

The National Agency for Pharmaceutical Products in Algerian Health Law 18-11

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ABSTRACT:

The National Agency for Pharmaceutical Products (ANPP) is a pivotal body within the Algerian health system, undertaking vital tasks to ensure the quality and safety of pharmaceutical products and medical devices circulated in the market. Its establishment was mandated by Health Law No. 18-11, reflecting the state's commitment to strengthening oversight in this strategic sector. This research aims to analyze the Agency's legal and regulatory framework, highlighting its legal nature as a public administrative institution, and its objectives in protecting public health and regulating the pharmaceutical market. The research also covers its administrative and technical structure, including the Board of Directors, Director-General, Scientific Council, and specialized committees, in addition to its technical and regulatory missions such as granting marketing authorizations and approvals, inspection, and quality control. The research concludes by reviewing its financial system and international cooperation relations, emphasizing its role as a safety valve for public health in Algeria

key words: National Agency for Pharmaceutical Products, Algerian Health Law 18-11, Pharmaceutical Products, Health Regulation, Public Administrative Institution.

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Introduction:

The National Agency for Pharmaceutical Products (ANPP) is a fundamental pillar of the Algerian health system, undertaking vital tasks to ensure the quality and safety of pharmaceutical products and medical devices circulated in the market. Its establishment came within the framework of legislative reforms enacted by Health Law No. 18-11 of July 2, 2018, which aims to modernize the legal framework governing the health sector in Algeria. This law represents a turning point in how pharmaceutical products are managed and controlled, giving paramount importance to the creation of a specialized body with technical and administrative independence to ensure effective oversight and protect public health.

This research aims to study and analyze the legal and regulatory framework of the National Agency for Pharmaceutical Products in light of Algerian Health Law 18-11 and related executive decrees. The research will cover the legal nature of the Agency, its objectives, its administrative and technical organization, as well as its regulatory and financial functions. The research will be divided into three main sections, each containing two sub-sections, and each sub-section with two branches, to provide a comprehensive and systematic analysis of the role of this pivotal agency in the Algerian health landscape.

Section One: Conceptual and Legal Framework of the National Agency for Pharmaceutical Products

The National Agency for Pharmaceutical Products (ANPP) is a pivotal body within the Algerian health system. Its establishment was mandated by the provisions of Law No. 18-11 concerning health, with its missions and organization detailed in subsequent executive decrees, notably Executive Decree No. 19-190. This section aims to define the legal nature of the Agency, clarify the administrative framework within which it operates, and review the main objectives it seeks to achieve in the context of protecting public health and regulating the pharmaceutical products market.

Subsection One: Legal Nature of the Agency and Administrative Oversight

ANPP possesses a unique legal nature that grants it autonomy in performing its duties, while being subject to administrative oversight that ensures coordination with national health policies. Understanding this nature and oversight is essential to determine the Agency's position within the state's administrative structure and its role in the health sector.

Branch One: Legal Nature

ANPP is defined as a public administrative institution (EPA), enjoying legal personality and financial autonomy¹. This classification grants it the ability to act in its own name, conclude contracts, and possess an independent financial standing separate from the state. Its administrative nature also confirms that it serves the public interest and is subject to public law in its management, unlike public industrial and commercial institutions. This independence aims to enable the Agency to make neutral technical and scientific decisions away from political or economic pressures, thereby enhancing its credibility and effectiveness in regulating pharmaceutical products.

Branch Two: Administrative Oversight and Headquarters

ANPP is subject to the oversight of the Ministry of Pharmaceutical Industry, which sets general guidelines and monitors the Agency's adherence to established objectives². Prior to the establishment of the Ministry of Pharmaceutical Industry, oversight was under the Ministry of Health. The Agency's headquarters are located in Algiers, and it may have branches or representative offices nationwide to ensure broader coverage and effective monitoring of the pharmaceutical products market across different regions of the country. This oversight aims to ensure the Agency's work aligns with the national health policy and the development of the pharmaceutical industry, while maintaining its technical independence.

Subsection Two: Agency Objectives under Health Law 18-11

The objectives of ANPP are primarily defined in Health Law No. 18-11 and related executive decrees, focusing on two main axes: ensuring the quality and safety of pharmaceutical products, and regulating the market to protect public health.

Branch One: Ensuring the Quality and Safety of Pharmaceutical Products and Medical Devices

Ensuring the quality and safety of pharmaceutical products and medical devices is the paramount objective of the Agency. This comprehensive mission includes several aspects, such as: registration of pharmaceutical products and medical devices before their marketing, after verifying their efficacy, safety, and quality³. The Agency also undertakes the approval of medical devices and monitors their compliance with

¹ Executive Decree No. 19-190 of July 3, 2019, defining the missions, organization, and functioning of the National Agency for Pharmaceutical Products, Official Gazette of the People's Democratic Republic of Algeria, Issue 43, published on July 7, 2019.

The ears Hassan Ali. Civil liability of pharmaceutical manufacturers: a comparative study. Beirut: Al-Halabi Legal Publications, 2006. p. 56

² Ministry of Pharmaceutical Industry, Official Website: <https://miph.gov.dz/>

³ National Agency for Pharmaceutical Products (ANPP), Missions: <https://anpp.dz/missions/>

Abood, Richard R., and Kimberly A. Burns. Pharmacy Practice and the Law. 9th ed. Burlington, MA: Jones & Bartlett Learning, 2019. P96

international and national standards. Its tasks also include quality control and expertise of pharmaceutical products and medical devices circulating in the market, through laboratory analyses and periodic inspections of pharmaceutical establishments. This regulatory role contributes to protecting patients from non-compliant or counterfeit products and ensures access to safe and effective medicines.

Branch Two: Regulating the Pharmaceutical Market and Protecting Public Health

In addition to ensuring quality and safety, the Agency plays a vital role in regulating the pharmaceutical market to protect public health. This includes contributing to the development of national strategies to ensure the availability of pharmaceutical products, especially essential medicines, and combating monopolies or shortages of certain products. The Agency also contributes to setting prices for pharmaceutical products in consultation with relevant authorities, to ensure fair prices and accessibility for citizens. Furthermore, the Agency works to monitor advertising for pharmaceutical products to prevent misleading consumers and contributes to combating the irrational use of medicines. These regulatory tasks aim to create a balanced pharmaceutical market that meets the needs of citizens and protects their health from unsound practices.

Section Two: Administrative and Technical Organization of the National Agency for Pharmaceutical Products

To ensure that the National Agency for Pharmaceutical Products performs its duties effectively and efficiently, an organizational structure has been established that defines its administrative and management bodies, as well as the scientific and advisory structures that support its work. This section aims to detail these organizational aspects, highlighting the role of each body and structure in achieving the Agency's objectives.

Subsection One: Administrative and Management Bodies

The administrative and management bodies are responsible for the overall supervision of the Agency, defining its policies, and ensuring the smooth operation of its work. This body primarily consists of the Board of Directors and the Director-General, each with specific powers and responsibilities.

Branch One: Board of Directors

The Board of Directors is the supreme body of the Agency, responsible for setting general policies and overseeing their implementation. The Board comprises representatives from several ministries and government bodies related to the health

and pharmaceutical sectors, as well as experts in the field¹. Its main powers include: approving the Agency's annual budget, endorsing work programs, evaluating performance, and making strategic decisions that ensure the achievement of the Agency's objectives. The Board also oversees the appointment of the Director-General based on a proposal from the supervising minister. This composition ensures diversity in expertise and governmental representation, thereby enhancing the effectiveness of the Board's decisions.

Branch Two: Director-General

The Director-General is responsible for the daily management of the Agency and is its chief executive officer. The Director-General is appointed by presidential decree based on a proposal from the supervising minister². Their duties include: implementing the decisions of the Board of Directors, managing the Agency's human and financial resources, representing the Agency before third parties, and preparing periodic reports on the Agency's activities. The Director-General plays a crucial role in coordinating between the various departments of the Agency, ensuring workflow fluidity, and achieving established objectives efficiently

Subsection Two: Scientific and Advisory Structures

The Agency relies on specialized scientific and advisory structures to provide the necessary technical and scientific support for its regulatory and organizational tasks. These structures ensure that the Agency's decisions are based on accurate scientific foundations.

Branch One: Scientific Council

The Scientific Council is a highly important advisory body in the Agency's work. It consists of experts and academics specialized in pharmacy, medicine, toxicology, and public health³. Its primary role is to provide scientific and technical opinions and recommendations to the Board of Directors and the Director-General on various issues related to pharmaceutical products and medical devices. The Scientific Council contributes to evaluating drug registration files, setting technical standards, and monitoring scientific developments in the pharmaceutical field, thereby enhancing the quality of decisions made by the Agency.

¹ Executive Decree No. 19-190, Article 10 et seq. (concerning the composition of the Board of Directors).

² Executive Decree No. 19-190, Article 15 et seq. (concerning the appointment and duties of the Director-General).
Correa Carlos M. Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement. Oxford: Oxford University Press, 2007.P102

³ Executive Decree No. 19-190, Article 20 et seq. (concerning the composition and duties of the Scientific Council).

Branch Two: Specialized Committees

In addition to the Scientific Council, the Agency includes specialized committees that work on studying specific files and providing detailed recommendations. Prominent among these committees are: the Pharmaceutical Product Registration Committee, which studies drug registration applications and evaluates their efficacy, safety, and quality. And the Medical Device Approval Committee, which reviews medical device files and ensures their compliance with standards. These committees consist of experts specialized in their fields and contribute to accelerating the decision-making process and providing the necessary technical expertise for the Agency's tasks.¹

Section Three: Agency Missions and Financial System

The missions of the National Agency for Pharmaceutical Products are diverse, encompassing crucial technical and regulatory aspects to ensure the safety and effectiveness of pharmaceutical products, in addition to regulating the financial aspect that guarantees its operational continuity and independence. This section focuses on detailing these missions and the financial system governing the Agency.

Subsection One: Technical and Regulatory Missions of the Agency

The Agency undertakes a wide range of technical and regulatory missions aimed at regulating the pharmaceutical products and medical devices market and protecting public health.

Branch One: Granting Marketing Authorization (AMM) and Approval Decisions

The process of granting Marketing Authorizations (Autorisation de Mise sur le Marché - AMM) for pharmaceutical products and approving medical devices is one of the Agency's most important technical missions. This process involves a thorough study and precise evaluation of registration files submitted by pharmaceutical laboratories, which include data on efficacy, safety, quality, manufacturing methods, and laboratory analyses². These procedures ensure that products reaching the consumer are safe, effective, and compliant with applicable scientific and technical standards. The Agency also conducts periodic reviews of registration and approval decisions to ensure the continuous compliance of products with updated standards.

¹ Outterson, Kevin, ed. *Beyond Intellectual Property: New Models for Supporting Health Innovation*. Cambridge: Cambridge University Press, 2023. P53 . National Agency for Pharmaceutical Products (ANPP), Decrees: <https://anpp.dz/%D8%A7%D9%84%D9%85%D8%B1%D8%A7%D8%B3%D9%8A%D9%85/>

² Executive Decree No. 19-190, Articles 2 and 3 (defining registration and approval missions). Epstein, Richard A. "The Pharmaceutical Industry at the Crossroads: Laws, Ethics, and Economics." *Journal of Law, Medicine & Ethics* 33, no. 3 (2005): 428–441.

Branch Two: Inspection, Auditing, and Quality Control

The Agency undertakes inspection and auditing tasks of pharmaceutical establishments, including drug factories, storage warehouses, and pharmacies, to ensure their adherence to Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), and Good Pharmacy Practices (GPP)¹. It also performs quality control of pharmaceutical products and medical devices circulating in the market by taking samples and conducting laboratory analyses to ensure their conformity with specifications. This regulatory role contributes to detecting counterfeit or non-compliant products and taking necessary measures to protect public health.

Subsection Two: Agency's Financial System and its Relationship with Others

The Agency's financial system ensures its operational independence, while its relationship with others defines the framework for its cooperation with local and international partners.

Branch One: Financial Resources and Expenditures

The Agency relies on diverse financial resources to fund its activities, primarily including: subsidies allocated from the state budget, revenues generated from fees related to registration, approval, and inspection services, donations and bequests, and any other resources authorized by law². These resources are allocated to cover the Agency's operating expenses, such as staff salaries, equipment and laboratory costs, research and development expenses, in addition to funding control and inspection programs. This partially self-funded approach aims to enhance the Agency's independence and reduce its total reliance on the state budget.

Branch Two: Financial Control and International Cooperation

The Agency is subject to strict financial control to ensure transparency and efficient utilization of resources. This control includes internal and external auditing, as well as oversight by competent state bodies³. On the level of international cooperation, the Agency establishes partnerships with similar international bodies and organizations, such as the World Health Organization (WHO) and European Medicines Agencies (EMA), with the aim of exchanging expertise and information,

¹ National Agency for Pharmaceutical Products (ANPP), Missions: <https://anpp.dz/missions/>
Hemphill, C. Scott, and Mark A. Lemley. "Expectations of Patent Validity and Pharmaceutical Innovation." *Stanford Law Review* 71, no. 4 (2019): 923–980

² Executive Decree No. 19-190, Article 25 et seq. (defining the Agency's financial resources).

³ Executive Decree No. 19-190, Article 28 et seq. (defining financial control mechanisms).
Hemphill, C. Scott, and Mark A. Lemley. "Expectations of Patent Validity and Pharmaceutical Innovation." *Stanford Law Review* 71, no. 4 (2019): 923–980

participating in setting international standards, and benefiting from training and development programs. This cooperation contributes to enhancing the Agency's capabilities and developing its performance in line with best global practices in the regulation of pharmaceutical products.

Conclusion :

The National Agency for Pharmaceutical Products in Algeria embodies a model of specialized regulatory bodies that play a vital role in protecting public health and ensuring the safety and quality of pharmaceutical products and medical devices circulated in the market. Its establishment and the definition of its missions under Health Law 18-11 and subsequent executive decrees reflect the Algerian state's commitment to strengthening oversight in this strategic sector.

This research has shown that the Agency possesses a legal nature as a public administrative institution, granting it the necessary independence to perform its technical and regulatory duties, while being subject to the oversight of the Ministry of Pharmaceutical Industry to ensure alignment with national policies. Its objectives, focusing on ensuring the quality and safety of pharmaceutical products and regulating the market to protect public health, have also been detailed.

Organizationally, the Agency relies on an integrated administrative and technical structure, including a Board of Directors that sets policies, a Director-General who handles executive management, in addition to a Scientific Council and specialized committees that provide technical and scientific support. Its technical and regulatory missions include granting marketing authorizations and approvals, inspection, auditing, and quality control, which are essential tasks to ensure product compliance with standards.

Regarding its financial system, the Agency relies on diverse resources that ensure its operational independence and is subject to strict financial control. Its international cooperation also enhances its capabilities and ensures its adherence to best global practices.

In conclusion, it can be said that the National Agency for Pharmaceutical Products represents a safety valve for public health in Algeria, and its role extends beyond mere oversight to include effective contribution to the development of the national pharmaceutical industry and ensuring the availability of safe and effective medicines for citizens. Continued support for this Agency and the development of its operational mechanisms will strengthen its position and ensure the achievement of its noble objectives in serving society.

-Bibliography List setting:

– **BOOKS**

- Abood, Richard R., and Kimberly A. Burns. Pharmacy Practice and the Law. 9th ed. Burlington, MA: Jones & Bartlett Learning, 2019.
- Correa, Carlos M. Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement. Oxford: Oxford University Press, 2007.
- DENNOUN Hassan Ali. Civil liability of pharmaceutical manufacturers: a comparative study. Beirut: Al-Halabi Legal Publications, 2006.
- Outtersen, Kevin, ed. Beyond Intellectual Property: New Models for Supporting Health Innovation. Cambridge: Cambridge University Press, 2023.

– **Journal article :**

- Epstein, Richard A. "The Pharmaceutical Industry at the Crossroads: Laws, Ethics, and Economics." Journal of Law, Medicine & Ethics 33, no. 3 (2005): 428–441.
- Hemphill, C. Scott, and Mark A. Lemley. "Expectations of Patent Validity and Pharmaceutical Innovation." Stanford Law Review 71, no. 4 (2019): 923–980

– **Legal texts:**

- Executive Decree No. 19-190 of July 3, 2019, defining the missions, organization, and functioning of the National Agency for Pharmaceutical Products, Official Gazette of the People's Democratic Republic of Algeria, Issue 43, published on July 7, 2019.

– **Internet websites:**

- Ministry of Pharmaceutical Industry, Official Website: <https://miph.gov.dz/>
- National Agency for Pharmaceutical Products (ANPP), Missions: <https://anpp.dz/missions/>