EPIC would be more suitable than a Public Establishment of an Administrative nature (EPA) because its activity must include a commercial aspect. It is in any case not administrative.
- It will be endowed with autonomy and statutes.
- Its functions require autonomy, which is also necessary for its financing.
- The laboratory must be able to bill for its services and open up to customers outside the Ministry of Health.

Conclude collaboration agreements with other actors, and especially the INSP. In any case, clarify its legal form and its position in the MSHP organization chart.

THE GENERAL HEALTH INSPECTION

Institutional aspects

The IGS reports to the Minister of Health and only acts on his mission orders. It has general competence and has no specific mission in the field of medicine. It has no direct links with the DNPL.

The projects to revise the texts currently underway include a project to create a Pharmaceutical Inspection[10], which would report to the Minister, the DNLP and the Order of Pharmacists. Currently, IGS pharmacists seem to prefer the assignment of inspector pharmacists to the DNPL in a specific control role. These controllers would no longer report to the Minister, but directly to the DNPL.

Role

Charged by the Minister of Health for any investigation relating to health safety, the IGS is supported, in the field of medicine, for its daily missions in the provinces by pharmacist inspectors attached to the DPS.

Functioning

The functioning of IGS is of interest to us from a medicinal point of view. Seven pharmacist inspectors are assigned to the IGS, not including the Inspector General, himself a pharmacist.

The IGS theoretically controls the pharmacist inspectors working at the regional level, but they, due to lack of financial and logistical resources, are in practice dependent on the authority of the DRS.

Recommendations

From a functional point of view

- Make a plea to the government to obtain the necessary means to carrying out IGS missions at the pharmaceutical level.

- Give the DNPL the means to directly exercise routine control functions for compliance with standards and good pharmaceutical practices, through the assignment of pharmacist inspectors.

- Clarify and formalize the inspection functions devolved to the General Inspection, to the Regional Health Inspectorate and, in the future, the DNPL.

[10] Draft revision of Law No. L94/012/CTRN on Pharmaceutical Legislation Title V.

From an institutional point of view

- Assign pharmacist inspectors reporting directly to the DNPL to the DNPL in a specific control role; continuing on this path is positive: it means moving towards a grouping of functions and resources, and therefore towards better efficiency.

- Clarify the situation of pharmacists assigned to the region. We propose that, within the framework of decentralization and for the sake of realism, they be, no longer de facto, but officially, placed under the authority of the Governor and the DRS.

THE CENTRAL PHARMACY OF GUINEA AND THE PUBLIC SYSTEM SUPPLY

The action of the PCG is not linked to the regulatory role (normative and control functions), but it conditions the activity of the country's state supply system. In addition, its link with the DNPL and the definition of the role of the DNPL require precise clarification.

Institutional aspects

The mission

The PCG is at the center of one of the essential missions of the DNPL: the organization of a reliable and rational system of supply of essential medicines for all public health facilities. It is even more central since it acquired relative autonomy with the status of EPA, then EPIC.

It is responsible for organizing the supply of the public sector: its mission is essential because the PCG must allow public and private non-profit health facilities to have access to

- quality products (medicines, medical consumables, materials, equipment and health products),
- permanently,
- by ensuring financial accessibility,
- by ensuring geographical accessibility to populations, •

while ensuring the financial balance (viability) of the establishment.

This role is also included in the agreement which, since October 2011, binds the PCG to the State. More than a mission, it is a challenge.

The PCG has a monopoly on the supply of all public health establishments which purchase on the basis of the “Essential Medicines List”. The PCG is also authorized to sell MEG to private structures: religious and private hospitals and pharmacies, NGOs, mining sector.

Mission expenses and State counterpart

The State, it is essential, must help the EPIC to achieve its mission, because it is its sovereign power to guarantee public health (The State remains the guarantor), in particular through access throughout the territory national access to quality medicines. The State must provide the PCG with compensation for the costs and difficulties inherent in its task, including, in particular:

- the dimensions of the country and the difficulty of covering the entire territory;
- the obligation to ensure regional distribution to the outskirts;
- the obligation to charge accessible prices;

- the obligation to provide low-cost products and devices with no added value unavailable in the private sector (massive fluids, infusion devices, etc.);
- the obligation of quality, which obviously has its price;
- the obligation to ensure its financial viability despite the “social” price of the sale;
- the fact that these obligations fall on the PCG, but not on the private sector, which does not have to undergo none of these requirements.

However, currently, far from helping the PCG, the State is adding to its difficulties and problems, firstly through its legal form as a Public Establishment:

- It is the State which appoints the Director and the Board of Directors: we remain in an administrative logic, subject to the vagaries of politics, instead of evolving towards a commercial logic of specific skills.
- PCG is subject to public procurement regulations, a very cumbersome and above all very slow procedure, which puts it at a disadvantage compared to its private competitors.
- The need for flexibility and responsiveness in emergency decision-making and action is incompatible with an administrative type status and functioning, with autonomy limited to the state framework.
- The PCG is subject to public accounting, which is cumbersome and additional contradiction.
- The TFPs cannot currently participate fully in management and take part in good governance since the structure is entirely state-owned. If the PCG becomes a private law, partnership structure, the PTFs (and other private actors) who wish to do so, and whose status allows it, will be able to become founding members (with the State) and participate, by right, actively in management. At the very least, those who are not authorized by their status to be a member of a Board of Directors may be statutorily admitted as a “permanent guest” (case of the WHO and the World Bank). The European Union, as well as bilateral cooperation, have (and/or had) representatives on the Boards of Directors of several African purchasing centers (Burkina Faso for example).
- An essential guarantee of good governance is the participation in decision-making bodies of the greatest number of stakeholders, which implies regular sharing of information between them, and taking into account the various interests present.

Then by the terms of the current agreement between the PCG and the MSHP:

- In return for the costs generated by the requirements of its mission (price, distribution throughout the territory, etc.) and the absence of profits, the State must provide the PCG with the necessary resources. Gold :

- o the Guinean State does not pay subsidies to the PCG but only grants it a partial tax and customs exemption limited in time (three years)11 ;
- o the State is an important client of the PCG but it is a bad payer, which endangers its cash flow, its repurchase possibilities and therefore the viability that it itself requires by agreement.

Finally by the procurement activities of the MSHP itself:

- the State (the Ministry of Health) itself awards direct contracts, the PCG being considered as a supplier, in the same way as private wholesalers. It thus poses itself as a competitor to its own structure!

The consequences of a weak state system

- The public supply chain is failing and stock shortages are many.
- Illicit imports and sales of counterfeit medicines are numerous.
- The quality of the medicine is not guaranteed and poses dangers to populations.
- The very low prices on the illicit market can only be explained by poor quality medicines, imported illicitly: this attracts the population towards falsified or counterfeit medicines which can kill. Quality has a price.
- Many territorial areas are not covered by the private sector and the public sector is failing: the private sector prefers to go to urban centers and where there is a solvent clientele, they have no national coverage obligation. and only supply medicines with a certain profitability!
- When the public supply system does not work, people turn to cheap or simply available solutions, and the illicit sector grows increasingly.

State control over the PCG

The current legal form, the EPIC public law establishment, is entirely state-owned. Its autonomy is relative, it does not go beyond the general administrative framework. The State controls the entire structure and especially:

- the bodies of the PCG: Board of Directors and Director,
- its accounting,
- its means of importing, by imposing public procurement legislation on it.

[11] In general, in other African countries, the State's counterpart to the difficulties of the public service mission of which it remains the guarantor is either a broad tax and customs exemption, or the payment of subsidies, the exemption no longer being justified. only if subsidies are actually paid. Exemption is the most logical, quickest and safest route.

In the event of a PCG with private law status:

- The MSHP (through the DNPL and the IGS) retains control over the entire public supply system.
- The PCG operates with public funds, therefore subject to the control of the Ministry of Finances.
- The State (DNPL and Finance) has or may have representatives on the Board of Directors and in the technical commissions.
- He has contractual control over the PCG and the execution of the service mission public which was entrusted to it by agreement.

Functioning

The situation of the PCG is the consequence of developments linked to its status, its missions, the interactions of the MHSP and the entire pharmaceutical sector (see appendix).

PCG situation

Having become EPA then EPIC, the PCG intended to supply only hospital pharmacies was immediately placed in competition with the newly created private sector and with the Essential Medicines Unit supported by UNICEF and intended to supply the health care sector. primary.

Lacking cash flow and adequate stocks, it was, moreover, penalized by the pricing system, by the empowerment of hospital pharmacies, by the non-payment of State debts and by a constant increase in its external debt. linked to purchases of medicines on the international market payable in hard currencies and resold on the national market in GNF, the value of which has experienced a constant deterioration (see annex).

This situation was aggravated by non-compliance with State obligations (agreement between the State and the PCG, non-application of integrated logistics by major national programs) and the implementation of parallel supply systems. by the main donors to meet the needs of the populations.

In 2010, PCG found itself in a situation of near bankruptcy with a total loss of confidence from suppliers and its customers whose purchases were made almost entirely in the public sector, a debt equivalent to almost five times its capital. (including receivables) and an absence of merchant stock.

Evolution

Following changes in the political situation in 2011, and the appointment of new management, the PCG has experienced significant organizational and functional developments over the past year, allowing a restart of commercial activity with a relaunch. of the supply circuit and measures allowing a gradual restoration of customer and supplier confidence.

These measures focused on:

- reclassification and re-motivation of its staff with a restructuring of teams;
- negotiations carried out with local wholesale importers for the implementation of DPAV – 3 wholesalers out of the 10 contacted responded favorably – with a financial cap allowing supplies to be restarted in derogation from the public procurement code;
- the opening with certain suppliers of credit lines of up to 5 millions of dollars;
- agreements made with certain laboratories for deferred payments;
- the establishment of a cash flow plan that can be reviewed each month with payment at quarter overdue;
- a start to resolve logistics problems (only one truck was functional in 2011) ;
- the implementation of a marketing strategy and the creation of a database of the customer base ;
- the creation of a sixth depot in Boké;
- advocacy with the government for the signing of the agreement provided for in the statutes between the MSHP and the PCG, for greater accountability and for the involvement of partners in integrated logistics;
- a renewal and opening (according to the recommendations made by the PTF) of the Board of Directors which no longer had legitimacy (mandate expired since 2007).

In this context:

- The Board of Directors was renewed and opened to users and one, then several representatives of the PTF (UNICEF, and World Bank as observer).
- An agreement was signed with the MSHP on October 14, 2011.
- Customers who had become accustomed to purchasing in the private sector were once again loyalty thanks
    - o to repeated requests from the Minister of Health;
    - o the establishment by the MSHP of different parameters as performance indicators for health structures (value of purchases, rate of purchases made at the PCG, percentage of client health centers in a region, etc.);
    - o the motivations put in place by the PCG: half-yearly ranking of hospitals, DPS, health centers, mobilization rate of health centers

health by DPS, etc., with the publication of the results and the attribution of material incentives.

- Availability in relation to the overall list of medicines increased from 10% in 2011 to 50% to 55% in 2012.

- Certain international organizations (UNFPA) have begun to adhere to the principle of integrated logistics and have participated in equipping provincial depots with cold rooms.

- An agreement was signed with the only national manufacturer, SODONGPHARMAGUI (but it is currently out of supply of raw materials).

- A strengthening of the transport capacity of the PCG was carried out.

The PCG is currently the only Guinean structure whose technical commission carries out external quality control of medicines, sometimes at the LNCQM but more frequently in a foreign private laboratory.

The gross results for the year 2010 of 1.40 billion GNF increased in the first quarter of 2011 to 1.775 billion GNF and are estimated at 4.5 billion GNF for the first quarter of 2012 with an announced availability of 50 to 55% compared to the overall list of the nomenclature.

The list of available MEGs is now distributed each month to health facilities and for the first time the Guinean government paid, upon delivery, for its orders for “Caesarean kits” falling within the framework of its free policy.

The pre-call for tenders for drug purchases at the end of 2011, which received responses from 20 suppliers, instead of 10 for the previous one, is a sign of the gradual restoration of supplier confidence.

The functional organization of the PCG, established with the support of the European Union, is coherent and functional and corresponds to that of a modern purchasing center (2008 European Union assessment - see appendix). The accreditation of part of the PCG by the Global Fund (ARV) confirms the confidence placed in the PCG by this organization.

But, due to its EPIC status and the application of public procurement code procedures:

- Limiting the validity of purchase orders to one year is inappropriate with the pharmaceutical industry's manufacturing plans which are made over two to three years.

- A period of 10 to 12 months after starting the process is necessary, within best conditions for obtaining the first deliveries.

- Staggering deliveries beyond 18 months no longer makes it possible to force the supplier to comply with specifications.

- In addition, this procedure only allows you to contact suppliers who do not require, when ordering, a prepayment incompatible with the administrative rules of payment after service provided.

The storage facility, which was partially renovated thanks to support from the Global Fund, does not yet meet, for the most part, the standards of good pharmaceutical practices and security of supplies.

The overarching issue of debt and receivables estimated at 25 billion GNF (approximately USD 3.5 million) remains a major question which will have to be addressed concomitantly with that of a possible change of status and the involvement of the TFPs.

Perspectives

A project to extend central and regional infrastructure and support regional rolling logistics is currently being studied with the Global Fund as part of round 10.

A project to reactivate the Users' Consultative Committee has been the subject of a new submission.

A “Medicines for all” project is currently being studied at the PCG, to:

- train the salespeople of the 412 health centers,
- train trainers: their training will be financed by UNICEF and this training will be managed by the DNPL,
- rehabilitate points of sale,
- make medicines available to health centers.

The principle of simultaneously relaunching the supply and demand for medicines can only create a dynamic favorable to the restoration of the medicine circuit.

However, previous experiences of boosting demand such as that carried out in 2010 (in a different context) for Primary Health Care Support showed a rate of return on investment estimated at 20% (see appendix 3).

A technical and financial audit of the PCG should be organized under the aegis of the European Union during the last quarter of 2012 and the first quarter of 2013.

Recommendations

From a functional point of view

- Lower the price of medicines by abandoning the DPAV as soon as possible for large-scale calls for tenders to obtain prices comparable to those of other national purchasing centers in the sub-region.

- Secure all of its supply/distribution circuits as part of the traceability of medicines and the quality approach.
- Consolidate and secure its financial circuits.
- Restore and consolidate cash flow.
- Clear the issue of supplier debt/State debt.
- Seek solutions for its recapitalization.
- Continue the integrated logistics approach with all PTFs and in particular with UNICEF.
- Strengthen its logistics and bring it up to standard, in compliance with “good practices”, the storage conditions of its health products.
- Strengthen technical links with the DNPL for shared information on all data concerning medicines, suppliers and public sector customers.
- Finance its “medicines for all” project and put in place the conditions essential to the sustainability of the operation of the project with an internal and external control system allowing the traceability of medicines and the security of financial circuits.

From an institutional point of view

- Give the PCG a private law status for real autonomy and resources of action freed from the burdens of state status (the non-profit organization is at first glance the only possible one in the Guinean legal arsenal).
- The State must by agreement entrust the PCG with a public service mission and with it the “delivery” function of the system, and strengthen the exercise of its normative and control functions (contractual approach), via the DNPL or an agency of the medicine.
- Provide through this agreement a counterpart to the requirements of the public service mission, via total tax and customs exemption.
- To do this, conclude a (new) agreement with the new non-profit organization structure: this is obligatory in the event of a change in the legal form of the PCG. But above all, the importance of the convention goes beyond the scope of its provisions and its content: it makes it possible to complete and strengthen what the private nature of a structure would take away as power from the State in relation to a legal entity. audience. The contractual link will replace the hierarchical link. The agreement must provide in particular for the organization of a regular exchange of information between PCG and DNPL, PCG and the Directorate of Healthcare Establishments, with a view to enabling better governance.
- Launch negotiations with the PTFs and potential partners of the non-profit organization for a decision in partnership based on a global agreement: we are thinking in particular, in addition to the PTFs, of civil society, of users: health committees, hospitals, NGOs, etc.

- Beyond the contractual relationship between the State and a private law structure, the contractualization will allow a PCG that has become truly autonomous to contract with, upwards, other actors in the health system – we are thinking in particular of vertical programs – and, downwards, with healthcare establishments for an improvement in efficiency of the entire drug supply chain.

- The State must ensure the financing of the PCG:
  - o by granting the MSHP a greater share of the state budget, for example by taking advantage of the resources of the Heavily Indebted Poor Countries Initiative fund mechanism;
  - o by granting it subsidies;
  - o by exempting it as much as possible from taxes and customs duties.

- By separate agreement: it is essential to provide by separate agreement a system of regular payment by the State of its own orders (army, hospitals, etc.) so as not to burden the PCG's treasury and in this case endanger its replenishment and even its survival.

- This new legal form will strengthen the State in its control role:
  - o by the DNPL as guarantor of the public service mission entrusted to the PCG and by its reinforced activity vis-à-vis the public system: inspection and supervision;
  - o via State representatives on the Board of Directors;
  - o through contractual control: verifying the proper execution of obligations conventional.

OUTLOOK AND GENERAL RECOMMENDATIONS

Synthesis

It must be noted that the organization and operation of the pharmaceutical sector in Guinea does not allow the government to meet its mission of providing its populations with quality health products at affordable prices. The main problems in this sector are:

- Financier :
  - o The share of the budget devoted to health is very low and even decreasing.
  - o Debt to PCG suppliers is a major obstacle to achieving its goals.
- Organizational
- Statutory

The question of regulating the pharmaceutical sector, which can only arise for a functional sector, goes far beyond the scope of the DNPL's current activities. Indeed, the illicit market developed and organized on a large scale quickly. It represents at least 60% of the drug market. Alongside the private and informal sectors, the public sector, whose essential supply and distribution tool is the PCG, is not yet sufficiently functional to constitute a reliable and financially accessible solution for poor populations.

However, the DNPL, having very insufficient material, financial and human resources, directs the majority of its activities on the one hand towards the only part of the private sector which already respects the regulations in force, on the other hand, when it can benefit from funding to do so, towards the supervision of pharmacies in public sector health facilities in their operation falls under the authority of the DNEHS.

The preceding conclusions and recommendations are proposals and lists of points for improvement, but the question is clearly posed of the feasibility and above all of the advisability of achieving the ideal provided for by the various legal and regulatory texts.

On the one hand because it is difficult to achieve the legal ideal in one step. It is certainly more useful to plan steps, stages, which will allow in each area, not to immediately arrive at an ideal, but to move towards it.

On the other hand, because the ideal advocated and imposed by the texts follows a traditional administrative logic, while the West, itself formerly the author of this administrative logic, has evolved towards a culture of management, of autonomous agencies specialists, accountability in the function, good governance: these concepts do not fit well within the framework of the administrative hierarchy.

Finally, because reality has evolved, in particular the pharmaceutical sector. The public sector has moved from free distribution of medicines to a real supply circuit involving import structures, storage work,

intermediary deposits to be remunerated, payment by patients, reassortment and reconstitution of stocks, in short a commercial type activity, with the additional constraints of affordable price, availability of the drug throughout the territory, while the commercial sector aims its profit, without worrying about the financial and geographical accessibility of a quality medicine. These changes perhaps make the texts partly inapplicable today, and in any case unsuitable.

As has been said, the legal and regulatory framework for the pharmaceutical sector in Guinea is theoretically satisfactory. All stakeholders, however, agree to recognize that the texts are not applied. This is certainly due to the obvious lack of resources. This is also and above all due to the fact that they do not provide a response to the current complexity of the sector.

Beyond the lists of specific recommendations intended to come closer to the texts, it seems urgent to initiate without delay a broader and more ambitious reflection on the governance of the sector as it currently stands. Let us put aside, for the time of reflection, the content of the legal texts to imagine the best response to provide for real State governance in the field of medicines in Guinea in the 21st century . Will training, computers and adapted programs and other one-off measures, added together, alone make it possible to modify the regulation of the sector to the point of being able to correspond to the requirements of the texts? And therefore eradicate the informal sector, which, according to the Law, does not exist and cannot exist?

We believe that we must think in terms of needs: the texts, possibly modified, will thus be part of a dynamic of recovery of the sector by the State.

- The first need is, for all Guineans, to have, throughout the country, quality medicines at an affordable price.

- The second need, once the first is well on the way to being achieved, is, for the State and in the general interest, to be able to regulate the entire sector. And therefore to fight against the illicit sector.

The first need, the management of the public supply circuit is a real profession with a commercial type of activity, with important technical and logistical aspects, even if its purpose is social. This requires entrusting it to an autonomous actor who will work under the responsibility of the State.

The second, the exercise of the regulatory function (normative function and control of their application), requires that the State evolves from an administrative hierarchy (and logic), towards an independent state regulatory authority (of the “agency” type) with a radical grouping of the skills necessary for regulating the sector within a single institution (standards, various authorizations, use of a control laboratory, expertise, inspection, sanctions, research, pharmacovigilance, etc.) and maximized functionality.

Recommendations: priorities, strategy and timeline

We therefore believe that it is necessary to integrate the lists of recommendations into this longer-term vision, and organize a strategy and a chronology which allow the MSHP (and more generally the government) and interested TFPs to evolve step by step towards these objectives. .

Be careful, however: this can only be achieved under the impetus and leadership of the State.

The public procurement circuit: delegating the service function

Principle

According to the needs defined in the previous paragraph, it is first a question of determining how to move forward to make the public circuit functional and efficient for the population as soon as possible. Once the response to this essential need of the populations is in place (which is one of the essential missions of any State), recourse to the illicit market will lose its main reason for existence.

Furthermore, this question resonates with the reflection, interest, sensitivity and perception of urgency of all TFPs and international organizations. They are the ones expressing it, and they are each tempted to set up their own supply chain, which is costly and not necessarily effective. In this case, nothing is built sustainably for the country.

The service function is not a sovereign power. An actor with a private law status, capable of developing this demanding commercial activity with all available means of management in the broadest sense must be entrusted by the State with a public service mission, by agreement setting out the terms and conditions. of the missions, with strict obligations, responsible for reporting to the co-contracting State, which remains the guarantor of the health of the populations. It seems indisputable that the current public establishment status (EPIC) of the PCG is a blocking factor in today's context. By applying the contractual approach advocated by the WHO, the service function must be entrusted by the State to an autonomous structure under private law, the non-profit association bringing together the State, users and partners being a form successfully tested in other countries[12] .

This reform can and must be undertaken without delay, by opening negotiations with all potential partners, future members of the Board of Directors of the non-profit association. The participation in the Board of Directors of all the founding actors is a guarantee of good governance, provided of course that they agree to get involved in the work of administrators and to devote the necessary time to it. For the public system to be effective: all actors must play the game of the public tool: MSHP in the first place, Programs verticals, PTFs, NGOs, etc.

The control of the State is threefold: (a) by the exercise of its regulatory function, which must be strengthened (DNPL), (b) by its presence within the Board of Directors and (c) by the control of the execution of contractual obligations.

[12] Burkina Faso and Rwanda, for example.

The question of recapitalization by the State and the possible participation of PTFs in the financing of certain positions will have to be negotiated.

Actions to be taken

The “entrance door” to an in-depth reform, involving the TFPs, is probably to respond first to the first need of the population, a need relayed by the clearly expressed concerns of donors: a public supply circuit and therefore a functional PCG. Real and concrete progress by the PCG in accomplishing its mission would make it possible to consider the rest of the reforms with more serenity and with the confidence of vertical programs and TFPs.

Taking the two needs defined above as objectives, we could prioritize the main areas of recommendations as follows, placed in chronological order and prioritized according to their feasibility:

- Providing the PCG with a new legal form (ASBL), more than a recommendation, is a priority element of any reform of the sector.
  - o Who? MSHP and PTF negotiation.
  - o Financing: State, and possibly PTF after negotiations, if ASBL.

- Clean up your financial situation on this occasion.
  - o Who? MSHP and PTF negotiation.
  - o Financing: State, and possibly PTF after negotiations, if ASBL.

- Respect the exclusive role of the PCG as a public purchasing center.

- Conclude a new PCG-ASBL/MSHP-Ministry of Finance agreement.
  - oWui? MSHP and Ministry of Finance and PCG Board of Directors
    ASBL.

- Carry out reforms to the functioning of the PCG.
  - oWui? Board of Directors (MSHP and PTF and PCG and other stakeholders).
  - o Financing: members of the non-profit organization: State and PTF.

Reform of the regulatory function: towards a medicines agency

Principle

Remember that the regulatory role can be defined as the action of determining, controlling or supervising the rules of conduct in a given area.

Many Western states are moving towards the regulation of specific sectors, such as medicine, food safety, financial markets, audiovisual, public markets,13 towards the creation of autonomous agencies, with the status of public establishment. independent of the Ministries. Guinea itself created an Authority a few years ago
of Post and Telecommunications Regulation in the form of a public establishment.

[13] The DRC recently created a Public Procurement Regulatory Authority, with the status of a public establishment.

The Regulatory Authority concentrates the normative and control roles; it is endowed with the necessary powers and means (definitions of rules, control, policing and sanctions).
Its activity requires both internal and external control. It brings together, autonomously, all the necessary skills, without depending on the hierarchy or a particular minister.

It is recommended that the MSHP and the Guinean government set a medium-term objective of creating a Medicines Regulatory Authority (or Medicines Agency). HAS
short term, to take all measures and carry out all possible reforms provided that they go in the direction of the creation of this regulatory authority and prepare it, mainly by grouping together skills, responsibilities and resources.

Without waiting for the creation of an agency, the priority actions to be carried out in the short term for regulation of the pharmaceutical sector in parallel with a supply circuit
functional public are:

Make the DNPL capable of fulfilling its functions

- Reorganize the DNPL according to its organization chart and clearly define the positions and functions of each person with a clear definition of job descriptions (you need help for this).

- Provide the DNPL with an IT tool that allows it to work normally.

- Strengthen operations in the areas of:
  - marketing authorizations,
  - the establishment of a control/inspection function with priority to inventory the pharmaceutical sector and ensure traceability of medicines, particularly among wholesalers, and effective control of imports,
  - to support and strengthen the area of vigilance.

Make support structures functional

- Create an autonomous and restricted MA commission as in Ivory Coast.

- Strengthen pharmacovigilance which could have a certain internal autonomy within the DNPL and behave as support structures (see above).

- Strengthen quality control with the help of the LNCQM which deserves to be pressed.

- Create an autonomous and restricted accreditation commission.

As always, there is a great need for training, it is a commonplace but it is relatively easy to do and essential.

Actions to be taken

- DNPL: equip it with computer equipment and vehicles, list and organize the necessary training and carry out other internal reforms: grouping and development of vigilance activities, archiving, reflection on leadership, etc.
  - Who? MSHP.
  - o Financing: State and possibly PTF after negotiations.

- Create a laboratory division at the DNPL.
  - o Who? Government.
  - o Financing: State.

- As soon as the DNPL has the minimum means, take inventory of the entire formal and informal pharmaceutical sector and gradually extend its authority over the entire sector, stop the expansion of the illicit market outside the official pharmaceutical markets. cities, program stages of the fight in stages for the decline of this sector.
  - o Who? IGS, Pharmaceutical Inspection and DNPL, Order of Pharmacists. The latter will have to create collaborations (customs, Ministry of Finance, port authorities, etc.).
- Modify the texts: overhaul of the CNM.
  - o Who? MSHP and government.
  - o Financing: State.

- Create the pharmaceutical inspection: modification of the texts.
  - o Who? MSHP and government.
  - o Financing: State.

- LNCQM: proceed with the modification of the status, its evaluation and achieve its accession at the WHO level, equip it,…
  - Who? MSHP and OMS.
  - o Expected funding: Global Fund + others.

Implementation and financing of reforms

TFPs are generally, and logically, reluctant to finance the exercise of sovereign functions of the State, especially since their political status does not always allow them to do so. Likewise, they are reluctant to participate in the financing of a sector if the State does not demonstrate, by increasing its own contribution, its political will in the face of the issues.

This is obviously the case for the pharmaceutical sector: if the PTFs today finance the acquisition and distribution of medicines, the negotiation of their participation in the recapitalization and financing of PCG reforms should involve a contribution from the 'State. This can happen, in addition to the change of legal form, by:

- payment by the State of its orders to the PCG (which for the first time was made in 2012);

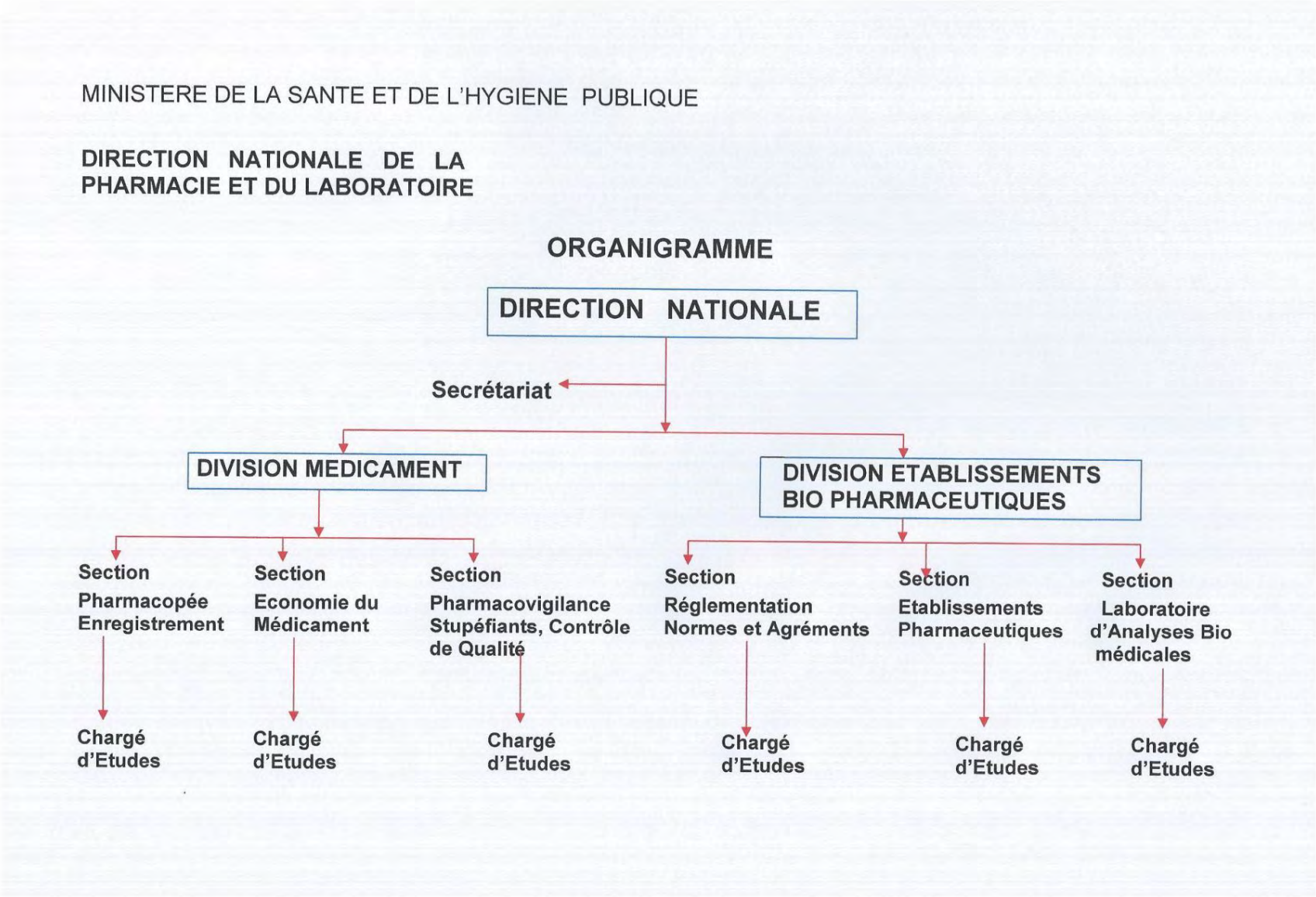
- the use of debt cancellation mechanisms for heavily indebted poor countries in the health sector to unlock investment opportunities in health

pharmaceutical sector and especially the cancellation of the PCG debt, provided that the necessary procedures are carried out;

- the total tax and customs exemptions contractually granted to the PCG;
- recognition of debts held by the PCG in respect of health facilities public;
- increasing the share of the state budget dedicated to the MSHP.

The influence of power is measured by the capacity to act; it is on this issue that the effectiveness of future reforms will be judged.

ANNEX 1. ORGANIZATIONAL CHART OF THE DNPL



ANNEX 2. COMPOSITION AND POWERS OF THE DNPL

The DNPL is made up of two divisions, each made up of three sections.

1. The drug division

It is more generally responsible for:

- to develop regulations relating to medicines and poisonous substances and to ensure the application of international conventions relating to narcotics and psychotropic drugs,
- to register medicines, vaccines, products and laboratory reagents,
- develop and update national lists of essential medicines, reagents and biomedical technical supplies,
- organize and supervise pharmacovigilance,
- to promote and popularize traditional pharmacopoeia,
- to assess national needs for medicines, reagents and technical supplies, to establish a database on medicine prices according to sources of supply and to keep import and local production statistics,
- to validate the specifications of the tender files for medicines, reagents, medical-surgical materials and to participate in the corresponding award committees,
- to monitor medication consumption,
- to develop ethical rules relating to promotion and advertising on the medicine.

This division includes the sections:

1. pharmacopoeia,
2. economics of medicine,
3. pharmacovigilance, narcotics and quality controls.

1.1. The pharmacopoeia section

This section is loaded:

- to examine the registration files of pharmaceutical products and laboratories taking into account the recommendations of the CNM,
- to organize a database concerning medicines whose marketing is authorized in Guinea,
- to revise the national form,
- to update and disseminate the National List of Essential Medicines,
- to monitor research activities on traditional medicines, their implementation pharmaceutical form and their uses,
- to develop regulations relating to the marketing of traditional medicines in collaboration with the traditional medicine service,
- to monitor the application of ethical rules on the promotion of medicines,
- coordinate the development or revision of flow charts and therapeutic guides.

1.2 The economic section of the medicine

This section is loaded:

- assess national needs for medicines,
- to gather information on sources of supply of medicines,
- to keep statistics on imports and local manufacturing of medicines,
- to validate the tender specifications for pharmaceutical laboratory products and to follow the procurement procedures concerning these products,
- to keep medication consumption statistics,
- to propose the keys for distributing credits for the purchase of medicines and consumables for public health facilities,
- to gather information allowing periodic reviews of the structure of selling price of pharmaceutical products,
- to participate in the training of prescribers and in informing the public regarding the rational use of medications.

1.3. The pharmacovigilance, narcotics and quality control section

This section is loaded:

- to gather, analyze and disseminate information within the framework of pharmacovigilance,
- to assess national needs for narcotics,
- to issue authorizations to import narcotics,
- to monitor the consumption of narcotics and provide periodic statistics to the INCB (International Narcotics Control Board),
- to participate in the work of the National Cell for the Fight against Drug Abuse,
- to develop and monitor the application of regulations on the quality control of medicines and biological products.

2. The biopharmaceutical establishments and laboratories division

It is generally loaded with:

- to develop infrastructure and equipment standards concerning establishments for the production, storage and distribution of medicines, reagents and medical-surgical materials, biomedical analysis laboratories in collaboration with the competent services of the department,
- to develop standards for the distribution of pharmaceutical pharmacies and laboratories biomedical,
- to study applications for approval for the opening of pharmacies of private biomedical laboratories and to monitor the conditions of their economic viability,
- -organize, coordinate and supervise pharmaceutical establishments and public laboratories,
- to ensure the regulations governing the exercise of the pharmaceutical and clinical biology professions,
- to participate in the training of staff in management and in general, in the areas of its competence.

The biopharmaceutical establishments and laboratory division includes the sections:

1. regulations, standards, approvals,
2. pharmaceutical establishments,
3. laboratories.

2.1. The regulations, standards and approvals section

This section is loaded:

- to develop regulations relating to pharmaceutical establishments,
- to examine requests for approval for the opening of establishments pharmaceuticals,
- to define the distribution standards for pharmaceutical establishments as part of the studies carried out on the health map,
- to follow the corresponding equipment programs,
- participate in the development of training modules as well as continuing education pharmacy staff.

2.2. The pharmaceutical establishments section

This section is loaded:

- to monitor the demographics of pharmacists, medical biologists, pharmacy technicians and their distribution across the national territory,
- to participate in improving the management of pharmaceutical establishments,
- analyze statistics relating to pharmaceutical establishments, in particular their number, their geographical distribution, their activity as well as their economic viability,
- to participate in the development of codes of ethics applicable to professions concerned,
- to participate in improving their qualifications,
- to maintain and strengthen close collaboration between advisory bodies in the field of pharmacy and laboratory (Order, Commissions, associations, unions),
- to develop the pharmacy supervision framework.

2.3. The biomedical analysis laboratory section

This section is loaded:

- to set the conditions for authorization to open medical biology analysis laboratories,
- to regulate the modalities of registration of reagents intended for laboratories medical biology analyses,
- to ensure the dissemination of the order relating to the “Guide to the proper execution of medical biology analyses”,
- to promote training plans through the network of Guinean laboratories, the national reference laboratory,
- to organize external audits of laboratories in a transversal manner,
- to intensify transversal links with the DRS and the DPS.

The reorganization of this organization chart is currently being studied at the request of the Minister of Health, as has been previously recommended in particular in the reports of

the European Union, with the transformation of the “biomedical analysis section” into a laboratory division (but the constraint of creating at least three sections per division can constitute an obstacle, particularly in terms of personnel and skills).

ANNEX 3. DNPL: OPERATION AND ACTIVITIES

The DNPL benefited from technical support from the European Union between 2004 and 2007 thanks to a financing agreement with organizational and technical support in the field of medicines and medical biology.

This structuring technical assistance was provided:

- in the field of medicines by two short-term technical assistants (an expert pharmacist for three months, an expert economist for three months),
- in the laboratory field by an expert biologist for one month.

But, due to the chronic absence of suitable means necessary to carry out its missions, adaptive strategies and mechanisms have been put in place to allow it to operate at a minimum.

1. The medicines division

To carry out its missions, this division has six pharmacists (three of whom are actually operational).

1.1. The pharmacopoeia section.

This section, which is made up of two pharmacists (a section head and a research manager), is responsible for the quality of the medicine by:

- management of registration requests,
- the issuance of marketing authorizations for medicines and health products, • import authorizations for medicines and health products,
- updating the list of essential medicines and the National Formulary of Medicine.

1.1.1. Registration and marketing authorization for medicines and health products (AMM).

In theory

Each formulation, each pharmaceutical form, each presentation and each dosage of the same medicine must benefit from a marketing authorization issued for five years.

Any modification to the formulation, presentation (packaging, technical instructions, color presentation of the product, etc.), or technical specifications must be the subject of a new MA application.

In the absence of any modification, a renewal request must be made every five years.

Applications for registration and issuance of MAs include several stages and proceed, theoretically, according to the following scheme:

1° The “technical admissibility” of registration requests made by pharmaceutical laboratories or under the cover of importing wholesalers or agencies is carried out in order to verify the administrative conformity of the files.

The file which must include the technical specifications of the product and samples allowing quality control and conformity control of these technical specifications to be carried out.

2° Compliant files are directed by “the standing committee” (in reality by the medicines division) towards:

- the National Medicines Commission for technical expertise in the area of competence of four of the five sub-committees for:
  - o possible medical expertise,
  - o study of compliance with the National List of Essential Medicines and Vaccines, with the Formulary and Therapeutic Guide, o compliance of prices compared to other equivalent molecules,
  - o looking for possible vigilance problems.

- the National Laboratory for the Quality Control of Medicines which must carry out a conformity check of the samples in relation to the technical specifications of the registration file/AMM and in relation to the standards defined by the pharmacopoeias and international bodies,

- the General Health Inspectorate.

3° After study of these requests by these organizations, all the expert reports are transmitted to the registration subcommittee which gives an opinion to the DNPL. This opinion, which is advisory and can be an acceptance of the file, a request for additional studies or a rejection, does not bind the DNPL.

4° After acceptance of the file by the DNPL, registration is carried out and a draft MA is drawn up after payment of the registration fees.

These rights, which were originally 100,000 GNF, increased to 900,000 GNF with the authorization of the Ministry of Finance (USD 125.19).

5° The marketing authorization is subject to the signature of the Minister of Health and the AMM is registered with the general secretariat of the government.

In practice and taking into account the functional problems of the CNM and the dysfunctions of the LNCQM, adaptive procedures have been implemented and the entire file is managed directly by the Medicines Division of the DNPL.

6° The administrative admissibility study of the files is carried out by the pharmacopoeia section.

7° Due to the operating difficulties of the CNM, the study of the registration and marketing authorization application file which should be carried out by the four technical sub-commissions of the CNM is entirely carried out by a single “sub-commission restricted technique”.

This restricted technical subcommittee, which meets at the DNPL under the chairmanship of the general inspector of health, is generally made up of three members including the head of the medicines division and the head of the medicine economics section of the DNPL. .

8° In certain cases, an external technical opinion is requested on a fraternal basis from clinical doctors from one of the two University Hospital Centers of Conakry.

9° The prices requested by the importer must, to be accepted, be close to the median prices of equivalent medicines existing on the Guinean market. A price that is too low casts doubt on the quality of the medicine and a price that is too high compared to the price of equivalent medicines cannot justify the granting of a marketing authorization.

10° A brief compliance check may be requested from the LNCQM which is, in principle, able to:

- validate the physical characteristics of the tablets (size, weight, dissolution speed) to the exclusion of other pharmaceutical formulations,
- validate the conformity of the active ingredient for all pharmaceutical forms using a simple – TLC – technique (provided that the laboratory has the corresponding reference molecules),
- carry out a semi-quantitative determination of the concentration of the active ingredient by carrying out TLC with successive dilutions of the product to be tested.

But, these simple determinations do not correspond to those required by the WHO for level 1 laboratories and, moreover, no register and no archive of analytical results are available.

11° After the decision of the “select committee”, the applicant is directly informed of the action taken (acceptance, rejection or request for additional studies).

In the event of a favorable opinion, registration is entirely carried out manually at the DNPL and there is no real database because the registration and marketing authorization management software (SIAMED) made available by the WHO does not has been more functional for five years.

There is no archive room, but some data is kept on the old DNPL software “Infophar” used on the division head's computer and whose data is saved on a USB key personally belonging to the Head of Division. These decisions are not the subject of official publication or publicity.

The technical subcommittee meets twice a year and deals with around fifty files each year.

There is an accelerated procedure for drugs appearing on the national essential drugs list (approximately six months).

WHO certifications are used for medicines used by international agencies with fast-track registration.

There are 2,256 MAs in the nomenclature and there are certain difficulties in finding the files every five years for renewal requests, nevertheless, except for large laboratories, it is the DNPL which informs importers of the end of validity of the MAs. and the impossibility of issuing import visas linked to this deadline.

The renewal of MAs is done almost automatically every five years for a restricted fee of 50,000 GNF (USD 6.95) at the request of importers / wholesalers / agencies and provided that there has been no modification of the medicine or its presentation.

1.1.2. Import authorization

In theory

Authorization to import health products is subject to the issuance by the DNPL of an import visa.

To benefit from an import visa authorizing the importation of health products, the laboratory or wholesale distributor must be registered and the medicine must have an MA.

In principle, only medicines registered in the National Formulary can benefit from an import visa but, in fact, any medicine with an MA can be imported.

In practice

Medicines and health products officially imported in 2011 correspond to an estimated value of 226.547 billion GNF, public and private sectors combined.

But, due to lack of software, it is not possible to know the amount of drug import authorizations issued in 2011.

Moreover :

- imports of medicines and health products carried out by natural or legal persons not approved by the DNPL are not its responsibility,
- many medicines and health products are imported as "ordinary goods" and are not counted in customs statistics as health products,
- part of official imports escape the control of the DNPL (30% according to the customs Service),

Consequently, the number, nature and quality of imported health products cannot be known, especially since they make it possible to supply the informal market without any control. And only the IGS has the possibility, at the request of the Minister of Health, to have batches of medicines or counterfeits imported fraudulently into Guinea withdrawn.

1.1.3. National forms

The production and updating of technical documents related to medicines also falls within the competence of this section:

- The National List of Essential Medicines was revised in 2006, 2009 and 2012 but was not published despite available financial support from WHO of USD 15,000. But a workshop to revise this list was organized in July 2012 with the participation of members of MSH.

- The nomenclature of generic pharmaceutical specialties intended for the public and private sectors produced in 2008 was revised in 2011 but was not published in. There is only one copy kept by the management of the DNPL.
- The National List of Social Medicines dates from 2009.

1.2. The drug economics section.

In theory

Since the head of this section was promoted to director of the DNPL in July 2011, this section only includes a pharmacist responsible for the missions of this section as defined in appendix 1 paragraphs 1.2

In practice

This section carries out various missions including missions assigned to the pharmacovigilance, narcotics and quality control section.

1.2.1. The representation of the DNPL on the technical commission of the PCG for the examination of calls for tenders for health products.

1.2.2. The production and management of tender files for orders from the DAAF of the MSHP.

Calls for tenders are made in dollars or euros on the basis of suppliers pre-selected by the PCG.

They are submitted to private suppliers as well as to the PCG which can bid in the same way as laboratories and wholesale distributors in the private sector.

A technical commission chaired by the Ministry of Economy and Finance composed of two members of the DNPL, two members of the PCG and a member of the administrative and financial management of the MSHP proceeds to examine the submissions.

After opening the bids in public and announcing the bid proposals in batches, the allocations are made by item.

If the PCG withdraws the call for tenders, it is retained as a service provider, but, given its status, it is required to launch a new call for tenders to international suppliers, which extends the delivery times of several months and increases the cost of medications.

In this context, the PCG is both judge and party as the bidder and potential winner of the contract.

But the need to pay a sum corresponding to approximately 30% of the market upon ordering and due to its cash flow difficulties, PCG cannot respond to calls for tenders for a high amount.

1.2.3. Setting import prices for medicines as a member of the “restricted technical subcommittee” for registration and granting of marketing authorizations and final decision-making body.

The only local producer SODONGPHARMAGUI which supplied up to 30 to 40% of the 40 molecules it produces for the Guinea market was able to be exempt, in this context, from certain taxes.

Determination of profit margins authorized for resale for:

- public structures: PCG, hospital pharmacy and health centers,
- the private sector: wholesalers, retail pharmacies.

1.2.4. Formations

In the field of training, training was carried out more than seven years ago with the support of the WHO in the areas of prescription and dispensing of medicines, but the lack of resources and geopolitical circumstances did not allow this area to be developed.

1.2.5. Psychotropic drugs and narcotics

The management of psychotropic drugs, narcotics and their precursors, which does not normally fall under this section, is carried out by the drug economics section since the absence, for almost 10 years, of the head of the pharmacovigilance and narcotics section.

This activity involves carrying out:

- the estimation of needs for psychotropic drugs and narcotics and the production of annual import forecasts,
- import authorizations and certificates
- quarterly and annual import statistics,
- quarterly, half-yearly and annual reports on the use and importation of narcotics (list of importers, origin of drugs, destinations).

This management is carried out using specialized software provided by the INCB (International Narcotics Control Board) which allows the production of certificates approved by the WHO (ISO 9001 2009 standard) and monitoring of the drug situation in Guinea (the documents could be produced and printed on demand).

The statistics are produced from data collected on the basis of national legislation resulting from the transcription of international legislation.

However, the collection includes uncertainties linked to non-compliance with national rules in the area of special prescriptions and the absence of keeping regulatory records for health facilities.

1.3. The pharmacovigilance, narcotics and quality control section.

This section in principle includes two pharmacists but in the absence of the section head for around 10 years, a pharmacist in charge of information was appointed in June 2008 at the request of PTF.

1.3.1. Narcotics and psychotropic drugs

This section is normally responsible for relations with the INCB responsible for control and compliance with UN conventions regulating narcotics and their precursors.

The INCB provided training support to the head of department of this section and provided a computer and appropriate software.

But all of these activities are carried out by delegation by the medicine economics section (see above).

1.3.2. Pharmacovigilance

At the beginning of the 2000s, awareness campaigns were carried out with the creation of pharmacovigilance committees, the production and distribution of pharmacovigilance sheets.

After the manager of this sector was laid off for 10 years, this activity remained dormant.

The pharmacist responsible for information resumed pharmacovigilance activity with the support of the WHO, which allowed him to follow training at the French-speaking pharmacovigilance course in Rabat, Morocco.

At the end of this training, the pre-existing pharmacovigilance sheets were perfected, then validated and implemented in 2009 as part of the national malaria control program with the help of funding from the Global Fund and with the training of focal points (resource people).

After several reports of adverse effects, a request for membership was made to the UMC (Uppsala Monitoring Centre), a WHO collaborating center for international drug monitoring.

“Associate member” status has been granted on a personal basis to the pharmacist responsible for the information responsible for pharmacovigilance, in the absence of his section head.

This status gives him access, on a personal basis, to the UMC database and journal and allows him to obtain answers to technical questions.

But this status does not authorize access to the data of other declarants, nor to carry out data analyzes or to receive invitations to specialized meetings.

Since 2009, 18 notifications have been made (including two in 2011) for antimalarials and vaccines.

Due to lack of material resources (the computer and Internet subscription used by this project manager are paid for from his own resources) only a few notifications were sent for a national vaccination campaign against yellow fever carried out in 2010 and for which 600 manifestations of adverse effects were noted in 30 serious ones with six suspicious deaths, three of which were due to hemorrhage.

These results were transmitted to the MSHP and WHO but not to the UMC.

2. The pharmaceutical establishments and laboratories division

This division responsible for infrastructure and equipment is currently being reorganized with the study, at the request of the MSHP cabinet council, of the elevation of the laboratory section to the rank of division.

Proposals from the DNPL are awaited by the MSHP for this reorganization.

This division is made up of seven pharmacists: a division head, three section heads and three research managers. All are considered operational.

The operational resources are very weak with obsolete computer equipment without protection (no UPS or antivirus software or updates, etc.) and, as a result, the databases have been lost several times and partially reconstituted from old files.

During the last computer incident in 2011, part of the files were lost and could not be reconstructed.

Although five computers were purchased in 2008/2009 by the West African Health Organization and one by the WHO for the DNPL, the day-to-day operation of the division is done without the use of IT.

2.1. The standards and regulations section

This section is responsible for issuing approvals and operating authorizations for all health structures.

In theory

Applications for approval of health structures and operating authorization include several stages and are carried out, theoretically, according to the following scheme:

1° Studies of the admissibility of applications for approval for the creation of private pharmacies, wholesale importers, medical agencies or industries,

2° Transmission of compliant files to the competent consultative bodies for opinion:

- ***National Medicines Commission, approval sub-committee of pharmaceutical companies and pharmacies,***
- ***Pharmaceutical inspection,***
- ***-National Order of Pharmacists.***

The study of files includes technical visits to the premises which must be approved.

3° Submission of files after validation to the "approval subcommittee" chaired by the president of the national council of the order of pharmacists and transmission of files to the DNPL with a favorable/ unfavorable opinion.

4°After validation of the approval file by the DNPL, the applicant must arrange the premises and apply for an operating order.

5°After observation by the pharmaceutical inspection of compliance with the development standards, an operating order is proposed for signature by the Minister of Health and registered at the general secretariat of the government.

The approval and the operating order are valid indefinitely to the extent that the conditions of approval remain unchanged.

These conditions are nominative for a responsible pharmacist and relate to the layout of the premises which any extension, relocation or new development renders obsolete.

Hospital pharmacies and health center pharmacies which were not originally intended to carry out commercial functions are not subject to either approval or an operating order.

In practice

The procedures are adapted taking into account the difficulties linked to:

- ***the non-functional nature of the National Medicines Commission, under approval commission,***
- ***the absence of material means of inspection and validation of conditions approval and compliance with the conditions for issuing operating authorizations,***
- ***the lack of legitimacy of the National Order of Pharmacists which was created in 1993 but which no longer has either legitimacy or authority due to the end of the mandate of the members of its office more than two years ago and the political commitment of its president.***

Its renewal, which depends on the MSHP and in particular the DNPL, has not been requested.

Furthermore, it seems that the National Council of the Order of Pharmacists has not been consulted since 1999 for the creation of wholesaler/ importer pharmacies.

In the absence of inspection capabilities, it is not possible to assess the number of health structures that have an operating order but no longer meet the standards that allowed them to obtain this order or that have approval but no operating order.

2.2. Pharmaceutical establishments section

This section is responsible for:

2.2.1. Information on pharmaceutical sector data.

Appointed in June 2008 at the request of PTF, the pharmacist in charge of information established:

- ***a situation of all the pharmacists trained at the faculty of pharmacy of Conakry since 1993,***
- ***a report on public service pharmacists which shows around 250 pharmacists in title and only 150 in positions,***
- ***-the list of pharmaceutical organizations with an operating order and/or approval (list which remains theoretical given the lack of means to carry out checks and validate the information in this file),***
- ***-the specific situation of approved medical agencies and delegates,***
- ***-a situation of personnel in health structures but which, due to lack of follow-up with the Human Resources Department, only constitutes a reflection of reality,***
- ***the list of WHO publications intended to be made available to health structures health.***

2.2.2. Supervision of all registered pharmaceutical establishments having obtained their operating order in terms of infrastructure, personnel, training and equipment.

Given the absence of documented databases, the supervision capacity is limited although this section is the only one to have logistical support from UNFPA (computer, software and vehicle) within the framework of Securing Reproductive Health Products.

Supervision is also carried out within the framework of approval procedures and operating orders.

The supervising pharmacist does not replace an inspector, but the results of supervision may prompt an inspection.

2.2.3. Sanctions

Sanctions that may be imposed by the DNPL against approved structures (suspension or revocation of the right to practice) can only be taken upon inspection or at the request of the National Order of Pharmacists. But sanctions can only be applied to registered and approved structures because the DNPL does not have jurisdiction over the informal drug market or over other structures that do not depend on it.

It should be noted the repeal in 2009, under the authority of the National Council for Democracy and Development, of 12 operating authorizations for wholesale distributors and a production company.

2.2.4. Monitoring of health structures

The section head can carry out his supervision thanks to the material support of UNFPA (service vehicle) in private pharmacies, wholesalers and pharmacists in the public sector to provide supervision, supervision and advice.

2.2.5. Training

A certain number of training courses were carried out more than seven years ago with the support of the WHO in the areas of prescription and dispensing of medicines, but training for pharmacists responsible for importing wholesale companies is considered useful by the DNPL.

2.3. The biomedical analysis laboratory section

The biomedical analysis laboratory section is subordinate to the biopharmaceutical establishments division of the DNPL. Only private laboratories are subject to the jurisdiction of this section. In 2012, there were eight private laboratories registered throughout the country (five were revoked).

The number of illicit laboratories installed throughout the national territory could not be assessed although they are present in all the major cities of the country.

Hospital laboratories and vertical program laboratories (HIV and AIDS and malaria supported by the Global Fund) do not fall directly under the jurisdiction of this section of the DNPL.

There is no control of para-public laboratories whose management staff are trained in the faculty of pharmacy or the faculty of science with essentially theoretical teaching.

The operational staff are trained at the ENSK (National School of Health of Kindia) which depends on the Ministry of Vocational Education which has no direct relationship with the MSHP (the MSHP participates, in principle, in the implementation of curricula). But, in the absence of suitable premises, equipment and credit, none of these training courses include significant practical training.

Negotiations have been underway for more than a year to include Guinea alongside Senegal, Mali and Niger in the West African Network of Laboratories supported by the WHO and the Mérieux Foundation for:

- develop training for technical staff,
- renovate the infrastructure of certain public laboratories,
- develop a quality assurance system,
- set up contaminated waste management,
- harmonize technical equipment,
- implement an external quality control system.

ANNEX 4. THE PCG

3.1. Historical

• The PCG replaced “Pharma Guinée”, internal service of the MSHP, the only authorized importer until 1992.

In this context, it inherited a plethora of staff, stocks of medicines that were barely usable and a captive clientele limited to hospital pharmacies.

On the occasion of its restructuring and its change of status from EPA to EPIC, the PCG received from the African Development Bank a capital allocation of 2.958 billion GNF consisting of medicines unsuitable for Guinean pathologies.

• This situation was aggravated by:
  o the creation at the same period of the “essential medicines unit” financed by UNICEF which deprived it of one of its main public health missions: the importation and distribution of MEG to health centers and corresponding working capital;

  o the establishment of “flat rate pricing” lower than the actual costs of the procedures practiced with “subsidies” that do not compensate for this deficit;
  o a price policy set by the MSHP in 1989 for health centers and in 1994 for hospitals which did not take into account either changes in market prices or very significant fluctuations in the national currency (see appendix 5);
  o outstanding customer debt denominated in constant francs (GNF) (mainly belonging to the State and difficult to recover) and supplier receivables denominated in hard currencies difficult to obtain, until recent years, for institutional reasons and whose exchange rate was constantly changing.

• A certain parallel can be drawn between the deterioration of the situation of the PCG and the fluctuations in the terms of trade of the Guinean franc, the rate of which rose from 1900 GNF/1€ in 2003 to more than 9000 GNF/1€ in 2005, Financial questions concerning the PCG have been studied since 1999, in various studies including "Evaluation of the supply and distribution systems of essential medicines in Guinea", mission 2AC/AEDES from January to April 1999 and in the “Project to strengthen the health system - Lot 1 - Study on secure funds for the acquisition of medicines” CREDES of 2004, but this point remains unresolved to this day

3.2. Support provided

Faced with this situation, support was provided to the PCG by the Global Fund and the European Union.

3.2.1. The Global Fund

The Global Fund provided material and financial support within the framework of an agreement signed with the MSHP which enabled the PCG:
  • the renovation of its ARV storage premises,
  • the delegation of management of the storage and distribution of ARVs,

- integration of the plan to combat AIDS and opportunistic diseases into the integrated logistics plan,
- the allocation of expenses for services rendered which originally amounted to 14% of the value of the products managed (this support has been reduced to 4% to date).

The role of purchasing center has not been delegated to the PCG to date for ARVs.

3.2.2. Support from the European Union

The European Union provided technical assistance to the PCG between 2004 and 2007 thanks to a financing agreement (PACS) in the form of technical assistance with organizational and technical support in the areas of:

- management with the support of a manager for 26 months,
- quality with short-term support (66 days),
- marketing support with two technical assistants (60 days/48 days),
- human resources (22 days).

But the “Financing Agreement No. 6452/GUI” of the “Complementary Support Project for the PACS Health Sector” establishes the principle that “The Health Coordination and PAME (Essential Medicines Support Program) components are institutional strengthening components for which the problem of financial viability does not arise as such.

The support provided by the European Union to the PCG has resulted in:

- In the field of management for the achievement of:
  - o complete manual of procedures from order to delivery, written, validated, implemented and operational,
  - o the implementation of efficient modern management techniques,
  - o the provision of Excel-based software intended for inventory management, supplies and depot customers,
  - o the establishment of traceability conditions for medicines and sterile single-use devices,
  - o the establishment of a sample library,
  - o the creation of a supplier and customer database,
  - o the establishment of specific addressing of medications stored in the stores,
  - o monitoring by batch and expiry date of drugs in the central stock,
  - o the implementation on an Excel basis of fixed asset tracking software with depreciation calculation,
  - o the establishment of analytical accounting, o
  - support for the implementation and improvement of the Sage Saari IT system which allows :
    - ÿ real-time accounting monitoring,
    - ÿ internal financial management control,
    - ÿ setting up a website,
    - ÿ carrying out staff training in management, IT and quality.

- In the quality area, technical support enabled the achievement or:

- o the overhaul and reorganization of the Quality Assurance and Internal Control Procedures Manual initiated in 1993 as part of cooperation with Tunisia,
- o a reference document for the pre-selection of suppliers and calls for tenders (DAO),
- o a supplier audit methodology,
- o a price database,
- o order performance indicators,
- o order planning,
- o implementation of the quality assurance procedures described on all procedures from the call for tenders to delivery,
- o quality control carried out abroad (Centrale Humanitaire Médico Pharmaceutique de Clermont-Ferrand) on samples taken from all deliveries.

• In the field of marketing, technical support provided on:
- o an organization of the marketing department,
- o a definition of the “medical delegate” profile,
- o teaching of the notion of “customer”,
- o creation of the list of correspondences between specialties and names common internationals,
- o carrying out surveys on the perception of the PCG by customers, the satisfaction rate and the needs achieved,
- o participation in MEG promotion campaigns.

• In the area of human resources, technical support was provided for:
- o -the establishment of an evaluation system,
- o -the evaluation of human resources,
- o -the definition of a salary policy.

This made it possible to efficiently structure the PCG with the exception of the area of human resources and the commercial area due to the absence of a Guinean pharmacist competent in these areas (Final evaluation of the PACS and PASSIP-European Union programs 2008) .

3.2.3. Situation assessment

Despite this support, the study of PCG order and delivery flows reveals a deterioration of service from 2003, a clear deterioration in 2005 and a situation which can be described as a virtual cessation of service from 2007.

The dissolution of the “essential medicines unit” which was no longer supplied by UNICEF in 1999 and its merger in 2007 with the PCG constituted an addition of additional costs without a contribution of stock.

The appearance of the illicit drug market in Guinea from the 1990s and parallel supply circuits intended to meet the needs of the populations which were organized by vertical programs (ARV, malaria, EPI) as well as the activity of certain operators (GTZ, Médecins Sans Frontières, UNICEF, UNFPA) can be considered as directly linked to the deterioration of public system services supply.

The deterioration of this situation was the cause:

- the gradual disappearance of PCG's paying customers (wholesalers and private pharmacists, NGOs and mining industry services) who for some paid in foreign currency,
- the disappearance of “obligatory” clients of the Ministry of Health (university hospitals, regional hospitals, health centers, etc.) who benefited from financial autonomy and who turned to private suppliers,
- a strengthening of the highly competitive illicit drug market.

This loss of customer confidence was accompanied by a loss of confidence from suppliers who no longer responded to calls for preselection or to calls for tenders while, until 2005, certain suppliers (UNIPAC – UNICEF Packing and Assembly Center – in particular) were likely to deliver small urgent orders upon simple oral request from the PCG with subsequent regularization.

This development in the situation resulted in the requirement, by suppliers, of 50% deposit on order and 50% on delivery until the end of 2007 and, subsequently, a request for payment of the entire amount when placing the order.

This situation resulted in:

- a disappearance of stocks with commercial value,
- a lack of cash flow,
- a supplier debt which in 2008 was greater than 4.9 times the assets (debt of 11.14 billion GNF and inventories plus customer receivables of 2.3 billion GNF) - (Final evaluation of the PACS and PASSIP programs - European Commission 2008),
- demotivation of PCG staff.

The order satisfaction rate, which could reach 80% in the 1970s, fell between 6% and 10% in 2011 (for example, in the second half of 2010 the LABE region which had purchased 1.56 billion GNF of health products had only been able to obtain 69 million GNF from the PCG).

In this context, an operation to support PHC was carried out in 2011 by UNICEF, GTZ and MSHP with the provision of batches of basic medicines to each health center. But this initiative to revive the functioning of the official drug circuit constituted more emergency humanitarian aid than sustainable development action.

By only strengthening demand by giving the capacity of health centers to replenish their cash flow through the sale of distributed medicines, the resupply of these health centers was carried out by purchases from private wholesalers due to the inability of the PCG , then in difficulty, to respond to the demand thus created.

The outcome of this initiative was a strengthening of the private sector, an increase in drug prices and the creation of commercial links between all public health structures and the private supply sector with the appearance of debt of certain health centers vis-à-vis private wholesalers.

ANNEX 5. FINANCIAL REGULATION OF THE PHARMACEUTICAL SECTOR

The mission of the public health system is to provide populations with quality medicines at the best price. The drug economics section of the DNPL is responsible for defining the price structure and the selling price of health products.

4.1. The pricing policy put in place after the 1994 devaluation is based on:

- a periodic review of the pricing policy,
- a renegotiation of profit margins (the last date was 2010),
- a study of the costs of service providers (profit margins, costs transport approach, local transit costs, stabilization coefficient, various fees, etc.),
- administration of drug prices by setting and publishing them periodically from the central repository.

The failure of the policy implemented in this area results from:

- a pricing system linked to subsidies,
- political instability which did not make it possible to carry out an evolving medicines policy,
- reduced availability of medicines,
- a price of the drug unrelated to the purchasing power of the population.

4.2. The basic price of medicines

The import price of medicines is determined by the medicine economics section of the DNPL when granting the MA. The tax-free price structure theoretically takes into account the wholesale price plus delivery costs, transit costs and various fees (around 24%).

Due to the instability of the context and the absence of a real pricing policy, the price retained by the DNPL for the MA of drugs are established in relation to the median price of equivalent molecules existing on the Guinean market.

In this context, we can estimate that the cost price of Conakry is around 125% of the supplier price excluding taxes.

4.3. Profit margins

The profit margins of public and private structures are also determined by the drug economics section of the MSHP. These profit margins were re-discussed in 2003 at the instigation of the General Health Inspectorate then in 2009 under the aegis of the National Council for Democracy and Development).

In the public sector:

- The PCG is authorized to apply a coefficient of 1.32 on its purchase prices for determine its transfer price.

- *o Currently the coefficients applied to the sale prices of medicines purchased in DPAV vary between 1.15 and 1.20.*

  It should be noted that these lower coefficients which are at the profitability threshold of a company are applied to high prices for health products purchased on site in DPAV from local wholesale distributors and resold to health structures at higher prices. to those of the acquisition and with limited management fees.

- *o DPAV purchases only concern limited quantities which therefore result in high and variable prices over time which are reflected in the sales prices to hospitals and health centers.*

- *o Procurement worth 10 billion GNF with staggered deliveries would be necessary to obtain prices on the international market corresponding to the mission of the PCG national supply structure.*

- *• Hospital pharmacies and health centers multiply the purchase price per PCG (or their purchases in the private sector when this is the case) by a coefficient of 1.3 to resell medicines to patients with the exception of certain social medicines for which the sale price is imposed.*

In the private sector;

Following the renegotiations carried out by the National Council for Democracy and Development in 2009, the profit margins of private structures were lowered:

- *• from 1.26 to 1.12 for importing wholesalers,*
- *• from 1.48 to 1.40 for pharmacies and pharmacies.*

4.4. The pricing system

The pricing system was put in place in 1992 in the context of the devaluation of the CFA franc and on the basis of the Bamako initiative (cost recovery, minimum care package, etc.).

In the public sector:

- *• Hospital pharmacy*
  - *o "Flat pricing" intended to make medicines more accessible to patients in hospitals supplied by the PCG and based on "split pricing" for which the real cost was covered, originally, on a flat rate basis for 35% by the patient (5% for the indigent and the remainder by the 'State through subsidies).*

  - *o "Subsidies" intended to make medicines more accessible are also intended to cover financial losses linked to medicines and pharmaceutical products which cannot be covered by the patient (small equipment and operating room consumables, necessary for sterilization, etc.).) or prohibited from prescription (medical gases, radiology developer and fixative, certain anesthetics such as ketamine, etc.).*

- Health centers.
  - o The “global pricing” applied by the health centers supplied by the essential medicines unit was based on the actual cost of the medicine representing the bulk of the cost of primary health care.

These prices set by decree remained blocked due to the political context. Due to changes in the price of medicines, subsidies were necessary to compensate for the differential with the real price until the merger of the essential medicines unit with the PCG unified the supply arrangements for health centers. with hospital pharmacies.

In the private sector:

- The selling price of medicines in the private sector is in principle calculated on the basis of the “wholesaler” purchase price multiplied since 2009 by a factor of 1.4.

4.5. Functioning

In the public sector:

The increase in drug prices, the blocking of subsidies and their government payment delays (in July 2012 the subsidies paid corresponded to the first quarter of 2011) are at the origin of the failure of the public supply system, the appearance of a parallel drug market and the implementation of adaptations
functional in hospital pharmacies and health centers.

- Hospital pharmacies
  - o To secure the availability of medicines and health products, Hospital pharmacies were empowered in 2001 and the proceeds from the sale of medicines were collected in a “medication account” which allowed restocking of health products and to cover the pharmacy's current operating costs (cleaning products, stationery, etc.).). o The revenue generated by these “external dispensations” – or expensive transfers which represent 45% to 60% of hospital revenue (see European Union report) – was in principle distributed as follows:

    - ÿ 50% intended for the purchase of medicines which were paid – when the rule was applied – into a special autonomous bank account or “medication account” mobilized by the pharmacist with the signatures of the director and the financial manager and after approval – when this -this existed – of the Medicines Committee (knowing that the purchase of medicines represents 30 to 35% of hospital expenses),
    - ÿ 20% dedicated to the operation of the pharmacy: purchase of cleaning products, stationery, payment of salaries of contract workers, etc.,
    - ÿ 30% contribution to the general operation of the hospital paid to the “account global ».

      In some cases, the hospital's "global account" and the "drug account" were merged and the purchase of drugs was subject to the discretion of the hospital director.

      These revenues were to be supplemented by subsidies paid by the MSHP.

These provisions, which had directed almost all purchases from public sector pharmacies to the private sector, have no longer been applied since the summer of 2011 at the request of the MSHP.

- Health centers

  Health centers which operate independently of management had similarly directed almost all of their purchases towards the private sector, but the unity of funds established in 2011, the instructions of the MSHP, the action of DPS pharmacists and the commercial policy of the PCG have gradually redirected these purchases over the past year towards the PCG.

In the private sector:

- Wholesale distributors

  In practice, wholesalers themselves determine their transfer prices to pharmacies based on their purchase price and include on the delivery invoice the prices that pharmacies must charge for resale.
  This situation is linked to permanent variations in the purchase prices of medicines on the international market which constitute an obstacle to strict application of official rules.

- Pharmacies

  Pharmacies must pay from their profit margin the license (around 20% of the rental value of the pharmacy), profit taxes (around 15% to 25% of profits) and employee salaries.

  In this context, low-cost health products are not supplied by the private sector.

4.6. User prices

The list of drug prices has never been updated and cannot be applied in the public sector with contradictory orders determining variations of 45% to 50% on drug prices.

The consumption multiplier coefficient in the licit sector is estimated at 2.5 compared to the price of Conakry excluding taxes.

Consequently, after prescription, depending on the availability and financial means of the buyer, the medicines available in the public sector are purchased according to the principle of "the split prescription" and first of all at the hospital pharmacy. or at the health center then by purchasing missing or out of stock medicines in the private sector but very often, and sometimes preferentially, in the illicit informal sector (at the nearest market) with, as a general rule, a lower price, unguaranteed quality and a degraded or counterfeit medicine or even devoid of active or dangerous ingredient.

4.7. Conclusions

The government's mission to provide people with medicines at the best price has not been fulfilled.

Price regulation is done in an uncontrolled manner depending on the situation of the public and private supply systems.

The main handicap of the public supply system is financial with:

- a debt estimated at 25 billion GNF ($3.5 million),
- customer payment arrears linked to political decisions and capacities government finances,
- a cash flow which does not allow it to enter into contracts allowing it to obtain medicines at the lowest prices.

The functioning of private and informal supply systems is dependent on the state's limited capacity for control.

APPENDIX 6. THE WORKSHOP ON SEPTEMBER 10 AND 11

The first part of the mission, which itself is a continuation of the round table, resulted in findings and avenues for reflection which were the subject of the July 12 report. The mission then wrote a draft report with lines of thought and proposed recommendations to be presented and discussed during a two-day workshop.

Encountered difficulties

Organizing the workshop was quite difficult. Initially scheduled for around September 5 and 6, the mission accidentally learned that several essential participants (the Director of the DNPL, the Inspector General of Health, the Director of the PCG) would be abroad all this week. They told us of their wish to participate in the workshop and asked us to postpone the workshop to September 10 and 11 (and therefore our return trip, planned for September 7). Unfortunately, Mr. Secretary General was unable to confirm these new dates and it was only on September 6 at 2 p.m. (the day before our return) that the invitation for the workshop to be held on September 10 and 11 was issued. finally signed.

Many guests, and especially the PTFs, were not aware of the invitation in good time and were therefore absent during the debates. No PTF was present or represented, except PMI/USAID, organizer of the workshop with the MSHP. On the other hand, the MSHP was well represented.

The course of the workshop

The first part of the workshop allowed:

- to specify to all participants the different sovereign functions normative and control standards falling under the State and the service functions likely to be delegated by public service devolution agreement to private law actors within the framework of the contractual approach;
- to evoke and discuss the regulatory mechanisms and the brakes of the system current supply and the solutions envisaged to make it functional;
- to discuss the role of the different organizations (DNPL, IGS, CNM, LNCQM) in support for the exercise of the control function, as well as the place and contribution of support structures;
- to discuss the conditions necessary for the proper functioning of the system national pharmaceutical company and the absolute priority of a functional and efficient public supply system, and therefore of a PCG.

The second part of the workshop covered:

- the question of administrative systems in relation to regulatory systems,
- the importance of the control and inspection function as well as the different levels of inspection up to the general health inspection,
- the question of the autonomy of vertical programs and donor circuits of substance as a destabilizing factor of the PCG,
- the public-private partnership,

- the “Medicines for all” project and the notion of commercial relations (of clientele) between the PCG and the CS-clients; on this occasion the problem of controlling points of sale was highlighted as well as the crucial question of the price of the medicine.

The third part of the workshop focused on:

- The very important theme of the non-profit organization on which the participants had focused at the during previous sessions.
- The question of PCG debt, a major cause of its dysfunctions, was specified by its director.
- The “medicines for all” project and the role of the PCG up to the periphery.
- The service role – that is to say the analysis of LNCQM health products allowing control – was clarified with the director of this laboratory compared to the sovereign control function.
- The prospects for development and operation of the LNCQM.
- Perspectives linked to the status of agency or national regulatory authority and the presentation of agency systems existing in English-speaking African countries.

The participants in the debates (in the absence of donors) generally reached an agreement on the two priority areas that the mission proposed:

1. the public supply circuit with a PCG in legal form of Association, the State first assuming the financial liabilities of the current structure or getting involved to resolve this essential question,
2. the grouping of skills related to medicines from their manufacture to their ingestion, including normative and inspection powers, within an autonomous state medicines agency.

The Director of the DNPL nevertheless expressed doubts about the interpretation and the possibility of application of the agreement concluded between the State (Ministry of Health and Ministry of Finance) and the PCG, particularly regarding the exclusivity entrusted to the PCG for all State orders – as well as on the transition to an independent regulatory authority, impossible, according to him, to be accepted by the authorities when we could simply strengthen the resources of the DNPL without restructuring it into an agency.

The debates were constructive and contradictory. They shed particularly important light on administrative type systems and regulatory systems by independent authority, on the prospects for modifying the status of the PCG and on the objective, at a term which remains to be defined, of the passage from the sovereign regulatory and control authority of the MSHP pharmaceutical system to an agency structure autonomous.

The workshop concluded with a press briefing by the Inspector General, the Deputy Director of the DNPL and various national health authorities.

Conclusion

In conclusion, it is too early to make a real action plan, because the possibly available budgets are not known, and the TFPs did not participate in the debates. A consensus nevertheless emerged during the workshop on the priority areas. Neither the perfect operationality of the public supply circuit, nor the creation of a regulatory authority are immediately achievable. With this in mind, actions must be taken in the short term, without delay. Even if the functional supply circuit is a condition for effective combat against the illicit market which is not currently met, the evolution towards a Medicines Agency must continue.

The emphasis must be placed, in the short term:

1. On the creation of a PCG in the legal form of an ASBL, with an involvement active participation of all stakeholders in its governance, and first and foremost donors, provided that transparent negotiations are initiated at the initiative of the State and that the latter assumes the liabilities of the PCG-EPIC or implies to resolve this essential question: the goal is to make the mission of the PCG effective and to benefit from a functional public supply circuit, an essential condition for putting an end to the illicit market. It is therefore a logical top priority.

2. On the minimum means (material, IT, logistics, human) of functioning of the DNPL, so that it can gradually carry out its essential normative and control missions, and in particular:
   - in its function of granting MA,
   - in its traceability and vigilance functions, •
   regarding the provision of functional pharmacist-inspectors to the DNPL, • on the functionality of the LNCQM or on the possible use of laboratories exteriors,
   - by the reform of the CNM and its simplification in an operational sense.

These reforms must move in the direction of grouping together all the skills (with the necessary means to exercise them) linked to regulation with a view to becoming a truly autonomous state regulatory authority (or medicines agency) which would allow the effective development of the function and concomitantly with the improvement of the public supply circuit.

ANNEX 7. LIST OF PERSONS MEET

Ministry of Health

- Dr Naman KEITA, Minister • Dr Younoussa BALLO, Secretary General • Maître Hawa BEAVOGUI, Legal Advisor

General Health Inspection

- Dr Aboubakar Sidiki DIAKITE, Inspector General • Dr Ibrahim CAMARA, Pharmacist Inspector • Dr Hibrahim BALDE, Pharmacist Inspector

National Directorate of Pharmacy and Laboratory

- Dr Kabiné SOUARE, National Director • Dr Binta BAH, Deputy National Director • Dr Karifa DOUNO, Head of the biopharmaceutical establishments division • Dr Lamine DAFFE, Head of the medicines division • Dr Fatoumata KOLON, Head of the pharmacopoeia section, registration, AMM, imports
- Dr Mariama Siré SANO, Head of narcotics, pharmacovigilance section • Dr Cécé Vieux COLIE, Responsible for pharmaceutical and pharmacovigilance training • Dr Lansana Sandry CAMARA, Research manager, Medicine economics section • Dr Simon Pierre BANGOURA, Research manager , Standards and regulations section • Dr Nagnoumane SANO, Head of pharmaceutical establishments section • Dr Said Khalil LAKISS, Head of the biomedical analysis department

Department of Administrative and Financial Affairs

- Mr Mamady Kemodo CONDE, DAAF Chef

National Directorate of Hospitals and Care Establishments

- Sékou CONDE, National Director

Strategy and Development Office

- Mr Aboubacar KABA, National Director

Equipment and Maintenance Division

- Mr Amadou Timbi BAH, Division Manager

National Malaria Control Program

- Dr. Kalil KEITA • Dr. Nouman Diakite

- *Dr. Mamady BERETE • Dr. Djantoun Traore*

National Program for Health Care and Prevention of STIs/ HIV/ AIDS

- *Dr Youssouf KOITA, National Coordinator*

Central Pharmacy of Guinea

- *Dr Moussa KONATE, General Director • Mr BANGOURA, Administrative and Financial Director*

National Laboratory for Quality Control of Medicines

- *Dr Mory FOFANA, Director*

CHU Ignace DEEN

- *Dr Mamadou CAMARA, Chief Pharmacist*

National Order of Pharmacists

- *Dr Mamadou CAMARA, Vice-president hospital pharmacists section • Dr Moussa KONATE, Vice-president wholesale importer section • Dr Karifa DOUNO, Substitute member*

PTF and international organizations

USAID

- *Dr Mariétou SATIN, Team Leader Health • Mr. Neil WOODRUFF, Team Leader • Dr Nashat HANAFI, PMI Adviser • Dr Lamine BANGOURA, PMI Specialist • Mr Alpha S. DIALLO, Program Adviser • Dr. Marouf BALDE, Public Health Specialist • Dr Odon MULANGU, Pharmacien • M. Gabriel DANIEL, Senior Technical Adviser*

UNICEF

- *Dr. Salvator NIBITANGA, Head of the health program*

OMS

- *Dr Christian AITAMA MAYIKULI, Emergency and medication focal point*

UNFPA

• Dr Kadiatou SY, National Program Officer • Dr Appolinaire DELANOU, PF/ Fistula Program Manager • Dr Kadiatou SY, SR Program Manager • Dr Aïssatou CONDE, UCH Program Manager • Dr Fatoumata Diaray DIALLO, Program associate

European Union

- *Miss Aurélie KONEN, International Aid/ Cooperation Officer, Commission European*
- *Mr Ivan MURILLO RONVEAUX, Program Manager-Infrastructure and Service basic, Delegation of the European Union*

Global Fund/ Global Fund

- *Dr Youssouf KOITA, Coordinator*

Private Sector: APDIM SARL

- *Dr Hawa SOW, Director General*

Divers

- *Professor Jean SAKANDE, Director, DGPML (General Directorate of Pharmacy of Medicine and Laboratories), Ministry of Health of Burkina Faso*

APPENDIX 8. LIST OF PEOPLE PRESENT AT THE WORKSHOP

Activité:
Lieu:
Date :

FICHE DE PRESENCE

N°	Prénoms et Noms	Fonction/Organisation	Provenance	10/09/2012	11/09/2012
1	Cécé Vieux Kolié	DNPL/DSHP	Conakry		
2	Michel BEIRY	C.N.T	Conakry		
3	Dr Karifa DOUNO	DNPL/DSHP	Conakry		
4	Dr BALDE OUMAR TAIBATA	Ordre des Medecin	Conakry		
5	Dr H. Bta Touré	Pharmacienne chef	Conakry		
6	Dr Abdoul Habib BEAVOGUI	Consultant PNA · MCHIP - DNPL/DSHP	Maférinyah		
7	Dr Namadia CAMARA	Pharmacie - Chef Ismaël Dée	Conakry		
8	Dr Fanta Bah	DNPL/DSHP	Coyah		
9	Dr Lamine DAFFE	DNPL	D/Medica		
10	Dr Apollinaire Delamou	UNFPA	Conakry		

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	Prénoms et Noms	Fonction/Organisation	Provenance	10/09/2012	11/09/2012
11	Prof Iakiss Saïd Kall	Chef Sect° labo/DNPL	MSHP	[illegible]	[illegible]
12	Dr Mariama Siré SIANO	Chef Sect. Stup. CQ	DNPL (MSHP)	[illegible]	[illegible]
* 13	Dr Camara Mamadou Y Koulifou	Assistant Technique	chy DELIVER	[illegible]	[illegible]
14	Dr HABA Nyankoye	DG/CNTS	CNTS (MSHP)	[illegible]	[illegible]
15	Dr Mory FOFANA	D/Labo Contrôle qlté	LCQM	[illegible]	[illegible]
16	Dr Camara Aly	Chargé d'étude	ANSF/MSHP	[illegible]	[illegible]
17	Mr Bah Alpha Issiaga	ISFC à la DAF/MSHP	DAF/MSHP	[illegible]	[illegible]
18	Mr Ousmane Camara	Coord/Dépôts	P.C.G	[illegible]	[illegible]
19	Dr Youssouf Doumbouya	Conseiller	PCG	[illegible]	[illegible]
20	Dr Zoumana CAMARA	Pharmacien Responsable	Laborex Guinée	[illegible]	[illegible]
* 21	Dr. Theoro Prosper Beda	Projet Faisons Ensemble	Medecin	[illegible]	
22	Dr CONTE Fodé Bakary	ANEHS	Dedecou	[illegible]	[illegible]
23		Financier/DNPSC	DNPSC	[illegible]	
24	DR Sorifa Alpha Fylla Dr Diallo Hamdatou Lamine	DNPL/MSHP	ANPL	[illegible]	[illegible]
25	Dr Mouna KOMATO	PCG	PCG	[illegible]	[illegible]
26	Dr Katiné SOUARE	DNPL/MSHP	MSHP	[illegible]	[illegible]
27	Mr Aboubacar Sidiki MAKISSE	SG/MSHP	MSHP	[illegible]	[illegible]
28	Dr Aminata Mouhamed	[illegible] PLM	—	[illegible]	
29	Dr Haba Nyan				

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Systems for Improved Access to Pharmaceuticals and Services

Activité:
Lieu:
Date :

FICHE DE PRESENCE

	N°	Prénoms et Noms	Fonction/Organisation	Provenance	10/09/2012	11/09/2012
	1	Cécé Vieux Koliè	DNPL / MSHP	Conakry		
	2	Michel BEIRY	C.N.T	Conakry		
	3	Dr Karifa DOUNO	DNPL / MSHP	Conakry		
	4	Dr BALDE OUMAR TAIBATA	Ordre des Médecins	Conakry		
	5	Dr H. Fta Touré	Pharmacienne chef ...	Conakry		
*	6	Dr Abdoul Habib BEAVOGUI	Consultant / MCHIP - JHPIEGO	Maferinyah		
	7	Dr Mamadou CAMARA	Pharmacien - Chef Ignace Deen	Conakry		
	8	Dr Bouréma Baldé	DNPL / MSHP	Conakry		
	9	Dr Lamine DAFFE	DNPL	D/Madina		
*	10	Dr Apollinaire Delamou	UNFPA	Conakry		

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