

## **Endogenous institutional change in favor of access to medicines: the case of Algeria**

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**Summary:** Ostrom's (1990) work on natural resources is one of the new models of governance and invites us to take a fresh look at how we think about politics, through which it opened a gap in understanding how individuals and organizations self-organize to collectively reap the benefits of renewable resources. We support the hypothesis that the notion of access to medicines must be considered as a common good in the Algerian health context. It should be carried out within the framework of "Focal Monopoly of Governance" presented by Meisel (2004) and is considered as a potential response to the institutional and political blockages of access to medicines in Algeria. We use the term "Focal Monopoly of Governance" to apply it to the question of access to medicines in Algeria, as a way of overtaking to coordinate the divergent interests between actors. This FMG would be intended to cover the needs of essential medicines under four levers of accessibility: qualitative, legal, economic and geographic.

**Keywords:** Algeria; Common good; Change ;Access to medicines.

**Jel Classification Codes:** I10; I18, I28.

### **I- Introduction :**

Since independence (1962<sup>i</sup>), Algeria has invested heavily in the field of health in order to improve the health conditions of the population first and the protection of women and children secondly. Health facilities, such as hospitals, clinics and public health centers, have been set up throughout the country. In terms of human resources, the number of doctors, dentists, pharmacists and nurses has been steadily increasing since the 1990s thanks to the increase in state-built training centers. Until the beginning of the 1990s, this multiplication of healthcare structures and medical staff led to a very strong growth in the public health sector spending supported by social security (Oufriha, 1997). Indeed, thanks to the efforts made by the public authorities in the field of health, several communicable diseases have been largely eradicated. The improvement of the standard of living of the majority of the population has led to the emergence what we call "civilization" disease characteristics of industrialized countries (diabetes, cancer, cardiovascular). Algeria has always made considerable efforts to socialize the consumption of medicines (principle of free admission, price subsidies, and general health insurance). However, since the beginning of the 1990s, the public authorities have been facing new economic, political and health challenges that require them to undertake far-reaching reforms. These health challenges include: the postponement of the financing of the expenditure on households; the aging of the population because of the demographic and epidemiological transition; blind reimbursement of non-essential medicines from the Social Security. This wave of profound reforms, leading to the liberalization of the Algerian pharmaceutical sector, has led to institutional changes in terms of choice and public decision-making in the political, social and economic spheres.

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As a result, inequalities at the national level are increasing in terms of the difficulties of access to medicines, so that the current system of medication management, set up by the public authorities, faces a challenge such that part of the population does not have access to essential medicines, especially heavy diseases (cancer). The social and societal utility of medicines is recognized by all health professionals (pharmacists, doctors, etc.) as well as by public decision-makers. In this respect, we support the hypothesis that the notion of access to medicines is a common good. Coordonier, (2012), believes that commons are not given, but rather stated, and defines it as "a property that one collective believes should be considered a benefit to all and to which everyone should have access" (p.3). This notion of access to medicines cannot be delegated to the private sector, because there are a number of stakeholders (public and private actors) to produce this collective quality. This collective utility is represented by the improvement of the health status of the populations. The dual character of the common good (non-rival and non-exclusive) means that everyone can enjoy it without preventing anyone from enjoying it. . According to Coordonnier (2012, p.4), the commons are then a social construction: "the common goods are the subject of a collective deliberation between actors aiming to identify the aims of economic development". This phase of formulation and social construction goes through a process of deliberation and enunciation taking into account all the conditions favoring its emergence, whose final objective will be the attainment of a goal. From this point of view, the commons generate positive externalities in that they contribute to the improvement of public health. This "political" staging of institutional change in favor of access to medicines requires the focusing of the conceptions of all the actors involved in order to put it on the schedule of the public decision-maker. Access to medicines is now an eminently political subject, in other words, it is at the center of debates both at the national and international bodies and organizations, whether public or private. It is an essential component in all health policies and requires all the appropriate consideration on the part of the public authorities for which they are responsible for putting in place the necessary mechanisms for taking this principle. Our work addresses a critical approach vis-a-vis of the public policy of access to medicines in Algeria for fifty years.

We rely on the work of Ostrom (2010) and Meisel and Ould Aoudia (2007), carried out respectively in the field of natural resources (water, wood) and that of governance, to transpose them to that of health. We will proceed in three stages. We first recall the applicability, the limits of the application and the results of Ostrom's work. It has come from case studies to show that other modes of governance exist, apart from the state and the market. We will then focus on presenting the Focal Monopoly of Governance as an instrument for coordinating medicine actors around the notion of access. This brings us subsequently to examine the applicability of this FMG to Algeria.

## **II- Applicability of Ostrom's work to the issue of access to medicines:**

Ostrom's central thesis states that, in a large number of situations, free interaction between actors enables them to overcome the conflicts of interest and dilemmas they face, by building themselves adequate institutions (robust<sup>ii</sup>). This interaction raises the question of which criteria will guide the selection of rules and institutions. Although Ostrom's work is part of the New Institutional Economy, his intellectual references are very diverse and move away from the NEI's vision about the place of efficiency. Regarding the choice of rules and institutions to adopt, it emphasizes the diversity of evaluation criteria that must be taken into account while remaining open to the question of who will fundamentally guide these choices. The construction of institutional systems and modes of governance can only be a process of trial and error and of long collective learning. The scope of Ostrom's work concerns the common natural resources most often renewable in a small-scale community. The main question raised by Ostrom is the depletion of these resources and their long-term management, while trying to understand why certain groups of individuals and institutions do sustainably manage their resources, while others do not arrive. Ostrom's theory invites us to take a fresh look at how we conceive of politics, through which it has opened a gap in understanding how individuals and organizations self-organize and govern themselves in order to collectively reap the benefits of renewable resources<sup>iii</sup>.

It then develops its theory of institutional change based on an impressive amount of field data and an interdisciplinary approach by presenting in a concrete way the places where resource management has been successful and attempts to suggest a theoretical synthesis. From long reflections on the organization of the Common Pool Resources (CPR), she has been led to construct a thorough institutionalist theory that has a much more general scope. This theory is guided by a certain social and political vision, centered on the virtues of "self-governance". His work on the governance of the commons (water, timber, etc.), showed that compromises between public and private actors are possible and feasible. It has shown that the management of the commons can be done by other modes of governance than nationalization (State) or privatization (enterprise). Ostrom argues that decisions must be made close to the place of action (the resource of the common good) by encouraging polycentric governance systems and never come up with a single solution. Based on the work of Olson (1965<sup>iiii</sup>), and the results of the observations of the organization of Common-Resource Pools, Ostrom has proved that private actors are able to solve collective action problems, by building them rules systems, modes of governance adapted to the specific problems confronting them. According to Ostrom's empirical results, the likelihood of resources collapsing or depleting is higher when they are found in large quantities or their economic value is high when the actors do not communicate with each other and fail to create rules and standards to manage the common good. Successful management of the "common good" involves putting in place effective rules for collective action. The relative success factors of this institutional change have the characteristic of being "incremental" (aggregating and increasing), "sequential" (in stages) and "autotransforming" (experience forms and takes shape), "in a political regime facilitating" (external factors are often determinant for success or failure). Each change transforms the structure of incentives and influences future strategic decisions. Throughout the analysis of success stories, Ostrom reaches the idea of similarities in "design principles". These principles provide answers to "how individuals, fallible and likely to adopt norms, they apply conditional strategies in complex and uncertain environments "(p. 223).

The Perception Principles of the Success Case Analysis are as follows: 1. The boundaries are clearly defined; 2. The concordance between the rules of appropriation and supply and local conditions; 3. Collective choice devices; 4. Surveillance; 5. Gradual sanctions; 6. Conflict resolution mechanisms; 7. Minimum recognition of the rights of organization; 8. Nested businesses for common resources belonging to larger systems (pages 114-115).

With these eight conditions, an institution is deemed stable, according to Ostrom: all the stable institutions observed combine these eight conditions and all the institutions that failed at least one of the eight. The cases examined in the fourth chapter of the Ostrom book are in the 20th century in the United States, and the dispute settlement procedures are much more complex because they go beyond the community and involve state institutions. The important element of the renewal brought by Ostrom is that what belongs to the common or collective perimeter has its origin in a political decision; whatever the level at which it is taken, from local to global. Collective action is then required in order to establish and strengthen the rules for taking the common goods. The work of Ostrom has a scope that goes beyond the question of the commons and that of the analysis of institutions. We therefore found it relevant to apply them to the case of access to medicines in Algeria.

### **III- Focal Monopoly of Governance: Endogenous Institutional Change Tool for Access To Medicines in Algeria :**

The work on public policy can be split in two: some work focuses on institutional or stakeholder change, while others focus on the study of policy instruments and ideas. Our Focal Monopoly of Governance is more in line with the second stream, the study of public policy instruments (Hoffler et al., 2010, p.132-133). In our view, the policy instrument approach enriches the analysis of public action as it relates to the analysis of the processes of change. In recent work on the instrumentation of public action, instruments are analyzed as "revealers" of change (Lascoumes and Le Galès, 2004). According to them, the analysis of the instruments of public action would make it possible to apprehend the relations between the State and society (op.cit p. 22). The instruments of public action are carriers of values, nourished by an interpretation of the social and precise conceptions of a specific representation of the mode of regulation envisaged.

Instruments of Public Action have the opportunity to set objectives to be achieved taking into account the diversity of actors. These instruments of change can have their effects on public policies. They can also be the subject of conflict and dissent between stakeholders (pharmaceutical companies, patient associations, representatives of different ministries, health professionals, etc.). We have already set before Ostrom's work as an essential tool for human cooperation for both natural resources and other "commons" at both local and global levels. Ostrom, through the analysis of success stories, raises the importance of design principles to the success of projects. This lesson seems to us more relevant and adapted to our case of access to medicines in Algeria.

Indeed, the enunciation of this collective common good, which is the access to medicines, must be the subject of a common conception shared by all the actors of the medicine. In a context of care and coverage of people's basic medicine needs, institutional change in favor of access to medicines is better achieved through the construction of local compromises between public and private actors around this common good. With the aim of bringing together the actors of the medicine, in Algeria, around a common conception namely the promotion of the notion of access to medicines, in which the State intervenes as "coordinator" of the set of the stakeholders, with a view to organizing this collective action oriented towards the provision of this common good. This engine of collective action is represented by the "Focal Monopoly of Governance" which is a mode of organization consisting in subordinating the logic of public and private actors to the common interest. Our goal here is to study the genesis of this instrument in the field of access to medicines in Algeria.

### **III.1- Presentation of the Focal Monopoly of Governance :**

The FMG was first presented by Meisel (2004) and then by Meisel and Ould Aoudia (2007) as a model of governance deviating from "Western models of governance". The FMG is a mechanism through which the French State has established itself as the single and undisputed focal point at the heart of the process of forming economic and social compromises (Meisel, 2004, p.47) Moreover, its mission is to make the interests of the economic, social, administrative and political elites compatible with each other and, above all, to promote their collective interest by avoiding situations of permanent conflict through a regulatory body in order to bring about the emergence of a common interest.

Meisel examines what were the institutions of governance, both companies and the state apparatus, in the France of the Thirty Glorious, which then knew an economic expansion never equaled\*. Raising concern about the importance of the cultural context in which governance unfolds, Meisel strongly relativizes the scope of rules, often perceived as valid at all times and places. In addition, it draws lessons from its analysis applicable to the developing country. This Focal Monopoly of Governance can rely on informal practices and interpersonal relationships to coordinate stakeholder interests (Meisel, 2004<sup>+</sup>). In addition to its original mission of coordinating actors, the formation of an FMG can also be considered as a more realistic and relevant alternative in developing countries, for two reasons according to Meisel and Ould Aoudia (2007). First, there is a high cost involved in establishing a formal and impersonal institutional framework. Indeed, in the analysis of changes, two types of approaches have long structured the debate: on the one hand, those who envisage rapid and radical changes emphasizing the cognitive dimensions of public action; on the other, institutional approaches that reflect continuity (path dependency).

Cognitive approaches lead to high costs and not a long-term perspective. Therefore, the approach by the instruments then makes it possible to prolong the approach by the dependence on the borrowed path). Secondly, the FMG can build trust by operating within the framework of the existing traditional social order and by using the modes of social regulation rooted in interpersonal bonds. This system makes it possible to varying degrees to regulate the interplay of special interests in the economic and social field in order to achieve a "common" interest. According to Meisel (2004, p. 72), the hypothesis of the French governance focal monopoly provides a perfect example of a governance mechanism in which trust plays a role of leverage. He associates this notion with that of social capital and organic sociability, in other words, the ability to cooperate

spontaneously, that is to say on the basis of shared, informal values, rather than rules by institutions such as the family or public authority, or formal contracts.

### III.2- Application to Algeria :

The political-economic transition is the process that allowed Algeria to bring about a global institutional change affecting all institutions at all levels simultaneously creating an economic downturn. In the early 1990s, political instability led to social instability, and subsequently spawned an armed conflict. This situation has led to a loss of confidence of civil society vis-à-vis the political power, and even to the senior officials of the state. This accelerated liberalization had led to a global deregulation of the medicine market, from the selection of essential medicines, the starting point of the accessibility process, to the authorization of the marketing of medicines, to all activities relating to importation and distribution. As a result, two logic emerged in the medicine market in Algeria, market logic and another ethics. The first one called "dominant" is represented by private actors seeking to maximize their profit in an attractive and lucrative market, the second one called "dominated" is related to the right of the population to access to medicines. Our major intuition is that the political and institutional change in Algeria has had difficulties to take place because of the existence of a balance of power in the social, economic and political spheres at all levels, national and international. The market logic, which currently prevails in the pharmaceutical sector in Algeria, means that the basic needs of certain sections of the population remain unfulfilled.

The establishment of this institution requires strong state intervention. Meisel argues that this type of regulatory system has been beneficial in countries where market incentives don't operate at the systemic level, that is, where signals from domestic and international markets are not sufficient to coordinate economic agents on a productive balance. In our case study, we use the term "Focal Monopoly of Governance" to apply it to the question of access to medicines in Algeria, as a way of overtaking to coordinate the divergent interests between actors. However, we do not hear it from the Williamson perspective (reduction of transaction costs), but rather to promote access to medicines as a common good. This FMG would be intended to cover the needs of essential medicines under four levers of accessibility: qualitative, legal, economic and geographic. For the mapping of this FMG, we have based on three types of sources: interviews with medicine actors (public and private), observations made during visits to industrial sites, and finally secondary documentation. We consider that this FMG should be based on four key levers:

- **The first lever** of our FMG is the selection of essential medicines, called qualitative accessibility based on a system of selection of essential medicines. The WHO defines the selection of essential medicines, through its expert committee on the use of essential medicines: "Essential medicines are those that meet the health needs of the majority of the population". They are selected based on their public health, efficacy, safety, and cost-effectiveness relative to other medicines. Essential medicines must be available in the context of an existing health system at all times and in sufficient quantity, be of appropriate dosage, be of guaranteed quality and be sold at a price that is affordable for the patient and the community. In the early years of independence, Algeria had made efforts to improve access to medicines<sup>±</sup>. The first efforts concerned the improvement of qualitative accessibility via measures to establish the principle of essential medicines as early as 1973 for a "better" organization of the system of medicine purchases based on a national need identified by a group of experts. Among these essential measures to regulate the market of the medicines was the creation of the National Commission of Nomenclature (NCN) in 1980 whose main role was to devote the concept of essential medicines according to the recommendations of the WHO. In addition to this task, NCC also assumed the role of marketing authorization board until it was suspended in 1997. Unfortunately, it did not exercise sufficiently its role as coordinating institutions. i.e. the establishment of a regulatory system for the national pharmaceutical policy, regulation of the pharmaceutical market (promotion of human resources development, quality assurance, analysis of the availability of medicines selected by it, rational use ). This dissolution revealed the lack of visibility on the part of the public authorities and ushered in a new era in the institutional field of medicine. The actors in this accessibility phase are composed of the National Commission for Nomenclature (NCN); the national center for pharmacovigilance (NCPM); the National Pharmaceutical Control Laboratory (NPCL) and patient associations.

- **The second lever** for legal accessibility is based on a flexible Intellectual Property Rights (IPR) system that favors the generic medicines. We are studying how the strengthening of pharmaceutical IPRs will impact the coherence of the accessibility policy process. Intellectual Property Rights (IPRs) are in essence institutional constraints to promoting access to medicines in developing countries that do not have a local pharmaceutical industry. The constructivist approach addresses the issue of strengthening IPRs not in static and / or dynamic terms and their effects on innovation or the terms of trade, but focuses mainly on the actors involved in this strengthening i.e. the stakeholders and their roles in ensuring access to medicines in developing countries. Monitoring the filing of pharmaceutical patents on essential medicines at the INAPI<sup>8</sup> level is essential for promoting access to medicines. Our aim was to highlight the legislative alignment initiated by the Public Authorities in the field of pharmaceutical invention patent under the TRIPS Agreement. This patent protection has not been seriously evaluated by the Ministry of Health. Studies on the impact of TRIPS on access to medicines in Algeria, whether governmental or academic, are not numerous. The main public and private actors in this sequence are: the holders of pharmaceutical patents, the national institute of industrial property.

- **The third lever** for affordability is based on a unique price mechanism for medicines. We assume that legal and economic accessibility are intrinsically linked in the policy process of medicine accessibility. Economic accessibility is determined by the funding and cost of the medicine for the population. The latter is based on the cost of acquiring medicines and includes the import or production price in addition to customs taxes and profit margins. The field survey revealed the absence of a single medicine prices system in Algeria. The lack of coordination among the various ministries involved in price setting (Ministry of Health, Ministry of Social Security, and Ministry of Commerce) is one of the failings of governance of the medicine. The main actors in this phase of accessibility are: pharmaceutical companies, Economic Committee for Pricing (Ministry of Health), Technical Reimbursement Committee (Ministry of Social Security).

- **Finally, the fourth lever** corresponding to geographical accessibility is based on a geographical coverage of needs through distribution channels. The physical accessibility is schematized by the distance to be traveled by patients to fetch medicines in medicine sales centers or distribution (pharmacies). This accessibility depends on the number and location of pharmacies in the area. Among the failures of governance, we note: the offensive strategies of pharmaceutical companies (multinationals) to control distribution channels. In our focal monopoly of governance model, geographical accessibility is the fourth and final dimension that determines the institutional framework for access to medicines. The main actors in this last sequence of the process are: pharmaceutical firms, local producers, distributor-distributors, public and private pharmacies.

#### **IV- Conclusion:**

Our approach to the governance of access to medicines differs from that of international institutions in that it "endogenizes" institutions specific to each country rather than those proposed by international organizations (World Bank, IMF, and WTO). It takes into account the phenomena of transition and social change. Our thesis is part of this paradigm of social and institutional change in the southern countries and in particular in Algeria. We relied on Ostrom's work on the governance of natural resources (water, timber, etc.) as well as his empirical results of his work that revealed the importance of self-organized coordination between actors with conceptions divergent to the success of the projects to apply them to the cases of access to medicines in Algeria. In the case of access to medicines in Algeria, our goal was to propose a solution through the focal governance monopoly that we take from Meisel (2004). Indeed, the FMG could constitute an instrument of coordination between the actors of the medicine, the reconciliation between the market logic (pharmaceutical companies) and the ethical logic (the access to medicines). Although our Focal Monopoly of Governance provides a solution to the current issues of access to medicines in Algeria, nevertheless it remains a model to put on the agenda of the Algerian decision maker.

## - Appendices:

<sup>i</sup> - In Algeria, the health sector has had two major historical periods. The first period, corresponding to the State monopoly of the import market since the independence of the country with a very unproductive sector (Report of the Ministry of Industry), reports a poor balance sheet over the period 1966 -1970, the second marks the transition from a public monopoly to private monopolies. With the implementation of the Structural Adjustment Program (SAP) from 1989 to 1995, all state expenditures have dropped considerably due to budget cuts in all sectors, including health.

<sup>ii</sup> -The concept of a robust institution stems from the empirical results on the resource governance modes "Robust Socio-Ecological Systems" and "Robust Resource Governance" which emphasizes the sustainability of institutions.

<sup>iii</sup> - Ostrom analyzes in depth various sustainable, self-organized and self-governing common resource systems: communal tenures in high mountain meadows and forests (Switzerland, Japan), irrigation systems (Spain, Philippines). It confronts, compares and completes the management of common goods from other examples (what made it did not work), what are the reasons for the failures (Turkish fisheries, irrigation systems in Sri Lanka? Lanka, Nova Scotia coastal fisheries) or more complex situations (larger scale such as aquifers in California between the 1960s and 1990s). The typical examples advanced by Ostrom (2010), are fishing sites, stretches of water, pasture grasslands, lakes, oceans, groundwater, forests, irrigation systems or even the internet.

<sup>iiii</sup> - Olson (1965) argues that while in large groups, only agent-based incentive systems can provide effective coordination, in small groups and, to some extent, in mid-size groups, behaviors are such that coordinating mechanisms to prevent stowaway behavior can be put in place instantly.

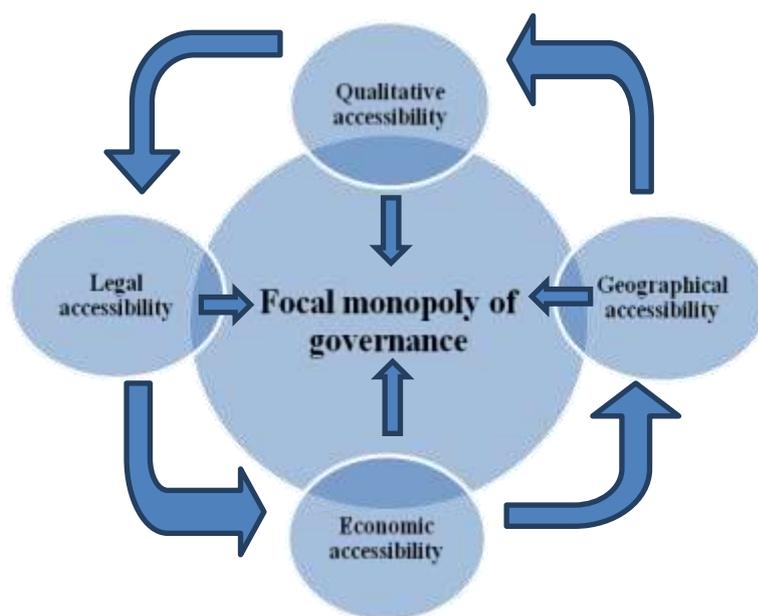
\* -These institutions, in the broad sense, are very different from those of the Anglo-Saxon model: a high concentration of ownership of capital and control in the enterprise; permeability with governance institutions in the public sector, and more generally, the state apparatus; a weak and weakly independent judiciary; a strong and interventionist executive power; a financial system dominated by the state and the banks it controlled; securities markets of modest size and little liquidity; largely informal regulation of the relationship between private interests or interest groups.

+ -The author shows how the "culture of governance" that prevailed in France during the period of the thirty glorious was based on very transparent interpersonal relations, with an institutional framework characterized by a "manifest absence of control and counter-regulatory bodies power. "

± -By qualitative accessibility we mean the careful selection of a limited range of essential medicines that promote equity and help set priorities for the health system.

§ -In order to know the perception of INAPI on the notion of access to medicines, we met the director of applications for patent filings at this institution and asked him about the strategy of the Institute vis-à-vis the integration and strengthening of Intellectual Property Rights in Algeria in the legal texts. The response of the patent manager was as follows: "[...] the role of INAPI is to promote innovation and protect the domestic industry against counterfeiting". For the request manager, the integration of the TRIPS agreement in the regulatory texts is an opportunity for Algeria to develop the industry and encourage innovation (Interview with the head of the department "Applications filing of patents ", carried out on 23 February 2011.

**Figure 1: Focal monopoly of governance in Algeria**



Source: authors

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