from March 26 to 29, 2018

# OUIDAH, BENIN Regulations, Markets, Health

QUESTIONING CURRENT STAKES OF PHARMACEUTICALS IN AFRICA

QUESTIONING CURRENT STA









## **BOOK OF ABSTRACTS**

## OUIDAH, BÉNIN Régulations, Marchés, Santé

INTERROGER LES ENJEUX ACTUELS DU MÉDICAMENT EN AFRIQUE

du 26 au 29 mars 2018

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## The possibility of promoting local production of pharmaceuticals in Africa

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Africa is characterized by huge disease burden, but poor access to medicines and high dependence on imported medicines. The continent suffers from various disadvantages including lack of adequate technological capability and higher costs. Some commentators highlight these constraints to raise doubts about the desirability of local production in small African countries. It is argued that local products would be costlier and hence it is better to reply on cheaper imported products. But such disadvantages are nothing unusual. The countries which are now industrialized suffered from similar constraints. These constraints did not prevent them from developing new industries, i.e., industries which initially did not exist or were underdeveloped in their countries. What made the difference is the industrial policy that these countries pursued. Similarly it is possible for African countries to develop a sustainable pharmaceutical industry.

Learning from the experiences of other countries, African countries need to formulate and implement a coordinated plan of action. The government must lead and coordinate the development process. This will involve a package of incentives and other measures to support local manufacturers. Incentives are necessary but are not sufficient for industrial development. Incentives have not always worked. What is worse it has at times resulted in unwanted negative consequences. The objective must be to ensure that as the local industry gets the opportunity to manufacture and to gain experience, costs will go down and an efficient industry will develop. Therefore what are crucial are associated measures to develop productive capacities, to reduce the cost differentials and to manage prices and quality.

Keywords : Africa, industrial policy, development, pharmaceutical industry

## Performative strategies and complexities linked to the emerging use of doping products among youth in North Benin

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This research focuses on understanding mechanisms related to the consumption of doping performanceenhancing products and how this is generalized to present a public health concern in certain areas of Northern Benin. These reflections are based on an ethnography of risk-related behaviors, especially the consumption of certain doping products (medication and other) among youth in the region. Findings presented here are the result of qualitative research conducted around perceptions of risk in a social environment torn between saving local values and the productivity gained by labor and physical activity. The data analyzed here are a result of long periods of observation and numerous individual and group interviews as well as from the tools of scenario expression that favored free discussion among adolescents and their usual social groups. Observation took place within households as well as within the social spaces of the young consumers of the products. These young people expressed finding themselves within new dynamics that led to the emergence of new social profiles. Success in this context was seen to be facilitated by the use of products that supported their labor. This was seen by abusive and off-label consumption of medications and other performance-enhancing products in the management of new requirements related to social objectives. This dynamic is described here on one hand by changes and complexities that are brought on within social groups, and on the other hand by the threats it engenders in social reproduction in different areas. This analysis is positioned in terms of the influence of social contexts in the social trajectories of consumption of these young people.

Keywords : doping, performance, risk behaviors, abuse, Northern Benin

#### Bringing together medication and history in Africa

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Over recent decades, medical anthropology has shown how social and material relations are intertwined by and for the production, distribution, and consumption of medication. What can history contribute to this reflection on the socialization, politicization, and materiality of medication, as well as the biological action that it brings to bodies? In other words: how does the power of medication on the body show itself over time and become a historical power that changes and reveals relationships to policies, economy, and society?

I will examine these questions through presenting the findings of my own studies and those of my colleagues on the political identity of medication distributors (including pharmacists) and on the politicization of medication's bodily effects as they are lived, witnessed, and fatally suffered in Africa at the end of and immediately following French colonialization. I am especially interested in conceptions of citizenship that define and are defined by the right to sell and take medication, and the need to regulate its efficacy within contexts of reform and destruction of the colonial administration. I hope to propose analytical tools that allow a better understanding of the dynamic and durable temporal dimensions of efficacy associated with medication in Africa.

Keywords : History, medicine, Africa, distribution

## Access to medicines and Intellectual Property Rights: Global problem, international context, challenges and solutions

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Access to affordable medicines of good quality is of particular concern to developing countries. To ensure access to patented products that are needed to address health concerns, the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organisation (WTO) and the Doha Declaration on the TRIPS Agreement and Public Health provide safeguards (so-called TRIPS flexibilities).

The presentation first will give a background of the access to medicines debate and in particular the important role played by the African countries in the origin of this debate. The presentation will also describe and analyse some of the failures of the current R&D (Research and Development) system/model for pharmaceutical products and the major threats to the access to medicines global debate. Finally I will address some challenges and possible solutions.

Keywords : Accessibility, Drug, Regulation, Patent

### **1.1** - Historical and juridical questioning of the markets

## Trusting or distrusting medicines in Ghana? Precaution, necessity and social embeddedness

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Transactions involving medicines are typically asymmetric: although neither buyer nor seller has complete information about a product's quality and efficacy – particularly in settings like Ghana with weak regulation – the uncertainty and risks are most pressing for the buyer. Drawing on in-depth interviews (N=220) and observation of medicine transactions, plus interviews with regulators (N=20), this paper explores how people in Ghana negotiate this situation to purchase and ingest medicines. In contrast with prevailing literature that emphasises the role of trust in enabling transactions to proceed under conditions of uncertainty, our data suggest that distrust is an equally important departure point. Starting from a position of underlying distrust, the majority of our interviewees took many precautions, scrutinising the medicine, and the outlet and retailer, before making a purchase, to minimise the risk of ending up with an ineffective product. In cases where buyers acted based on trust (taking no precautions), this was underpinned either by necessity or by deeply embedded social relationships between seller and buyer that render precaution taking both unnecessary and counter-productive. However, the effectiveness of relying on socially-embedded relationships of trust to procure good-quality medicine is limited because of the dispersed and under-regulated nature of wider supply chains.

Keywords : Trust, Ghana, medicines, precaution, embeddedness

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### **1.1** - Historical and juridical questioning of the markets

## The pharmacists facing medication public policy changes in Morocco

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This article addresses the issues that are surrounding medication in Morocco through a socio-historical approach which would highlight the reset of the profession of pharmacist and the medicine market changes. The pharmaceutical trade has gradually been set since the Independence of Morocco as a regulated liberal profession (setting public price of medicine, supervising the opening of drugstores and medicine sales). This profession was introduced in Morocco by the French Protectorate to serve essentially foreign and French citizens. After the Independence in 1956, the Moroccan state maintained the French organization model of the profession. The firms and sites of pharmaceutical production inherited from the Protectorate were revived by the state and taken over by foreign enterprises that have played decisive roles in the development of local pharmaceutical production. Today there are 12500 pharmacists in Morocco who represent the main lever of a medication trade that is dominated by the private sector. The production of medicine is actually monopolized by a dozen of laboratories which increasingly tend, in the era of globalization and open markets, to import rather than produce locally. This fact constitutes a major change concerning the medication public policy launched during 1960s. The capacity of the state to regulating the trade has proved to be limited within a market highly controlled by the private sector at various levels (production, importation, wholesale distribution...). As a result, not only the annuity cases have increased, but also the retailing sales cost excessively high compared to the income of a large part of the population that lacks medical security and free access to medication in public dispensaries. For the Moroccan state, the political and social risks due to the exclusion of the majority of the population from having access to medication have worsened since the eruption of the "Arab spring". The country has been shaken, like other North African countries (Tunisia, Egypt...), by popular uprisings that drove the government to set a new social medication policy. Such public measures have targeted the price system, refund conditions, and the indicatives to substitute branded medicines to generic products. These measures are brought about within a context of profound change concerning the conditions of access to the practice of the profession of pharmacist: profession massification, loss of monopoly related to practicing many activities such as drug preparation, retail for animal usage, biological and medical test and analysis production... The showdown of many actors in the pharmaceutical field in Morocco (state, manufacturers, pharmacists...) lead to sight manifold logic that animates the medication public policy and the tensions that cross the profession of pharmacist.

Keywords : Pharmacists Medication public State Morocco

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### **1.1** - Historical and juridical questioning of the markets

## Empty stocks and loose papers : ways to get medicines in Northern India

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Compared to most Sub-Saharan African countries, India's pharmaceutical industry has been highly successful for the last 40 years. Often presented as "the Pharmacy of the developing world" by international NGOs such as Médecins Sans Frontières, India's capacity to produce quality and affordable medicines has been recognized globally; the country has played a major role in providing medicines such as antiretroviral therapies to countries lacking the technical capacity to produce their own – and notably to Sub-Saharan Africa. On that ground, the Indian pharmaceutical infrastructure appears as much more developed than in most Sub-Saharan countries. However, one country's pharmaceutical infrastructure includes elements such as health coverage, medical suppliers and regulatory authorities and this should be taken into account to understand the ways in which Indian patients access medicines in their own country. Indian patients rarely enjoy the benefits of such dynamism especially in rural and poor areas. A number of reasons account for the limited access to quality essential medicines: drug shortages, prescription malpractices, regulatory negligence and so forth. Studies show in particular that the weakness of public services co-exists with the vigor of a private, often unregulated, retail market.

simultaneously from the patient's point of view, from the formal public and private practitioners' point of view and from the health authorities' point of view. Informality then constitutes one crucial aspect of the government of healthcare in the rural areas of contemporary India and the analytical stake is less to explain how informality is or how it should be tackled, overcome and governed than how the government of healthcare is produced through informality. Informality plays indeed a part in the contemporary "government rationale" (in the sense of Michel Foucault 2004) but the informality at play in Northern India differs from that in Benin for instance (Baxerres 2014). In a way our argument follows what Jan Breman has shown in the case of the informal economy in India, where he explains that informal economy should be seen as part of the wider logics of unregulated capitalism (Breman 2014). We try to understand more specifically the consequences of such capitalism on access to health. We will insist particularly on the role of unlicensed practioners and retailers. So as to make our point, we rely upon a study combining sociological interviews and qualitative ethnographic observation. The interviews and observations were led by the two authors in Bihar in December 2016. Our investigation has been carried in one particular district of Bihar and in several blocks, that is to say sub-districts. Purposive sampling was used to provide in-depth sociological interviews with public and private health providers and patients. We conducted qualitative face-to-face interviews in Hindi with 31 Public Health providers (at PHC, block and district level), 30 private providers (informal and formal), and 40 patients. We met drug administrators, managers, health workers, drug sellers, village doctors, and patients in different villages, village clinics, drug stores, primary health centers, referral or district hospital, all involved in the prescription, provision or consumption of medicines in the same district. This communication will question the contrasting image of India as an international pharmaceutical power and the complexity of access to medicines at local level.

Keywords : informality, village doctors, quacks, procurement, access to medicines, India, Bihar

## The "virtuous" trajectories of the pharmaceutical businessmen in Ghana

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Medication in Ghana, like other places in the world, is subject to multiple economic and commercial influences. However, this West African country has been shaped since colonial times by Anglo-Saxon pharmaceutical legislation and economic practices that encourage the state to leave certain aspects to the "invisible hand of the market": prices of medications and profit margins left to free economic operators, relatively few restrictions on pharmaceutical advertising, little government control over the activities of wholesalers, etc. I will present several specificities of the Ghanaian pharmaceutical market that will encourage a reflection on the contemporary forms of medication markets and the different types of regulation (state, commercial, health) that frame the complex realities of the current neoliberal context. This presentation is based on data collected between August 2014 and June 2016 with pharmaceutical wholesalers in Accra. Participant observation was conducted in the Okaishie market, where a large part of wholesale activity occurs, during 8 research visits of about 15 days each. Over fifty semi-structured interviews were conducted with retailers, informal intermediaries, directors and commercial representatives of wholesalers and pharmaceutical firms, and institutional actors involved in Ghanaian regulation. Medication trade in Ghana is supported by a multitude of businesses with very different characteristics related to capital investment, number of employees, variety and quantity of medication distributed.

All of these, from the smallest to the biggest, seemed to have their place within the Ghanaian pharmaceutical market. Data collected showed that these were understood to show the different steps of evolution in the commercial growth curve, going from retailer, to wholesaler, to wholesale-importer, to producer. Among these, at the bottom of the curve, there were informal intermediaries whose function was very useful to the actors located further above in the curve.

Together, these actors all helped to make the market work optimally, reaching the most distant customers and the most remote areas of the country. In this presentation I explore the consequences of these observations in the pharmaceutical sector by paying particular attention to how these actors are trained as well as their commercial and public health logics, as well as, more broadly also questioning contemporary forms of the market.

Keywords : wholesale distribution, pharmaceuticals, markets, Ghana, neoliberalism

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## Study of a merchant specialized in the sale of street drugs : the example of Roxy's market in Adjame

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- Document not translated -

Cette étude sur le marché Roxy d'Adjamé s'est deroulée de novembre 2013 à octobre 2014. C'est une étude transversale à visée descriptive et analytique dont l'objectif est de proceder à la description de l'organisation du circuit de la vente informelle de medicaments à Abidjan. La presente communication à pour objectif de decrire les caracteristiques sociodemographiques des vendeurs de médicaments de la rue et les methodes de fixation de prix de ceux-ci.

Les principales techniques de collecte de l'information utilisées font references à la recherche documentaire, à l'observation directe et à l'execution d'entretien avec les vendeurs.

Les resultats de nos investigations montrent que la vente des médicaments sur le marché de Roxy, mobilise à 95% des femme majoritairement de nationalité ivoirienne. Elles sont pour la plus part analphabetes (75%). La fixation des prix depend fortement du lieu d'approvisionnement des médicaments. Ainsi, les médicaments disposant d'une autorisation de mise sur le marché sont plus cher que les médicaments n'en disposant pas. Dans la categorie des médicaments disposant d'une autorisation de mise sur le marché, les sirops, les médicaments en rupture de stock dans les pharmacies et les medicaments dont la delivrance demande un delai d'attente d'un jour ou plus dans les pharmacies, sont plus chers sur le marché illicite.

Keywords : street drugs, Roxy market, marketing authorization, Côte d'Ivoire

## Influents intermediaries: Pharmaceutical representation and its actors in Benin

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In Benin, in a context of low production of medicines, pharmaceutical representatives are an important category of actors in the construction of medicine's markets. As the main intermediary between firms and other actors in the field of the pharmaceutical industry (State, Prescribers, distributors, etc.), their main activity lies in theory in promoting the products of the firm (s) they represent.

Pharmaceutical representatives are weakly organized. There is no regulation which frame their activities, and they are not systematically listed by the pharmacy regulatory body, the Direction of Pharmacy, Medicines, or Diagnostic Exploration (DPMED). There are also no official statistics on the costs by the pharmaceutical industry for promotion in the country. In addition, they have also invested in distribution. Some of them are employed directly by pharmaceutical companies, others in representative agencies. So it is useful to know who are the pharmaceutical representatives in Benin, how they are organized and what is their role in the construction of different pharmaceutical markets (public / private / informal, rural / urban, generic / originator, etc.) existing in Benin.

The findings presented here comes from research done for a PhD thesis in socio-anthropology. Data collection is ongoing and will continue during 2018. These data are of a qualitative nature and are from interviews and sessions of direct and participative observation. Observation sessions are being done with pharmaceutical representatives in their daily activities. Interviews are being done with the representatives and other actors as health professionals, health council staff, etc.

In this paper, we present a typology of the different types of pharmaceutical representatives. We analyze the pharmaceutical markets they promote and the economic and political issues they crystallize. We propose an analysis of the modalities of participation of these specific actors, whose profession is not yet constituted, with the construction of the markets of pharmaceuticals in Benin.

Keywords : medicines, pharmaceutical representative, regulation, socio-anthropology, Benin

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#### Drug depots: a key player in formal and informal sales in Madagascar

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Madagascar is characterized by a plurality of pharmaceutical distribution players operating in the public and private sectors: wholesale distributors, pharmacies, drug depots, drug distribution channels via vertical programs from non-governmental organizations and UN agencies, management by third parties of pharmacy units in hospitals. Informal sales actors operate alongside these formal actors. Their practices are intrinsically linked. The characteristics of Malagasy pharmaceutical distribution methods are as follows: scarcity of pharmacists, establishment of drug depots to compensate for the small number of pharmacists, high number of wholesalers, heaviness and rigidity of the registration procedures of the drug. Among these various actors, the depositories (drug depots) hold an inescapable place in the distribution both formal and informal of drugs in Madagascar.

Starting from a rapid assessment of the organization of the distribution of medicines in Madagascar and the different categories of actors involved, this presentation will aim to "zoom in" more particularly on a category of actors who hold a key place in the distribution both formal and informal medicines in Madagascar: the drug depots. Through this analysis, this presentation will show the different points of articulation between the sectors, and their deep entanglement.

Keywords : Madagascar, medicine, formal sector, drug depots, informal market, pharmaceutical system

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## **2.1** - Regulation of distribution of the public health pharmaceuticals

#### The regulation of antimalarial medicines by Benin and Ghana under Global Health Programs conditionality's

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Benin and Ghana, two countries geographically close, nevertheless have very different pharmaceutical regulatory systems. Benin has a Directorate of Pharmacies and Ghana Food and Drugs Authority, with very unequal autonomy, human and financial resources. In addition, Ghana has the second largest pharmaceutical industrial sector in West Africa after Nigeria (thirty-six pharmaceutical companies), while Benin has only one pharmaceutical firm created in 1983. These differences partly explained by the history of the countries, their colonial legacy, and the economic and industrial development policies adopted in the aftermath of their independence. Those have defined in part the regulatory devices as they are today and the state of capabilities to manufacture medicines locally.

In Benin and Ghana an international aid plays a major role in national budgets. Both countries depend entirely on grants from transnational actors for the purchase of Artemisinin Combination Therapies-ACTs distributed in the public sector and since 2010 for part in the Ghanaian private sector. Global health initiatives promote ACT supply policies with a strong focus on financial support for imports that completely exclude, in the case of Ghana, local manufacturers of medicines that have part of the technical means to locally produce ACTs. Transnational actors play the role of "standardization agents" by contributing to the definition and dissemination of a number of technical and financial standards around medicines.

In this paper, I question the power that the states of Benin and Ghana have in the regulation of ACTs under global health programs conditions. I analyze the strategies developed by local firms, governments, their partners and regional actors, in order to fight against the forms of domination in the process of production and appropriation of norms around generic drugs. These strategies are built around regaining control over supplies and importations of ACTs in Benin and Ghana, and promoting local drug production in Ghana. The national drug policies deployed by Ghana and more in the minority by Benin, and by the West African Health Organization at the regional level, can be considered as protests against norms and standards of global health programs and ways to recover pharmaceutical, political and economic sovereignty.

The data presented in this paper come from a PhD in sociology that is currently underway and aims to produce a comparison between the national drug policies of Benin and Ghana. The qualitative methodology used consists of semi-structured interviews with the country's pharmaceutical directions, regulatory authorities, pharmaceutical company managers and pharmacists, as well as observations within a Ghanaian pharmaceutical firm (60 hours on the production line). An important work in the National Archives of the Government of Ghana in Accra has also been done.

Keywords : Ghana, Benin, medicines, policies, regulation

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## **2.1** - Regulation of distribution of the public health pharmaceuticals

## China and the mass distribution of artemisinin-based malaria medication in the Comoros Union

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In the Comoros Union, a partnership with the Chinese government implemented a malaria elimination project from 2007-2015 using the strategy of free mass distribution of artemisinin-based malaria medication. Many transnational and local actors criticized this program, while others lauded it for its success. At the end of the eight-year program, the disease was almost completely eliminated from the country, but experts doubt the sustainability of these results. Recent data shows that malaria incidence is currently increasing quickly on the island where the country's capital is located.

Artemisinin-based malaria treatment changed the face of malaria treatment in sub-Saharan Africa and led to China's first Nobel Prize in medicine in 2015. Developed as a result of Mao Zedong's initiative to use Traditional Chinese Medicine to treat malaria in Asia, artemisinin-based treatment did not enter the global market until the early 21st century with the help of the European and North American pharmaceutical industry. The production, use, and regulation of artemisinin-based medications have provoked new controversies as well as social and political relationships. This paper uses the results of ethnographic fieldwork conducted in China, Geneva, and the Comoros Union to reflect upon some of the effects of the circulation of these medications and situate these effects within the broader context of Chinese global health and development work in sub-Saharan Africa.

This paper explores the social and political relationships related to the circulation of artemisinin-based malaria medications as well as China's increasingly visible role in global health and development in Africa. In the Comoros Union that was under French rule until 1975, how is the growing Chinese influence on health care interpreted? What kind of alternative does the Chinese approach to health offer to individuals living within this post-colonial context? These questions are addressed through the exploration of social and political relationships created by the malaria elimination program and the circulation of artemisinin-based malaria treatment more generally.

Keywords : China, Comoros, Malaria, Artemisinin, Mass Drug Distribution

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## **2.1** – Regulation of distribution of the public health pharmaceuticals

## The Market for Artemisinin-Based Combination Therapies and the New Era of "Market Makers"

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The pharmaceutical market is not tailored to cater the needs of patients who are located in the economically disadvantaged Southern countries, particularly in Sub-Saharan Africa. International organizations are working in numerous ways to overcome this challenge and to increase the access to medicines at affordable prices in the global South. They recommend and proscribe drugs, shape national policies, assure drug quality, provide funding and technical assistance, manage the supply chain, negotiate prices with manufacturers, decide who can compete and influence the behavior of competitors. Recently, some international organizations like Drugs for Neglected Diseases Initiative (DNDi) and Medicines for Malaria Venture (MMV) have successfully ventured into new drug development for tropical diseases. This has resulted in the evolution of complex relational dynamics and interdependencies between states, firms and international organizations. The structural power to bargain in such relationships often does not lie with states but rather with international organizations who create conditions under which firms would agree to invest in a particular venture. Thus, international organizations have acquired the role of "market makers" who not only convert the need for medicines into real demand but also shape the institutional environment for market functioning by setting up the rules of exchange for market transactions.

However, this phenomenon is not well studied. In this regard, this study sheds light on the role of international organizations in the creation and functioning of the market for artemisinin-based combination therapies (ACTs) for malaria. It explains the role of WHO treatment guidelines in the global acceptance and legitimization of ACTs and WHO prequalification program in assuring quality. It further elaborates on the importance of donor funding, negotiation with manufacturers, the introduction of new ACT formulations to increase competition and stabilization of the supply of raw artemisinin on the reduction of treatment prices. It also explains how business strategies of firms are shaped by the action of international organizations.

Keywords : Medicines, Antimalarial, Markets, Regulation, ACT

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#### Pharmacogovernance and Postmarket Drug Safety in Kenya

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Background: Pharmacogovernance, defined as the manner in which governing structures; policy instruments; and institutional authority (e.g., ability to act, implement and enforce norms, policies and processes) are managed, promotes societal interests for patient safety and protection from adverse drug events. Transnational actors contribute to pharmacogovernance in Kenya by mobilizing institutional will for accountability, effective policy, laws, and resources to maximize drug safety through participation in global and domestic policy networks. The objective of this study was to investigate the relationship between specific modes of engagement among global (exogenous) and domestic actors at the national and sub-national level to identify their effect on pharmacovigilance and pharmacogovernance in Kenya. Methods: Key informant interviews and document analyses were conducted following ethics approval from University of Toronto, Canada and Moi University, Kenya. Data were analyzed to identify key themes related to the relationship between global actors' patterns of engagement with national actors and pharmacogovernance in Kenya. Semantic analyses of key informant interviews were conducted to gather their perspectives of governance for drug safety and the priority setting process at federal, county and corporate levels.

Results: Global actors engaged with state actors to influence policy, practice, and pharmacovigilance priorities in Kenya with positive and negative outcomes. Engagement characterized as dependent (advocacy, empowerment, delegated) or interdependent (collaborative, cooperative, consultative) was mostly associated with strengthening legislation; capacity building; and stakeholder coordination. Independent engagement (fragmentation) hindered risk communication between public, private, and NGO health programs.

Conclusion: Pharmacogovernance advances a therapeutic culture that values drug safety and mechanisms (policy, regulation, resources, ethics, etc.) to assure it is achieved. The framework to assess pharmacogovernance can guide decision-making regarding policies and investments that strengthen pharmacovigilance and the state and exogenous actor relationship. In Kenya, domestic investments in pharmacogovernance would lessen risks for 1) ad hoc drug surveillance; 2) pharmacovigilance fragmentation; 3) shifting priorities; and 4) cross purpose interests.

Keywords : Drug safety, Global actors, Governance, Kenya, Pharmacovigilance, Regulation

#### Logiques institutionnelles autour du misoprostol et de l'avortement au Bénin, Burkina Faso et Togo. Des acteurs nationaux en tension entre risques sociaux et risques sanitaires

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L'objectif de cette communication consiste à décrire et à analyser les logiques et enjeux d'acteurs variés autour de l'acceptation officielle du misoprostol dans des pays d'Afrique. Outre son usage pour le traitement des ulcères gastriques, l'efficacité de ce médicament a été prouvée dans les soins obstétricaux et plus spécifiquement pour traiter les hémorragies du post-partum, le déclenchement de l'accouchement et, ce qui nous intéresse plus spécifiquement ici, les avortements incomplets.

En aval des recommandations de l'OMS pour ces usages, la reconnaissance institutionnelle du misoprostol varie d'un pays à un autre et des organisations internationales, souvent anglo-saxonnes, qui militent pour le droit et/ou la santé des femmes semblent avoir un rôle prépondérant. Quels apprentissages pouvonsnous tirer de la manière dont s'organise le plaidoyer dans les 3 pays considérés ? Quels sont les acteurs nationaux et internationaux impliqués dans l'acceptation officielle de ce médicament ? Quelles en sont les différentes étapes ? Quels sont les différents enjeux mis en évidence dans les interactions entre les acteurs ? Ce sont ces différentes questions que cette communication aborde sous le prisme des normes de régulation qui oriente les politiques d'Etats parfois décrits comme étant « sous régime d'aides, ainsi que les perceptions des acteurs impliqués dans l'élaboration de ces politiques. En somme, il s'agira d'analyser les modalités de publicisation d'un médicament dans une dynamique de politique publique qui définit ses conditions d'usage. Offrant un paysage de santé globale différent de celui mis en évidence dans le cas des maladies prioritaires (sida, paludisme, tuberculose) qui impliquent des partenariats public-privé et de la coopération bi et multinationale, cette communication appréhendera les rapports entre les acteurs locaux (personnels de santé, décideurs locaux) et des organisations internationales investies souvent de manière militante dans le droit et la santé des femmes.

Notre approche est qualitative et repose sur des enquêtes socio-anthropologiques conduites de 2014 à 2017 dans les capitales de trois pays d'Afrique de l'Ouest : Bénin (Cotonou) ; Burkina Faso (Ouagadougou) ; Togo (Lomé). Notre analyse est également enrichie de notre participation à des conférences internationales portant sur l'avortement en Afrique ayant eu lieu en 2016 (Addis-Abeba) et 2017 (Tunis) et qui regroupaient des organisations internationales et des acteurs nationaux de pays d'Afrique.

In fine, les points de vue des acteurs soulignent la prégnance de la morale qui se cristallise sur la sensibilité à affronter la question de l'avortement sur la place publique. Les recommandations sanitaires internationales, censées être prises en compte au niveau des pays, se heurtent à la gouvernance nationale. Cernée par des considérations culturelles et religieuses, celle-ci tend à renvoyer tout débat public sur l'avortement dans la sphère privée. Mais les organisations internationales, en lien avec des associations locales de promotion des femmes ainsi que de gynécologues-obstétriciens, tentent de différentes manières, que nous expliciterons, de (re)mettre à l'agenda cette question.

Keywords : avortement, misoprostol, Bénin, Burkina Faso, Togo

#### **Regional integration of pharmaceutical law in West Africa**

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Pharmaceutical law rules pharmaceutical activities including elaboration, production, imports, exports, trading, distribution, marketing, etc. As a part of health sector, pharmaceutical law contributes to the establishment of a safe health system in each State. Long time excluded from regional and subregional integration processes, pharmaceutical sector is nowadays subject of several initiatives of reconciliation of West African States' regulations. Thereby, there is an awareness that legal pluralism within a same region strongly influences the regulation of drug markets. Today, no State can isolate itself and regulate efficiently its drug market. This security of health systems is no longer sought only at the national level but is subject of regional and even continental ownership. It is no longer a matter of monopolization of pharmaceutical systems' control by States. Legal integration of pharmaceutical standards in West African region is becoming a crucial issue in terms of health security. It is a matter of a process that would bring support to States for health protection throughout the region. A regional governance of pharmaceutical system is an imperative. Therefore, WAEMU and ECOWAS are setting-up a process of legal integration in pharmaceutic context. This implies a transfer of some legal competences by States to supranational organization for the process of reconciliation. However this competences' transfer is not complete. It leaves a margin to State members to keep a command over their pharmaceutical system governance using legal and communal tools and integration means.

Pharmaceutical system' operating at the internal and subregional level widely depends on the mean of legal integration used by the organization. But it is possible to observe in the pharmaceutical field that harmonization is the privileged mean of legal integration. In addition, the type of legal adopted by communal institutions in pharmaceutical field will allow to assess the States member flexibility with respect to the communal standard.

Communication aims to analyse the link between communal pharmaceutical law and pharmaceutical system control at the internal level. What are the means legal tools through which skills' sharing works between government and subregional organizations ?

Keywords : West Africa ; Pharmaceutical law ; ECOWAS ; legal integration ; WAEMU

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#### "AIDS is everyone's business": Pharmaceuticals power plays, money, and unintentional consequences

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Escobar (1995) argues that development was not a natural process of knowledge that uncovered problems and dealt with them, rather it was a RESPONSE to the problematization of poverty, by the West (predominantly the U.S.A.) that took place after WWII. In as such it should be seen as a historical construct that provides space in which poor countries were known, specified, and intervened upon. The mechanism for which this happens are in the forms of knowledge and power created by the processes of "institutionalization and professionalization." Applying this theoretical lens from "development", this paper demonstrates the similarities in the way in which the AIDS Response is not a natural process but similarly problematized by foreign interests. Drawing on policy statements, spending reports, debates on international agreements such as TRIPS and newspapers at the global level combined with ethnographic examples from interviews and documents at the local level in Lesotho, I show how foreign aid, the expansion of operational/clinical research, pharmaceutical centrality within health systems, and national and regional power plays, weave together to promote biomedical technical solutions while dominating, and in some cases undermining, local engagement. I highlight the ways professionalization and institutionalization are employed to establish systems of knowledge and power that benefit western pharmaceutical and biotechnological interests. In the case of Lesotho, similar to many other hyperendemic post-colonial/protectorate/apartheid zones, I explore the qualitative implications for the transmission of HIV information and response strategy on a population that perceives foreign pharmaceutical companies as turning a profit off of a disease and insider local elites as getting rich. Three generations into clinical trials and operational research there is a nagging sensation that even through disease black bodies are pawns in the global financial system. Depicting developing countries as innocent victims to the Pharmaceutical companies is not an accurate representation. Evidence indicates that leaders in developing countries are actively striking back and trying to manipulate the situation to their benefit. The paper demonstrates how pharmaceutical multinationals and many governments have not responded to the crisis as a "health problem" but treat the crisis as "business as usual" weighing carefully, interests, costs, and profits. The overall objective of this research is to illuminate the unintentional consequences of particular institutional practices to improve the engagement of diverse stakeholders in re-balancing biomedical/technical approaches with context and culturally appropriate responses to the epidemic.

Keywords : Development, Financing, Foreign Aid, AIDS, Research, TRIPS, Fast, Track

### **3.** – Stakes and re-launch of local production

## The unique experience of the Brazilian cooperation in setting up a generic medicine plant in Mozambique

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Since 2003, the Brazilian government, relying on its experience of local production of antiretrovirals and other generic medicines in public plants, has provided support to Mozambique to implement its own medicine plant. This South-South Cooperation sets itself apart from other recent initiatives promoting local pharmaceutical production in Africa, as it is neither a joint venture nor a branch of the Brazilian public pharmaceutical laboratories. Rather, it is a situation whereby one state provides to another state, without charge, the technology, training and funding for the creation of a public-owned industry with public health purposes. Thus, the international purchase of equipment, transfer of the pharmaceutical production files and ongoing training of local staff for production and quality control are carried out by a team from Farmanguinhos, Brazil's major public-owned pharmaceutical laboratory.

Currently, the Mozambican plant, called Mozambican Medicines Society (SMM in its Portuguese acronym), occasionally produces and sells four essential medicines to the Mozambican Ministry of Health (MoH) and to private domestic wholesalers. With the help of Farmanguinhos, the SMM wishes to establish contacts in India and China for the purchase of Active Pharmaceutical Ingredients and for partnerships for technology transfer with private pharmaceutical companies. It also aims at prequalification by the World Health Organization, originally to participate in international tenders to sell its ARV production to the MoH HIV treatment program, which is entirely funded by international donors. Securing a regular production is still a challenge to SMM as is financial autonomy, since trained human resources are hard to retain and the Mozambican government has trouble financing its public enterprises. The recent political crisis in Brazil also endangered the cooperation continuity, making the SMM consider new possibilities of funding and partnership.

Based on interviews and observations carried out within doctoral research in Brazil and Mozambique with political actors from both governments, experts and technicians working for Farmanguinhos and at the SMM, this communication will outline the steps and the practical conditions for the installation of the SMM. From its exceptional conception to the technical hurdles, shared with other public and private pharmaceutical laboratories in Africa, we will show the stakes for local production in a limited resource country.

Keywords : Local Pharmaceutical Production, South-South Cooperation, Generic medicines, Mozambique

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# The alliance between humanitarian medicine and a pharmaceutical multinational to produce ASAQ at Sanofi-Maphar in Morocco (2004-2018)

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The market for the artesunate-amodiaquine fixed-dose combination, one of the drugs recommended by the WHO to treat malaria, has until now mainly been supplied by Sanofi-Maphar's factory in Morocco. Yet Sanofi, which monopolized the market until 2013, is now facing stiff competition from Indian manufacturers producing the drug at under \$1 per unit. The ASAQ market accounts for one quarter of the world market for artemisinin-based combinations. Sanofi and Indian and Chinese manufacturers all produce combinations certified by the WHO prequalification system and thus meet the standards of the major international donors, mainly the Global Fund.

This paper analyses the originality of the innovation, appropriation and industrialization model in this case. The technology used to combine in a single tablet two incompatible molecules is the outcome not of Sanofi's industrial research, but of the initiative of MSF and the wall-less laboratory that it created: Drugs for Neglected Diseases Initiative (DNDI).

The technical and clinical development of the drug relied on funding by governments and a philanthropic consortium that brought together the Universities of Bordeaux, Oxford, and Sains in Malasia, as well as several R&D companies in France and Germany, and the Centre for Malaria Research in Burkina Faso. It was the DNDI that maintained control on the technology and that demanded a public good model without intellectual property rights. The first phase of industrialization was a partnership agreement between the DNDI and Sanofi, based on a no-profit no-loss model and on a set price of \$1 (in 2004). Sanofi contributed industrial investments to adapt the technology to the Maphar factory in Casablanca, and to comply with WHO prequalification standards. Sanofi's ASAQ produced in Morocco is registered in 34 African countries and in India. The agreement between the DNDI and Sanofi does not cover the entire ASAQ economy. First, beginning in 2011, the DNDI undertook a technology transfer process at another production site in Tanzania. Second, several Indian manufacturers freely duplicated the unpatented technology, taking advantage of various routes of knowledge dissemination. ASAQ's trajectory illustrates new assemblages between multinationals, humanitarian medicine, and global health, the result of which are reduced and controlled profits, and a process of industrial dissemination in Africa, Asia and Europe – particularly Italy – where the semi-synthetic raw material used by Sanofi-Maphar is produced.

This research draws on two sets of documents collected and interviews held in 2009 and 2010 (ANR PHARMASUD) and in 2016 (ERC GLOBALMED) with the main players in the project: WHO-TDR, MSF, Sanofi, Bordeaux University, and the private-sector research firms involved in the FACT consortium. I visited the Sanofi-Maphar factory in Morocco in May 2016 to reconstruct the process of industrialization and certification of ASAQ. I interviewed the academic researchers and private-sector firms that had been involved in the creation and dissemination of the technology from 2002 to 2004 in Bordeaux, 2007 to 2008 in Casablanca, and 2011 to 2016 in Tanzania.

Keywords : humanitarian medicine ; multinational ; public good ; Morocco

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#### Local pharmaceutical production in Ghana, Benin and Ivory Coast: Conditions of emergence, evolution and current challenges

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Ghana, Benin and Côte d'Ivoire present contrasting situations in terms of local production of medicines. While Ghana counts thirty-six pharmaceutical companies and has the second largest pharmaceutical industrial sector in West Africa after Nigeria, Benin has one pharmaceutical company and Côte d'Ivoire eight. This paper questions how and why countries that are geographically close present such differences in this area.

Colonial legacy, economic and industrial development policies adopted in the aftermath of independence, are all elements to take into account in order to understand the itineraries of these three countries. Ghana developed its pharmaceutical industrial policy as soon as it gained independence in 1957, relying heavily on European and North American multinationals, while Benin and Côte d'Ivoire have long favored safeguarding and strengthening the supply system based on medicines importations (via France) set up during the colonial era. It was not until 1983 that the only pharmaceutical firm (privately owned) was created in Benin and from the end of the 1980s that Cote d'Ivoire began its industrialization under the leadership of liberal governments encouraging private business.

In this paper we retrace the sociohistorical of local production in these countries, from the context of independence to the current period of relative enthusiasm for local production of medicines in Africa. We show how global events like the debt crisis of the 1980s, Structural Adjustment Programs, the devaluation of F-CFA in 1994, have implications for local production of medicines and supply systems more generally. We examine the different configurations that local production businesses can take over the years and the role played by States, local pharmacists, multinationals and Asian generics manufacturers. The challenges of the viability and quality of such businesses against the standards promoted by WHO around quality of medicines will also be questioned in light of the national drug and industrial policies.

The data presented in this paper on Ghana and Benin come from a PhD in sociology that is currently underway and aims to produce a comparison between the national drug policies of Benin and Ghana. The data on Ivory Coast was collected as part of the "Regulation and Production" working package of the Globalmed research project. The qualitative methodology used consists of semi-structured interviews with the country's pharmaceutical directions, regulatory authorities, pharmaceutical company managers and pharmacists, as well as observations within a Ghanaian pharmaceutical firm (60 hours on the production line). An important work in the National Archives of the Government of Ghana in Accra has also been done.

Keywords : West Africa, medicines, local production

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## How India's pharmaceutical industry shapes local production in sub-Saharan Africa

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How does India's pharmaceutical industry shape the prospects for local pharmaceutical production in sub-Saharan Africa? India, the third largest pharmaceuticals producer in the world, is known by activists and industry groups as the "pharmacy to the developing world" for its large-volume of supply of relatively lowcost, generic medicines to countries in the global South. It is often presented as a 'win-win' example of South-South trade, where Indian industry and consumers abroad – including in Africa - benefit. Yet a different context emerges from local production in Africa, where various initiatives over the last decade have sought to overcome a dependence on imported medicines.

This paper draws on extensive primary fieldwork, including over 170 interviews with key stakeholders in India, Kenya, Uganda, Tanzania, South Africa, Ghana and Ethiopia, to explore how India's pharmaceutical industry shapes local production. In various policy initiatives supporting the promotion of local production in Africa, the Indian industry, as well as its Chinese counterpart, has largely been cited as a competitive threat. Indeed, given the Indian industry's economies of scale and capabilities across different aspects of the industry, amongst other factors, many local firms find it difficult to compete with the Indian industry. Local production is largely reserved to a limited amount of local pharmaceutical production, and is dependent on imports of active pharmaceutical ingredients. Local firms' activities are limited to some final formulation activity as well as marketing and retailing.

At the same time, some of the most advanced local pharmaceutical manufacturing plants in sub-Saharan Africa are Indian-owned, while many more have Indian management and technical expertise. The Indian industry can be a key source of technology, ingredients and industry knowledge for efforts to establish local pharmaceutical production within sub-Saharan Africa. Generic medicines supplied from India can be lower-cost for consumers and the governments' public health supply. Some such medicines are supplied through global donor organisations, which local firms are excluded from.

Ultimately, however, some involvement of the Indian industry on the continent is necessary as local production is not, nor seems likely to be in the foreseeable future, completely self-sufficient. Thus, relationships with India are significant for local pharmaceuticals production in sub-Saharan Africa. The paper argues that working with India's pharmaceutical industry may be crucial for establishing local pharmaceutical production.

Keywords : Pharmaceuticals, India, local, Africa

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## Analysis of the potential constraints and success conditions of a Unit of Phytomedicne Production (U-PHARMA) in Burkina Faso.

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The aim of this research was to analyse the potential constraints and success conditions for local medicine production in Burkina Faso, based on a case study of the unit of phytomedicine production and marketing (U-PHARMA).

Data collection was been done by unfolding the material safety data sheets, doing direct interview with the personnel of U-PHARMA as well as the technical and administrative personnel of the Institute of Health Sciences Research (IRSS). The diagnosis was done by analysing and synthesising the data gathered. This case study showed that U-PHARMA did not have a juridical status that allows it to benefit from a autonomy in its activities management. This institutional anchorage constituted the main constraint that did not allow the unit to implement its activities in the logics of competitive profit-oriented business, able to cover the demand from the clientele. The unit disposed of a referential (procedures manual) for the management of its various activities that is trapped by the rules and procedures of administrative acts management in the public service. Regarding the economic and financial diagnosis, it allowed us to see that U-PHARMA has evolved in a production and marketing dynamic showcased by an ongoing increase of cash flow over the last five years.

Although there is a huge potential of the unit to generate its own revenue, some practices and characteristics related to public services constituted obstacles to the promotion of the unit and lead to chronic disruptions.

Keywords : Constraints, Success, Medicine, Phytomedicine, Production Unit

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### **4.1 -** From the drug to the system

## Care for injection drug users in Dakar: success and failure of treatment with methadone as seen by patients and caregivers

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Introduction: In 2011, the estimated number of injecting drug users (IDUs) in Dakar was 1324, according to UDSEN Study. The Integrated Addiction Treatment Center of Dakar (Cepiad) was opened in December 2014 to offer them care, a harm reduction program (HIV, HBV and HCV), a methadone opioid substitution treatment program and activities for social and professional reintegration. Since 2016, Cepiad hosts a cohort study of IDUs in Senegal (Codisen) funded by ANRS, with the main objective of defining a pilot care and prevention model validated and adapted to IDUs with co-morbidities. The research project includes clinical, addictology and socio-anthropological components.

Purpose and method: The presentation proposes to explore successes and failures of methadone treatment seen by caregivers and IDUs in relation to caregivers / patients relationships, based on individual interviews conducted with Cepiad health care professionals and IDUs, as well as observations carried out within Codisen project.

Results: In December 2017, 241 IDUs are included in the methadone program. Among them, 177 regularly take methadone treatment, 61 no longer comply with treatment for various reasons: voluntary abandonment, exclusion, incarceration ... According to caregivers, methadone delivery allowed to reduce mortality among IDUs and contributes to HIV response. The medical team declares that patients' complaints (inappropriateness to the body, interactions with other treatments) are constantly taken into account and doses of methadone are adjusted and delivered according to each patient's profile. Methadone is perceived by IDUs as beneficial for their health and their social adaptation. Most of them, considering addiction as a disease, perceive methadone as a curative treatment that ensures they get out of addiction. Others, more critical, see substitution treatment as a new drug or perceive themselves as guinea pigs for the combination of methadone with treatments for associated pathologies. The different meanings attributed to methadone reveal the degree of trust / distrust in the care relationship, and IDUs adherence to Cepiad's patient status.

Conclusion: The Senegalese methadone treatment experience shows that addictaion care is possible in West Africa. To better answer demands, other treatments are expected, with differences in perceptions between health professionals and IDUs.

Keywords : methadone, IDUs, Care, CEPIAD, Dakar

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### 4.1 - From the drug to the system

#### Drugs and the art of palliative care in Togo's health system

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Very often, reflections on African health systems focus on their subjects of research by disregarding the minimum functioning that can be recognized, and how it is ensured or generated. In Togo, the qualitative research that we conducted in two (2) health district hospitals (District No. 3 of Lomé-commune and that of Tchamba in the central region of the country) allowed us to discover the importance of drugs in maintaining the minimum of functioning that we observe today in health public services and the health system in general. In fact, drugs ensured a central role in the production of the financial resources necessary for the functioning of health structures. This role was reflected in our analyzes of the functioning of health services since the periods of economic and socio-political crisis that weakened the state, but also the crises of the health system caused by the payment exemption policies in 2000s.

Keywords : Drugs, health system, art of going, state, Togo

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### 4.1 - From the drug to the system

## Enacting the ethics of care through pharmaceuticals in community mental health in Ghana

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Over the last decade Ghana has trained increasing numbers of mental health workers in an effort to expand community-based care. Drawing on ethnographic research with community mental health workers in rural Ghana, this paper explores the ways in which pharmaceuticals are employed as the materialisation of their professional expertise and their enactment of care.

Community mental health workers are expected to visit rural communities to screen for psychiatric disorders, refer for diagnosis and prescription, offer 'psychosocial support', and supervise pharmaceutical treatment. However, a lack of psychiatrists means that in practice many community mental health workers are directly involved in the prescription and administration of psychopharmaceuticals both as forms of emergency chemical restraint via injection and as longer-term therapeutic intervention. Indeed, given the lack of transportation, poor road networks, and limited time for home visits, pharmaceuticals become the primary means through which health workers enact their professional status as medical experts and care providers, despite uncertainties surrounding diagnosis, the limited efficacy and damaging side effects of psychopharmaceuticals, and the complex psychosocial needs of poor rural families living with severe mental illness.

Psychopharmaceuticals are officially free of charge in Ghana, unlike other pharmaceuticals within the state health system which, when available, are covered by health insurance or purchased from hospital pharmacies. Furthermore, since some have powerful sedative properties, they are also deployed with the aim to replace mechanical restraint, which contravenes national and international human rights directives. However frequent shortages of supply mean that mental health workers must improvise in order to enact their professional role and meet families' and communities' demands for care and control. Some purchase pharmaceuticals to sell to families, while others insist this contravenes professional ethics. This creates contested debates among mental health workers around the moral economy of pharmaceuticals, and the implications for their use in the enactment of care.

This paper sheds light on the ways in which community mental health workers work with pharmaceuticals as the primary technology of 'modern' mental health care. The forms of improvisation through which they respond to the shortage of pharmaceuticals highlight the complex ethical dilemmas facing health workers in Ghana, as in other African settings, in attempting to provide such care in the context of a fragile, underfunded health system in which mental health is a very low priority.

Keywords : mental health, Ghana, ethics, care, community

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## 4.2 - From the system to the drug

#### Complementary health care services by public, private for-profit and private not for profit providers: Understanding the multiplicity of biomedical care services in West Africa

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In West Africa, a multiplicity of biomedical care is offered by different types of institutions (public, private for-profit, non-profit, faith-based, mission hospitals, informal, etc.) that are developing diversely between countries and within urban and rural contexts.

Through ethnographic research conducted during periods of 4 to 6 months in 2015 and 2016 in health facilities in Benin and Ghana, as well as a longitudinal study of 8 to 9 months with 30 families in each country and well as quantitative analyses, we examine the multiplicity of health care services being offered as well as the differences between the two countries. This research analyzes the history and development of health facilities, their operation, services offered, and the background of the professionals who offer them. We look at the demand for services and examine the different situations that influence patient choice of health facility.

The socio-economic status of health care providers as well as patients will be a key element to understanding these situations. However, taking into consideration the history of the health care system of both of these two countries (such as the training of health care professionals since the colonial period) as well as recent national political events related to privatization and heath care financing (politics of structural adjustment, launch of national health insurance), allow us to extend this analysis. By proposing to move beyond the usual regard divided by health sector (public/private/informal), this presentation will provide a broad understanding of biomedical healthcare being offered in West Africa and highlight the different challenges (social, economic, political, health) that are confronted.

Keywords : health care services, public, private, informal, health facilities

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### 4.2 - From the drug to the system

## Local adaptations of methadone treatment for addiction in Senegal

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In 2011, the estimated number of injecting drug users (IDUs) in Dakar was 1324, according to UDSEN Study. The Integrated Addiction Treatment Center of Dakar (Cepiad) was opened in December 2014 to offer them care, a harm reduction program (HIV, HBV and HCV), a methadone opioid substitution treatment program and activities for social and professional reintegration. Cepiad is the first addiction treatment center of its kind in West Africa.

Until April 2017, 205 patients were included in Cepiad methadone program. A cohort study of IDUs in Senegal (Codisen) started in June 2016, funded by ANRS, with the main objective of defining a pilot care and prevention model validated and adapted to IDUs with co-morbidities. The research project includes clinical, addictology and socio-anthropological components.

The aim of this presentation is to describe the local adaptations of methadone treatment in Cepiad by analyzing patients' perceptions and expectations. As part of Codisen project, the method included qualitative interviews with 30 patients taking methadone and participatory observation through immersion in Cepiad.

Since February 2015, methadone dispensation in Cepiad outpatient department is implemented through on-site taking under the supervision of health workers for safety reasons related to methadone toxicity and risk of overdose, and also to favor patients' observance. This approach is similar to WHO Directly Observed Treatment Short Course (DOTS) applied to treat TB. IDUs face difficulties with daily methadone intake and consider this treatment long and cumbersome. They experience fatigue due to their uncertainty about treatment completion and interferences with their family or professional obligations. They request the possibility of taking methadone home, particularly during Ramadan. To meet these expectations, Cepiad team has experimented new treatment modalities from September 2016: UDIs may take methadone at home on weekends and holidays. Treatment use is controlled through: (1) urinary tests on return, (2) methadone delivery by the Outreach team for patients with psychiatric comorbidities, (3) exclusion criteria. The first results of the study show that IDUs and health workers were satisfied vis-à-vis this organization which reduced constraints related to the daily delivery of methadone Cepiad. Taking methadone home was a pragmatic solution that facilitates the social and professional reintegration of IDUs. Personal strategies adopted by IDUs, other uses of treatment and home-based methadone arrangements will be a matter for further analysis.

Keywords : Adaptations, CEPIAD, IDU, Methadone, Perceptions

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## 4.2 - From the system to the drug

#### Medicines at the center of public health systems: between technical standards of public health and local social norms

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This paper presents a sociological study of medicines and consumables sales practices from the case of Bingerville public hospital, in Ivory Coast. We seek to understand, in relation to technical standards, the social mechanisms related to the persistence of drug trading practices in the public hospital of Bingerville, a locality in the district of Abidjan, the economic capital of Côte d'Ivoire. This leads us to study social norms as well, because the two fields of normativity influence each other in the same socio-cultural environment. This allows a look that is analytical, holistic and reveals: i) ideological influences legitimizing the persistence of commercial drug practices at the Bingerville Public Hospital; ii) symbolic resources mobilized; and iii) interrelations at work between the actors involved.

Medicine and free healthcare are a central element in the sustainable management of malaria in Ivory Coast. Despite technical standards (laws, regulations, professional and criminal sanctions) in force and punitive consequences, it is observed that the costs of drugs sold at Bingerville Public Hospital are higher than those approved by the NPSP and practiced. in private pharmacies in the same locality. This being the case, what are the social mechanisms for legitimizing the persistence of non-standard practices in the management of malaria?

It is through a socioeconomic study, both quantitative and qualitative that we will try to answer the question asked. Qualitative data is collected through desk research, direct observation and semi-structured interviews. These are transcribed from the MAXQDA 10 software. SPHINX software helped with the processing of the quantitative data. In addition, the hypothetico-deductive analytical posture was adopted from the theory of strategic analysis of M. Crozier and E. Friedberg (1977).

Thus, the results of this study show first that the persistence of non-technical practices revealed as a reality with strong ideological correspondences to those of local social norms. Then, they specify that the overvaluation of the costs of the drugs, the deactivation of the technical norms are perceived by the caregivers as symbolic resources of motivation. Finally, they confirm that the donation or the purchase of drugs are factors structuring relationships of dependence and the prolongation of parental ties, friendly between caregivers and caregivers.

Keywords : medicine, market practice, social norms, health, socio-economics.

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### 4.2 - From the system to the drug

#### Therapeutic failure in Cameroon: a powerful indicator of the current limitations of the health care system in AIDS treatment

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In 2017, 18 million people worldwide were taking antiretroviral therapy. As access to these treatments becomes more widespread in developing countries, as part of UNAIDS' public health strategy to eliminate the AIDS epidemic by 2030, the emergence of viral resistance, linked to therapeutic failures, is a growing threat both individually and collectively. Studies in sub-Saharan Africa show therapeutic failure rates of 17% to 33. In Cameroon, where nearly 200,000 people are being treated with ARVs, the prevention, detection and management of treatment failures face many constraints. The objective of this study was to analyze, through an anthropological approach, the context, determinants, perceptions and modalities of treatment failure management.

Between 2010 and 2012, a study was conducted at four care sites: Yaoundé Central Hospital, Douala Laquintinia Hospital, Nylon District Hospital and 2 Lady Research Project (ANRS 12169). Semi-directive interviews and observations were conducted with 85 patients and 53 health professionals.

Therapeutic failure was often detected late due to a lack of routine viral load measurement. The reporting procedures are strongly marked by guilt on the part of caregivers who blame patients for failure. The methods of medical and psychosocial care vary from one site to another. Interventions were generally focused on the timing of treatment change, with little support for long-term compliance.

Therapeutic failure leads to a reconfiguration of caregiver-caregiver relationships. The ambivalent attitude of caregivers oscillated between compassion and reprobation. It reflected the distress of doctors faced with failure, perceived as a questioning of their practices. The limited accessibility of third-line therapies makes the occurrence of a new failure dramatic.

Therapeutic failure is a major public health problem, yet was not perceived as such. It is a powerful indicator of the limitations of the current capacity of the health system in Cameroon. Effective strategies for the prevention and early management of therapeutic failures require widespread access to viral load, third-line treatment, and better long-term medical and psychosocial support. They require national and international mobilization to preserve the effectiveness of ARVs which may provide hope to eradicate the epidemic.

Keywords : Therapeutic failure, Africa, Antiretroviral drugs, HIV, Cameroon

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#### When the origin of pharmaceuticals influences their use

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Through an ethnography of the pharmaceutical systems of Benin, Ghana, and Cambodia conducted from 2014 to 2016, we explored the perceptions of individuals about the origin of medications and how these perceptions influenced pharmaceutical purchases and use. These reflections are based on interviews and observations conducted in the three countries with pharmaceutical retailers and wholesalers, and their relationships with their clients and consumers of medication.

It appeared right away that individuals, more or less influenced by distributors, perceived different categories of medication related to assumed geographic origin and price. A value scale of the types of medication available was seen in the three different contexts. At the top of the scale were medications that were perceived to be manufactured by the formal colonial powers ("French medication" in Benin and Cambodia, "UK products" in Ghana), followed by those produced either in the study countries or neighboring countries ("medication from Nigeria and Ghana" for Benin, "Vietnamese medication" for Cambodia), and finally medications that were mass imported from countries further away ("Indian products" in Ghana or Cambodia).

These perceptions did not always correspond to the real origins of the medications and showed the impact of colonial history and contemporary politics on the use of pharmaceuticals. The question of the "subjective" quality of products, as mobilized by producers and distributers, appeared central in how pharmaceutical markets are structured in these countries and in the practices of individuals. In response to their overall financial ability, as well as the amount that they have to spend at the time of purchase, these individuals conducted an arbitrage between the desired quality of the products and their price. In this presentation we will show the arrangements of these arbitrages (effects sought: curative, preventative or health maintenance, for adults or children, etc.) as well as the social, political, and economic challenges that underlies this categorization of the country's pharmaceutical offering.

Keywords : perceptions, pharmaceuticals, origin, quality, markets

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### **5.** - Pharmaceutical consumption under the influence

#### Pharmaceutical ambivalence in Ebola treatment centers: A "magic bullet" that kills (Guinea, 2014-2015)

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At the phase of its "social life" shaping uptake, pharmaceutical ambivalence (cure and poison) is usually exposed by side effects. Generally, users balance advantages and disadvantages of treatment and engage in tolerating side effects, within certain limits. The ethnographic investigation of patients' relationships to pharmaceuticals in Ebola Treatment Centers in Guinea (2014-2016) does not validate this model. During the Ebola outbreak in West Africa, any confirmed case had to be managed in an Ebola treatment center and treated for its symptoms, with rehydration solutions, antibiotics, anti-inflammatories, anti-pyretic compounds, and micro-nutrients. Our study with Ebola survivors, conducted as part of Postebogui research project, which collected experiences and perceptions of 42 young adults, shows that most of them refused these treatments. They resisted the injunctions of health workers or used strategies to simulate taking pills and then threw medicines out of medical gaze. They considered pharmaceuticals a poison delivered to deliberately kill them.

Our presentation aims at explaining the perceiption of drugs as a poison by people who have experienced Ebola treatment centers. It describes their initial representations of the disease and its treatments, etiological theories and rumors, factual elements that supported these perceptions during their hospitalization, and elements that later made them switch to an opposite interpretation. We then analyze the perceptions of the healing process of Ebola virus disease and the role of pharmaceuticals. Finally, we discuss the singularity of this radical relationship to ambivalent pharmaceuticals, and its social effects.

Keywords : pharmaceuticals, representations, poison, Ebola, Guinea

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### **5.** - Pharmaceutical consumption under the influence

#### Care-seeking behaviors among households of different socioeconomic classes in urban and rural Ghana

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Medications are ubiquitous items in many households and their importance cannot be over-emphasized. Research has shown that about 30 to 40% of health expenditure goes toward medicines. As the most tangible aspect of the therapeutic itinerary, medicines continue to generate much interest among researchers. In recent years, care-seeking behaviors, including treatment decisions, have become an important subject of study to reveal underlying relationships between healthcare providers, medicine sellers, and their patients/clients. In a context such as Ghana, where the establishment of widespread national health insurance is well advanced, studying care-seeking behaviors also allows for a better understanding of how health financing shapes health behaviors.

The goal of this research is to explore how households of different socio economic classes in urban and rural Ghana treat common illnesses. The following key research questions guide this paper: 1) What are the differences in care-seeking behaviors and use of pharmaceuticals by households of different socioeconomic statuses in urban and rural Ghana? 2) How does national health insurance and access to different sources of care and medication impact these practices?

Findings presented here are based on the analysis of data collected with 15 households of varied socioeconomic status in urban Accra and 15 households (with the same socio-economic distribution) in and around rural Breman Asikuma. Methods of data collection included bi-monthly household monitoring of medication use as well as semi-structured interviews with household mothers and sometimes grandmothers or fathers. These data were analyzed qualitatively with a thematic approach. Findings from the data show that most illnesses were treated at home in both urban and rural households, regardless of socio-economic class. Most household members were covered by national health insurance, but due to practical reasons and perceived mastery of prescription practices, preferred to self-medicate rather than seek care from health facilities for illnesses not considered to be "serious". A greater difference in the types of facilities visited and of pharmaceuticals purchased was seen between different socioeconomic classes in urban Accra, most likely because of the greater diversity of types of medication and sites available in this area compared to rural Breman Asikuma, where all the families had similar careseeking behaviors.

Keywords : medication, Ghana, care-seeking, insurance, treatment decisions

# The influence of pharmaceutical marketing on physicians' prescription behavior in Egypt

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Pharmaceutical companies develop and manufacture medicinal products to improve people's health. However, the profit orientation of these capitalist industries prompts them to push the usage of their products at the expense of people's health. This, in turn, would maximise their sales and profits. As a result, public health is under threat not only in Egypt but also the world over. To achieve their capitalistic aims, pharmaceutical firms leverage on physicians' authority to prescribe medicinal drugs and on their social stature, whom the society values and trusts their recommendations. Pharmaceutical companies use an array of marketing strategies and enticements to incentivise the physicians to prescribe their products. These strategies bias physicians' prescription behaviour in favour of certain drugs. This, in turn, results in misuse and/or overuse of these drugs. Therefore, people's health and finances, as well as the country's economy, are adversely affected. Despite the broad existence of this phenomenon, little research studied it in the Egyptian context. Moreover, this phenomenon was always studied from the physicians' side while the industry's perspective was always ignored. In an attempt to fill these gaps and study pharmaceutical marketing's influence on physicians' prescription behaviour in Egypt, 17 semi-structured qualitative interviews were conducted with 13 physicians, three medical representatives, and one marketing manager. The interviews were conducted in three governorates, Al Ismailia, PortSaid, and Cairo. Using narrative and thematic analyses approaches to derive the findings, I argue that pharmaceutical marketing consciously and unconsciously entices the physicians to favour certain products over similar alternatives. Moreover, the physicians often fail to acknowledge their vulnerability to pharmaceutical marketing and often claim their self-immunity. Their self-invulnerability belief renders them even more vulnerable because they fail to safeguard themselves against these meticulously-tailored strategies. Lastly, the close-similarities among many products made the physicians comfortably pursue personal gains because they believe that they are not compromising on their patients' wellbeing. Therefore, it is not ethically problematic to benefit personally. Understanding pharmaceutical marketing and how it influences physicians' prescription behaviour help the physicians to stay true to the essence of their profession and provide policymakers with a firm foundation to safeguard the physicians, the patients, and the country's economy against these capitalist bodies.

Keywords : Pharmaceutical marketing, prescription-behaviour, incentives, public health.

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#### **Study of Protection Mechanisms for Participants in Clinical Trials Approved in Two Ethics Committees' Research Health in Benin**

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Background: In order to improve practices in clinical trials (CTs) rules, codes and statements were taken. It proves important to check if the Cts always receive adequate ethical framework and evaluated in accordance with the values and cultural standards. The general objective of this work is to study the participant mechanisms protection in clinical trials approved by two ethics committees' research health of Benin.

ethod: To study the participants mechanisms protection in clinical trials (CTs) literature review and semistructured individual interviews with various key actor are focused on nine components: registration, scientific evaluation, ethical evaluation, regulatory approval, consent process, vulnerable person protection; minimizing side effects, side effects treatment notify serious adverse effects to ethics committees and confidentiality.

Results: All CTs were subject to scientific assessment, ethical evaluation; describe process consent, vulnerable person protection; minimizing side effects, side effects treatment; notify serious adverse effects to ethics committees. Some CTs are not registered; others don't indicate the authorities' approval, or bodies monitoring.

Conclusion: This study shows that mechanisms to protect participants in clinical trials evaluated by the two ethics committees in Benin exist. These protection mechanisms are generally implemented by different players.

Keywords : clinical trial, protection of participants

## FACA® syrup production test, anti-sickle cells phytomedicine based on standardized bark powders

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Sickle cell disease is a major public health problem. It is the first genetic disease in the world. FACA syrup offers an alternative treatment. It is a dry powder preparation of two components, the roots barks of Zanthoxylum zanthoxyloides Lam. (Rutaceae) Zepernick, Timler and Calotropis procera. Ait. R.B.r. (Asclepiadaceae). The product was developed at Institute for Research in Health Sciences (IRSS) from a traditional recipe used in Burkina Faso for treatment of sickle cell crises. This study aimed to establish physical-chemical, pharmaco technical and microbiological control parameters essential for the standardization of the phytomedicine. This valuation concerned specifications of moisture content, pH, the fingerprint by thin layer chromatography, pesticide residues, heavy metal content, microbial quality, and total ash. These charcteristics were determined by the methods prescribed by the World Health Organization (1998) and the European Pharmacopoeia 6th edition. The results have shown that dry syrups and reconstituted syrups were sweet, slightly spicy with a bitter after taste, a white room color and a faint odor. The density at the preparation was 0.985 and the pH was 5.93. After 2 months of storage in the laboratory, the organoleptic parameters of the reconstituted syrups have not changed. They were mold free, the density remained around 1 and the pH between 5 and 4. These parameters have shown that the quality of plants powders and these medicine comply with the recommendations of the European pharmacopoeia. Faca syrup may contribute to the better management of sickle cell disease in children.

Keywords : FACA syrup, sickle cell disease, plant powder, medicinal plant, quality control.

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## Dosing Therapies: Artemisia annua whole plant therapy, resistance, and evidence production in Senegal

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Artemisinin-based combination therapies (ACTs) are the current front-line treatment for uncomplicated malaria recommended by the World Health Organization. Due to fears about the spread of artemisinin resistance in Sub-Saharan Africa, where the majority of malaria cases and deaths occur, global health regulatory bodies like the WHO and the Global Fund to Fight AIDS, TB, and Malaria promote the careful surveillance and protection of the chemical compound artemisinin through pharmaceutical regulation and clinical practices. In this global public health space where the fear of losing pharmaceutical effectiveness drives much of the recommendations that the WHO promotes to fight malaria, I wish to investigate the question of legitimization within the context of the humanitarian control of malaria. In this paper, I analyze the work of an international network of pharmacologists and plant biologists that aims to legitimize the use of whole plant therapy of Artemisia annua, the plant from which artemisinin was first isolated by Chinese pharmacologists in the 1970s. The WHO's stance on whole plant therapy is one of discouragement, and this network has attempted to produce the kind of evidence that would overturn this stance. They wield the concept of synergy and argue that the fear of the spread of artemisinin resistance,

stance. They wield the concept of synergy and argue that the fear of the spread of artemisinin resistance, on the heels of chloroquine resistance, should be a lesson to global health decision-makers that they should look for new ways of fighting malaria that do not put an isolated pharmaceutical agent at the foundation of their strategies. Based on interviews with pharmacologists and plant biologists and fieldwork with a community-based organization in periurban Dakar, Senegal, I discuss what is at stake for different members of this network and how the space of "informal" clinical trials opens up fraught questions about medical pluralism and evidence.

Keywords : Malaria, Artemisinin, Senegal, Artemisia annua

# Prescription practices for improved traditional medicines (MTA) in public health facilities in the city of Ouagadougou

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The introduction of innovations in "traditional" medicine has shown an accelerated dynamic during the post colonial period. These observed changes promoted the development of a new class of therapeutic substances called "improved traditional medicines" (MTA). From an ethnographic logic underlying decision-making choices about prescription, this article highlights the determinants that limit the prescription of MTA as essential medication and the foundations of the acceptability of this therapeutic resource.

Semi-structured interviews and direct observation were mobilized to collect data. The study population consisted of the prescribing public sector and of producers of MTA and NGOs in health. Research findings showed a wide variability of knowlege related to MTA among prescribers matching of heterogeneous prescribing practices, relating to particular conditions. Medication is one of the popular items of contemporary medical anthropology. Indeed, this therapeutic tool which is both a "social and cultural object ", largely transcends the medical world to become part of logical society. However, the adoption of MTA by prescribers seemed to face many challenges.

*Keywords : Key words: Traditional medicine improved, prescription, practices, perceptions.* 

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# **6.2** - The questioning before the diffusion and standardisation in the global context

#### Madagascar's Traditional Health Marketplace On The Move: Social & Economic Dynamics Between Local Stakeholders of Pharmacie Gasy

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While the practices of "traditional medicine" are often specific to a unique geographic and cultural locale, the mobility of the associated materials and practices are not bounded nor static. The discourse of medicinal plant economies and traditional knowledge have historically been separated by scale: the economic aspects being defined by being highly mobile and on the international level, and traditional knowledge defined as a phenomenon which is fixed and highly localized. This study challenges this epistemological portrait of local medico-botanical knowledge as stationary, with specific attention to Northern Madagascar's Pharmacie Gasy.

90% of Madagascar's flora is endemic and 27% of Madagascar's plants are estimated to have medical applications. Pharmacie Gasy, Madagascar's "traditional" system which employs the island's unique flora, arranges vendors, patients, and healers into a consortium of information and material exchange. The marketplace for pharmacie gasy between Diego-Suarez, Madagascar and the surrounding rural areas is formed by social threads of segmented knowledge across multiple locations, interlocutors and objects. Based on interviews, plant identifications and participant observations in 2013 and 2015, I conceptualize flow, borders, epistemological friction and the myth of stagnation as related to the knowledge economy of pharmacie gasy.

Beyond the reductive criteria of "utility" and "efficacy", I analyze the constellation of stakeholders engaged in a more nuanced valuation process of materials and services upstream of the national and international scales. By mapping the social and spatial arrangement of the marketplace, I present how the value and validity of "traditional knowledge" are locally determined by relationships of healers, vendors, collectors and clients mediated by factors such as systems of belief, lifestyle, interpersonal trust, and proximity to the forest. My data reveals that pharmacie gasy's division of labor between plant collection, identification, prescription, and diagnosis imbues the services and materials with dynamic local values that resist being flattened or rendered inert.

Keywords : health, market, plant knowledge, local, Madagascar

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# **6.2** - The questioning before the diffusion and standardisation in the global context

#### Distribution and commercialization of traditional medicine: perceptions, practices, and uses in Benin

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In Benin, the population's access to quality medication is an important challenge. The lack of essential medicines and the high cost of many pharmaceutical products as well as socio-cultural practices explain the use of traditional medicine. The role of traditional medications in addressing healthcare needs cannot be ignored. This presentation presents the findings of a study that was conducted in an urban research site, in and around the city of Cotonou, to identify the actors involved in the distribution and commercialization of traditional medicines, describe distribution and commercialization practices, and explore popular perceptions related to these medications and their uses.

Qualitative data collection was conducted using ethnographic research methods including semi-structured interviews and observation. Over fifty individuals from different sociological and professional backgrounds were interviewed: producers of traditional medicines, distributors, and clients.

In and around Cotonou, there is a strong diversity in the types of traditional medicines produced, as well as the types of production facilities, products available, and the actors involved. In general, the distribution and delivery of these medications operates informally, especially on urban buses, street markets, supermarkets, and the homes of producers. In addition, many producers of traditional medicines also provide healthcare in the places where they sell their medications.

In spite of official policies that allow for the development of traditional medicine facilities, traditional medications have still had difficulty integrating into the classic circuits and markets of industrial pharmaceutical medications. Many questions have emerged related to the quality and efficacy of traditional medicines encouraged by the presence of diverse actors, a weakness in overall organization, and continued general anarchy.

Keywords : traditional medicines, practices, uses, Benin, distribution

### 6.2 - The questioning before the diffusion and standardisation in the global context

#### When "Abibi Duro" becomes cosmopolitanzed : The commodification of herbal medicines in rural and urban Ghana

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Herbal medicines have been instrumental in the cure of ailments even before their incorporation into the health care delivery system of Ghana. Apart from their use as home-made remedies, herbal medicine practitioners also made extemporaneous preparations of herbs for the treatment of patients with different health conditions. Herbal medicines have gradually moved beyond the level of being used as home-made remedies and as extemporaneous preparations to becoming like cosmopolitan medicines in form and outlook (packaging), a reflection of the innovation in pharmaceutical production in Ghana. Despite the political commitment towards the development of herbal medicines as far back as the 1960's and the consequent incorporation into the primary healthcare delivery system, there has emerged a huge and booming market for manufactured herbal medicines in recent times. The numerous herbal medicine peddlers, shops, clinics, vans and advertisements exemplify the proliferation of manufactured herbal medicines on the Ghanaian pharmaceutical market as well as its increased usage. The herbal department of the Food and Drugs Authority (FDA) in Ghana records an average of 10 herbal products presented for registration weekly. Encased in such a phenomenon are issues surrounding commodification and pharmaceuticalization of health extensively explored with cosmopolitan medicines by Medical Sociologists/Anthropologists (Senah, 1997; Van der Geest 2006; 2011; Baxerres, 2011). Focusing on the medicines and the actors in the industry from the point of manufacture through to distribution and consumption, this paper will seek to explore the nuances surrounding the supply and demand of manufactured herbal medicines in two different socio-cultural and socio-economic contexts of rural and urban locations of Ghana. The paper will explore among others, the motivations for venturing into the herbal medicine business by manufacturers, the basis for producing the kinds of medicines they do, the logic behind customers preference for the kinds of herbal medicines they purchase and the sociocultural influences surrounding the demand and use of manufactured herbal medicines for various conditions. Ultimately, the paper will present a comprehensive picture of the rural-urban comparison of the commodification of manufactured herbal medicines and the pharmaceuticalization of health in Ghana.

Keywords : Abibi duro, commodification, pharmaceuticalization, Ghana, manufactured herbal medicine

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# **6.2** - The questioning before the diffusion and standardisation in the global context

## Who owns the plants ? Contestation between the state and herbal medicine manufacturers in Ghana

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Although herbal medicines and varying modes of indigenous healing practices have been part of Ghana's cultural heritage, they remained at the backstage of the official health care system during the colonial period. Unable to push for quick and widespread acceptance of allopathic health care, in 1892, the colonial administration banned the practice of traditional healing in the Gold Coast (now Ghana). Efforts of the first post-colonial administration – and to some extent latter day administrations - to restore the lost image of traditional healers and healing did not succeed due mainly to politico-economic instability. However, from about the early 1970s when Ghana's economy, like those of most developing countries, fell into the economic morass of what development analysts refer to as 'Africa's Lost Decade,' herbal medicines began to move steadily from the colonially-imposed backstage to front stage actors. The near-collapse of the health sector due to Ghana's inability to import medicines, repair malfunction medical gadgets or procure new ones and the heavy exodus of health personnel called for the development of a new health care strategy. One important consequence of this development is the exponential growth of the herbal medicine industry engendered among others, by a liberalized economy and mass media communication, growth in the ICT industry, the emergence of large market and demand for herbal medicines by the local population and Ghanaians in the Diaspora.

In the domain of health care, one of the tasks of every government (state) is to regulate the manufacture, distribution and consumption of medicines so as to safeguard the health and wellbeing of the population. In Ghana, the desire of the state to promote herbal medicines while at the same time ensuring their safety for mass consumption has meant that herbal medicines, like cosmopolitan medicines, must be subjected to regulatory measures. This has generated contestation between the state medicine regulatory agencies and herbal medicines producers. The issues of contestation range from who is qualified to produce herbal medicines to who has patent right over these medicines.

The main orientation of this paper, therefore, is to interrogate some of the controversies surrounding the production, distribution and consumption of herbal medicines, the nature, forms and consequences of these controversies and the coping mechanisms adopted by the contending actors. Ultimately, this paper is intended to contribute to the macro discourse on the multiple stakes surrounding medicines in contemporary Africa.

Keywords : cultural heritage, traditional medicine, colonialism, contestation, safety, mass consumption

#### Representations and social uses of antimalarial drugs in Togba

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Benin has changed its national malaria management policy since 2004, opting for therapeutic combinations based on Arthemisinin (ACT). These have been adopted as a simple malaria treatment drug by the World Health Organization (WHO) in endemic countries. Various approaches have been developed to ensure wide dissemination of these drugs. The aim of this research is to understand the representations and social uses of pharmaceutical antimalarial drugs in Aïzo of Togba (municipality of Abomey- Calavi). Specifically, it aims to (i) identify the different social uses of pharmaceutical antimalarial drugs in Togba; (ii) to analyze the social representations and ancestral knowledge of the socio-cultural group Aïzo related to malaria and its interference on the uses of pharmaceutical antimalarial drugs ; (iii) to examine the influence of the costs of malaria treatment on the social uses of pharmaceutical antimalarial drugs in Aïzo de Togba; and (iv) finally to analyze the institutional issues behind the social uses of pharmaceutical antimalarial drugs in Aïzo de Togba; and (iv) finally to analyze the institutional issues behind the social uses of pharmaceutical antimalarial drugs in Aïzo de Togba; and (iv) finally to analyze the institutional issues behind the social uses of pharmaceutical antimalarial drugs in Togba (it) finally to analyze the institutional issues behind the social uses of pharmaceutical antimalarial drugs in Aïzo de Togba; and (iv) finally to analyze the institutional issues behind the social uses of pharmaceutical antimalarial drugs in Togba (it) finally to analyze the institutional issues behind the social uses of pharmaceutical antimalarial drugs in Togba (it) finally to analyze the institutional issues behind the social uses of pharmaceutical antimalarial drugs in Togba (it) finally to analyze the institutional issues behind the social uses of pharmaceutical antimalarial drugs in Togba (it) finally to analyze the institutional issues behind the social uses of pharmaceutical antimalarial drugs in To

A qualitative methodological approach was adopted to examine these issues. Interviews were conducted with 30 actors including 20 mothers / fathers of children under five years of age at the household level, six pharmaceutical drug vendors, two health workers and two herbalists in the second half of 2015. Analysis of data treatment was conducted according to the thematic analysis method.

Research findings showed that (i) in the case of malaria, mothers / fathers of children practice selfmedication to calm the pain felt by their child with informal market medications (ii) the pharmaceutical antimalarial drugs are always used in combination with medicinal plants for the treatment of malaria of children and sometimes adults; (iii) the financial reasons associated with the direct costs and indirect treatment costs of malaria in Aïzo reinforce self-medication practices; (iv) the various previously recommended drugs are still rooted in the behavior of some mothers when it comes to the curative treatment of malaria including the use of Chloroquine. It appeared that the health system at the center of which pharmaceutical antimalarial drugs are found was associated with "traditional" knowledge that shaped popular knowledge about health in Aïzo of Togba.

Keywords : Social representations, malaria, sel-medication, usage and Togba

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#### Drugs containing clay at the traditional medicine unit of the Ivory Coast: between standardization and personalization

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Vis-à-vis the high cost of the medical services, a strong dependence on externally supplied drugs and of the weakness of medical coverage, the World Health Organization (WHO) has recommended that developing countries make use of local resources to address the health needs of their populations. The Ivory Coast has established a pilot Traditional Medicine Unit to support collaboration between conventional medicine and traditional medicine. Located within an urban hospital structure (CHU of Treichville), the Traditional Medicine Unit (UMT) opened on August 9th, 2013. Its opening allowed for the treatment of pathologies such as: malaria, typhoid fever, sickle cell disease, diabetes, arterialhypertension, viral diseases, cancer, colopathie, osteoarthritides, etc.

As a place for consultation and sale of "traditional drugs" containing clay, the unit of traditional medicine offers an alternative of care to patients. Anthropology and the methodology of evaluation in public health were mobilized. Interest related to the statute of the drugs traditional containing clay of the unit of traditional medicine of Treichville made it possible to identify that drugs containing clay prescribed within the unit meet the standards of the traditional drugs used for human use. This was confirmed by the national laboratory of the public health of Ivory Coast (LNSP-CI) and at the University Kwame Nkrumah of Kumassi in Ghana. These tests related to microbiological quality, pharmacological tests, physico-chemical tests and toxicological tests. Produced in liquid, solid, paste forms and powders, the drugs containing clay were exclusively made by AboutouKouassi, argilotherapist, and were prescribed during doctor visits by general practitioners and adapted during the following consultations by the argilotherapist.

Keywords : Drugs; clay; unit of traditional medicine; standardized; Ivory Coast

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# Between politics and medical: difficulties and ambiguities of methadone substitution treatment in Senegal

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Introduction : Injecting drug users (IDUs) in the Global South are often seeking care for their addiction in a context where health systems do not offer them services and national policies are hostile to opioid substitution drugs. In Dakar, since 2015, an Integrated Center for the management of addictions (CEPIAD) has been offering medical and social support including opioids substitution treatment (OST) using methadone. This presentation aims to describe the political adjustments that led to the introduction of this "drug-treatment" and to analyze the medical ambiguities raised by its release in Dakar. Method : The data used for this presentation come from qualitative studies (interviews, focus groups and participating observation) with several populations in Dakar (IDUs, health and social support actors, caregivers, associations, state authorities) between 2012 and 2016 in Senegal. These data were completed by a survey of resource persons between February and March 2018.

Results : CEPIAD offers integrated management of addictions, including opioid substitution treatment for heroin users, using methadone (previously unauthorized in Senegal). In March 2018, 252 injecting drug users were included in the methadone program, of which 64 stopped treatment for various reasons. The urgency of a health intervention with the CDI shown by the initial epidemiological survey (2011), which reveals very high prevalences for the hepatitis C virus and for HIV and HBV, a major mobilization argument. The initiating team CEPIAD to advocate and implement strategies to make substitution treatment and harm reduction possible to limit the achievement of CDI and the possible extension to the general population. IDUs in treatment have various representations of the function and effects of methadone, related to their expectations of a "miracle drug". Caregivers, attentive to the demands of the IDUs, adopt, for certain aspects, attitudes of flexibility by readjusting the treatment according to their needs and wishes, while setting limits on the specific bases.

Conclusion : The Senegalese experience of methadone delivery, the first of its kind in West Africa, plunges the sub-region into an international dynamics of treatment for IDUs. However, to better take into account the specificities of Africa, it is necessary to integrate into this treatment program some significant components such as organizational, political, legal and economic aspects.

Keywords : Methadone, medication, harm reduction, injecting drug users

#### Using medical abortion in Madagascar: a trivialized practice?

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Madagascar is characterized by a deterioration in the public health supply. Access to biomedical care is limited, including in gynaecological and reproductive health. Abortion is illegal, as is the prescription of abortion medications. However, it is estimated that abortive complications are the second leading cause of maternal deaths in health facilities in Madagascar.

In order to identify risk factors that could lead to complications of abortion, an anthropological study was carried out in 2015-2016 in two rural and urban areas of Madagascar. Semi-directive interviews were conducted with 60 women who had experienced abortion complications, 20 health professionals and 20 traditional practitioners.

We return here to the stakes, uses and meanings of medical abortion in the specific context of Madagascar. The results of our study show that nearly a third of the women surveyed used misoprostol for abortion, and that it is readily available to some private sector health professionals, formal drug vendors (urban pharmacies, rural drug depots) and informal channels. Due to the approximate knowledge of women and health professionals about how misoprostol is used for abortifacient purposes (dosage, route of administration, terms of pregnancy), there are wide variations in how misoprostol is used, which may lead to incomplete abortions or complications. There are several reasons why this abortion method is preferred. Misoprostol has a high social profile: women are aware of its existence, its abortion effects and the places where it can be purchased. It is easily accessible, prescription is not needed, and relatively inexpensive. It is perceived as easy to use (oral or vaginal), and does not necessarily require the intervention of a third party, which allows some women to abort in secret. Being perceived as a "modern" medicine, women give it great effectiveness, a source of confidence.

These results raise questions about the trivialization of the use of medical abortion, in a context where the use of modern contraceptive methods meets with great reluctance on the part of women and where the maintenance of a contraceptive method is a problem. These findings highlight the need to inform women and train health professionals and pharmacists in the use of misoprostol as an abortifacient drug.

Keywords : Madagascar, medication abortion, misoprostol, trivialization, complications

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## The marketing of traditional and "neo-traditional" treatments of viral hepatitis in North Benin

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The objective of this study is to describe the market of traditional healing of hepatitis B and C in the north of Benin. The study is inspired from research titled "viral hepatitis in Benin: risks and conventional and alternative treatments". Documentary research, individual interviews and observations were the three methods used to conduct this purely qualitative work. The results show that the market of traditional and "neo-traditional" treatments was in full expansion in the north of Benin. The marketing of traditional and "neo-traditional" treatments of chronic diseases in general and particularly hepatitis B and C were related to a competitive supply of treatments between conventional and traditional medicine. The expansion of traditional and "neo-traditional" treatments of hepatitis B and C can be explained by the wide advertising of neo-traditional treatments, the insufficiency of modern centres for the treatment of viral hepatitis and the limits of the treatments provided by these centers.

Keywords: viral hepatitis, neo-traditional treatments, marketing, north Benin

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#### Market Entry and Operation Strategies of Indian Pharmaceutical Firms in Francophone West Africa: Findings from the Case of Mali

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The Indian pharmaceutical industry has evolved into a generic powerhouse, and several Indian firms have become truly global players. They present a successful case of foreign expansion by emerging country multinationals. However, the extant literature on the international expansion of Indian pharmaceutical firms has mainly focused on "hows" and "whys" of their penetration into on highly regulated markets such as the US and Europe. Studies have taken a reductionist approach towards pharmaceutical markets in developing countries, particularly Sub-Saharan Africa, treating them as an intermediate step before moving to developed countries. This simplistic approach towards the African market has restricted our understanding of its richness engendered by the complex interactions between firms, states, and international organizations.

In this light, our goal was to understand the organization of pharmaceutical supply-chain in Francophone West Africa by focusing on Mali and to analyse the market entry and operation strategies of Indian firms within the influence of this broader institutional environment.

First, we conducted semi-structured interviews with actors at various levels in the pharmaceutical supplychain in Mali. It was supplemented by another set of semi-structured interviews of the managers of Indian firms. Second, Malian market authorization list for pharmaceutical products was analysed to provide additional evidence concerning the activity and strategic choices made by Indian firms. Third, we also extracted trade data between 2001 and 2016 from International Trade Centre website to analyse the growth of Indian pharmaceutical firms in Francophone West African countries. Lastly, we undertook a review of the literature including national legislation and reports by international organizations. We demonstrate that the general architecture of supply-chain of medicines in Mali consists of four distinct market segments: government-funded public market, donor-funded public market, formal private market and informal market. These market segments differ in their in their construction, organization, regulation, functioning, and size. We further reveal that the business strategy of Indian firms is guided by the institutional characteristics of the market segment in which they intend to operate. Thus, firms use different strategies for different segments resulting in a combination of entry modes directed towards the overall penetration of the market.

*Keywords : market-entry, Indian firms, medicines, Africa, internationalization* 

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## Registration of multi-source generic medicines intended for the public sector: a model for sub-Saharan Africa

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The procurement agencies of French-speaking African countries preselect their procurement sources as part of their tendering procedures through an agreement process based on an evaluation of all documentary information on products and manufacturing sites and product samples sent by the tenderers. In order to be contracted, the suppliers are required to register the pharmaceuticals they will provide, sending to the National Pharmaceutical Regulatory Authority (NRA) a technical dossier, very similar to the one previously sent to the procurement agency, but in another format. Unfortunately, this obligation is generally not respected by the suppliers and no repressive measures are taken in case of absence. A legal and technical solution is therefore needed, to improve the qualification and registration's efficiency of the pharmaceuticals purchased by the public procurement agencies.

The objective of this research was to elaborate a new organisational model of the qualification process for the public procurement sources, that will comply with all technical (Quality assurance standards and norms), public health (protection of the populations) and regulatory (registration by the NRA) requirements, and to propose to all stakeholders a streamlined approach for the public sector procurement contracts. Starting from an analysis of the organisational and operational challenges in the product preselection and registration dossiers evaluation processes, from the procurement agency point of view and NRA point of view in Togo, we highlighted the system weaknesses and malfunctioning elements, and proposed improving measures, redistributing the roles among the national stakeholders. The process review conducted with the Togolese institutions confirmed the need (i) to improve coordination between the national procurement agency and the NRA in the procurement sources qualification process, (ii) to normalise both the preselection and registration procedures and the technical dossier format, defining a unique procedure and document format, complying with the regulatory requirements, (iii) to set up a specific registration process for the multi-source generic medicines purchased by the national procurement agency and intended for the sole public sector (this being justified by the specificity of the packaging type or pack size of the product targeting the public sector). A detailed action plan to adapt the procedures and the regulatory framework, aiming at setting up and implementing such a system was developed, based on (i) an in-depth analysis of the existing regulation and procedures, (ii) the definition of a common technical dossier complying with the CTD format and adapted to the requirements for multi-source generic medicines registration, and (iii) defining and implementing all juridical reforms required for this regulatory evolution. The main implementing constraints were also identified and measures to overcome it were defined.

The model proposed offers a pragmatic and innovating solution, based on an adaptation of the regulation for multi-source generic medicines registration intended for the sole public sector, also redefining the respective roles and responsibilities of the stakeholders in the public sector procurement process. We hope that this proposal, shared with other French-speaking African countries stakeholders, will help to adapt the regulatory framework and regional guidelines in order to improve and accelerate the provision of effective and secure multi-source medicines in the public sector.

Keywords : multi-source medicines, preselection, registration, regulation, normalisation

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#### Detection using simple and advanced analytical techniques, of antimalarial drugs (therapeutic combination artemisinin: CTA) of lower quality marketed in Benin

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Contexte: les médicaments de qualité inférieure représentent encore une menace pour la santé publique, en particulier en Afrique subsaharienne, qui est victime d'une part disproportionnée du fardeau mondial du paludisme. Il est essentiel et urgent de renforcer les mécanismes de lutte contre les médicaments de qualité inférieure. Ceux-ci regroupent: les médicaments contrefaits, les sous-standards et les produits dégradés. L'une des approches est la surveillance régulière du marché grâce à des contrôles de qualité. Méthode: 12 échantillons de médicaments à base d'artéméther et de lumefantrine ont été collectés dans le circuit formel (officine de pharmacie) et informel (marché, abords de rue) de médicaments à Cotonou (Bénin). D'autres échantillons similaires ont été également collectés au Rwanda (13 échantillons) et en RD Congo (9 échantillons). La chromatographie sur couche mince (CCM) comme t est d'identification classique et simple a été appliquée au Bénin dans le Laboratoire de Chimie Analytique et Analyse des Médicaments (LCAM; UAC/FSS), tandis le Laboratoire de Chimie Analytique (LCA; ULg/Département de pharmacie) en Belgique et préqualifié OMS pour le contrôle de qualité des produits de santé a été sollicité pour analyser les échantillons au moyen des techniques analytiques utilisant des équipements plus sophistiqués notamment la spectroscopie Raman pour l'identification de l'artémether, de la luméfantrine et/ou autre composé chimique présent dans les médicaments tandis que la chromatographie liquide à haute performance (CLHP) couplée à un détecteur à barrette de diodes a été utilisé pour confirmer l'identification des principes actifs mais surtout pour connaître leur teneur. Résultats: Les résultats obtenus en Belgique ont confirmé l'absence de l'artémether et de la luméfantrine

dans l'échantillon suspect de CTA en provenance du Bénin, alors que certains échantillons CTA du Rwanda et de la RDC étaient de qualité inférieure dans la mesure où l'on avait obtenu des teneurs hors normes (sous-dosage et surdosage) par rapport à la déclaration des fabricants.

Conclusion: La contrefaçon / falsification de médicaments à base de combinaison thérapeutique d'artémisinine (CTA) est un véritable fléau qui doit être combattu par une forte collaboration entre les autorités nationales de réglementation (ANR) pharmaceutique et les laboratoires de contrôle de la qualité qualifiés.

Keywords : Drugs of lower quality, Artemether / Lumefantrine, TLC, HPLC, Raman Spectroscopy

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