# *The role of the National Agency of Pharmaceutical Substances toward the Public Health's protection in Algeria*

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**الملخّـــص:**

يهدف هذا المقال إلى تقديم فكرة عن الأهداف الأساسية التي يفترض أن تحقّقها عملية الضّبط في مجال المنتجات الصيدلانية والمستلزمات الطبية في الجزائر بغرض حماية الصّحة العامة، من خلال الدّور المنتظر من الوكالة الوطنية للمنتجات الصيدلانية باعتبارها سلطة إدارية مستقلة.

**الكلمات المفتاحية :** الضّبط،الصحة العامة،المواد الصيدلانية،السلطات الإدارية المستقلة

**Abstract:**

This article aims at giving an idea about the main objectives intended to be achieved by the regulation process, in the field of pharmaceutical products and medical supplies in Algeria in order to protect public health through an expected regular role of the National Agency for Pharmaceutical products as an independent administrative authority.

**Keywords:** Regulation, Public health, Pharmaceutical products, Independent administrative authorities

**Introduction:**

During the last twenty years the economic regulation has gained an unequal position in the European countries .The trade and privatization's liberation did not achieve ***"capitalism's non-intervention".*** The more markets are free the more they compile with more rules, leading to the appearance of ***"the rise of the regulatory state"*** concept, through the state intervention reinforcement. It is set by assigning independent regulatory agencies to tasks of regulation by means of delegation and by rendering a series of legal reliable rules accompanied by some mechanisms ***"Public Agencies"*** to focus on compliance with these rules[1] and promote it.

The birth and the multiplicity of independent administrative authorities in Algeria was obligatory since **1990** subsequently to the wave of global regulatory reforms since the mid-eighties[2] and the most interesting thing is the expansion in the use of regulatory instruments ***" Independent Administrative Authorities"*** in the field of the networking public utilities (like electricity and gas, telecommunications, water ,transport...) but today we notice that a lot of fields such as human rights, public freedom, press, public health... are living on the margin of this expansion.

When we highlight the National Agency for pharmaceutical products as an independent authority which is in charge of regulating vital pharmaceutical sectors and medical supplies, the great deal of this agency neglecting by public authorities becomes so obvious; despite the important role it should play to preserve public health and regulate pharmaceutical products markets as well as medical supplies. Therefore, the necessity to activate it has today become an urgent demand.

In this article we will try to clarify the expected role of this independent administrative authority in order to protect the public health through handling three issues:

- ***A- The legal nature of the National Agency for pharmaceutical products.***
- ***B- The goal of regulation in the field of pharmaceutical products and medical supplies.***
- ***C- The expected tasks from the National Agency for pharmaceutical products.***

**A/ The legal nature of the National Agency for pharmaceutical products:**

In **2008** and for the occasion of the amendment of the law relating to the protection and promotion of health for the year **1985**[3], the Algerian legislature who established the independent administrative authority in the field of pharmaceutical products and medical supplies used in human medicine, has put it in charge of regulating this vital sector.

When considering the consistence of this law, we find that the Algerian legislature, through article **07** of this amendment, published: (**1-1-173**), has inserted this organism within the category of the independent administrative authorities ***"the national agency for pharmaceuticals used in human medicine named below* "The Agency"** ***is created".***

What is understood from the previous article is that the agency has the right to get the same advantages as the independent administrative authorities by granting it with powers: ***control, supervision, authorization, consultation...*** and ***regulation*** in the field of pharmaceutical products and medical supplies as it will be dealt with below.

But till this day no decrees have been set allowing this agency to enhance its activities. In the third paragraph of the previous article, the Algerian legislature has transferred all that has a relation with the organization of the agency to the regulation.

**A/1- The Agency is an Independent Administrative Authority:**

The second paragraph from the article (**1-173**) states that: **"*the agency is an independent administrative authority having a legal personality***

***and a financial autonomy".***

The clear description of this agency presented by the Algerian legislature puts it outside the traditional division of powers (executive, legislative, and the judiciary). In spite of the controversy that accompanied the emergence of these organisms in Western Democracies, it has guaranteed its position within the institutional construction of these countries[4] . This is justified by the fact that the process of economic regulation indeed, is bound to government intervention and therefore to the control of these authorities' activities by both the state and the administrative judges. In the end, this is aims at meeting the public economic interests[5].

However, in Algeria, it is noticed that the appearance of these organisms did not provoke any kind of controversy about its insertion within the state institutional construction. The Algerian legislature always limits himself to imitating from the Western systems without worrying about the effects of this imitation. That is why; these authorities have automatically found their positions within the state institutional constructions.

The availability of the ***independence*** requirement is very important for this agency to perform the functions of the economic regulation in the field of pharmaceutical products. Thus, many scholars are there to set a range of criteria in order to measure the extent of these organisms independence, by putting **05** basic requirements*:* ***the agency head state, board members, the relationship with parliament and government, organizational and financial independence, organizational competencies***[6].

By reference to paragraph **02** from article (**173-1**) as well as to the last paragraph from article (**173-5**) of the amended health law, we find out that the Algerian legislature has admitted both the financial independence and moral personality of this agency. It has also been granted its autonomy in drawing its basic status, though the requirements mentioned above have not yet been implemented.

**A/2- National Agency for pharmaceutical products formation:**

By referring to the comparative law we find out that the most developed countries including the European Union countries and The United States of America rely on the regulatory agencies in the field of pharmaceutical products, such as: in USA; the Food and Drug Administration (**1860-1930**) (**FDA**)[7],The European Drugs Agency (**1955**)[8]. On the national legislation level, in France, for instance, we find the National Agency of Medicines and Health Products Security (**ANSM**) (**2012**)[9] (***L'Agence national de sécurité du médicament et des produits de santé***).

The Algerian legislature, through the article (**2-173**) has constituted **04** specialized committees within this agency which are:

**** The Committee for Medicines Registration.***

**** Committee validation of the pharmaceuticals and medical supplies used in human medicine.***

**** Control committee of medical and scientific information and publicity.***

**** Price Study Committee for pharmaceuticals and medical supplies used in human medicine.***

It is noticeable that this division within the agency resembles at some extent the one undertaken by the American Food and Drug Administration (FDA)[10] with the difference that division within the latter is more complex.

The most striking element is that the four agency committees have not yet been installed, despite the fact that the Algerian legislature has assigned a number of functions to these committees through the amendment of the health law (**2008**) as explained below.

**B- The goal of regulation in the field of pharmaceutical products:**

Pharmaceuticals and medical equipments are considered to be among the products that are submitted to the most stringent regulation in the developed world. In fact, the main objective of this regulation is to protect public health. Although this sounds to be a mere objective, its achievement needs to set large and complex rules and resolutions.

An attempt is done here to shed the light on the basic principles on which the regulation in the field of Pharmaceutical products and medical supplies rely. They are **05** basic principles[11]:

**(Safety & Security), (Effectiveness and Competency), (Purpose), (Risk & Benefits), (Quality).**

**B/1- Safety & Security:**

Product safety is the basic principle for all products. From an ideal point of view, it should not constitute any damage in use or consumption. Regulatory authorities require from laboratories and manufacturers of these products to take the appropriate measures to prove and ensure the safety of pharmaceutical products which are under the process of development.

**B/2-3- Effectiveness /Competency & Purpose:**

Effectiveness or competency is the cornerstone for achieving the objective of the regulation. The manufacturer must be effective to cure patients or at least improve their health state. To evaluate the effectiveness, the ***purpose of the manufacturer*** must also be taken into account. That is to say; the objective set for its manufacturing and expressed in the guide to use, in the case of drugs, or in the statement of the purpose in the case of medical device. This is due to the stringent resolutions issued by the regulatory authorities that have to be considered by the manufacturers.

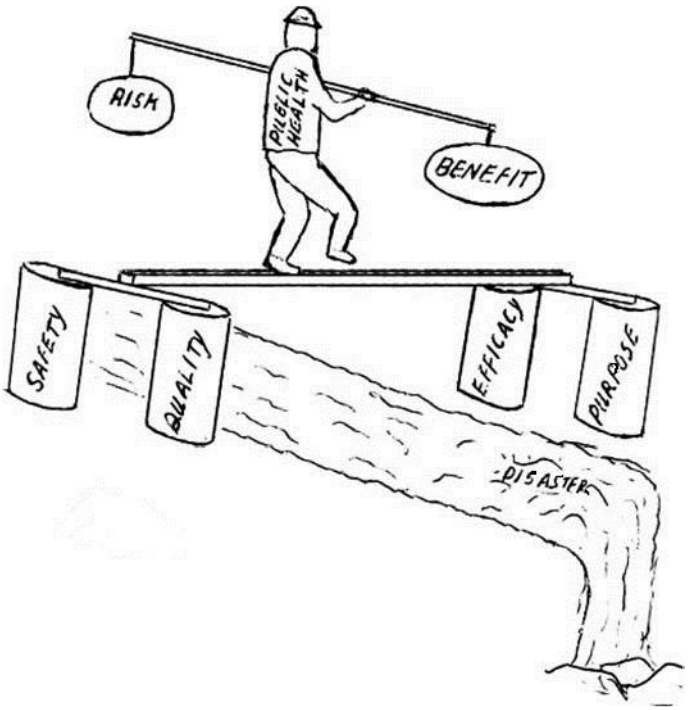
**B/4- Benefits &Risks:**

Many drugs show great variation in their effectiveness on sick people, consequently, it is the duty of regulatory authorities to impose restrictions on manufacturers through obliging them to test the medicines and medical devices before exposing them on the markets and make sure that the benefits must overcome the risks .Besides, these organisms must make sure that product is not of a threat to public health.

**B/5- Quality:**

The quality of products is often paired with safety and appropriateness to the ***purpose***, even though these characteristics are not sufficient to describe the quality of a product. Thus, the quality lies in the availability of the previous principles in addition to the descriptions and standards conformity condition, in accordance to the quality guarantee systems placed rigidly by regulatory authorities.

**Figure 1 - *Regulatory principles***




**C/ The Agency tasks:**

By referring to the amended and completed law **08-13** which is related to the health, it is possible to divide the agency tasks into two sections: **(1)** ***Preliminary regulation tasks*** **(2)** ***Post regulation tasks.***

**C/1- Preliminary regulation tasks:**

By Preliminary regulation, we mean those rules and procedures that must be followed obligatory in order to have access to any market. In this case, a skimming of the article (**4-173**) through the paragraphs (**1-2-3**) of the above mentioned law, we discover the legislator's attempt to make of the agency the unique organism in charge of granting **"*the right to enter the market*"** or the right to exercise in the sector of pharmaceutical products and medical supplies by means of the following:

**Visas delivery of pharmaceuticals and medical supplies importation.*

**Registration of medicines and the ratification of pharmaceuticals and medical supplies.*

**Fixing the prices of pharmaceuticals and medical supplies.*

**C/2- The Post regulation tasks:**

They are all the functions and tasks given to the agency in the articles (**3-173**) and (**4-173**) as being an independent administrative authority having in charge the market regulation, with the exclusion of the previously mentioned paragraphs, as a matter of fact, it can be divided into **04** tasks**:(1)** ***Censorship functions*** **(2)** ***Consulting functions*** **(3*) Regulatory functions***

**(4)** ***Punitive functions.***

**C/2-1- Censorship functions:** In the field of pharmaceutical products, they are divided into two sections:

**Control of pharmaceutical products and medical supplies.*

** Publicity, scientific and medical media control.*

Concerning the first censorship, the following tasks are made clear through paragraphs **03** and **06** of Article (**173-3**) but the second censorship; it has been mentioned in the paragraphs **07** and **10** of Article (**4-173**) of the previous law. To sum up, the censorship aims mainly at protecting public health and particularly consumers of false advertising and misleading media in the domain of pharmaceuticals and medical supplies.

**C/2-2-Consulting functions:**

The agency as a specialized body assures consulting functions for both the public authorities and the peoples, considering the two elements of skillfulness and specialization expected to be available in its working staff; as it is made clear in paragraphs **11**, **15** and **18** of Article (**173-4**). The agency for instance, has the right to express opinion when it is about drawing strategies related to the sector development, drafting the annual report...

**C/2-3- Regulatory functions:**

The legislator did not directly admit the regulatory specialization to the agency, but it was only granted the right to take part and make suggestions about the process to draft regulation through paragraph **17** of Article (**4-173**).

However, in the same article, in paragraph **08** the legislature allows the agency to take measures in case there is any danger threatening public health, ***but what nature are these measures? Can they compare to decrees?*** To answer these questions, we must wait until the installation of this agency and the beginning of its work.

**C/2-4- Punitive functions:**

The process of repression as an option granted to the independent administrative authorities is one of the most interesting controversial topics because of the close relationship the agency has with the economist customers. Because they may commit violations in their field of activity, all legislations have granted repressive power to these organisms in accordance with the justification of their behavior evaluation within markets, thus reinforcing public economic interest and preventing market turmoil[12].

The Algerian legislature has provided several penalties for violations in the pharmaceutical sector and medical supplies due to the threat on public health that these violations may represent: As an example; ***violations related to the manufacturing, distribution, importation, publicity...***

The most interesting element from the second chapter of the previous law is the absence of any mention concerning the organism in charge of imposing penalties. Therefore, we believe that due to the legal position which the agency has as an independent administrative authority, it is given the right to perform repression practices in this field once installed by public authorities.

**Conclusion:**

The basic principles that under which lies the regulatory process in the field of pharmaceutical products and medical supplies cannot be reflected in reality only through activating the national agency having in charge the regulation of this vital sector which suffers from marginalization by the public authorities. what is noticeable in Algeria is the institutions fragility and structural defects that contribute to failure in almost various sectors[13], today's urgent requirement is the need for a strong political will which bears sincere intentions for the sake of achieving real reform in the health sector and other sectors in order to give to the concept of good governance, its real meaning.

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