Registration of Pharmaceutical Products in Algerian Legislation

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Abstract:

Algerian legislation regulates pharmaceutical products (PP) under Health Law No. 18-11, which provides an exhaustive classification of such products and restricts their handling exclusively to authorized pharmaceutical establishments. This regulatory approach reflects the potentially hazardous nature of pharmaceutical products (PP) and their direct implications for public health. The legislator has also established a legal framework aimed at protecting consumers of pharmaceutical products (PP) through a set of obligations imposed on pharmaceutical establishments, most notably the mandatory registration of pharmaceutical products prior to their commercialization. This registration process is based on a comprehensive assessment of therapeutic value, safety, quality, and security, thereby safeguarding the health and well-being of end users. In addition to the provisions set forth in Health Law No. 18-11, several implementing decrees and administrative decisions have been issued to define and regulate the registration procedures applicable to pharmaceutical products.

Keywords*: Pharmaceutical Products (PP); Registration; Consumer Protection.*

Introduction:

Any individual has the right to engage in the production and commercial exploitation of various products through manufacturing and by exercising the different legal acts associated with them. However, legislators have imposed restrictions on this freedom by reserving the handling of certain products to specific categories of authorized persons. Among such products are pharmaceutical products (PP),[1] the production and distribution of which have been exclusively entrusted to pharmaceutical establishments.[2] The rationale behind limiting the manufacture of PP to legally authorized entities lies in the sensitive and potentially hazardous nature of these products, as well as their direct impact on the physical health and safety of consumers and users.

To ensure that safe and effective PP reach consumers and perform the

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therapeutic functions for which they were developed, while minimizing the risk of adverse effects that could cause harm, legislators have imposed a series of obligations on pharmaceutical manufacturing establishments. These obligations apply both before and after PP are placed on the market. Among the most significant pre-marketing requirements is the obligation to register PP. Article 230 of Law No. 18-11 on Health stipulates that: "Any pharmaceutical product and medical device intended for use, whether industrially manufactured, imported, or exported, must, prior to being marketed, be subject to a registration or approval decision issued by the National Agency for pharmaceutical products (NAPP) referred to in Article 223 above, following consultation with the registration and approval committees established within the Agency."

The legislator further regulated the registration process through Executive Decree No. 20-325 concerning the procedures for the registration of PP.[3] This decree constitutes the subject matter of the present study, which seeks to address the following research question: What procedures must be followed for the registration of pharmaceutical products?

To answer this question, the study is divided into two sections. The first examines the authority responsible for reviewing registration applications, while the second focuses on the procedures and modalities governing the registration of PP . The analysis is conducted using the analytical method, with particular emphasis on the legal texts relevant to the subject matter.

The first topic:
The Authority Competent for the Registration of Pharmaceutical Products

The Algerian legislator has entrusted the responsibility for the registration of Pharmaceutical Products (PP)to the National Agency for Pharmaceutical Products(NAPP). This mandate is established under Article 230 of Health Law No. 18-11, which provides that:

"Any pharmaceutical product or medical device intended for use, whether industrially manufactured, imported, or exported, must, prior to being marketed, be subject to a registration decision or approval granted by the NAPPreferred to in Article 223 above, following consultation with the Registration and Approval Committees established within the Agency…"

A review of Executive Decree No. 19-190,[4] as amended and supplemented, which defines the missions, organization, and functioning of the NAPP, further confirms this responsibility. Article 5 of the Decree stipulates that:

"The Agency shall be responsible for the registration, approval, and control of PP and medical devices, and shall contribute to the implementation of the national policy concerning PP and medical devices used in human medicine.

In this capacity, it shall, in particular, be entrusted with the following tasks:

- *Registering PP and granting, renewing, suspending, withdrawing, assigning, or transferring registration decisions, where appropriate, following the opinion of the PP Registration Committee.*

Subsequently, the Decision of 28 Dhu al-Qi'dah 1443, corresponding to 28 June 2022, established the internal organization of the NAPP.[5] Article 2 of this Decision sets out the Agency's organizational structure, which operates under the authority of the Director General and with the assistance of the Secretary General. The organizational framework comprises several specialized directorates, including the Directorate of Pharmaceutical Product Registration, the Directorate for Medical Device Approval, the Directorate of Technical Control, Inspection and Vigilance, the Directorate of Control and Expertise, the Directorate of Laboratory Services and Pharmaceutical Research, the Directorate of Information Systems, the Directorate of Human Resources and Training, the Directorate of Finance and Accounting, the Directorate of Logistics, as well as regional branches.

The Decision also specifies the functions assigned to each directorate within the Agency. Given its direct relevance to the subject of this study, particular attention should be devoted to the Directorate of Pharmaceutical Product Registration.

Directorate of Pharmaceutical Product Registration: This Directorate is entrusted, in particular, with the following responsibilities:[6]

- *Registering PP intended for human use and issuing, renewing, amending, and, where necessary, withdrawing registration decisions;*
- *Issuing pharmaceutical pricing certificates for products subject to registration immediately upon the determination of their prices by the Intersectoral Economic Committee for Medicines;*
- *Conducting scientific assessments of the benefits, risks, and therapeutic value of PP, as well as evaluating their pharmacoeconomic impact;*
- *Providing opinions regarding temporary authorizations for the use of unregistered medicines;*

This Directorate comprises three sub-directorates:

- *Sub-Directorate for the Technical and Regulatory Control of PP.*
- *Sub-Directorate for Drug Pricing.*
- *Sub-Directorate for the Scientific and Documentary Evaluation of PP.*

First requirement: Functions and Composition of the Pharmaceutical Products (PP) Registration Committee

As previously noted, the NAPP is the competent authority responsible for the registration of PP. Following the promulgation of Executive Decree No. 20-325 governing the procedures for the registration of PP, the legislature established the PP Registration Committee. An examination of this decree reveals that the Algerian legislator clearly defined both the functions and composition of the Committee in the first section of Chapter One.

First section: Functions of the Pharmaceutical Products (PP) Registration Committee

The functions of the PP Registration Committee are set out in Article 2 of Executive Decree No. 20-325 concerning the procedures for the registration of PP. The Committee is entrusted with issuing opinions on applications for the registration of pharmaceutical products, as well as requests for temporary authorizations for the use of unregistered medicines.

The Committee is also responsible for examining and providing opinions on various matters submitted to it by the Director General of the NAPP, particularly applications submitted prior to the registration of pharmaceutical products, requests for the renewal or amendment of registration decisions, and applications relating to the transfer, withdrawal, or assignment of registration decisions. Its authority further extends to all issues concerning clinical and technical data associated with the registration of pharmaceutical products.

In addition, the Committee provides its opinion on the therapeutic benefit, efficacy, safety, and security of every pharmaceutical product subject to registration that contains well-established active substances, and, where appropriate, on generic medicines and similar biotherapeutic products. It also assesses any extension or modification of the therapeutic indications of PP and contributes to the scientific evaluation of the benefits, risks, and therapeutic value of pharmaceutical products.[7]

Second section: Composition of the Pharmaceutical Products (PP) Registration Committee

Pursuant to Article 4 of Executive Decree No. 20-325 on the procedures

for the registration of pharmaceutical products, the Committee has a multidisciplinary composition comprising:

- *A representative of the Minister responsible for the pharmaceutical industry, possessing expertise and qualifications in the pharmaceutical field, who serves as Chairperson of the Committee.*
- *A representative of the Minister responsible for health, possessing expertise and qualifications in the pharmaceutical field.*
- *A representative of the National Health Security Agency, possessing expertise and qualifications in the pharmaceutical field.*
- *An expert in pharmaceutical chemistry.*
- *An expert in galenic pharmacy (pharmaceutical technology).*
- *An expert in pharmacology.*
- *An expert in toxicology.*
- *An expert in pharmacovigilance.*
- *An expert in biology.*
- *A representative of the Clinical Experts Committee from the therapeutic specialty concerned with the matters included on the Committee's agenda.*

The Committee may also seek the assistance of any individual whose expertise and qualifications can contribute to the effective performance of its duties.

With regard to the Chairperson of the Committee, appointment is made by decision of the Minister responsible for the pharmaceutical industry upon nomination by the relevant authorities for a term of three years. Similarly, the experts serving on the Committee are appointed by decision of the Minister responsible for the pharmaceutical industry upon proposal of the DGNAPP, also for a three-year term.

The PP Registration Committee, especially the one formed for medicinal products, has been structured in such a way as to ensure the quality of the advice that it provides. The multidisciplinary nature of the Committee significantly contributes to the quality of the advice that it provides, and the NAPP relies upon the Committee's advice in its decisions regarding the registration of pharmaceutical products.

To ensure the impartiality of the members of the Committee, the legislator has required that all members of the Committee have no interest, either directly or indirectly, in the production, importation, or marketing of pharmaceutical products. To this end, each member of the Committee must sign a declaration stating that they have no conflict of interest.[8]

Second requirement: Organization and Operation of the Pharmaceutical Products (PP) Registration Committee

As previously noted, the Committee is headquartered within the NAPP, and its secretariat is provided by the Agency's competent departments. The Committee also operates under its own internal rules of procedure.[9]

Regarding its meetings, the Committee convenes in ordinary session once each month upon invitation by its Chairperson. It may also meet in extraordinary session whenever necessary at the request of the DGNAPP.[10]

The Chairperson is responsible for issuing meeting notices, which must be communicated to Committee members at least eight days before the scheduled meeting date. In the case of extraordinary sessions, this period may be reduced to three days.

Committee meetings are valid only when attended by a majority of its members. If the required quorum is not reached, a second meeting must be scheduled within eight days following the postponed session. In such circumstances, the Committee may validly deliberate regardless of the number of members present.

With respect to decision-making procedures, the Committee expresses its opinion on matters submitted for consideration and adopts its recommendations by a simple majority vote of the members present. In the event of a tie, the Chairperson has the casting vote.[11] *The Committee's opinions are recorded in official minutes and entered into a numbered register authenticated by the Chairperson.*

The Committee is also required to prepare an annual report detailing its activities. This report is submitted to the DGNAPP, with a copy transmitted to the Minister responsible for the pharmaceutical industry.

The second topic:

Procedures for the Registration of Pharmaceutical Products

The registration of PP before the competent authorities constitutes the initial stage in the sequence of procedures that must be completed prior to the marketing of any pharmaceutical product. This stage plays a pivotal role in strengthening consumer confidence in PP made available on the market. To complete the registration process, pharmaceutical establishments are required to comply with specific procedures prescribed by the legislation governing pharmaceutical products. These procedures primarily involve the submission of a preliminary registration application (First Requirement) followed by the submission of the formal registration application (Second Requirement).

First requirement: Submission of the Preliminary Registration Application

The legislator requires any pharmaceutical establishment intending to register a pharmaceutical product to first submit a preliminary registration application to the NAPP.[12] This application must be filed by the Technical Director Pharmacist of the pharmaceutical manufacturing and/or operating establishment.[13]

First section: Procedure for Submitting the Preliminary Registration Application

Every pharmaceutical establishment must submit a preliminary registration application using the official form specifically designed for this purpose.[14] The model form was established by the Decision of 26 Safar 1443 corresponding to 3 October 2021, which sets out the procedures for examining applications and specifies the model preliminary registration application form for pharmaceutical products. The form includes detailed information concerning the pharmaceutical product subject to registration, notably:

- *Information relating to the pharmaceutical product, including the trade name, International Nonproprietary Name (INN), pharmaceutical dosage form, dosage strength, and the qualitative and quantitative composition of the active substance(s) and excipients.*
- *Information concerning the applicant pharmaceutical establishment, including its name and address, the number and date of its authorization, and the name of the Technical Director Pharmacist.*
- *The purpose of the pharmaceutical product application, such as local production, manufacturing from raw materials, manufacturing from intermediate products, primary packaging, secondary packaging, or importation.*
- *The category of the preliminary registration application, including products containing a new active substance, extension of a pharmaceutical dosage form, new combination products, dosage-strength extensions, new presentations, generic products, and similar categories.*
- *Therapeutic value, including the submission of a therapeutic benefit sheet when the product (INN, dosage form, dosage strength, and route of administration) is not included in the National Formulary.*
- *Economic value, including, for locally manufactured products, the ex-factory selling price and integration rate, and for imported*

products, the public price in the country of origin and, where applicable, the public price in another reference country.

Upon submission of the preliminary registration application, the pharmaceutical establishment is required to pay 25% of the registration fees and is issued a receipt acknowledging the filing of the application.

Second section: Examination of the Preliminary Registration Application

Once the preliminary registration application has been submitted by the pharmaceutical establishment, it undergoes the following review process:

- *First: The services of the NAPPassess the admissibility of the application within five (5) days. This review consists of verifying the completeness of the information provided in the preliminary registration application form, the accuracy of the information relating to the applicant pharmaceutical establishment and its Technical Director Pharmacist, and the validity of the establishment's authorization to carry out pharmaceutical activities in accordance with the applicable regulatory framework.*[15]
- *Second: Following the acceptance of the application, the competent departments of the NAPP undertake a substantive review of the preliminary registration application. This review focuses on assessing both the therapeutic value and the economic value of the pharmaceutical product. The Agency is required to issue its decision regarding the admissibility of the application within thirty (30) days from the date of its acceptance.*

1. Assessment of Therapeutic Benefit:

The assessment of therapeutic benefit consists of evaluating the extent of the clinical value provided by a pharmaceutical product in comparison with other PP that have already been registered and marketed, as well as determining the position that the product may occupy within the therapeutic strategy adopted for the treatment of a specific disease. The primary objective of this assessment is to ensure that the pharmaceutical product offers genuine therapeutic value sufficient to justify its authorization for marketing and medical use, thereby safeguarding patient interests and protecting public health.

The assessment of therapeutic benefit is based on a set of fundamental criteria. The first of these is the evaluation of the product's efficacy and tolerability. Efficacy relates to whether the product can achieve the intended therapeutic outcomes. Tolerability relates to the adverse effects and potential complications associated with the product. Another criterion is the product's place within the relevant therapeutic strategy. This is

determined by comparing the product with existing therapeutic alternatives and modalities to determine whether the product offers any advantages to existing therapies.

The assessment further encompasses an evaluation of the severity of the disease for which the pharmaceutical product is intended. The significance of therapeutic benefit varies according to the nature, seriousness, and prevalence of the disease concerned. Consequently, the availability of safe and effective medicines becomes particularly critical in the context of severe or chronic diseases. In addition, the therapeutic objectives pursued by the pharmaceutical product are carefully examined, whether these relate to preventive treatment aimed at avoiding the onset of disease, curative treatment intended to eradicate the disease or limit its progression, or symptomatic treatment designed to alleviate symptoms and improve the patient's overall health status. Collectively, these criteria underscore the importance of the scientific and technical assessment of therapeutic benefit as a fundamental stage in the evaluation of PP prior to their registration and commercialization.

This assessment also evaluates the anticipated public health benefit of the pharmaceutical product in relation to products already registered and marketed, taking into account the specific therapeutic indication, the availability of equivalent alternative treatments, the prevalence of the disease, and the population affected by it.[16]

In cases where the assessment of the therapeutic benefit of a pharmaceutical product raises some reservations or uncertainties regarding its efficacy, safety or therapeutic positioning, the DGNAPP may request the opinion of the Clinical Experts Committee for the therapeutic class of the product.[17] *The purpose of this procedure is to further strengthen the scientific and technical evaluation of the product through the involvement of experts in the field.*

The Clinical Experts Committee examines the dossier of the product and issues an opinion regarding the concerns raised. The opinion can relate to the efficacy of the product, its adverse effects, or its suitability for use in comparison with other products in the same therapeutic class. The regulations specify a time frame for the Committee to issue its opinion. The Committee is required to issue its opinion within 30 days of being referred the dossier. This time frame ensures a balance between the need to thoroughly verify the safety and efficacy of PP and the need to process applications for product registration in a timely manner so that patients are not delayed in gaining access to required medications.

2. Assessment of Economic Benefit:

The assessment of economic benefit plays a crucial role in determining

the ex-factory selling price or the free-on-board (FOB) export price of a pharmaceutical product, thereby ensuring consistency between the proposed price of the medicine and its therapeutic value. The economic benefit assessment is based on several key criteria, including:

- *The degree of local integration achieved in the manufacturing of the pharmaceutical product;*
- *Social security reimbursement arrangements, the daily treatment cost, and the overall treatment cost of imported pharmaceutical products;*
- *The results of the therapeutic benefit assessment of the pharmaceutical product.*

Where the findings of the economic assessment give rise to reservations or concerns, the DGNAPP may request the competent departments of the ministry responsible for the pharmaceutical industry to conduct an additional evaluation of the economic and/or pharmacoeconomic assessment.

Upon completion of the assessment of both the therapeutic benefit and the economic benefit of the pharmaceutical product subject to the pre-registration application, two possible outcomes may arise:

- *Approval of the therapeutic and economic benefit assessment: Where the evaluation of the therapeutic and economic benefits of the pharmaceutical product is favorable, the application is submitted to the DGNAPP, who shall notify the applicant pharmaceutical establishment of the approval of the pre-registration application within a period not exceeding ten (10) days.*
- *Existence of major reservations or non-compliance: Where significant reservations are identified or the product is deemed non-compliant, the DGNAPP shall refer the pre-registration application, together with the results of the therapeutic and economic benefit assessments, to the PP Registration Committee for its opinion. The Committee must issue its opinion within a period not exceeding thirty (30) days from the date of referral.*

The DGNAPP shall communicate the outcome of the pre-registration application review to the applicant pharmaceutical establishment within ten (10) days from the date of deliberation and transmission of the Registration Committee's opinion.

- *Rejection of the pre-registration application: Any rejection of a pre-registration application must be duly reasoned. In such cases, the applicant may lodge an appeal before the Agency within thirty*

(30) days from the date of notification of the rejection decision.[18]

Second requirement: Submission of the Registration Application

Where the pre-registration application has been approved, the pharmaceutical establishment must submit its registration application within a period not exceeding one (1) year from the date of notification of the approval. The registration application must be accompanied by a Common Technical Document (CTD) prepared in accordance with internationally recognized standards, together with the following elements:

- *Samples of the pharmaceutical product subject to the application, in quantities determined according to the requirements of product quality control.*
- *Reagents, reference materials, and any specific means necessary for quality control testing of the pharmaceutical product, together with all relevant supporting documentation.*[19]

Nevertheless, the pharmaceutical establishment may request an extension of the deadline for submitting the registration dossier for a period of ninety (90) days, provided that the request is legally justified and submitted before the expiry of the one-year period. Such an extension may be renewed at the discretion of the DGNAPP. If the one-year period expires without either the submission of the registration application or a request for extension, no registration application may subsequently be filed with the NAPP.

First section: Components of the Registration Dossier

The pharmaceutical product registration dossier must contain the following information and documentation:

- *The name or trade name and address or registered office of the applicant pharmaceutical establishment, the Technical Director Pharmacist, and, where applicable, the manufacturer.*
- *The proprietary (trade) name of the medicinal product.*
- *The qualitative and quantitative composition of all constituents of the medicinal product, including the International Nonproprietary Name (INN) or, where appropriate, the chemical designation of each substance.*
- *An environmental risk assessment of the medicinal product, where applicable.*
- *A detailed description of the manufacturing process.*
- *Therapeutic indications, contraindications, and adverse effects.*
- *Dosage, pharmaceutical form, method of administration, storage conditions, and shelf life.*
- *Comprehensive elucidations regarding the precautionary and*

safety protocols to be adhered to during the storage, administration to patients, and disposal of waste, along with an outline of any possible environmental hazards linked to the pharmaceutical product.

- *A description of the quality control methods employed by the manufacturer.*
- *Results of:*
  - *Pharmaceutical studies (physicochemical, biological, or microbiological);*
  - *Preclinical studies (toxicological and pharmacological);*
  - *Clinical trials.*
- *The Summary of Product Characteristics (SmPC) sanctioned by the pharmaceutical regulatory agency in the nation of origin.*
- *A proposed Summary of Product Characteristics prepared in accordance with Annex I, together with specimens of the primary and secondary packaging and the package leaflet intended for the Algerian market, prepared in accordance with Annex II, in clearly legible Arabic and any other foreign language commonly used in Algeria.*
- *Marketing authorization issued in the country of origin, the Pharmaceutical Product Certificate (CPP), a Certificate of Free Sale, or any other document demonstrating that the medicinal product is registered and marketed in the country of origin, issued by the competent pharmaceutical regulatory authorities.*
- *Documentation demonstrating that all parties involved in manufacturing and clinical trials, and where applicable those responsible for the final product, are authorized in their respective countries to carry out the activities declared in the registration dossier and comply, in particular, with Good Manufacturing Practices (GMP).*
- *Copies of any marketing authorizations granted for the medicinal product in other countries.*
- *The pricing structure of the medicinal product.*
- *A designation indicating whether the medicinal product is:*
  - *A biotherapeutic product;*
  - *An immunological medicinal product;*
  - *A radiopharmaceutical product.*
- *All documentation and information relating to pharmaceutical studies, preclinical studies, and clinical trials must be accompanied*

by detailed summaries prepared in accordance with the regulatory requirements applicable in this field.[20]

The Common Technical Document (CTD) containing the required information is structured into five modules:

- *Module 1: Administrative and regional information.*
- *Module 2: Summaries relating to quality, non-clinical, and clinical data.*
- *Module 3: Information concerning the quality of the active substance(s) and the finished pharmaceutical product.*
- *Module 4: Non-clinical study reports.*
- *Module 5: Clinical study reports.*

The registration dossier for medicinal products must be submitted in the Common Technical Document format for all applications relating to registration, renewal, and/or amendment of a registration authorization. This format applies to all categories of medicinal products, including biopharmaceuticals, immunological products, and radiopharmaceuticals.

Second section: Processing of the Registration Application Dossier

Upon submission of the registration application dossier to the NAPPand payment of 75% of the applicable registration fees, the Agency issues the applicant pharmaceutical establishment an acknowledgment of receipt.

The competent departments of the NAPPexamine the application within eight days to verify the completeness of the dossier, the validity of the supporting documents, and the payment of the required registration fees. Where the dossier is found to be incomplete, the applicant pharmaceutical establishment is duly notified.

Once the registration dossier is deemed admissible, the competent departments of the NAPP undertake a technical evaluation of the PP concerned, with the assistance of experts and/or specialized institutions whenever necessary. If the evaluation reveals deficiencies or raises observations, the pharmaceutical establishment is requested to provide supplementary information.

To ensure the objectivity and integrity of the evaluation process, the legislator requires that experts participating in the assessment have no direct or indirect interest in the production, importation, or marketing of the PP under evaluation. Accordingly, they must sign a written declaration confirming the absence of any conflict of interest.[21]

For certain medicinal products, the evaluation of the registration dossier is conducted in two distinct phases:[22]

The first phase consists of a documentary assessment, involving a scientific review of the documentation relating to the regulatory status,

quality, safety, and efficacy of the pharmaceutical product subject to registration.

The second phase comprises a technical assessment, which includes both the documentary technical evaluation relating to quality, safety, and efficacy and the examination of tests and analyses conducted to verify that the pharmaceutical product possesses the composition and characteristics described in the registration dossier.[23]

Nevertheless, documentary and/or technical assessments may be simplified for certain categories of medicinal products, particularly:[24]

- *Medicinal products intended for public health emergencies, including orphan drugs, medicines intended for the treatment of life-threatening diseases, PP included in national prevention programs, medicines incorporated into national cancer and HIV/AIDS control programs, immunological products such as vaccines and sera, radiopharmaceuticals, and antidotes.*
- *Medicinal products for which analyses of the finished product cannot be performed locally.*

In the context of an abridged evaluation procedure, the Agency may also take into consideration assessments conducted by a foreign pharmaceutical regulatory authority or by an authority recognized by the NAPP for the purpose of supporting the registration application.

Upon completion of the abridged evaluation reports and the assessment of the registration dossier, the DGNAPP submits the relevant documentation to the Medicines Registration Committee within thirty days from the date of acceptance of the registration dossier for the purpose of obtaining its opinion. This period may be extended by a maximum of thirty additional days where supplementary information is required.

The DGNAPP presents the essential elements of the registration dossier together with the technical evaluation reports prepared by the Agency's competent departments to the Medicines Registration Committee. The Committee is required to issue its opinion within thirty days from the date of referral. This period may likewise be extended for a maximum of thirty additional days where supplementary information is deemed necessary.

Following the Committee's deliberations, its decision is transmitted to the DGNAPP within eight days from the date on which the deliberations are formally approved.

Upon completion of the dossier evaluation, the pharmaceutical establishment submitting the registration application is required, within fifteen days, to provide a certificate confirming that none of the elements submitted in support of the application have been modified, except for

amendments previously approved and communicated to the NAPP during the technical evaluation process.

After obtaining the opinion of the Committee, the NAPP must decide on the registration application within one hundred and fifty days from the date on which the registration dossier is accepted. In exceptional circumstances, this period may be extended by an additional ninety days.

Third section: Outcomes of the Registration Application Review

1. Rejection of the Pharmaceutical Product Registration Application:

Following the examination of the registration application by the PP Registration Committee, the application may be rejected, particularly in the following circumstances:

- *The pharmaceutical product is deemed detrimental when utilized under the standard conditions outlined in the registration documentation.*
- *The applicant has insufficiently demonstrated the therapeutic effectiveness of the pharmaceutical product.*
- *The pharmaceutical product fails to align with the qualitative and quantitative specifications stated in the registration dossier.*
- *The processes for manufacturing and/or quality control do not guarantee the quality, efficacy, and safety of the pharmaceutical product.*
- *The documents and information provided in support of the application do not adhere to the stipulations of the decree regulating the registration of pharmaceutical products.*
- *The medico-economic assessment does not provide justification for the market introduction of the pharmaceutical product.*[25]

In such cases, the DGNAPP notifies the pharmaceutical establishment of the decision refusing registration. The rejection decision must be duly reasoned and justified.

2. Granting of the Pharmaceutical Product Registration Authorization:

Once the registration application has been approved, a registration authorization is granted to the pharmaceutical establishment, provided that it is duly licensed in accordance with the applicable legal requirements. Pursuant to Article 40 of Executive Decree No. 20-325, the registration authorization for PP must include the following information:

- *The trade name of the pharmaceutical product;*
- *The International Nonproprietary Name (INN);*
- *The pharmaceutical dosage form and strength;*
- *The type of packaging and presentation;*
- *The storage conditions and shelf life of the pharmaceutical product;*

- *The name and address of the registration authorization holder;*
- *The name and address of the operator responsible for the registration authorization;*
- *The names and addresses of all entities involved in the manufacture of the final product, together with the locations where intermediate products, bulk products, primary and secondary packaging operations are carried out, and batch release sites where applicable;*
- *The classification and dispensing status of the pharmaceutical product, including whether it is intended for hospital use and/or community pharmacy distribution.*

Where appropriate, the registration authorization must be accompanied by specific restrictive measures, particularly those relating to the inclusion of the product in one of the regulatory schedules governing medicinal products, according to the conditions applicable to its dispensing and prescription, and/or the restriction of its use exclusively to healthcare institutions. The detailed characteristics of the product and the patient information leaflet are annexed to the registration authorization.

The legislator has established a validity period of five (5) years for the registration authorization,[26] commencing from the date of its signature. However, the holder or operator of the authorization may apply for its renewal within 180 days prior to its expiry date, following consultation with the Registration Committee.[27]

During the validity period of the registration authorization, the holder or operator is required to notify the NAPP of any modifications, particularly those concerning:

- *New data leading to revisions of the initial registration dossier, particularly information pertaining to the origin and quality of the active ingredient;*
- *Updated information regarding the evaluation of the benefit-risk ratio of the pharmaceutical product;*
- *Revisions to the Summary of Product Characteristics (SPC) and/or the patient information leaflet;*
- *Essential adjustments to the manufacturing and quality control processes outlined in the registration application, reflecting scientific and technological advancements, to guarantee that the pharmaceutical product is produced and regulated according to recognized scientific benchmarks;*
- *Any prohibitions or limitations imposed by the relevant health authority in the country of origin or in any other nation where the*

pharmaceutical product is distributed;

- *Any new information that could influence the safety profile or the utilization of pharmacovigilance data related to the pharmaceutical product in question.*

The National Agency for PP may also mandate the holder or operator of the registration authorization to supply evidence demonstrating that the benefit-risk ratio of the pharmaceutical product continues to be favorable.

Moreover, if the registered pharmaceutical product is not effectively marketed or exported within eighteen (18) months from the date on which the registration authorization is communicated, the National Agency for PP reserves the right to revoke the registration authorization.[28]

Third requirement: Withdrawal, Transfer, and Assignment of Pharmaceutical Product Registration Decisions

First section: Withdrawal of the Registration Decision

Where the NAPP determines that a pharmaceutical product poses a risk to health security or fails to meet the required quality standards, it may order the temporary withdrawal of the product's registration decision. If, within a period of twelve (12) months, the holder or operator of the registration decision fails to remedy the deficiencies or address the reservations that justified the withdrawal, the temporary withdrawal shall automatically become permanent.

The lifting of a temporary withdrawal or its conversion into a definitive withdrawal may only occur after obtaining the opinion of the Registration Committee. In all cases, the withdrawal decision must be duly reasoned and justified.

The legislator has exhaustively specified the entities authorized to submit requests for the temporary or definitive withdrawal of the registration decision of any pharmaceutical product, namely:

- *The Minister responsible for the pharmaceutical industry;*
- *The Minister responsible for health;*
- *The holder and/or operator of the pharmaceutical product registration decision;*
- *The National Health Security Agency;*
- *National institutions operating under the Ministry of Health;*
- *National and international pharmaceutical regulatory authorities;*
- *Institutions specialized in pharmacovigilance.*

Following either a temporary or definitive withdrawal, the holder or operator of the registration decision is required to take all necessary measures to cease the distribution of the pharmaceutical product concerned. Furthermore, the holder must recall all marketed batches of the

product and either destroy or return them, while fully complying with all measures and procedures imposed by the NAPP.

Second section: Transfer or Assignment of the Registration Decision

Pursuant to Article 49 of Executive Decree No. 20-325, any transfer or assignment of a registration decision necessitates the issuance of a new registration decision by the NAPP.

Such a transfer or assignment may only be effected in favor of a legally authorized pharmaceutical establishment after examination of an administrative dossier submitted by the latter in accordance with the provisions of the Decree, particularly Article 43. The original registration decision remains valid until the issuance of the new registration decision.

Conclusion

The present study demonstrates that the Algerian legislator has placed significant emphasis on the registration of PP prior to their placement on the market. This approach is reflected in the legislative and regulatory framework governing pharmaceutical products, particularly following the establishment of a dedicated ministry responsible for pharmaceutical production. Such a regulatory framework is intended to ensure the protection of consumers, while enabling the marketing and distribution of PP under conditions that do not pose risks to the health and safety of users.

Nevertheless, the study has also revealed certain regulatory ambiguities. Executive Decree No. 20-325 concerning the procedures for the registration of PP applies, in principle, to all PP as defined in Article 207 of Health Law No. 18-11. These include medicinal products, pharmaceutical chemicals, galenical preparations, pharmaceutical raw materials, dietary foods intended for special medical purposes, and all other substances necessary for human medicine.

However, a careful reading of Article 25 of the aforementioned Decree indicates that, with regard to the composition of the registration application dossier, the legislator refers to a ministerial decision issued by the Minister responsible for the pharmaceutical industry. Upon examining the regulatory instruments adopted in this field, it appears that the relevant decision is that of 28 Ramadan 1442, corresponding to 10 May 2021, which establishes the composition of the registration dossier and the dossier for the renewal of the registration decision exclusively for medicinal products intended for human use. Such products constitute only one category within the broader concept of pharmaceutical products.

This raises an important legal and practical question as to whether the same registration dossier requirements should also apply to the other categories of PP covered by Executive Decree No. 20-325. The uncertainty

arises because Article 1 of the aforementioned ministerial decision expressly provides that:

"Pursuant to the provisions of Articles 25 and 42 of Executive Decree No. 20-325 of 6 Rabi' al-Thani 1442, corresponding to 22 November 2020, concerning the procedures for the registration of pharmaceutical products, this Decision aims to determine the composition of the registration dossier and the dossier for the renewal of the registration decision for medicinal products intended for human use."

Accordingly, the absence of specific regulatory provisions governing the registration dossiers of the remaining categories of PP creates an area of legal uncertainty that warrants further clarification by the competent regulatory authorities in order to ensure consistency and legal certainty in the implementation of the pharmaceutical registration framework.

Accordingly, the following recommendations are proposed:

- *The issuance of specific regulatory decisions defining the documentation requirements for the registration of PP other than medicinal products is strongly recommended.*
- *Legal and scientific oversight of pharmaceutical product registration procedures should be strengthened to ensure the efficacy, safety, and quality of PP prior to the granting of marketing authorization.*
- *Efforts should be directed toward simplifying and expediting registration procedures without compromising scientific and technical standards, thereby ensuring the timely availability of medicines and medical products.*
- *The legal and regulatory framework governing the registration of PP should be regularly updated to keep pace with scientific and technological advancements in the pharmaceutical sector.*
- *The principle of transparency should be firmly embedded in the evaluation of registration dossiers through the establishment of clear, objective, and well-defined criteria for the acceptance or rejection of registration applications.*
- *Pharmacovigilance systems should be further reinforced to monitor adverse effects and potential risks associated with PP following their commercialization, thereby ensuring the effective protection of public health.*
- *Cooperation between national and international health authorities should be intensified to facilitate the exchange of expertise, scientific knowledge, and regulatory information relating to the evaluation and registration of pharmaceutical products.*

References:

1-Article 207, Law No. 18-11 of 2 July 2018 Relating to Health, as amended and supplemented by Ordinance No. 20-02 of 30 August 2020, concerning the definition of pharmaceutical substances under Algerian health legislation, Official Gazette of the People's Democratic Republic of Algeria, No. 46, 29 July 2018; amended by Official Gazette of the People's Democratic Republic of Algeria, No. 50, 30 August 2020, provides that: "Pharmaceutical substances, within the meaning of this Law, include the following:

- *Medicines;*
- *Pharmaceutical chemicals;*
- *Galenical substances;*
- *Raw materials for pharmaceutical use;*
- *Dietary foods intended for special medical purposes;*
- *Any other substances necessary for human medicine."*

2- Article 219, ibid.
3-Executive Decree No. 20-325 of 6 Rabi' al-Thani 1442 AH, corresponding to 22 November 2020, Concerning the Procedures for the Registration of Pharmaceutical Products, Official Gazette of the People's Democratic Republic of Algeria, No. 69, 22 November 2020.
4-Executive Decree No. 19-190 of 3 July 2019 Determining the Missions, Organization and Functioning of the National Agency for Pharmaceutical Products, as amended and supplemented by Executive Decree No. 20-391 of 19 December 2020 and Executive Decree No. 21-525 of 26 December 2021.
5-Decision of 28 Dhu al-Qa'dah 1443 AH, corresponding to 28 June 2022, Establishing the Internal Organization of the National Agency for Pharmaceutical Products, Official Gazette of the People's Democratic Republic of Algeria, No. 57, 4 September 2022.
6-Article 6, ibid.
7-Article 3, Executive Decree No. 20-325.
8-Article 7, ibid.
9-Articles 13 and 14.
10-Article 8, ibid.
11-Article 11, ibid.
12-Article 21, ibid.
13-Article 2, Decision of 26 Safar 1443 AH, corresponding to 3 October 2021, Determining the Procedures for Examining the Application and the Model Application Form for the Prior Registration of Pharmaceutical Products, Official Gazette of the People's Democratic Republic of Algeria, No. 87, 17 November 2021.
-14Article 22, ibid.
15-Article 4, ibid.
16-Article 6, ibid.
17-Article 2, Decision of 12 Jumada al-Awwal 1442 AH, corresponding to 2-7 December 2020, Establishing the Duties, Composition, Organization and Operation of the Committee of Clinical Experts, Official Gazette of the People's Democratic Republic of Algeria, provides that:
"The Committee shall be responsible for issuing opinions on the therapeutic benefit, efficacy, and safety of any pharmaceutical product and any medical device intended for

use in human medicine, upon request of the Director General of the National Agency for Pharmaceutical Products, within the framework of the following procedures:

- *Prior application for the registration of pharmaceutical products;*

18-Article 12, ibid.
19-Article 24, Executive Decree No. 20-325.
20-Article 4, Decision of 28 Ramadan 1442 AH, corresponding to 10 May 2021, Determining the Composition of the Drug Registration File and the File for the Renewal of the Registration Decision for Medicinal Products Used in Human Medicine, Official Gazette of the People's Democratic Republic of Algeria, No. 55, 14 July 2021
21-Articles 29 and 30, Executive Decree No. 20-325.
22-Article 32, ibid.
23-Article 2, Decision of 11 Jumada al-Awwal 1442 AH, corresponding to 26 December 2020, Determining the Procedures for the Documentary and/or Technical Evaluation of the Registration File and the List of Medicinal Products Concerned, Official Gazette of the People's Democratic Republic of Algeria, No. 78, 27 December 2020.
24-Article 3, ibid.
25-Article 38, Executive Decree No. 20-325.
26-Article 41, ibid.
27-Article 42, ibid.
28-Article 44, ibid.