PEOPLE'S DEMOCRATIC REPUBLIC OF ALGERIA

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MEDICAL SCHOOL
DEPARTMENT OF PHARMACY

End of study memoire

Presented with a view to obtaining the Doctorate Degree in Pharmacy

Entitled:

The role of the pharmacist in the pharmaceutical industry

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GRATITUDE

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Finally, we would like to express our sincere gratitude to everyone who has contributed directly or indirectly to the completion of this work.

DEDICATION

With enormous pleasure and an open heart and immense joy, may I dedicate this work to:

My father

My eternal example, my moral support and my source of happiness, and my right arm, the one who has always sacrificed to see me succeed. May God protect you.

My mother

The light of my days, the source of my efforts, my life and my happiness; mom whom I adore; to you my dear mother.

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Thank you for always being by my side, I wish you a life full of happiness and success, may God preserve our family life.

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My dear friends "Mohamed, Asaad, Chihab, Adel, Aziz, Tarek, Alla, Faical"

Thank you for your encouragement in difficult times, I wish you success and joy in your life, and I hope with all my heart that our friendship will last forever. I love you.

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Thank you for your moral support, your patience, and your understanding throughout this work. I wish you a bright future.

SOUISSI Abdenor

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Summary:

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Abbreviations list:

ACP	Algerian central pharmacy
ALDAPH	Algeria Denmark Pharmaceutical
ANPP	National Agency for Pharmaceutical Products
CEO	Chief Executive Officer
CHP	Central hospital pharmacy
CTD	Common technical document
GMP	Good manufacturing practices
HR	Human recourse
ICH	International Council for Harmonization
INN	International nonproprietary name
ISO	International Organization for Standardization
MA	Marketing authorization
MIP	Ministry of Pharmaceutical Industry
N / A	Not applicable
NPPC	National pharmaceutical production company
NSCI	National Society of Chemical Industries
PEIC	Public Establishment of an Industrial and Commercial nature
PIA	Pasteur Institute of Algeria
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
R&D	Research and Development
SAP	Structural adjustment plan
SOCOTHYD	Society of Hydrophilic Cotton & Articles of Hygiene
SPC	Supplementary Protection Certificate
SUPAC	Scale-up and Post-Approval Changes
TD	Technical director
WHO	World Health Organization

General Introduction

Introduction:

The pharmaceutical industry has become one of the most developed sectors in recent times. The gradual advancement of science and technology in general has been one of the factors that have spurred the growth of this sector. Like other industrial sectors, the pharmaceutical industry has moved towards the development of more sustainable production systems, products and processes.

The pharmaceutical industry is considered by the Algerian public authorities as an important and strategic sector because of its economic weight and its symbolic significance, since it represents the health and well-being of all citizens.

Due to the in-depth knowledge in the field of pharmaceutical products and medical devices acquired in the pharmacist's training course and the measures that govern the procedures for obtaining approval for the production of pharmaceutical products and medical devices established by the authorities. The pharmacist is a vital element for the development and evolution of the pharmaceutical industry.

"The technical director pharmacist is responsible for ensuring that each batch of pharmaceutical product or medical device is manufactured and controlled in accordance with the laws and regulations in force and in compliance with the requirements set out in the registration decision and/or the decision of approval »[1]. The technical director pharmacist thus new name of the pharmacist the regulations in force. He justifies, at all times, that the manufactured products comply with the characteristics to which they must respond and that the pharmaceutical establishment has carried out the necessary checks from the stage of assembly of the raw materials arriving up to the stage of the finished product. To undertake research, testing and analysis related to the development, production, storage, quality control, distribution of drugs and medical devices in the interest of public health.

Further than that, his duties do not stop there, even after the marketing of the product, he is in charge of pharmacovigilance and materiovigilance. It is also considered as the junction who directly connects the establishment to the authority represented by the competent services of the Ministry of Pharmaceutical Industry and the Ministry of Health.

Our objectives are:

- Bring light on the new ministry regulations to the pharmaceutical industry.
- Identify the current regulations that organize the companies' work.
- Determine the role of the pharmacist in multiple occupations in the pharmaceutical industry.
- Solve the lack of information problem to better understand the pharmacist placement in this field.

[1] Edge of the 11 Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the pharmacist technical director and pharmacist assistants of the pharmaceutical manufacturing establishment. Article 2.

In our work we have divided it into 2 parts:

- In the first part, we present a bibliographical summary on:
  The diagram of the pharmaceutical industry sector in Algeria.
  Identify the regulations in force that organize the pharmaceutical industry.
  Highlight the national and international stakeholders who organize the Algerian pharmaceutical industry.
  Description of the drug cycle.
  Determination of the missions and qualification of the industrial pharmacist.

- In the second part, a presentation through a roadmap the missions and objectives of a pharmacist in the pharmaceutical industry to actually practice in the field, and for this we have developed a questionnaire for technical director pharmacists and assistant pharmacists which is made available to them on the Google Forms website.

Bibliographic synthesis

Chapter 1:

General information on the pharmaceutical industry

I General information on the pharmaceutical industry in Algeria:

1) Historical development and legal framework of the Algerian pharmaceutical sector:

To better understand the current situation of the Algerian pharmaceutical sector, it is necessary to retrace its evolution from independence to the present day.

The national pharmaceutical sector experienced two major periods before and after its liberalization in 1990.

1.1) The period of state monopoly (1962 to 1990)

During the colonial period, the pharmaceutical industry was limited to a single company, namely BIOTIC, created in 1952.[2] At independence, a project is launched which sees the light of day in 1962, it is PHARMAL.[3]

This period was marked by direct management of the sector by the health administration, a management ensured around the Algerian central pharmacy (ACP), created in 1963 under the authority of the Ministry of Public Health, ensured the functions of production, import and wholesale distribution.[4]

A development plan for the pharmaceutical industry was initiated (thirty industrial pharmacists were trained in major European universities), the National Society of Chemical Industries (NSCI) hired, and other projects were created, namely:

- The SOCOTHYD medical consumables unit created in 1970[5] (Society of Hydrophilic Cotton & Articles of Hygiene).
- Launch of Pasteur Institute project.

As part of the restructuring of all major public sector companies in the early 1980s, the ACP was restructured around three institutions "the three PHARMS"[6]responsible each of them for the importation and distribution of the drug:

-ENCOPHARM East.

-ENOPHARM in the West.

[2] Hamadi A.: "Towards a systemic approach to governance: the case of access to medicines in Algeria", Doctoral thesis in economics, University Lille 1, 2013, p. 97.

[3] Ziani F.: "Analysis of drug consumption in Algeria: case of the wilaya of Sétif", thesis of magister in economics, A.MIRA University of Bejaia, 2010, p.64.

[4] Hamadi A, op.cit, p. 97.

[5] https://www.socothyd.com/new/reseau.php.

[6] Belhacene O. and Ferfera MY. : "The contrasting effects of the involvement of foreign laboratories in the Algerian pharmaceutical industry", Algeria, International Colloquium, Fifty years of experience in State-Economy-Health development, 2014, p.55.In:https:// www.ajol.info/index.php/cread/article.

-ENAPHARM in the center.

The local production of drugs was ensured by the national pharmaceutical production company (NPPC), created by decree 82/161 promulgated in April 1982, became autonomous in February 1989 and gave birth to the Saidal group[7], as well as the creation of the central hospital pharmacy (CHP), the sole structure responsible for supplying public health structures.

The pharmaceutical sector was a sector reserved for the State, and it was governed by law n°85/05 of February 16, 1985, relating to the protection and promotion of health. Despite significant investments, particularly during the 1970s and 1980s, the pharmaceutical industry has not been able to develop, and national demand can only be satisfied by resorting to imports, as shown in the table below.

Year	Medication use	Import	Import coverage rate
1972	503.51	417.91	83%
1974	606.74	533.93	88%
1978	1230	1125.5	91.5%
1980	1630	1480	90.80%

Table 1: Evolution of the consumption and importation of drugs from 1972 to 1980 (in millions of Algerian dinar)[8]

1.2) The period of liberalization of the sector (1990 to the present day)

This liberalization allowed the emergence of SAIDAL and other private laboratories in partnership with multinational pharmaceutical companies (Sanofi, Pfizer, Rhône Poulenc, Glaxo Wellcome and Novo Nordisk.)

The Algerian pharmaceutical market has been liberalized since the promulgation of law 90-10 of April 14, 1990[9]on Money and Credit (LMC), this text puts an end to the State monopoly on foreign trade and Law 90-16 of August 07, 1990[10], which authorizes the installation in Algeria of dealer wholesalers authorized by agreement to import goods for resale.

The State has also promulgated Legislative Decree No. 93-12 of October 5, 1993[11], relating to the promotion of investment, the targeted objective of which is to attract foreign and national direct investment[12]and in 1992, publication of decree 92-284 relating to the registration of pharmaceutical products[13].

[7] http://www.saidalgroup.dz.
[8] Hamadi A, op, cit, p98
[9] Official Journal of the Algerian Republic n°16 of 18/04/1990.
[10] Official Journal of the Algerian Republic n°34 of 11/08/1990.
[11] Official Journal of the Algerian Republic n°64 of 10/10/1993.
[12] Belhacene O. and Ferfera MY.: op.cit. p.56.
[13] Official Journal of the Algerian Republic n°53 of 12/07/1992.

Since 1995, and within the framework of the structural adjustment plan (SAP) imposed on the country by the international financial institutions, Algeria has experienced a remarkable development of access to external markets in all economic activities.

Several legal and legislative texts governing the pharmaceutical sector have been promulgated:

• The obligation to invest in production is required[14], then lifted (order of the Minister of Health dated June 6, 2005).

• Willingness to regulate imports by suspending registrations[15].

• Order of September 23, 2001, establishment of the reference price.

• Political will to promote generic drugs and political will to promote national production.

• The ban on the import of 128 locally produced medicines (instruction of September 2003) then its cancellation in 2005, its reinstatement in 2008 (the ministerial decree of October 30, 2008, making it compulsory to invest in local production and ban on the importation of locally produced drugs).

A clear effort on the part of the health administration to regulate the technical and legal framework necessary for the opening of the market:

-The establishment of a national drug control laboratory.

- Retail distribution was provided by ENDIMED (National Company for the Retail Distribution of Medicines)[16].

-The SAIDAL company implemented a restructuring plan which resulted in its transformation into an industrial group grouping together three subsidiaries (Pharmal, Antibiotical and Biotic) in 1997[17].

In January 2014, SAIDAL proceeded by way of absorption, with the merger of its 100% owned subsidiaries: Pharmal, Antibiotical and Biotic.[18]

2) The creation of the Ministry of Pharmaceutical Industry

2.1) Introduction :

In Algeria, the creation of the Ministry of Pharmaceutical Industry coincided with the Covid-19 health crisis, this coincidence has given increased importance and attention to the role of this sector.

This new structure provides an appropriate environment to contain such large sector by:

1- Expand regulations to promote and support the pharmaceutical industry.

2- Require qualified and highly specialized people oriented towards the pharmaceutical field by establishing the obligation of continuous training in the field.

[14] Order n°46 of the Minister of Health of 07/10/1998.
[15] CNOP. : "Issues and perspectives of the pharmaceutical environment in Algeria", Paris, 2008, p.2.
[16] Joint-stock company resulting from the restructuring of the three PHARMS, created on September 24, 1997.
[17] http://www.saidalgroup.dz.
[18] https://www.saidalgroup.dz/qui-sommes-nous/

3- Allocate a budget and the necessary resources for the development of the pharmaceutical industry.

It also relieves the Ministry of Health, which must pay more attention to public health in all its scope, essentially linked to prevention, the organization of care, the adoption of national programs and the management and monitoring of public and private health establishments and structures.

This industrial activity in Algeria is still dependent on other countries. This is due to the absence of local production of raw materials (active ingredients), because the only source of these for pharmaceutical companies is the importation from the countries that manufacture them.

2.2) Objectives of the Ministry of Pharmaceutical Industry

The Ministry of Pharmaceutical Industry has set some goals clarified in the official journal to promote this field. And specified the actions carried out around each objective.

We have categorized and organized them as follows:

1- Fundamental development of the field of pharmaceutical industry

2- Continuous improvement of establishments

3- Ensure sufficient availability of pharmaceutical products

4- Ensure adequate accessibility of pharmaceutical products to consumers

5- Promotion of the national product

6- Develop strategies for future work plans

7- Expansion of research and development studies

2.2.1) Objectives of the development of the pharmaceutical industry sector:

The measures followed are:

— To draw up the policy of the pharmaceutical industry, to ensure its development, to monitor and control its implementation.

— To develop and propose a pharmaceutical strategy oriented towards the promotion of national production, to implement it and to monitor it.

— Developing and proposing the management policy for State holdings in the public sector of the pharmaceutical industry and overseeing its implementation.

— To develop and propose measures and actions aimed at ensuring the availability, quality and accessibility of pharmaceutical products and medical devices.

— To encourage the implementation of investment projects in the field of the pharmaceutical industry and to ensure their facilitation, in particular productive investment as a substitute for imports.

— Organize the framework for foresight and the promotion of strategic and technological monitoring in the pharmaceutical industry.

— Contribute to the emergence of an economic, technological, scientific and regulatory environment favorable to the development of the pharmaceutical industry sector.

— To propose and take any measure aimed at ensuring the regulation of pharmaceutical activities, particularly in the field of registration, approval of pharmaceutical products and medical devices.[19]
— To propose and take any measure aimed at regulating the activities of pharmaceutical establishments in terms of manufacture, import, export, operation and distribution.
— To take any measure allowing the achievement of the objectives fixed by the policy of the pharmaceutical industry sector, and to follow the implementation of the programs of its development.
— To identify the mechanisms needed to promote innovation and technological development in the pharmaceutical industry sector to propose, in conjunction with the parties concerned.

2.2.2) Objectives in relation to pharmaceutical establishments

— To ensure the strengthening and consistency of the productive capacities of pharmaceutical establishments manufacturing pharmaceutical products and medical devices, in accordance with the objectives set and national priorities.
— All actions aimed at developing training and qualification capacities in the professions of the sector and ensuring their implementation.
— Ensure the regulation of investment projects by directing them towards the production of essential pharmaceutical products with high added value.[20]
— To ensure compliance with the legislation and regulations in force relating to the quality, efficacy and safety of pharmaceutical products and medical devices.
— To encourage the registration of pharmaceutical manufacturing establishments in international approval and certification processes.
— To promote any measure likely to facilitate and allow operators access to new technologies in the field of the pharmaceutical industry.[21]

2.2.3) The availability of pharmaceuticals

The measures followed are:
— Drawing up the registration and certification policy and overseeing its development and implementation, in particular its orientation towards products with high added value in national production.
— To take all measures likely to guarantee the availability of pharmaceutical products and medical devices, particularly in terms of market regulation.
— To issue temporary authorizations for the use of unregistered medicinal products, in accordance with the legislation and regulations in force.
— To ensure the implementation of import programs for pharmaceutical products and medical devices in addition to national production.[22]

[19] Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 2.
[20] Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 3.
[21] Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 7.

— Establish and update the list of essential pharmaceutical products and medical devices as well as the national formulary of medicines, the pharmacopoeia and the national nomenclatures of pharmaceutical products and medical devices. [23]

2.2.4) Accessibility of pharmaceutical products

The measures followed are:

— Ensure the continuous upgrading of the legislative and regulatory framework aimed at ensuring the accessibility of pharmaceutical products and medical devices.

— To develop a national price-fixing policy, for national production as well as for imports, tending to ensure accessibility to these products and to oversee its implementation.

— Developing a pricing strategy within the framework of the pharmaceutical policy and overseeing its implementation.

— To assess the costs of new therapeutic strategies and determine the procedures for their introduction, in consultation with the parties concerned.[24]

2.2.5) The promotion of the national product

The measures followed are: enrich with the paragraph of the law of 18-11 part promotion and publicity

— Ensure the promotion of the national production of pharmaceutical products and medical devices intended for export.[25]

— Promote investment in local manufacturing correlated with export projection.

— The requirement for prescribers to use the names of drugs in INNs to make it easier for pharmacists to dispense generic products.

— Manufacture locally in addition to the substitution which is authorized by regulation.

— Encourage community pharmacists to promote the national product through the National Social Insurance Fund (CNAS) convention increase bonus.

— The integration of the reference tariff for the reimbursement of drugs according to the number of molecules manufactured and placed on the market.

2.2.6) On a strategic level

— To monitor the development of market trends in the national, regional and international pharmaceutical industry, and to take any measure likely to ensure its balance.

— Ensure the use of new information technologies to monitor the development of market needs and supply in terms of pharmaceutical products and medical devices.

— See to the creation of a database and the preparation of periodic and short-term reports on the evaluation of the pharmaceutical industry sector.[26]

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[22] Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 4.

[23] Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 7.

[24] Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 5.

[25] Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 6.

— To ensure permanent technological watch at the international level allowing access to innovative molecules.[27]
— Strengthen legislation and controls on the supply chain, and encourage international collaboration to combat counterfeit products.

2.2.7) Research and development

— To encourage research and development within pharmaceutical manufacturing establishments.
— To propose any incentive measures for research and development activity in the field of the pharmaceutical industry.
— Ensure the promotion of innovation in the field of the pharmaceutical industry.[28]

2.3) Organization of the central administration of the Ministry of Pharmaceutical Industry:

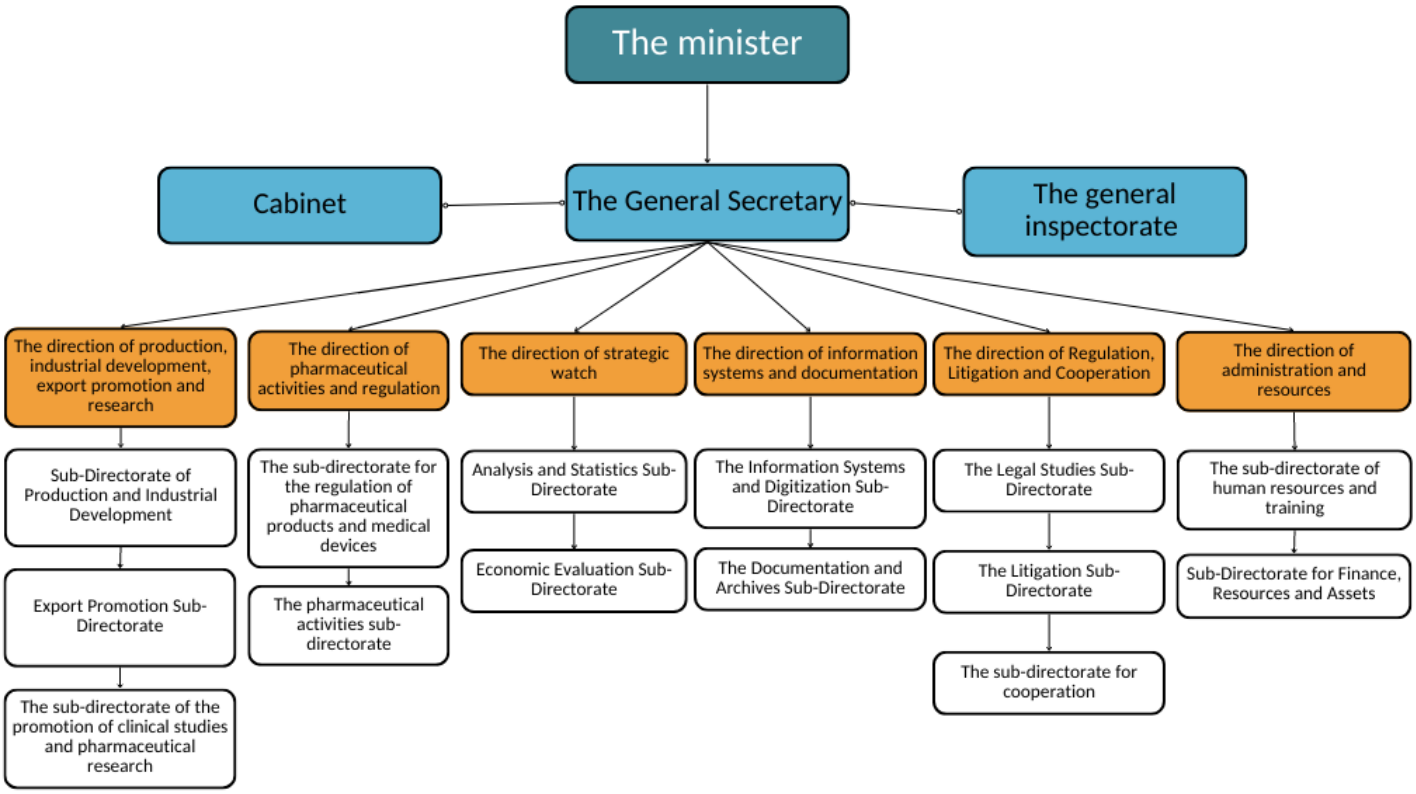


Figure 1: Organization chart of the Ministry of Pharmaceutical Industry[29]

[26] Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 7.
[27] Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry. Article 4.
[28] Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 8.

• **The General Secretary:** assisted by two (2) directors of studies, to which are attached the office of mail and communication as well as the ministerial office of internal security of the establishment.

• **The chief of staff:** assisted by six (6) research and synthesis officers, responsible for:

— The preparation and organization of the Minister's participation in government activities.

— Monitoring the economic situation in the sector.

— Monitoring programs to promote research, investment and development in the pharmaceutical industry.

— To issue temporary authorizations for the use of unregistered medicinal products, after consulting the national agency for pharmaceutical products.[30]

• **The general inspectorate of the pharmaceutical industry:** has the following missions:

— To ensure the application of and compliance with legislation and regulations relating to the pharmaceutical industry sector.

— To ensure the rational use, preservation, maintenance and security of the immovable and movable assets made available to the structures of the central administration, establishments and bodies under supervision.[31]

— The General Inspectorate may propose any measure likely to improve and strengthen the exercise of the activities of the structures, establishments and bodies inspected.[32]

• **The following structures:** Includes directions and sub-directions

2.3.1) The direction of production, industrial development, export promotion and research:

Is mainly responsible for:

— Promote and support investment projects in local production with a strong focus on new technologies and innovative products.

— Promote research and development in the field of the pharmaceutical industry through incentive measures.

— To set up an incentive policy in favor of the export of pharmaceutical products and medical devices.

It includes three (3) sub-directorates:

1. Sub-Directorate of Production and Industrial Development
2. Export Promotion Sub-Directorate
3. The sub-directorate for the promotion of clinical studies and pharmaceutical research[33]

2.3.2) The pharmaceutical activities and regulation department:

[29] https://www.miph.gov.dz/fr/le-ministere/organigramme/

[30] Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry.

[31] Executive Decree No. 20-273 of 11 Safar 1442 corresponding to September 29, 2020 on the organization and operation of the general inspectorate of the Ministry of the Pharmaceutical Industry. Article 3.

[32] Executive Decree No. 20-273 of 11 Safar 1442 corresponding to September 29, 2020 on the organization and operation of the general inspectorate of the Ministry of the Pharmaceutical Industry. Article 4.

[33] Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry. Article 2.

Is mainly responsible for:

— To study all measures intended to regulate the market for pharmaceutical products and medical devices.

— Organize and regulate the activity of importing and distributing pharmaceutical products and medical devices.

— Approving pharmaceutical import, operation and distribution establishments as well as companies specializing in medical promotion.

It includes two (2) sub-directorates:

1. The sub-directorate for the regulation of pharmaceutical products and medical devices
2. The pharmaceutical activities sub-directorate[34]

2.3.3) The strategic watch department:

Is mainly responsible for:

— To initiate any prospective study related to the activities of the pharmaceutical industry.

— Assess the needs of the pharmaceutical products and medical devices market.

— To set up information system for monitoring stocks of pharmaceutical products and medical devices in order to avoid the occurrence of stock shortages.

— Establish the list of essential pharmaceutical products and medical devices, as well as the national formulary of medicines and the pharmacopoeia.

It includes two (2) sub-directorates:

1. Analysis and Statistics Sub-Directorate
2. Economic Evaluation Sub-Directorate.[35]

2.3.4) The information systems and documentation department:

Is mainly responsible for:

— See to the implementation of the information systems necessary for decision-making and the evaluation of programs in the sector.

— Develop a national strategy for the digital transformation of the sector.

It includes two (2) sub-directorates:

1. The Information Systems and Digitization Sub-Directorate
2. The Documentation and Archives Sub-Directorate.[36]

2.3.5) The Regulation, Litigation and Cooperation Department:

Is mainly responsible for:

— Undertake legal studies concerning the sector.

— Ensuring compliance with procedures for settling disputes.

[34] Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry. Article 3.

[35] Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry. Article 4.

[36] Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry. Article 5.

— Promote bilateral and multilateral cooperation and prepare and coordinate the sector's participation in meetings of specialized regional and international organizations.

It includes three (3) sub-directorates:

1. The Legal Studies Sub-Directorate
2. The Litigation Sub-Directorate
3. The sub-directorate for cooperation.[37]

2.3.6) The direction of administration and resources:

Is mainly responsible for:

— To undertake any measure likely to ensure adequate working conditions and the effective management of labor relations.

— Managing operations relating to the training and development of personnel in the sector.

— Drawing up draft budgets and ensuring their execution.

It includes two (2) sub-directorates:

1. The sub-directorate of human resources and training
2. Sub-Directorate for Finance, Resources and Assets[38]

II Pharmaceutical companies:

1) Company components:

The company is an organized and hierarchical human group because it can only exist following the association of a group of people. The functions and tasks are distributed among the various staff members who can be internal or external components.

1.1) Internal stakeholders:

These are the parties who work within the company to which they are formally or directly bound by a contract.

- The company's management: it is the body that regulates the operation of the company. The preferences of the leaders determine the objectives, the organization, the policy and the strategy of the company.

- Executives: these are the members of the company who are between the basic employees and the management. They perform tasks that call for reflection and that require high-level knowledge.

- Basic employees (workers): They perform simple, routine business tasks.

Internal participants can thus be represented by the following pyramid:

[37] Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry. Article 6.

[38] Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry. Article 7.

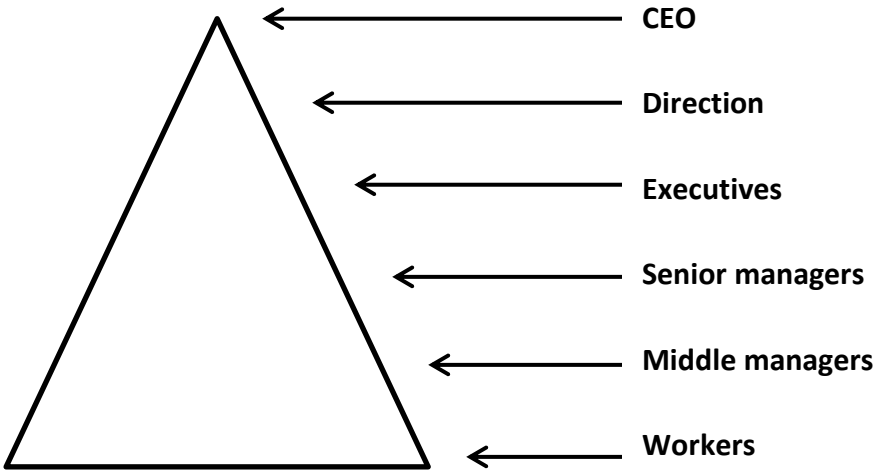


Figure 2: The different components of the body.[39]

1.2) External stakeholders:

- Shareholders: these are natural or legal persons who participate in the capital of the company either in genre or in money (cash).

- Customers: They are natural or legal persons who buy the goods and services produced by the company.

- Providers: They are those who provide the company with the goods and services necessary for its activity (raw materials).

- Bankers: They are essential financial intermediaries for the company's activity. They present a place of deposit (funds) and a means of financing, through loans.

- Public powers: They are responsible for enforcing the general interest of the country by imposing certain rules and constraints through the law and administrative formalities.

- Trade unions: These are the employee representatives to the general management. Their role is to defend the interests of the employees and to ensure them the maximum of advantages.

2) Definition of a pharmaceutical company:

The pharmaceutical establishment is a company organized according to the legal forms provided for by the Commercial Code and subject to the approval of the Minister responsible for the pharmaceutical industry.

The pharmaceutical establishment is under the responsibility of a technical director pharmacist who meets the required professional qualification and practice conditions.[40]

Pharmaceutical establishments are required to comply with the rules of good manufacturing, storage, distribution, pharmacovigilance and materiovigilance practices specific to each activity.[41]

[39] Business economics by Abderraouf MTIRAOUI- P 04

[40] Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 3.

[41] Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 5.

3) Types of establishments in the pharmaceutical industry:

Pharmaceutical establishments for pharmaceutical products and medical devices are:

— Manufacturing establishments.
— Operating establishments.
— Import establishments.
— Wholesale distribution establishments.
— Export establishments.[42]

Pharmaceutical establishments may carry out one or more activities.

4) Missions of the pharmaceutical establishment:

The missions of pharmaceutical establishments vary according to the specialization of their activity, we mention them as follows:

4.1) The manufacturing pharmaceutical establishment:

The pharmaceutical manufacturing establishment is responsible for ensuring the activity of manufacturing pharmaceutical products and/or medical devices with a view to their sale to wholesale distribution establishments, public establishments, or export establishments, or their use in clinical or bioequivalence studies.

Manufacturing includes all operations covering the purchase of raw materials and starting products, production, quality control, release of batches, storage and sale of finished or intermediate products as well as the corresponding controls.[43]

The manufacturing establishment may also outsource one or more operations to one or more other pharmaceutical manufacturing establishments, in accordance with the laws and regulations in force. The relations between these parties are defined by a contract which sets the object, the obligations as well as the responsibilities of each party.[44]

Production includes all the operations involved in the preparation of a product, from the receipt of raw materials, through their processing, packaging and repackaging, labeling and re-labeling, until obtaining of the finished product.

The pharmaceutical manufacturing establishment performs one or more production, quality control, release of finished products or research and development operations.[45]

The manufacturing facility can also lend itself to research and development.

4.2) The operating pharmaceutical establishment:

[42] Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 2.
[43] Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 6.
[44] Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 8.
[45] Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 7.

The pharmaceutical operating establishment is responsible for ensuring the operational activity of decisions to register pharmaceutical products and/or approve medical devices.

The operating pharmaceutical establishment must ensure all operations related to the registration, approval, pharmacovigilance, materiovigilance, release and monitoring of batches of pharmaceutical products and medical devices and, if where appropriate, of their withdrawal, in accordance with the legislation and regulations in force.

The holder of the registration or certification decision and the operator assume joint responsibility for the delegated operations.[46]

4.3) The importing pharmaceutical establishment:

The importing pharmaceutical establishment is responsible for ensuring the activity of importing pharmaceutical products and/or medical devices, with a view to their resale as is to wholesale distribution establishments and public establishments or to their use in clinical studies, while satisfying the storage, quality and release conditions of said batches of pharmaceutical products and/or medical devices.

The importing pharmaceutical establishment may also ensure the import of raw materials and/or packaging items, with a view to reselling them as is to the manufacturing or exporting pharmaceutical establishments.[47]

4.4) The pharmaceutical wholesale distribution establishment:

The pharmaceutical wholesale distribution establishment is responsible for ensuring the activities of purchasing, storing and transporting pharmaceutical products and medical devices other than experimental medicinal products, with a view to their wholesale distribution and as-is to establishments, pharmaceutical wholesalers, pharmacies and private and public health establishments.

The pharmaceutical wholesale distribution establishment may also provide, on behalf of pharmaceutical establishments and community pharmacies, services relating to its activity, in particular storage, transport, data collection and commercial promotion.[48]

4.5) The exporting pharmaceutical establishment:

The exporting pharmaceutical establishment is responsible for ensuring the activities of purchasing and storing pharmaceutical products and/or medical devices manufactured locally or imported with a view to exporting them.[49]

[46] Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 9.
[47] Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 10.
[48] Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 11.
[49] Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 12.

5) Organization and operation of the pharmaceutical establishment:

The organization of the pharmaceutical establishment is determined according to the legal form provided for by its statute in accordance with the legislation in force.[50]

- **Legal forms of pharmaceutical companies:**

There are several legal forms that allow you to create a business that meets all expectations, alone or with partners. This choice is fundamental, even crucial, because it will set the appropriate mode of taxation, as defined by the tax legislation, as well as the resulting responsibilities and obligations.

The figure below summarizes the different forms of a pharmaceutical business that can be implemented:[51]

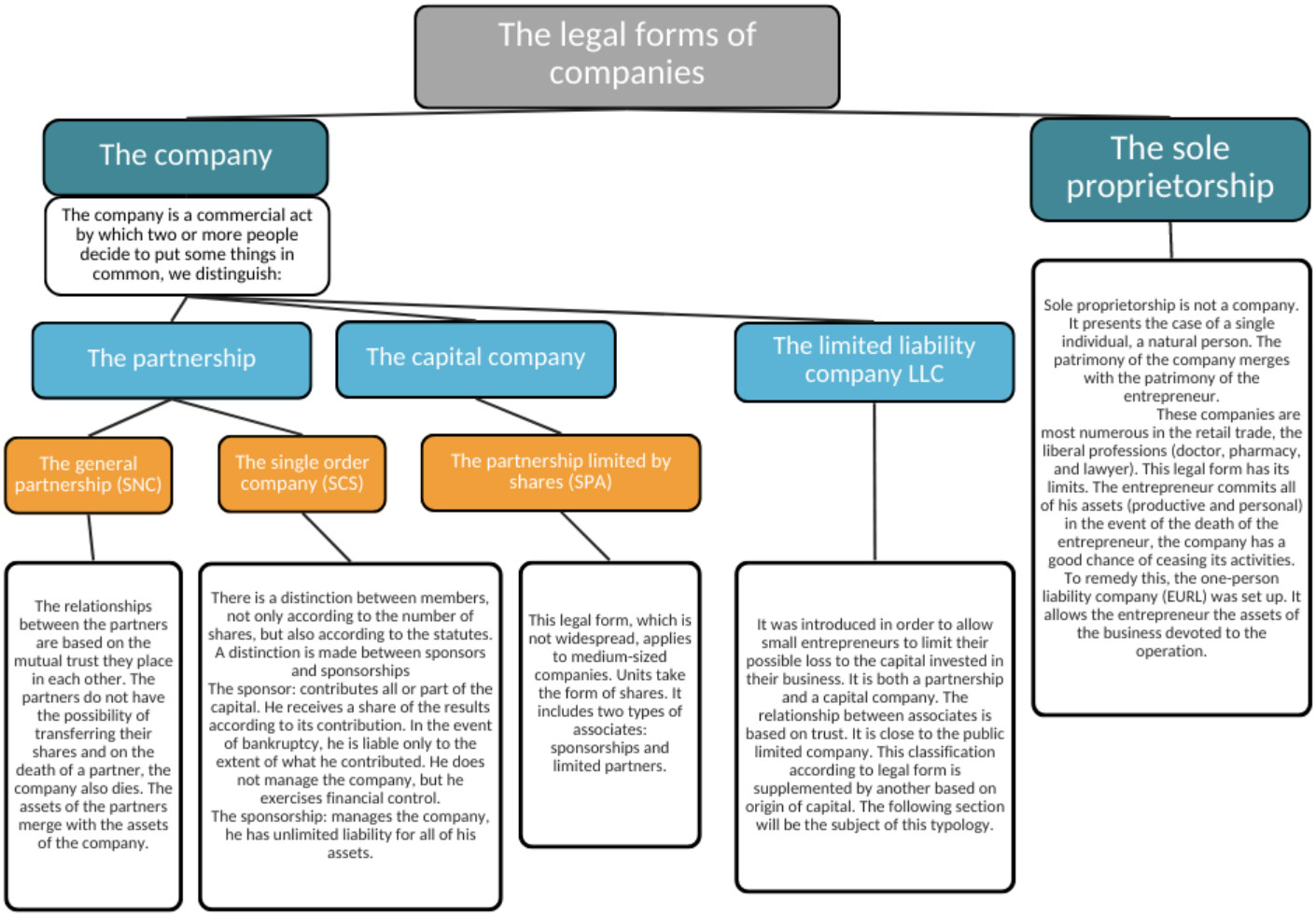


Figure 3: The different forms of a pharmaceutical company

[50] Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 13.

[51] Department of Blida- 2019-2020- Dissertation Title: Drug marketing strategy and plans: Typical marketing plan for a locally produced generic by –Alili Mohamed El Amine, Arabji Youcef and Benmiloud Mohamed Nossair- Figure 2.

- **The technical direction:**

The technical management of each pharmaceutical establishment is under the responsibility of a technical director pharmacist assisted, at least, by an assistant pharmacist. When the activity of the pharmaceutical establishment requires it or within the framework of the extension of the activity of the pharmaceutical establishment, the technical director pharmacist is assisted in his task by several assistant pharmacists, whose conditions are fixed by decree of the Ministry responsible for the pharmaceutical industry.[52]

The technical director pharmacist of a pharmaceutical establishment must provide proof, in addition to his diploma as a pharmacist, of registration with the council of ethics of pharmacists and of technical skills relating to the activity of the pharmaceutical establishment.

Pharmacist assistants must prove, where applicable, the qualifications required for their practice.[53]

6) Agreement request files:

6.1) Element of the file of the application for prior approval of the pharmaceutical manufacturing establishment:

The request for prior approval for the implementation of the pharmaceutical manufacturing establishment is submitted to the competent departments of the Ministry responsible for the pharmaceutical industry by the pharmacist technical director of the said establishment, in accordance with the established approval application form.

The application for prior approval of the pharmaceutical manufacturing establishment is accompanied by a file comprising:

— The prior approval application form for the pharmaceutical manufacturing establishment.
— A copy of the statutes of the pharmaceutical establishment.
— A copy of the commercial register.
— The employment contract of the technical director pharmacist.
— The title deed or the rental lease.
— The plan of the entire pharmaceutical establishment at 1/100th with layout and allocation of premises.
— The plan specifying the location of the main equipment.
— The plan detailing the air and water treatment systems.
— Plans specifying the flows of people, raw materials, packaging items, intermediate products, finished products and waste related to pharmaceutical operations.
— Description of the quality system of the pharmaceutical establishment.

[52] Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 14.
[53] Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 15.

— Description of the type and organization of quality control.
— Description of the means provided to avoid cross-contamination.
— The proposed pharmaceutical operations.
— The list of production and quality control equipment.
— The list of the different pharmaceutical forms of medicinal products or classes of medical devices.
— The range of products expressed in the international common name of pharmaceutical products or in the name of medical devices as well as the estimated quantities to be produced annually and the daily production capacities expressed in sales units.
— Technical support for technology transfer agreements, where applicable.
— The subcontract, if applicable.
— The list of pharmaceutical operations concerned by the activities and the conditions of performance, in the case of outsourced activities.
— The detailed configuration of the pharmaceutical establishment mentioning all the places of production and storage of gases in fixed tanks or bottles and similar, for gases for medical use.
— The designation of the radiopharmaceutical according to the type (radiopharmaceuticals, positron-emitting radiopharmaceuticals, radioactive precursors intended for their production, generators of radionuclides), the risk management and radiation protection approach, proof of the competence of the technical director in radiation protection and the authorization of the atomic energy commission, for radiopharmaceuticals.
— The state of progress of construction in the case of a renewal of prior approval for construction.

A receipt for submission of the file is given to the requesting pharmaceutical establishment.

- **Treatment methods:**

The relevant departments of the ministry responsible for the pharmaceutical industry only receive the application files for prior approval of the pharmaceutical manufacturing establishment deemed to be complete.

Experts called upon by the relevant departments of the ministry responsible for the pharmaceutical industry examine and assess the application for prior approval of implementation. They must submit the technical evaluation reports within ten (10) days.

The dossier, accompanied by the evaluation reports, is submitted to the technical commission set up by the minister in charge of the pharmaceutical industry.

The technical committee has a period of eight (8) days to give its opinion on the application for approval. It ensures that the information is accurate and complies with the rules of good manufacturing practice and the regulatory provisions in force.

At the end of the evaluation of the technical commission, and if the file is considered complete, the admissibility of the file is notified to the pharmaceutical establishment requesting the prior approval of implementation.

The Minister for the Pharmaceutical Industry decides on the pharmaceutical establishment's application file for prior approval within 30 days. This decision is notified to the applicant pharmaceutical establishment.

The prior approval for production is issued by the minister in charge of the pharmaceutical industry for a renewable period of one (1) year.[54]

6.2) Elements of the file for the application for approval to open the pharmaceutical manufacturing establishment:

At the end of the project, the pharmaceutical manufacturing establishment must file an application for approval to open a pharmaceutical manufacturing establishment by its technical director pharmacist, with the competent services of the ministry responsible for the pharmaceutical industry. .

The application for approval to open the pharmaceutical manufacturing establishment is accompanied by a file comprising:

— The elements of the dossier for the application for prior construction approval.

— The application form for authorization to open a pharmaceutical manufacturing establishment drawn up for this purpose by the competent services of the ministry responsible for the pharmaceutical industry.

— The authorization to operate a classified establishment, issued by the competent services of the ministry responsible for the environment.

— The notice of compliance with safety standards drawn up by the civil protection services.

— A document relating to the conditions for securing the premises and the pharmaceutical documentation

— A document relating to the quality risk management process.

— The projected organization chart reflecting the organization of the pharmaceutical establishment, which will feature the key positions of responsibility, the state of the workforce and their qualifications.

— The receipt for payment of the fee for the request for an expertise from the pharmaceutical establishment.

A receipt for submission of the file is issued to the requesting pharmaceutical establishment.

- **Treatment methods:**

The competent departments of the ministry responsible for the pharmaceutical industry only receive the application files for approval to open the pharmaceutical manufacturing establishment deemed to be complete.

Experts called upon by the relevant departments of the ministry responsible for the pharmaceutical industry examine and assess the opening approval file. As well as carry out a

[54] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the elements of the application file for approval of the pharmaceutical manufacturing establishment, the procedures for processing the file as well as the list of substantial modifications. Chapter 1.

manufacturing site expertise. They must submit the technical evaluation reports within ten (10) days.

The file accompanied by the technical evaluation reports and the on-site expertise is submitted to the technical commission.

The technical committee has a period of eight (8) days to give its opinion on the application for approval. It ensures that the information is accurate and complies with the rules of good manufacturing practice and the regulatory provisions in force.

At the end of the evaluation of the technical commission, and if the file is considered complete, the admissibility of the file is notified to the pharmaceutical establishment applying for the authorization to open.

The Minister of the Pharmaceutical Industry decides on the application for authorization to open the pharmaceutical establishment within 30 days. This decision is notified to the applicant pharmaceutical establishment.

The prior approval for implementation is issued by the Minister responsible for the pharmaceutical industry for a renewable period of five (5) years.[55]

6.3) Elements of the pharmaceutical establishment's approval application file:

The application for approval of the pharmaceutical establishment is submitted to the competent services of the Ministry responsible for the pharmaceutical industry by the technical director pharmacist of the said establishment, in accordance with the established approval application form.

6.3.1) Operating:

The request for prior approval for the establishment of the operating pharmaceutical establishment is accompanied by a file comprising:

— The pharmaceutical establishment approval application form.
— A copy of the statutes of the pharmaceutical establishment.
— A copy of the commercial register.
— The title deed or the rental lease.
— The list of laboratories to be represented.
— The technical contract drawn up between the pharmaceutical establishment and the laboratories represented.
— The organization chart of the pharmaceutical establishment.
— The provisional recruitment plan by category.
— A copy of the manager's or general manager's identity document, his/her pharmacist diploma or university degree at bachelor's level, minimum, with professional experience of two (2) years in the pharmaceutical sector.
— A copy of the pharmacist's technical director pharmacist's diploma.

[55] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the elements of the application file for approval of the pharmaceutical manufacturing establishment, the procedures for processing the file as well as the list of substantial modifications. Chapter 2.

— A copy of the identity document of the technical director pharmacist.
— The employment contract of the technical director pharmacist.
— The certificate of registration with the council of ethics of pharmacists.[56]

6.3.2) Wholesale distribution:

The application for approval of the pharmaceutical wholesale distribution establishment is accompanied by a file comprising:
— The pharmaceutical establishment approval application form.
— Two copies (2) of the specifications.
— A copy of the statutes of the pharmaceutical establishment.
— A copy of the commercial register.
— The title deed or the rental lease.
— The plan of the entire pharmaceutical establishment at 1/100th drawn up by an approved architect, specifying the description of the premises, the area of which must include storage areas, order preparation and administration.
— The list of pharmaceutical products or medical devices intended for distribution.
— The organization chart of the pharmaceutical establishment.
— The provisional recruitment plan by category.
— A copy of the manager's or general manager's identity document, his or her pharmacist diploma or university degree at minimum license level, with two (2) years' professional experience in the pharmaceutical sector.
— A copy of the pharmacist's technical director pharmacist's diploma.
— A copy of the identity document of the technical director pharmacist.
— The employment contract of the technical director pharmacist.
— The certificate of registration with the council of ethics of pharmacists.[57]

6.3.3) Importing:

The application for approval of the importing pharmaceutical establishment is accompanied by a file comprising:
— The application form for approval of the importing pharmaceutical establishment.
— A copy of the statutes of the pharmaceutical establishment.
— A copy of the commercial register.
— The title deed or the rental lease.
— The plan of the entire pharmaceutical establishment to 1/100th drawn up by an approved architect, specifying the description of the premises, the area of which must include the storage areas, the preparation of orders and the administration.
— The list of pharmaceutical products or medical devices intended for import.

[56] Order of 9 Rabie Ethani 1443 corresponding to November 14, 2021 setting the elements of the application file for the approval of the operating pharmaceutical establishment, the procedures for processing the file, as well as the list of modifications of a substantial nature. Chapter 1.
[57] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the elements of the application file for approval of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices, the procedures for processing the file as well as the list of modifications substantial. Chapter 1.

— The organization chart of the pharmaceutical establishment.
— The provisional staff recruitment plan by category.
— A copy of the manager's or general manager's identity document, his/her pharmacist diploma or university degree at bachelor's level, minimum, with professional experience of two (2) years in the pharmaceutical sector.
— A copy of the pharmacist's technical director pharmacist's diploma.
— A copy of the identity document of the technical director pharmacist.
— The employment contract of the technical director pharmacist.
— The certificate of registration with the council of ethics of pharmacists.[58]

III General information on The regulatory bases in force:

1) Good Manufacturing Practices:

Established by States or the European Commission as part of the development of "quality procedures", BPFs are the French translation of Good Manufacturing Practice (GMP) and apply to the manufacture of medicinal products for human or veterinary use.

Good manufacturing practices for medicinal products constitute one of the elements of quality management which guarantees that products are manufactured and controlled in a consistent manner, according to the quality standards adapted to their use and required by the marketing authorization, clinical trial authorization or product specifications. Good manufacturing practices apply to both production and quality control.[59]

1.1) General provisions :

All pharmaceutical products for use in human medicine manufactured locally or imported, including those intended for export and experimental drugs must be manufactured in accordance with the rules of good manufacturing practices.

The pharmaceutical establishment is required to ensure that all the manufacturing operations of the pharmaceutical product submitted for registration and placed on the market are carried out in accordance with the information provided in the registration dossier validated by the authorities competent.

Good manufacturing practices are enforceable against pharmaceutical establishments by the competent authority, and are applied to pharmaceutical products for which they constitute a regulatory reference.

[58] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the elements of the import pharmaceutical establishment approval application file, the procedures for processing the file as well as the list of substantial modifications. Chapter 1.
[59] GUIDE TO GOOD MANUFACTURING PRACTICES, Anfel Bouarrata.

The fundamental requirements of good manufacturing practices relate to the pharmaceutical quality system, personnel, premises and equipment, documentation, production, quality control, outsourced activities, complaints, batch recall and auto -inspection.[60]

1.2) Good manufacturing practices for pharmaceutical products intended for human medicine:

The pharmaceutical establishment is responsible for ensuring that an effective pharmaceutical quality system is in place and that roles, responsibilities and authorities are defined, communicated and implemented throughout the organization. It must also carry out repeated self-inspections as part of the quality assurance system, with a view to monitoring the implementation and compliance with good manufacturing practices and proposing the necessary corrective measures.

Quality management covers everything that can, individually or collectively, influence the quality of a pharmaceutical product. It represents all the measures taken to guarantee that pharmaceutical products are of the quality required for the use for which they are intended.

Quality control ensures that the necessary and appropriate tests have been carried out, that raw materials and packaging items are not put into service, or products offered for sale or distribution, before their quality has been found to be satisfactory. .

Quality control must be independent from production, which is a fundamental element of its proper functioning. In this context, the pharmaceutical manufacturing establishment must have a quality control department, placed under the authority of a person with the appropriate qualifications and experience.

Good documentation is an essential part of the pharmaceutical quality assurance system and is essential to ensure compliance of operations with the requirements of good manufacturing practices.

The types of documents used to manage and record compliance with Good Manufacturing Practices are:

— The inventory of pharmaceutical establishments, describing the manufacturer's activities subject to good manufacturing practices.

— The instructions which consist of the specifications, the manufacturing formulas, the manufacturing, packaging and control instructions, the procedures, the protocols and the related specifications.

— The records which are the certificates of analysis and the reports.

The evaluation of the finished products must take into account the production conditions, the results of the controls during manufacture, the examination of the manufacturing

[60] Executive Decree No. 22-247 of Aouel Dhou El Hidja 1443 corresponding to June 30, 2022 relating to the rules of good manufacturing practice for pharmaceutical products for use in human medicine. Chapter 1.

documents, the conformity to the specifications of the finished product and the examination of the final packaging.

Manufacturing premises and equipment must be located, designed, built, adapted and maintained to suit the operations to be carried out.

The plans of the premises, their layout, their design and their use must tend to minimize the risk of error and allow effective cleaning and maintenance to avoid contamination, including cross-contamination, the deposit of dust or dirt and any damage to product quality.

Cross-contamination must be avoided by paying particular attention to the design of premises and equipment. This must be supported by the design of the process and by the implementation of adequate technical or organizational measures, including effective and reproducible cleaning processes to control the risk of cross-contamination.

A quality risk management process, including potency and toxicology assessment, should be used to assess and control the risks of cross-contamination of manufactured products. The results of this process must be used to define the technical and organizational measures to be implemented in order to control the risks of cross-contamination.

Depending on the level of risk, it may be necessary to dedicate premises and equipment for manufacturing and/or packaging operations in order to control the risk presented by certain drugs.

Any pharmaceutical activity outsourcing contract must be accompanied by a quality contract.

The pharmaceutical establishment must put in place a suitable system and procedures to register, evaluate, investigate and examine complaints concerning a pharmaceutical product suspected of being defective and, if necessary, to remove it efficiently and quickly from the distribution channel.[61]

2) Registration of pharmaceutical products:

The placing on the market of a drug in Algeria is conditioned by a decision of registration in the national nomenclature. This is granted by national pharmaceutical product agency after advice from the committee recording.

In accordance with the provisions of the legislation and regulations in force, the placing on the market of any industrially manufactured, imported or exported ready-to-use

[61] Executive Decree No. 22-247 of Aouel Dhou El Hidja 1443 corresponding to June 30, 2022 relating to the rules of good manufacturing practice for pharmaceutical products for use in human medicine. Chapter 2.

pharmaceutical product is subject to a registration decision issued by the National Pharmaceutical Products Agency after consulting the registration committee.

Prior to any request for registration of a pharmaceutical product, the pharmaceutical establishment must file a pre-submission request with the national pharmaceutical products agency.

Only approved pharmaceutical manufacturing and/or operating establishments can file an application for registration of a pharmaceutical product with the national pharmaceutical products agency.

The procedures for registering pharmaceutical products are set by order of the Minister responsible for the pharmaceutical industry.

Pharmaceutical products subject to an import registration application must be registered and marketed in the country of origin on the date of submission of the registration application. However, the methods of registration of these products, registered and not marketed in the country of origin, are fixed by order of the Minister in charge of the pharmaceutical industry.[62]

2.1) Pre-submission request for registration

Pharmaceutical establishments must file the pre-submission request on a form established for this purpose. A receipt justifying the payment of 25% of the registration fees is attached to the pre-submission request, in accordance with the legislation and regulations in force vigor.
A deposit receipt is given to the requesting pharmaceutical establishment.

After the study of the pre-submission request by his services, the director general of the national pharmaceutical products agency can:
— Invite the requesting pharmaceutical establishment to submit its file to begin the registration procedure, if its pre-submission request is admissible.
— Seek the opinion of the committee of clinical experts concerned by the therapeutic class and then contact the registration committee for an opinion.
— Submit the pre-submission request directly to the registration committee for an opinion.

The commission must give its opinion on the request for pre-submission within a period not exceeding thirty (30) days, from the date of its referral.[63]

[62] Executive Decree No. 20-325 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the registration procedures for pharmaceutical products. Chapter 2.
[63] Executive Decree No. 20-325 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the registration procedures for pharmaceutical products. Chapter 2, Section 1.

2.2) Application for registration

When the pre-submission request is accepted, the requesting pharmaceutical establishment must file, within a period not exceeding one (1) year, its registration request accompanied by a file and the following elements:

— Samples of the pharmaceutical product, subject of the request, the quantity of which is determined according to the needs of the quality control of the product;

— Reagents and specific means necessary inherent to the quality control of the pharmaceutical product as well as the related documents.

A request for extension of the deadline for submission of the registration dossier by ninety (90) days duly substantiated, renewable at the discretion of the Director General of the National Agency for Pharmaceutical Products, may be submitted by the pharmaceutical establishment, before the expiry of the one (1) year period.[64]

The technical file is drawn up by the manufacturer, more precisely, by a team composed, at least, as follows:

• Technical Director Pharmacist (TD), assisted by competent staff in the field of regulatory affairs, who will be responsible for the coordination between the various stakeholders of this project, the preparation of any regulatory document relating to the product (notice, vignette, case… etc.) then the organization of the final file in order to present it to the management of the pharmacy.

• Pharmacist in charge of production, at the head of a team of operators, responsible for preparing the production premises, manufacturing the first batches of products; and of course records of product manufacturing batches tracing the history of each manufactured batch.

• Pharmacist responsible for quality control, with a team made up of chemical technicians and biologists, take care of the preparation of analytical files and thus the control of: raw materials (active ingredients, excipients, water, etc.), intermediate products (mixture of active ingredient + excipients), finished products, and packaging items, environmental control of manufacturing premises (water, air, search for possible traces of contamination).

• Pharmacist responsible for quality assurance, responsible for validating the technical documentation relating to the product, maintaining its quality at the pre-established level, initially; and to set up improvement plans in a second.

• Responsible for the warehouse of raw materials and packaging items, which will be responsible for inventory management and forecasting for supply.

• Maintenance service, for the follow-up of the installations and qualifications of the machines as well as the establishment of the preventive maintenance programs.

• Sales department is responsible for studying the market and the various costs and prices.

[64] Executive Decree No. 20-325 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the registration procedures for pharmaceutical products. Chapter 2 Section 2.

The collaboration between each of the stakeholders mentioned above is an inescapable condition for the success and the outcome of the project, it is almost impossible to imagine the work of one of them independently.[65]

The registration file is in the form of a common technical document. It is written in the internationally harmonized format (CTD).

- **Presentation of the CTD format**

The CTD is organized into five modules. Module 1 is specific to each region. Modules 2, 3, 4 and 5 are common to all regions. Compliance with this guideline ensures that these four modules are provided in a format accepted by WHO and regulatory authorities.

ICH-CTD	DESCRIPTION
Module 1: Administrative Information and Prescribing Information	This module is not part of the CTD and contains documentation specific to each region such as administrative documentation (cover letter, application form, GMP certificate, labeling).
Module 2: Common Technical Document Summaries	This module summarizes modules 3, 4 and 5.
Module 3: Quality	This module contains the chemical and pharmaceutical technical documentation of the active ingredient and the finished product.
Module 4: Non-clinical Study Reports	This module contains the pharmacological, pharmacokinetic and toxicological data obtained on the animal.*
Module 5: Clinical Study Reports	This module is a critical appraisal of data and other clinical reports. **

Table 2: Summary of the different modules of the MA dossier in CTD format.

*: not applicable for generic products

**: replaced by bioequivalence studies in the case of the generic product

For generic and similar bio-therapeutic drugs, the presentation of a bioequivalence study and any other therapeutic equivalence test are mandatory. However, certain generic drugs and similar bio-therapeutics are exempt from studies and trials. The exemption criteria for said studies and trials, as well as the list of generic and similar bio-therapeutic medicines concerned, are set by order of the Minister responsible for the pharmaceutical industry.

For certain medicines, the national pharmaceutical products agency can grant the registration decision on the basis of a documentary and/or technical evaluation of the registration file, after consulting the registration committee.

[65] University of Batna 2. Department of Pharmacy Module: Industrial Pharmacy (5th year) -Dr. Ouahab Ammar- Marketing authorization (3.1. Registration process in Algeria).

The registration dossier is subject to an admissibility examination by the departments of the National Agency for Pharmaceutical Products, within eight (8) days.

The examination concerns the verification of the completeness of the file and the authenticity of the documents composing it as well as the payment of the registration fees relating thereto.

- If the registration dossier is deemed admissible, a technical assessment is carried out by the competent departments of the national pharmaceutical products agency, which can call on experts and/or competent establishments in the field, if necessary. These experts or establishments must not have any direct or indirect interest, even through an intermediary, in the manufacture, import or marketing of the pharmaceutical products subject to their expertise.

- If the registration dossier is incomplete, it is declared inadmissible. A notification is made to the requesting pharmaceutical establishment.

The director general of the national pharmaceutical products agency submits the essential elements of the registration dossier and the technical evaluation reports of the competent services of the national pharmaceutical products agency to the commission, which must give its opinion and which must decide within a period not exceeding thirty (30) days from the date of referral.

The commission must send its opinion to the director general of the national pharmaceutical products agency on the applications submitted to it, within a period not exceeding eight (8) days, from the date of the adoption of its deliberation. .

The national pharmaceutical products agency must decide, after consulting the commission, on the registration application within a period not exceeding one hundred and fifty (150) days, from the date of admissibility of the registration file, in accordance with the provisions

In all cases, the time limit is suspended when additional information is requested.

The requesting pharmaceutical establishment is required to provide the additional information within the deadlines given to it. After this period, the registration request becomes null and void.

The application for registration of the pharmaceutical product is refused, after consulting the committee, when it appears that:

— The pharmaceutical product is harmful under the normal conditions of use provided for in the application for registration;

— The therapeutic effect of the pharmaceutical product is insufficiently demonstrated by the applicant.

— The pharmaceutical product does not have the qualitative and quantitative composition declared in the registration dossier.

— The manufacturing and/or control processes do not guarantee the quality, efficacy and safety of the pharmaceutical product.
— The documentation and information provided in support of the application do not meet the provisions of the decree provided for therein.
— The medico-economic evaluation proves unfavorable to the marketing of the product.

Any decision to refuse registration notified by the Director General of the National Agency for Pharmaceutical Products to the requesting pharmaceutical establishment must be reasoned.[66]

2.3) Pharmaceutical product registration decision

The decision to register the pharmaceutical product can only be issued to duly approve pharmaceutical establishments. The holder and/or operator of the registration decision are responsible for placing the pharmaceutical product on the market.

The decision to register the pharmaceutical product must mention the following information:
— The trade name of the pharmaceutical product.
— The international non-proprietary name (INN).
— The pharmaceutical form and strength.
— The type of packaging and presentation.
— The conditions and shelf life of the pharmaceutical product.
— The name and address of the holder of the registration decision.
— The name and address of the operator of the registration decision.
— The name and address of the various participants in the manufacture of the finished product, the production site of: intermediate products/packaging (primary and secondary) and batch release, if applicable.
— The list of the pharmaceutical product and its use (hospital and/or pharmacy).

It must be accompanied, where appropriate, by restrictive measures, in particular registration on one of the lists restricting the use of the medicinal product, according to the conditions of accessibility and prescription and/or the limitation of use in the only hospitals.

The decision to register a pharmaceutical product is valid for a period of five (5) years, from the date of its signature. It is renewable at the request of the holder and/or operator of the registration decision, after consulting the commission. This request accompanied by a file is presented one hundred and eighty (180) days before the expiry date of the said decision.

If within eighteen (18) months following the notification of the registration decision, the registered product is not actually placed on the market or exported, the National Agency for Pharmaceutical Products reserves the right to declare the withdrawal of the registration decision.

[66] Executive Decree No. 20-325 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the registration procedures for pharmaceutical products. Chapter 2, Section 2.

During the period of validity of the registration decision, the holder and/or operator of the registration decision is obliged to immediately declare to the national pharmaceutical products agency any modification, in particular:
— New information resulting in the modification of the initial registration application dossier, in particular that relating to the origin and quality of the active substance.
— New information relating to the assessment of the benefit/risk ratio of the pharmaceutical product.
— The necessary changes relating to the manufacturing and control methods mentioned in the application for registration, taking into account scientific and technical progress so that the pharmaceutical product is manufactured and controlled according to approved scientific methods.
— Any prohibition or restriction imposed by the competent health authority of the country of origin or any other country where the pharmaceutical product is marketed and any other new information which could influence the exploitation of the safety report of the pharmaceutical product concerned.

The national pharmaceutical products agency may at any time ask the holder and/or the operator of the registration decision to communicate the data demonstrating that the benefit/risk ratio remains favorable.[67]

3) Approval of medical devices

The placing on the market of any industrially manufactured, imported or exported ready-to-use medical device is subject to an approval decision issued by the National Agency for Pharmaceutical Products, after consulting the Medical Devices Approval Commission.

Medical devices are classified in order of criticality, according to the potential risk to the patient as follows:
Class I: Low potential risk.
Class IIa: Moderate potential risk.
Class IIb: High potential risk.
Class III: Potential critical risk.
The classification of medical devices cited above takes into account the evolution of the international consensus.[68]

3.1) Application for approval

Only approved pharmaceutical manufacturing and/or operating establishments can submit an application for approval of a medical device to the national pharmaceutical products agency.

[67] Executive Decree No. 20-325 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the registration procedures for pharmaceutical products. Chapter 2, Section 3.
[68] Executive Decree No. 20-324 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the procedures for the approval of medical devices. Chapter 2.

The application for approval submitted to the National Agency for Pharmaceutical Products must be accompanied by a technical-administrative file including the following information:

— Administrative on the medical device and the applicant.

— Technical, from the design of the medical device to the finished product.

— Scientific and clinical data, if available.

The Director General of the National Pharmaceutical Products Agency may request any additional information he deems necessary, in particular on the medical device concerned.

In the case of medical devices requiring clinical studies, the clinical data must appear in the approval file. A proven equivalence of the medical device can justify the existing clinical study data.

The services of the National Pharmaceutical Products Agency examine the admissibility of the approval file, within a period not exceeding eight (8) days.
The examination concerns the verification of the completeness of the file and the authenticity of the documents composing it as well as the payment of the related homologation fees.

-When the approval dossier is deemed admissible, a technical assessment is carried out by the competent services of the national pharmaceutical products agency, which can call on experts and/or competent establishments in the field, if necessary.

(The experts participating in the technical evaluation of the registration files must not have any direct or indirect interest, even through an intermediary, in the manufacture, import or marketing of the medical devices subject to their expertise).

- When the homologation file is incomplete, it is declared inadmissible. A notification is made to the requesting pharmaceutical establishment.

The technical evaluation consists of studies, evaluations and tests to be carried out, in accordance with the norms and standards in the field, in order to verify that the medical device does indeed have the composition, performance and inherent characteristics, in particular the quality, efficacy, safety and performance indicated in the approval dossier submitted.
The evaluation consists of four (4) phases:

— The technical-regulatory assessment.

— Evaluation of physical, chemical and biological tests.

— Evaluation of the risk analysis report.

— Evaluation of clinical data, if applicable.

The Director General of the National Agency for Pharmaceutical Products presents the essential elements of the approval dossier and the technical evaluation reports to the

commission, which must give its opinion, within a period not exceeding thirty (30) days of the date of referral.

The commission must send its opinion to the director general of the national pharmaceutical products agency on the applications submitted to it, within a period not exceeding eight (8) days, from the date of the adoption of its deliberation. .

At the end of the evaluation of the file, the applicant pharmaceutical establishment is invited to provide, within a maximum period of fifteen (15) days, a certificate certifying that no modification has occurred in the elements produced at the support of the application subject to the approval of the modifications brought to the attention of the national agency for pharmaceutical products during the technical evaluation.

The national pharmaceutical products agency must decide, after consulting the commission, on the application for approval, within a period not exceeding two hundred and forty (240) days, from the date of admissibility of the application file approval.

The application for approval of the medical device is refused after consulting the committee, when it appears, in particular that:
— The characteristics and performance of the medical device are altered.
— The medical device does not have the composition and does not comply with what was declared in the approval file.
— The safety report is considered unfavorable.
— The manufacturing and/or control processes do not make it possible to guarantee the quality, safety, efficacy and performance of the manufactured medical device.
— The documentation and information provided in support of the application do not comply with the provisions of this decree.
Any decision to refuse approval notified by the Director General of the National Pharmaceutical Products Agency to the pharmaceutical establishment requesting approval must be reasoned.[69]

3.2) Medical Device Approval Decision

The approval decision for the medical device can only be issued to duly approve pharmaceutical establishments. The holder and/or operator of the approval decision are responsible for placing the medical device on the market.

The approval decision for the medical device must mention the following information:
— The trade name of the medical device.
— The designation of the medical device.
— Classification of the medical device.
— The characteristics of the medical device.
— The name and address of the holder of the approval decision.

[69] Executive Decree No. 20-324 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the procedures for the approval of medical devices. Chapter 2, Section 1.

— The name and address of the operator of the approval decision.
— The name of the manufacturer(s) and the address of the site and/or sites of manufacture of the medical device.
— The conditions and shelf life of the medical device.
— The certifying body (ies) or equivalent body (ies).
It must be accompanied by the obligation to indicate on the labeling and the instruction manual, all the essential information for the protection of health.

The approval decision for a medical device is valid for a period of five (5) years, from the date of its signature. It is renewable at the request of the holder and/or operator of the approval decision, after consulting the commission. This request accompanied by a file is presented, at the latest, ninety (90) days, before the expiry date of the said decision.

During the period of validity of the registration decision, the holder and/or operator of the registration decision is obliged to immediately declare to the national pharmaceutical products agency:
— Any modification made to the components of the initial declaration.
— Any prohibition or restriction imposed by the competent health authority of the country of origin or of any other country where the medical device is marketed and any other new information which could influence the assessment of the safety report of the medical device concerned.

If within eighteen (18) months following notification of the approval decision, the approved medical device is not actually placed on the market or exported, the National Agency for Pharmaceutical Products reserves the right to declare the withdrawal of the approval decision.[70]

IV Organization :

1) National:

1.1) Stakeholders in the Algerian pharmaceutical sector:

We can classify them according to the nature of their intervention into two distinct categories:

- Public and private establishments carrying out the activities of production, import and distribution of pharmaceutical products.
- Institutions regulating the pharmaceutical market.

1.1.1) Economic enterprises

In the Algerian pharmaceutical sector, the SAIDAL group holds the monopoly.
Several other Algerian and foreign companies and private laboratories are active in this field.

[70] Executive Decree No. 20-324 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the procedures for the approval of medical devices. Chapter 2, Section 2.

A- Public sector companies

Alongside the SAIDAL group, two other players are involved in public sector production, namely the Pasteur Institute of Algeria (PIA) and SOCOTHYD.

1. The SAIDAL group

The SAIDAL group is the largest pharmaceutical company in Algeria and one of the largest in Africa.

SAIDAL was created in April 1982. In 1989 and following the implementation of economic reforms[71], SAIDAL becomes an Economic Public Company endowed with management autonomy. Organized into an industrial group, SAIDAL's main mission is the development, production and marketing of pharmaceutical products for human and veterinary use. SAIDAL has undertaken to diversify its production through partnership agreements with foreign companies (Pfizer, Rhône Poulenc, Glaxo Wellcome and Novo Nordisk).[72]

2. The Pasteur Institute of Algeria (PIA)

Pasteur Institute of Algiers was created in 1894, its mission at the start was to provide anti-rabies treatment for people bitten.[73]

In 1971, and by Ordinance No. 71-45 of 06/21/1971, the Pasteur Algeria Institute was established as a non-profit public utility establishment, endowed with civil personality and financial autonomy. The Pasteur Institute in Algeria changed its legal status in accordance with Executive Decree No. 94-74 of 03/30/1994, to become a public establishment of an industrial and commercial nature (EPIC). It has a triple mission:

- Research and reference in the fields of microbiology, parasitology and immunology.
- Production and distribution of serums and vaccines for human and veterinary use.
- Training of scientific and technical personnel in its fields of activity.

3. SOCOTHYD

Founded in 1970, the SOCOTHYD company (absorbent cotton and hygiene articles company) has two production sites, one in Issers, specializing in the manufacture of dressing products (cotton products, gauze products , plaster bandages, medical plaster and crepe bandages), and the other in Bordj Ménaïel, specializing in the manufacture of personal hygiene items.

SOCOTHYD has a distribution network, which is made up of approved agents selected according to defined criteria. Its authorized agents ensure the distribution and installation of SOCOTHYD products in the different regions of the country.[74]

4. The central hospital pharmacy (CHP)

The central hospital pharmacy is a Public Establishment of an Industrial and Commercial nature (PEIC), placed under the supervision of the Ministry of Health, Population and Hospital Reform,

[71] http://www.saidalgroup.dz.
[72] O Belhacene O.et Ferfera MY.: op.cit., p.65.
[73] https://www.pasteur.dz/fr/presentation/histoire.
[74] https://www.socothyd.com/new/reseau..php

and is a central player in the Algerian pharmaceutical industry and a supplier a must for public health establishments.[75]

Within the framework of the national health policy, the CHP is responsible for the supply and distribution of pharmaceutical products to public health establishments located throughout the national territory.

B- Private sector companies

Between local and foreign laboratories, among the most important we can mention:

1. BIOPHARM

BIOPHARM is an industrial and commercial group which invested in the pharmaceutical sector in the early 1990s, and which today has a production unit to international standards and a distribution network to wholesalers and pharmacies.[76]

2. MERINAL laboratories

MERINAL Laboratories were created in 1969, specializing in the manufacture of drugs in dry form (tablets, capsules, and sachets). From the start of the production unit in 2002, MERINAL opted for a development strategy centered on generics and on the constitution of a range of products belonging to MERINAL.[77]

3. BEKER laboratories

BEKER laboratories were created in 2004, by the emergence of the first site in Dar el Beida[78].Entity under Algerian law, BEKER laboratories specializes in the development, manufacture and marketing of generic pharmaceutical products in the form of tablets and capsules, meeting international standards. Relying on the expertise of their R&D team, BEKER Laboratories manages the entire development process of all their products in their specialized units, thus allowing total control of product quality.

4. Sanofi Algeria

The Sanofi-Aventis subsidiary located in Ain Benain produces a very wide range of drugs[79]. The objective of this subsidiary is to obtain a 30% market share of drugs and to constitute a private group, to encourage local production and the training offered to health professionals in diabetes and oncology (doctors, pharmacists and specialists).

5. GSK Algeria

The subsidiary of the Glaxo Smith Kline laboratory created in 2005 in Boudouaou, for an amount of 21 million Euros. Employs 200 people and produces Glaxo Smith Kline antibiotics (Clamoxyl, Augmentin, Floxapen). All these drugs are originators.[80]

[75] http://www.pch.dz
[76] https://www.biopharmdz.com/index.php
[77] https://merinal.com/about-us.html
[78] http://bekerlaboratoires.com/
[79] O Belhacene O.and Ferfera MY. op.cit, p 63.
[80] Les cahiers du cread n°107-108 2014 THE CONTRASTING EFFECTS OF THE INTERVENTION OF FOREIGN PHARMACEUTICAL LABORATORIES IN THE ALGERIAN SECTOR OF THE PHARMACEUTICAL INDUSTRY by Ouerdia BELLAHCENE and Mohamed Yassine FERFERA

6. Novo Nordisk Algeria

Novo Nordisk has been present in Algeria for a very long time. Indeed, the first shipment of insulin was sent in 1936[81]. It was years later with the economic opening of the country that the representative office was established in 1992, then the legal entity followed in 1994 under the name of ALDAPH (Algeria Denmark Pharmaceutical).

Novo Nordisk Algeria is today the leader in diabetes and also in hemophilia and growth hormone.

1.1.2) Private importers

After the opening of the sector to private operators, a hundred import authorizations were approved by the Ministry of Health. In 2010, there were 139 importers against 44 in 2004.

1.1.3) Wholesaler distributors

Wholesale distributors ensure the wholesale distribution of pharmaceutical products, they are responsible for supplying pharmacies (Drug stores) located throughout the national territory. To carry out their activities, wholesale distributors must have the authorization of the authorities responsible for public health.

1.1.4) Private pharmacies

The dispensary pharmacy "is the establishment assigned to the retail dispensation of pharmaceutical products as well as the execution of magistral and officinal preparations"[82]. The private pharmacies in charge of the retail distribution of pharmaceutical products their numbers are growing remarkably.

1.2) The National Agency for Pharmaceutical Products (ANPP):

Created in 2009 and launched in 2017. The National Agency for Pharmaceutical Products is an independent administrative authority whose essential missions include the registration of medicines as well as the approval of pharmaceutical products and medical devices intended for human medicine.[83]

1.2.1) Missions:

- The registration of pharmaceutical products and the granting of the registration decision and its renewal and, where applicable, its suspension, its withdrawal, its assignment and its transfer, after the opinion of the registration of pharmaceutical products.
- The approval of medical devices and the granting of the approval decision and its renewal and, if necessary, its suspension, its withdrawal, its assignment and its transfer, after opinion of the commission of licensing of medical devices.
- Control of the quality and expertise of pharmaceutical products and medical devices and the maintenance of standard substances and reference products at the national level.
- Contribute to the development of development strategies for the pharmaceutical sector.
- Inform the competent authorities in order to take the necessary measures to protect public health when a pharmaceutical product or a medical device presents or is suspected of presenting a danger to human health.

[81] http://www.novonordisk.dz/about-novo-nordisk/novo-nordisk-algeria.html,
[82] Art 249 of law n°18-11 of July 02, 2018.
[83] The National Pharmaceuticals Agency: A Dark Future. April 15, 2018 by SN

- Issue an opinion on temporary authorizations for use (ATU) of unregistered medicinal products.
- Contribute to the definition of rules of good manufacturing practices, storage, distribution and dispensing of pharmaceutical products.
- Carry out on-site audits and inspections carried out by inspectors under the agency and relating, in particular, to the control of the application of the rules of good pharmaceutical practice and the standards of medical devices, in accordance with the legislation and the regulations in force.
- Carry out the scientific evaluation of the benefits, risks and therapeutic value of pharmaceutical products and medical devices as well as their medico-economic evaluation.

— To contribute to the establishment of nomenclatures of pharmaceutical products and medical devices and to their updating.

— Contribute to the development of the list of essential pharmaceutical products and medical devices.

— Contribute to the development of the national drug and pharmacopoeia formulary.

— To issue the certificate of the prices of medicines at registration, once fixed by the intersectorial economic committee for medicines.

— To participate in drawing up the list of medicines reimbursable by social security bodies.

— To issue prior authorizations for the promotion and advertising of registered pharmaceutical products aimed at healthcare professionals.

— To issue an opinion on requests for the performance of clinical studies and bioequivalence studies.

— To issue an opinion on the standards, rules of good practice, procedures and methods applicable to clinical studies on pharmaceutical products and medical devices.

— To undertake any study, research, training or information action in the fields of its competence and to contribute to the promotion of scientific research in the field of pharmaceutical products and medical devices and to constitute the databases there in related.

— To organize seminars, conferences, study days and other events related to its missions.

— To participate in the development of draft legislative and regulatory texts governing pharmaceutical products and medical devices.

— To implement international cooperation actions, in accordance with the legislation and regulations in force.

— To draw up an annual report on its activities which it sends to the minister in charge of the pharmaceutical industry.[84]

2) International:

2.1) The International Council for Harmonization (ICH):

The realization that it was important to have an independent evaluation of medicinal products before they are allowed on the market was reached at different times in different regions. However in many cases the realization was driven by tragedies.

[84] http://www.anpp.dz/presentation.html

For most countries, whether or not they had initiated product registration controls earlier, the 1960s and 1970s saw a rapid increase in laws, regulations and guidelines for reporting and evaluating the data on safety, quality and efficacy of new medicinal products.

2.1.1) History:

The International Council for Harmonization (ICH), formerly the International Conference on Harmonization (ICH) held the inaugural Assembly meetings on 23 October 2015 establishing ICH as an international association, a legal entity under Swiss law.

This step built upon a 25-year track record of successful delivery of harmonized guidelines for global pharmaceutical development as well as their regulation, and a longer standing recognition of the need to harmonize.

The birth of ICH took place at a meeting in April 1990, hosted by EFPIA in Brussels. Representatives of the regulatory agencies and industry associations of Europe, Japan and the US met, primarily, to plan an International Conference but the meeting also discussed the wider implications and terms of reference of ICH.

Since ICH's inception in 1990, the ICH process has gradually evolved. ICH's first decade saw significant progress in the development of ICH Guidelines on Safety, Quality and Efficacy topics. Work was also undertaken on a number of important multidisciplinary topics, which included MedDRA (Medical Dictionary for Regulatory Activities) and the CTD (Common Technical Document). As ICH started into a new millennium, the need to expand communication and dissemination of information on ICH Guidelines with non-ICH regions became a key focus. Attention was also directed throughout the second decade towards facilitating the implementation of ICH Guidelines in ICH's own regions and maintaining already existing ICH Guidelines as science and technology continued to evolve.

Now in its fourth decade of activity, ICH's attention is directed towards extending the benefits of harmonization beyond the founding ICH regions. A significant step was taken in 2015 to facilitate this which saw ICH undergoing a series of organizational changes. These changes constituted a number of reforms including: increasing international outreach; changing ICH's governance structure; disseminating more information on ICH processes to a wider number of stakeholders; and establishing ICH as a legal entity to provide for a more stable operating structure.

The resulting ICH association establishes an Assembly as the over-arching governing body with the aim of focusing global pharmaceutical regulatory harmonization work in one venue that allows pharmaceutical regulatory authorities and notably concerned industry organizations to be more actively involved in ICH's harmonization work.[85]

2.1.2) Missions:

With ICH's establishment as an international non-profit Association under Swiss law on October 23, 2015, ICH's mission has been embodied in its Articles of Association as follows:

- To make recommendations towards achieving greater harmonization in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration and the maintenance of such registrations;

[85] https://www.ich.org/page/history

- To maintain a forum for a constructive dialogue on scientific issues between regulatory authorities and the pharmaceutical industry on the harmonization of the technical requirements for pharmaceutical products;
- To contribute to the protection of public health in the interest of patients from an international perspective;
- To monitor and update harmonized technical requirements leading to a greater mutual acceptance of research and development data;
- To avoid divergent future requirements through harmonization of selected topics needed as a result of therapeutic advances and the development of new technologies for the production of medicinal products;
- To facilitate the adoption of new or improved technical research and development approaches which update or replace current practices;
- To encourage the adequate implementation and integration of common standards through the dissemination of, the communication of information about and coordination of training on, harmonized guidelines and their use;
- And to develop policy for the ICH Medical Dictionary for Regulatory Activities Terminology (MedDRA) whilst ensuring the scientific and technical maintenance, development and dissemination of MedDRA as a standardized dictionary which facilitates the sharing of regulatory information internationally for medicinal products used by humans.[86]

2.2) The Food and Drug Administration (FDA):

2.2.1) History:

The Food and Drug Administration is the oldest comprehensive consumer protection agency in the U. S. federal government. Since 1848 the federal government has used chemical analysis to monitor the safety of agricultural products -- a responsibility inherited by the Department of Agriculture in 1862 and later by the FDA.

Although it was not known by its present name until 1930, FDA's modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act, a law a quarter-century in the making that prohibited interstate commerce in adulterated and misbranded food and drugs. Harvey Washington Wiley, Chief Chemist of the USDA Bureau of Chemistry, had been the driving force behind this law and headed its enforcement in the early years, providing basic elements of protection that consumers had never known before that time.

Since then, the FDA has changed along with social, economic, political and legal changes in the United States. Examining the history of these changes illuminates the evolving role that FDA has played in promoting public health and offers lessons to consider as we evaluate current regulatory challenges.[87]

[86] https://www.ich.org/page/mission
[87] https://www.fda.gov/about-fda/fda-history

2.2.2) Missions:

The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of US's food supply, cosmetics, and products that emit radiation.

FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.[88]

2.3) The European Medicines Agency (EMA):

The European Medicines Agency (EMA) is an agency of the European Union (EU) in charge of the evaluation and supervision of medicinal products. Prior to 2004, it was known as the European Agency for the Evaluation of Medicinal Products or European Medicines Evaluation Agency (EMEA).[89]

Founded in 1995, the European Medicines Agency (EMA) has worked across the European Union (EU) and globally to protect public and animal health by assessing medicines to rigorous scientific standards and by providing partners and stakeholders with independent, science-based information on medicines.

EMA has a 25-year track record of ensuring efficacy and safety of human and veterinary medicines across Europe, and promoting research and innovation in the development of medicines.

EMA's success is based on cooperation within the European medicines regulatory network – a unique partnership between the European Commission, the medicines regulatory authorities in the European Economic Area countries, and EMA. Working together has encouraged the exchange of knowledge, ideas and best practices, in order to ensure the highest standards in medicines regulation.

Today, seven EMA scientific committees and more than 30 working parties provide scientific expertise for the regulation of medicines by drawing on a pool of several thousand European scientific experts from the network.[90]

[88] https://www.fda.gov/about-fda/what-we-do#mission
[89] EMEA becomes EMA 14th December 2009
[90] https://www.ema.europa.eu/en/about-us/history-ema

Chapter 2:

The industrial pharmacist.

Introduction:

The pharmacist has the capacity and the responsibility to be the number one actor in the pharmaceutical industry, through his knowledge and his involvement in medicines throughout history.

In order to fully understand the missions and obligations of the pharmacist in this field, it is essential to understand the link which unites the pharmacist to the pharmaceutical industry, which is the drug.

I General information on drugs:

1) Definition of the drug:

According to the definition of the WHO Drug Dictionary Enhanced and that of European Directive 65/65, a drug is "*any substance or composition presented as possessing curative or preventive properties with regard to human diseases. Any substance or composition that can be administered to humans with a view to establishing a medical diagnosis or restoring, correcting or modifying is also considered to be a medicinal product*".[91]

It is composed of an active substance (or active ingredient), which has a therapeutic effect, and excipients (binders, coating agents, fillers, artificial flavors), intended to confer particular characteristics on the final product.

There are two kinds of active substances: biological molecules and chemical molecules.

The drugs developed recently are therefore either derived from chemical research or from the application of biotechnologies (vaccines, antibodies), the techniques used are different, but the process and the stages of development, as well as the criteria for approval of a new drug by the health authorities remain comparable.

2) Stages of the development of a new drug:

A molecule that will manage to pass all the stages of tests and clinical trials to become a drug, the path from innovation to the patient is long, complex and costly, which goes from research to the discovery of a new molecule to the marketing authorization application. According to the European Federation of Pharmaceutical Industries and Associations, the development of a new drug costs on average 780 million euros.[92]

2.1) Preclinical studies:

Before testing the drug candidate in humans, it must pass various examinations so that safety is guaranteed. Internationally accepted guidelines are applied[93] which is oriented according to the principles of the "3Rs" (reducing waste, reusing and recycling resources and

[91] https://www.iracm.com
[92] Guillaume VDR. : "Can we defend the pharmaceutical industry", p 102.
[93] ICH Guidelines.

products).[94] Toxicological and safety studies on animals to determine the dangerousness on humans[95]is carried out by toxicologists. If the active substance does not present undesirable side effects so far, it is then produced in small quantities for the clinical trials that will follow.

2.2) Clinical trials:

Clinical trials of a drug candidate mark the beginning of its experimentation in humans. The objective is to evaluate the safety of the drug and its effectiveness in healthy or sick volunteers. The drug will be able to arrive on the market if its benefit/risk balance is positive that is to say if its health benefit is greater than its potential disadvantages.

• **Phase I:** is carried out on about twenty volunteers, healthy or sick depending on the molecule evaluated. This involves testing it for the first time in humans in order to observe its evolution in the body as a function of time (kinetics) and to assess its toxicity. For this, the volunteers are generally accommodated for a few days in a specialized center in order to undergo a battery of examinations to check a large number of parameters.
• **Phase II:** takes place in sick volunteers. The aim is to determine the minimum effective dose of the drug and its possible adverse effects. A first step makes it possible to determine the minimum effective dose for which the adverse effects are unobservable or minimal. A second phase consists of administering this dose to 100 to 300 patients, if possible to seek a benefit.
• **Phase III:** is the final phase before marketing. It makes it possible to evaluate the effectiveness of the drug on a larger cohort of patients: from a few hundred in the case of cancer, to thousands for very common diseases such as hypertension. The volunteers are most often divided into two groups in order to compare the effectiveness of the drug candidate with a reference treatment (if there is one) or with a placebo. This phase often lasts several years, the time to recruit patients and monitor the evolution of their state of health.[96]

Marketing authorization: If studies show that the drug is effective and safe, a marketing application (which will include data from animal and human studies, drug manufacturing techniques, prescribing information and package insert) will be submitted to the regulatory authorities who will analyze this information and decide whether the product is sufficiently safe and effective to allow it to be marketed.[97]The drug will then be made available to patients, only original drugs go through these long stages, generics do not go through this long trial cycle.
The first two phases last about two to three years each while the third lasts three to four years. Out of ten products entering phase I, five products enter phase II and only one obtains MA to enter phase IV.[98]

[94] https://www.interpharma.ch
[95] Abecassis PH. and Coutinet N.: Op.cit., p. 116.
[96] https://www.inserm.fr/dossier/medicament-developpement/
[97] https://www.msdmanuals.com.
[98] P PAURICHE, F.RUPPRECHT op.cit., p. 9.

• **Phase IV (pharmacovigilance):** exists after marketing. It makes it possible to follow the use of the drug over the long term in real conditions of use in order to detect rare adverse effects, late complications or even prescription biases.

Any health accident related to taking medication is reported to regulatory institutions. The companies also submit a drug tracking report every six months, for the first two years of the drug's life, then annually for the next three years and finally every five years for as long as the drug is on the market.[99]

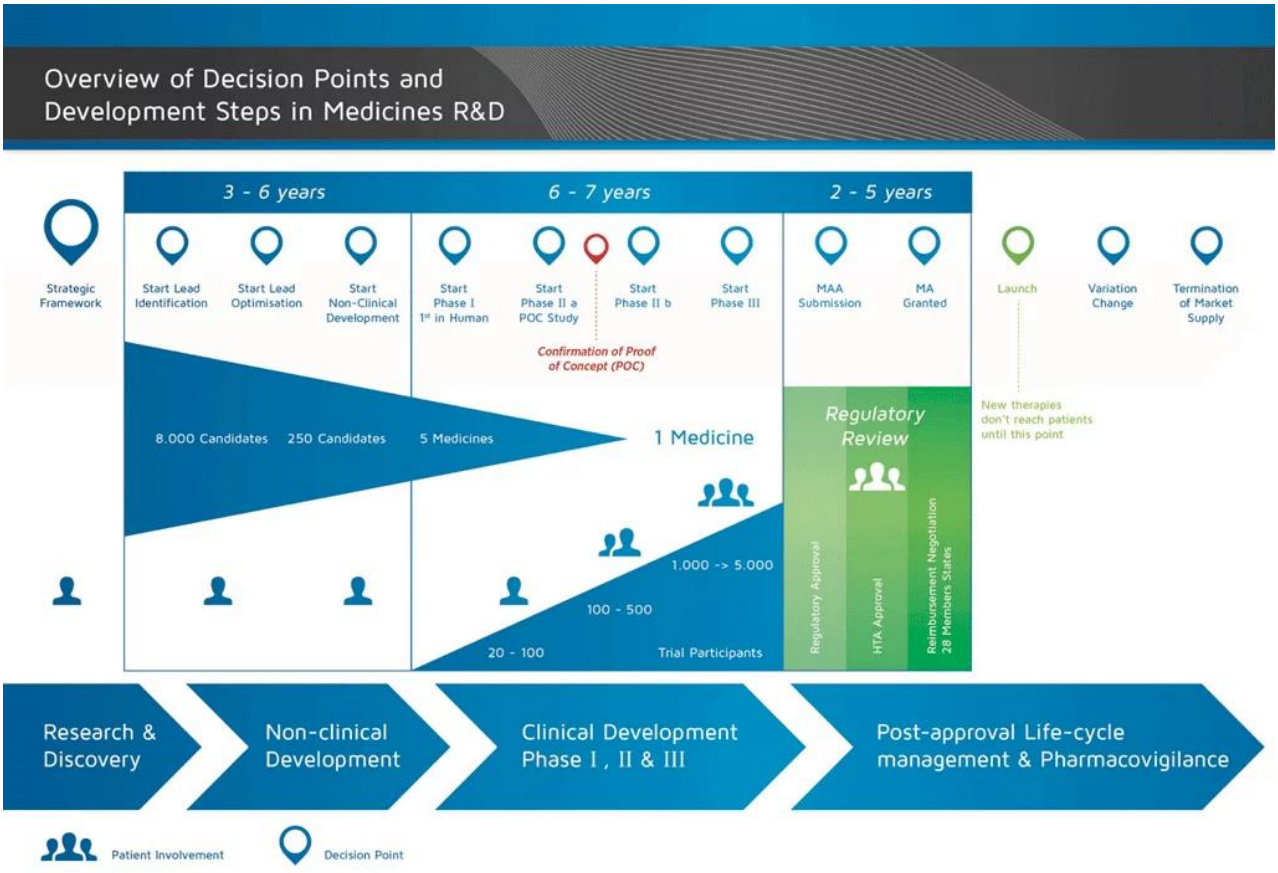


Figure 4: Genesis of a drug (From the idea to the product)[100]

This simplified version shows that it takes on average 13 to 15 years between the moment a patent is filed and the placing on the market of the finished drug via the MA.

3) Legal Forms of Medicines:

There are two legal forms of drugs; they can be of the following categories:

• **Originator medicinal product (ethical):** original medicinal product also referred to as "reference" "or innovative" medicinal product, is a medicinal product whose active substance (or a new dosage or a new presentation) has not yet been used as a medicinal product for human for

[99] LEEM. : Op.cit., p.47.
[100] LEEM. : Economic report, Op.cit., p.44

the given indication[101], these molecules are protected by a patent, the duration of which is 15-20 years, during this period, no company can copy them, their price is high, and they are prescription drugs and generally reimbursable. High R&D expenditures for originators which represent the highest and most profitable market share.

• **Generic drug:** after expiry of the patent, a drug identical or equivalent to that of a brand may be produced under a new trade name. The active substance is identical to that of the branded product, the only possible differences being the presentation and the excipients[102]. Their manufacture meets the same standards of requirement as all other drugs.

4) Regulatory protection of innovation:

4.1) Patent:

A patent is an intellectual property right that protects an invention. It makes it possible to obtain a monopoly of exploitation on an invention.

Pharmaceutical patents are issued, like all other patents, for a period of 20 years from filing and subject to payment of annuities. However, pharmaceutical products require marketing authorization (MA) in order to be marketed. This authorization is generally not issued for several years. Also, to compensate for this period during which the patent cannot be exploited, a special title has been created, the Supplementary Protection Certificate (SPC), which extends the rights of the owner of a patent relating to a pharmaceutical product.[103]

4.2) Supplementary Protection Certificate (SPC):

The SPC was first introduced in France in 1990 and then on a European scale in 1992. The United States had already introduced the Waxman Hatch Act in 1984, which extends the life of patents and facilitates the marketing of generic products.[104]

Pharmaceutical incentives, including Supplemental Protection Certificates (SPCs), are the foundations upon which innovation is built. The purpose of the SPC was to compensate for some of the effective patent life lost during the development of a drug [On average, it takes 12 to 13 years to develop a drug and obtain marketing authorization. In practical terms, this means that 12 to 13 years out of 20 of the effective term of a patent are lost].

As such, the SPC Regulation offers companies researching and developing new medicines the certainty that if a medicine comes to market, it will be protected from unfair competition for a limited period of time. This is what allows innovative companies to continue to take the risk of investing in the very long, complex, risky and expensive process of bringing new medicines to

[101] Pinel J.: "Counterfeit and sub-standard medicines: a life-threatening situation", p 6.
[102] Young people, chemistry and life sciences. : "The pharmaceutical industry and biotechnologies", Educational dossier produced as part of the conference programme, p6.
[103] Amendment of Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.
[104] Pauriche P. and Rupprecht F.: op.cit, p 12.

patients, health systems and society and which is paving the way to low-cost generics for use by health systems.

Figure 5: Illustration of the two cases of SPC[105]

5) Medical devices :

5.1) Definition

Medical device means "*any instrument, device, equipment, material, product, with the exception of products of human origin, or other item used alone or in combination, including the accessories and software necessary for the proper functioning of the device. ci, intended by the manufacturer for use in humans for medical purposes and whose primary intended action is not achieved by pharmacological or immunological means or by metabolism, but whose function may be aided by such means . Also constitutes a medical device the software intended by the manufacturer to be used specifically for diagnostic or therapeutic purposes.*
Medical devices which are designed to be implanted in whole or in part in the human body or placed in a natural orifice, and which depend for their proper functioning on a source of electrical energy or on any source of energy other than that which is generated directly by the human body or gravity, are called active implantable medical devices".[106]

[105] https://www.efpia.eu/about-medicines/development-of-medicines/intellectual-property/supplementary-protection-certificates/
[106] Public Health Code (article L.5211-1).

5.2) Classification of medical devices

Medical devices are classified into 4 categories, depending on their potential health risk. Each category is associated with specific evaluation and control rules:

- Class I (lowest risk class): which includes, for example, corrective glasses, vehicles for the disabled, crutches.
- Class IIa (moderate/measured potential risk) which includes: for example, contact lenses, ultrasound devices and dental crowns.
- Class IIb (high/significant potential risk): which notably includes lens disinfection products.
- Class III (highest risk class): which includes for example breast implants, stents, hip prostheses.

The classification of a medical device is the responsibility of the manufacturer. To do this, the manufacturer relies on classification rules established by the Medical Devices Directive, depending on the medical purpose that the latter claims for his product.

II General information about the pharmacist:

A pharmacist is a healthcare professional, drug specialist, whose role is to ensure the compliance of pharmaceutical care and therapeutic patient education.

The pharmacist is essentially known as the drug specialist whether in a community pharmacy, a hospital pharmacy or the pharmaceutical industry. But, due to his versatile medical and scientific training, he is also involved in many other sectors such as medical biology, public health, research or education.

1) The community pharmacist

The community pharmacist is the owner of the pharmacy (holder) or deputy (employee). To operate a pharmacy, in addition to management in their own name, a pharmacist can set up a one-person limited liability company (LLC).

He is responsible for:

- Ensures the dispensing and proper use of medicinal products for human and veterinary use.
- Ensures that the patient fully understands the treatment.
- Offers the patient pharmaceutical follow-up (monitoring of compliance, effects of treatments, pharmacovigilance).
- Feeds the patient's Pharmaceutical Record to better secure the dispensing of drugs and improve coordination between healthcare professionals.
- Contributes with other health professionals to personalized patient support (therapeutic education); collaboration with the hospital environment in the context of pharmaceutical reconciliation.
- Makes magistral and officinal preparations.
- Participates in public health, prevention and screening actions; thus integrates new missions such as flu vaccination into his daily life.

- Contributes to health safety systems (pharmacovigilance, materiovigilance, health alerts, and batch withdrawals).
- Can carry out dosage adjustments and renewals of treatment under certain conditions.
- Contributes to continuity of access to medication 7 days a week, 24 hours a day; Participates in the continuity of care.
- Participates in the protection of public health and the environment by collecting unused medicines reported by patients.[107]

2) The Hospital Pharmacist

Hospital Pharmacist is a currently registered pharmacist working in a public/private sector hospital pharmacy service. It is responsible for ensuring the safe, appropriate and cost-effective use of medicines.

He is responsible for:

- Manages purchasing, supply, holding and management of health products.
- Dispensing these health products to hospitalized or ambulatory patients (analysis of prescriptions with pharmaceutical intervention if necessary, possible preparation of the doses to be administered, delivery, advice on proper use).
- Carries out clinical pharmacy actions such as medication reviews, medication reconciliation on entry and exit of patients.
- Makes magistral, hospital and officinal preparations (medicines for pediatric use, anti-cancer, radio-pharmaceuticals, parenteral nutrition, innovative therapy medicines) or for biomedical research.
- Ensures the traceability of certain drugs and implantable medical devices.
- Participates in pharmacovigilance, materiovigilance and other health vigilance actions.
- Ensures the security of the drug circuit through quality and safety of care and risk management actions.
- Controls raw materials, preparations, water for hemodialysis.
- Manages the sterilization of medical devices.
- Participates in the drug commission, biomedical research, training and teaching actions for pharmaceutical and other paramedical staff and, depending on the establishment, therapeutic education, pharmacokinetics, hygiene.[108]

[107] https://www.ordre.pharmacien.fr/Les-pharmaciens/Le-metier-du-pharmacien/Fiches-metiers/Officine/Pharmacien-titulaire-d-officine

[108] https://www.ordre.pharmacien.fr/Les-pharmaciens/Le-metier-du-pharmacien/Fiches-metiers/Etablissements-de-sante/Pharmacien-hospitalier

3) The Industrial Pharmacist:

Introduction:

The industrial pharmacist can intervene at the different stages of the life of a drug, from the discovery of the molecule to the marketing of the product.

In the pharmaceutical industry, the pharmacist is present at all stages of the manufacture of a drug. He can thus devote himself to a research mission by actively participating in the discovery of new molecules or, in the next step, verifying their efficacy and harmlessness as a clinical research associate. But he can also choose to become a production manager, supervising all the manufacturing phases.

The doctor of pharmacy has the capacity to occupy several jobs in the pharmaceutical industry, two of which are obligatorily occupied by a pharmacist, which are: The technical director pharmacist and the assistant pharmacist.

3.1) The technical director pharmacist:

The technical management of any pharmaceutical manufacturing, operating, importing, exporting and wholesale distribution establishment must be provided by a pharmacist. The technical director pharmacist is personally responsible for the application of all the rules technical and administrative enacted in the interest of public health.

3.2) The assistant pharmacist:

The assistant pharmacist aims to help the technical director pharmacist to accomplish his various missions. He can share his missions but not his responsibilities.

III Missions and Qualifications:

The missions and qualifications of the technical director pharmacist and the assistant pharmacist differ according to the type of establishment.

1) The technical director pharmacist and assistant pharmacist of the pharmaceutical manufacturing establishment:

1.1) The qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical manufacturing establishment:

- **Professional experience :**

The technical director pharmacist must have professional experience in the field of the pharmaceutical industry of at least two (2) years (However, part or all of the required period of experience may be justified by internships in the pharmaceutical industry involving manufacturing operations), in one or more licensed pharmaceutical manufacturing establishments.

The duration of the internship is not required when the pharmacist holds a higher education diploma in the field of the pharmaceutical industry.

- **Special activities:**

In the case of an establishment manufacturing innovative therapies, the technical director pharmacist must provide proof of specific titles and activities in these fields of activity or be assisted by a person who demonstrates this competence.

In the case of an establishment manufacturing radiopharmaceuticals, the technical director pharmacist must have appropriate training on the aspects of the quality management system specific to this type of drug and radiation protection skills or be assisted by a person possessing these skills.

In a medical equipment manufacturing establishment, the technical director pharmacist must be assisted by a person with proven competence in the manufacturing of medical equipment.[109]

- **The exercise decision:**

The exercise decision is a decision issued by the Minister responsible for the pharmaceutical industry and meets the conditions provided for by the legislation and regulations in force to the technical director pharmacist as well as to the assistant pharmacists of the pharmaceutical manufacturing establishment prior to the exercise of their function.[110]

The technical director pharmacist and the assistant pharmacist must submit an application accompanied by a file consisting of:

— Application form
— A copy of the pharmacist's diploma
— A copy of the identity card
— Any document justifying the experience
— A photo ID
— The certificate of registration with the ethical council of pharmacists
— The employment contract.[111]

- **Training :**

For the technical director pharmacist:

On the one hand, the technical director pharmacist must have the appropriate skills and experience.

[109] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article11.
[110] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article12.
[111] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article13.

On the other hand, the pharmaceutical establishment must provide initial training in good manufacturing practices or standards governing the quality of medical devices, as well as continuous training, both technically and in terms of quality management, to allow him to gain skills in order to comply with the evolution of his missions.[112]

For the assistant pharmacist:

The pharmaceutical establishment must provide assistant pharmacists with initial training in good manufacturing practices or standards governing the quality of medical devices as well as ongoing training, allowing them to gain skills in order to comply with the evolution of the tasks which are entrusted to them.[113]

- **Replacement cases:**

- In the event of the absence or impediment of the technical director pharmacist, his replacement must be notified to the competent services of the ministry responsible for the pharmaceutical industry, and may not exceed a period of one (1) month.
In the event of approval of extension by the competent services of the ministry responsible for the pharmaceutical industry on justified request not exceeding a period of six (6) months.
The identity of the pharmacists providing replacements, the dates and durations of these replacements are kept in the pharmaceutical establishment for a period of five (5) years.[114]

- In the event of definitive cessation of his activity, the technical director pharmacist or the assistant pharmacist is required to inform the competent services of the ministry responsible for the pharmaceutical industry for the cancellation of his decision to exercise. The pharmaceutical establishment must notify them and also the ethics council for pharmacists, at least three (3) months before the departure date.[115]
In this case, a new technical director pharmacist or assistant pharmacist is appointed within a maximum period of fifteen (15) days.[116]

1.2) The missions of the technical director pharmacist and the assistant pharmacists of the pharmaceutical manufacturing establishment:

1.2.1) The technical director pharmacist

The technical director pharmacist ensures the application of the technical and administrative rules enacted in the interest of public health as well as the rules of good manufacturing practices.

[112] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article14
[113] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article15
[114] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article16
[115] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article18
[116] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article17

As part of his duties, he is responsible in particular for:
— To sign, after having read the file, the registration or approval decision requests presented by the establishment or any other request related to the activities it organizes and supervises and also to declare, beforehand, to the services authorities of the ministry responsible for the pharmaceutical industry, any modification relating to the quality, safety and efficacy of the pharmaceutical product or medical device in the initial registration or approval file.

- **In relation to the personnel in the establishment:**

— To designate the assistant pharmacists, in collaboration with the management of the establishment. He informs the relevant departments of the ministry responsible for the pharmaceutical industry of their absence or resignation.
— To participate in the deliberations of the administrative or supervisory bodies of the pharmaceutical establishment, when these deliberations concern or may affect the exercise of the missions under its responsibility, listed in this order.
— Ensure that initial and continuing training programs are implemented and kept up to date. He is also required to submit the annual staff training plan.
— To exercise hierarchical authority over all personnel linked to the activities that he organizes and supervises.

- **About manufacturing:**

— To ensure that a pharmaceutical quality management system is applied and respected.
— To justify, at any time, that the products manufactured comply with the characteristics to which they must respond and that the manufacturing pharmaceutical establishment has carried out the necessary checks.
— To take all measures to ensure that the conditions of transport, storage and preservation of medical samples cannot harm the safety, efficacy and quality of the samples.
— To ensure that each batch of pharmaceutical products or medical devices is manufactured and controlled, according to the requirements adopted for registration or approval, and to ensure their compliance with the registration or approval file.[117]
— To coordinate and quickly carry out all recall and withdrawal actions for pharmaceutical products or medical devices.
— To ensure that the transport conditions guarantee the proper preservation, integrity and safety of pharmaceutical products and medical devices or related inputs.
— Organize and monitor all of the establishment's pharmaceutical operations, in particular manufacturing, pharmacovigilance, materiovigilance, monitoring and withdrawal of batches of pharmaceutical products and medical devices concerned, as well as storage operations therein related.

[117] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article2

The technical director pharmacist can share these missions with the people occupying the positions of responsibility defined within the pharmaceutical establishment, for specific stages in the manufacture and control of a batch.
Any sharing of missions between the technical director and the personnel occupying positions of responsibility, relating to the conformity of a batch must be defined in a document formally accepted by all the parties. This document must detail the missions concerning the compliance of the batch with good manufacturing practices and the registration or approval decision.[118]

- **In relation to the ministry:**

— To declare, on a weekly basis, to the competent services of the Ministry of the Pharmaceutical Industry the stock status of pharmaceutical products
— To submit, annually, an inventory of pharmaceutical products, according to the procedures set by decision of the Minister responsible for the pharmaceutical industry.[119]
— To declare to the competent services of the ministry in charge of the pharmaceutical industry expired products, incinerated products.
— To submit to the competent services of the ministry responsible for the pharmaceutical industry, the provisional production programs and the provisional program for the importation of raw materials and packaging items.
— To report to the establishment's managers any obstacle or limitation to the exercise of its missions.
— To inform the competent departments of the ministry responsible for the pharmaceutical industry of any disagreement relating to the application of the technical and administrative rules which opposes it to an administrative or supervisory body.

- **Other assignments:**

— To participate in the development of the research and development program;
— To report to the National Pharmaceutical Products Agency any placing on the national market of a drug or medical device that it considers to be falsified, within the meaning of the legislative and regulatory provisions in force, of which it is responsible for the manufacture.
— To ensure that self-inspections are carried out at regular intervals, according to a pre-established program and that the necessary corrective and preventive measures are put in place.[120]

The technical director pharmacist must be able to exercise his authority and have the resources and responsibilities necessary to accomplish his missions.[121]

[118] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article3
[119] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article5
[120] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article 4
[121] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article6

1.2.2) The assistant pharmacist:

The assistant pharmacists have the task of assisting the technical director pharmacist in the exercise of his missions, he can delegate his tasks to them but not his responsibilities.[122]

The number of assistant pharmacists is fixed according to the number of staff, (it is taken into account the people who engage in manufacturing operations),[123] as following:

— One assistant pharmacist, for every thirty (30) people.

— One more assistant pharmacist, for every forty (40) additional people.[124]

For the replacement periods, they are granted the same powers and missions as those attributed to the technical director pharmacist and exercise them effectively for the duration of the replacement.[125]

2) The technical director pharmacist and assistant pharmacist of the importing pharmaceutical establishment:

2.1) Qualifications of the technical director pharmacist and assistant pharmacists of the importing pharmaceutical establishment:

- **The exercise decision:**

The decision to exercise is a decision issued by the Minister responsible for the pharmaceutical industry and meets the conditions provided for by the legislation and regulations in force to the technical director pharmacist of the importing pharmaceutical establishment prior to the exercise of their function.[126]

The technical director pharmacist must submit a file consisting of:

— A copy of the pharmacist's diploma of the technical director pharmacist.

— A copy of the identity document of the technical director pharmacist.

— The employment contract of the technical director pharmacist.

— The certificate of registration with the council of ethics of pharmacists.[127]

[122] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article7

[123] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article9

[124] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article8

[125] Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article10

[126] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article12

[127] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article15

- **Training :**

For the technical director pharmacist:

On the one hand, the technical director pharmacist must have the appropriate skills.

On the other hand, the pharmaceutical establishment must provide him with initial training in good import practices or standards governing the quality of pharmaceutical products and medical devices, as well as continuous training, both technical and regulatory, to allow him to gain skills in order to comply with the evolution of his missions.[128]

For the assistant pharmacist:

The pharmaceutical establishment must provide assistant pharmacists with initial training in good import practices, administrative and regulatory aspects and standards governing import operations, as well as ongoing training, both technical and regulatory, allowing them to gain skills in order to comply with the evolution of the tasks entrusted to them.[129]

- **Replacement cases:**

- In the event of the absence or impediment of the technical director pharmacist, his replacement must be notified to the competent services of the ministry responsible for the pharmaceutical industry, and may not exceed a period of one (1) month.

In the event of approval of extension by the competent services of the ministry responsible for the pharmaceutical industry on justified request not exceeding a period of six (6) months.

The identity of the pharmacists providing replacements, the dates and durations of these replacements are kept in the pharmaceutical establishment for a period of five (5) years.[130]

- In the event of definitive cessation of his activity, the technical director pharmacist is required to inform the competent services of the ministry responsible for the pharmaceutical industry for the cancellation of his decision to exercise, and the modification or withdrawal of the approval.

In this case, a new technical director pharmacist is appointed within a maximum period of fifteen (15) days.[131]

2.2) Missions of the technical director pharmacist and the assistant pharmacists of the importing pharmaceutical establishment:

The technical director pharmacist and the assistant pharmacist of the importing pharmaceutical establishment are responsible for ensuring that each import operation of

[128] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article 13

[129] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article 14

[130] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article16

[131] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article11

pharmaceutical products or medical devices is carried out in accordance with the legislation and regulations in force, and in compliance with good import practices.[132]
They must have a contract with the pharmaceutical establishment and carry out their activity, full time, in the pharmaceutical establishment.[133]

The technical director pharmacist assisted in the exercise of these functions by one or more assistant pharmacists ensures, under his responsibility, the management of the pharmaceutical establishment[134]. He can only delegate some of his tasks to them. (He may also be assisted by any other specialist with qualifications in the field of activity of the pharmaceutical establishment when the importation concerns medical devices, in particular by an engineer or technician in electronics or electrical engineering, in the case import of equipment.)[135]
The names of assistant pharmacists must be declared to the competent departments of the ministry responsible for the pharmaceutical industry.
For the replacement periods, the assistant pharmacists are granted the same powers and missions as those attributed to the technical director pharmacist and exercise them effectively for the duration of the replacement.[136]

The technical director pharmacist can share his missions for all import stages with the assistant pharmacist.
Any sharing of missions between the technical director pharmacist and the assistant pharmacist must be defined in a document formally accepted by all parties.
This document must detail the missions concerning the compliance of import operations with good import practices.[137]

The missions of the technical director pharmacist and assistant pharmacists:
The technical director pharmacist as well as the assistant pharmacists of the pharmaceutical establishment ensures the application of the technical and administrative rules, as well as the rules of good import practices.

In this context, they are responsible, in particular:

- **About import:**

— Ensure compliance with the rules of good import practice.
— To ensure compliance with health and safety rules.

[132] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article3
[133] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article9
[134] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article2
[135] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article5
[136] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article8
[137] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article4

— Ensure the maintenance and archiving of documentation.
— Organize and monitor all pharmaceutical import operations, in particular pharmacovigilance and materiovigilance.
— Ensure that all batches of imported pharmaceutical products and medical devices undergo the necessary checks with the national pharmaceutical products agency before they are placed on the market, in accordance with the legislation and regulations in force, the technical requirements -regulatory, particularly in terms of their primary and secondary packaging. And that the necessary checks relating thereto have been carried out.
— To ensure compliance with the regulations in force regarding the transport and storage of pharmaceutical products and medical devices, as well as the procedures for preparing and shipping orders.
— To ensure compliance with the regulations in force regarding the management of substances with narcotic and/or psychotropic properties, in accordance with the legislative and regulatory provisions in force.

- **In relation to the personnel in the establishment**:

— To appoint the assistant pharmacists, in collaboration with the management of the pharmaceutical establishment.
— To inform and train the personnel under their responsibility, in collaboration with the administration of the pharmaceutical establishment.[138]

For the technical director pharmacist, He must:
— Inform the relevant departments of the ministry responsible for the pharmaceutical industry of his absence or resignation.
— Inform the competent departments of the ministry responsible for the pharmaceutical industry of any anomaly relating to the application of the technical and/or administrative rules noted during the performance of their duties.[139]

The technical director pharmacist must be able to exercise his authority and have the resources and responsibilities necessary to accomplish his missions.[140]

3) The technical director pharmacist and assistant pharmacist of the operating pharmaceutical establishment:

[138] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article6
[139] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article10
[140] Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article7

3.1) Qualifications of the technical director pharmacist and the assistant pharmacists of the operating pharmaceutical establishment:

- **The exercise decision:**

Prior to the exercise of his functions, the technical director pharmacist with the operating pharmaceutical establishment must have a decision to exercise (like all types of establishment) issued by the Minister responsible for the pharmaceutical industry and satisfy under the conditions provided for by the laws and regulations in force.[141]

The technical director pharmacist must submit a file consisting of:

— A copy of the pharmacist's diploma of the technical director pharmacist.
— A copy of the identity document of the technical director pharmacist.
— The employment contract of the technical director pharmacist.
— The certificate of registration with the council of ethics of pharmacists.[142]

- **Training :**

For the technical director pharmacist:

On the one hand, the technical director pharmacist must have the appropriate skills.

On the other hand, the pharmaceutical establishment must provide him with initial training in good operating practices or in the standards governing the quality of pharmaceutical products and medical devices, in the administrative and regulatory aspects and the rules governing the registration operations of pharmaceutical products and approval of medical devices as well as continuous training, both technical and regulatory, to enable it to gain skills in order to comply with the evolution of its missions.[143]

For the assistant pharmacist:

The pharmaceutical establishment must provide assistant pharmacists with initial training in good operating practices, administrative and regulatory aspects and standards governing operating operations, as well as ongoing training, both technical and regulatory, allowing them to gain skills in order to comply with the evolution of the tasks entrusted to them.[144]

- **Replacement cases:**

- In the event of the absence or impediment of the technical director pharmacist, his replacement must be notified to the competent services of the ministry responsible for the pharmaceutical industry, and may not exceed a period of one (1) month.

In the event of approval of extension by the competent services of the ministry responsible for the pharmaceutical industry on justified request not exceeding a period of six (6) months.

[141] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article12.
[142] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article15.
[143] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article13.
[144] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article14.

The identity of the pharmacists providing replacements, the dates and durations of these replacements are kept in the pharmaceutical establishment for a period of five (5) years.[145]

- In the event of definitive cessation of his activity, the technical director pharmacist is required to inform the competent services of the ministry responsible for the pharmaceutical industry for the cancellation of his decision to exercise, and the modification or withdrawal of the approval. In this case, a new technical director pharmacist or assistant pharmacist is appointed within a maximum period of fifteen (15) days.[146]

3.2) Missions of the technical director pharmacist and the assistant pharmacists of the operating pharmaceutical establishment:

The technical director pharmacist and the assistant pharmacist of the operating pharmaceutical establishment are responsible for ensuring that each operating operation for the registration of a pharmaceutical product or the approval of a medical device is carried out and controlled, in accordance with the legislation and regulations in force and in compliance with good operating practices and the requirements set out in the registration decision or the approval decision.[147]
They must have a contract with the pharmaceutical establishment and carry out their activities full-time in the pharmaceutical establishment.[148]

The technical director pharmacist assisted in the exercise of his functions by one or more assistant pharmacists ensures, under his responsibility, the management of the pharmaceutical establishment.[149]

The names of assistant pharmacists must be declared to the competent departments of the ministry responsible for the pharmaceutical industry.[150]
For the replacement periods, they are granted the same powers and missions as those attributed to the technical director pharmacist and exercise them, effectively, for the duration of the replacement.[151]

[145] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article16.
[146] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article 11.
[147] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article3.
[148] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article9.
[149] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article2.
[150] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article5.
[151] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article8.

The technical director pharmacist must assume his missions for all stages of operation. These missions can be shared with the assistant pharmacist.
Any sharing of missions between the technical director pharmacist and the assistant pharmacist must be defined in a document formally accepted by all parties.
This document must detail the missions concerning the conformity of the operations of exploitation, release and monitoring of batches of pharmaceutical products and medical devices with good operating practices and the registration or approval decision.[152]

The missions of the technical director pharmacist and assistant pharmacists:

The technical director pharmacist as well as the assistant pharmacists of the operating pharmaceutical establishment ensures the application of the technical and administrative rules enacted in the interest of public health as well as the rules of good operating practices.
In this context, they are responsible, in particular:

— To prepare files for the registration of pharmaceutical products and/or the approval of medical devices;
— Organize and monitor all pharmaceutical operations in accordance with the laws and regulations in force;
— To justify, at any time, that the pharmaceutical products and medical devices, under their responsibility, comply with the characteristics which they must meet and that the necessary checks relating thereto have been carried out.
— Release and track batches of pharmaceutical products and/or medical devices.
— To coordinate and carry out, quickly, all the actions of recall and withdrawal of pharmaceutical products or medical devices.
— Monitoring and reporting adverse effects of pharmaceutical products and medical devices, and pharmacovigilance and materiovigilance cases.
— To manage the samples requested in connection with the registration of pharmaceutical products or the approval of medical devices.
— Ensure the maintenance and archiving of documentation.[153]

For the technical director pharmacist, he must:
— Appoint the assistant pharmacists, in collaboration with the management of the pharmaceutical establishment.
— Inform the relevant departments of the ministry responsible for the pharmaceutical industry of their absence or resignation.
— Be able to exercise his authority and have the resources and responsibilities necessary to accomplish his missions.[154]

[152] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article4.
[153] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article6.
[154] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article7.

—Inform the competent departments of the ministry responsible for the pharmaceutical industry of any anomaly relating to the application of the technical and/or administrative rules noted during the performance of their duties.[155]

4) The technical director pharmacist and assistant pharmacist of the operating pharmaceutical establishment:

4.1) Qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical wholesale distribution establishment:

- **Professional experience:**

The technical director pharmacist of the pharmaceutical wholesale distribution establishment must have professional experience in the pharmaceutical field of at least one (1) year.[156]

- **The exercise decision:**

The exercise decision is a decision issued by the Minister responsible for the pharmaceutical industry and satisfies the conditions provided for by the legislation and regulations in force to the technical director pharmacist of the pharmaceutical wholesale distribution establishment prior to the exercise of their function.[157]

The technical director pharmacist must submit a file consisting of:

— A copy of the pharmacist's diploma of the technical director pharmacist.

— A copy of the identity document of the technical director pharmacist.

— The employment contract of the technical director pharmacist.

— The certificate of registration with the council of ethics of pharmacists.[158]

- **Training:**

For the technical director pharmacist:

On the one hand, the technical director pharmacist must have the appropriate skills.

On the other hand, the pharmaceutical establishment must provide him with initial training in good distribution practices or standards governing the quality of pharmaceutical products and

[155] Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article10.

[156] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article12.

[157] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 13.

[158] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 16.

medical devices, as well as continuous training, both in terms of quality management, to allow him to gain skills in order to comply with the evolution of his missions.[159]

For the assistant pharmacist:

The pharmaceutical establishment must provide assistant pharmacists with initial training in good distribution practices and standards governing the quality of pharmaceutical products and medical devices, as well as ongoing training, allowing them to gain skills in order to comply with the evolution of the tasks entrusted to them.[160]

- **Replacement cases:**

- In the event of the absence or impediment of the technical director pharmacist, his replacement must be notified to the competent services of the ministry responsible for the pharmaceutical industry, and may not exceed a period of one (1) month.

- In the event of approval of an extension by the competent services of the ministry responsible for the pharmaceutical industry upon justified request not exceeding a period of six (6) months.

The identity of the pharmacists providing replacements, the dates and durations of these replacements are kept in the pharmaceutical establishment for a period of five (5) years.[161]

- In the event of definitive cessation of his activity, the technical director pharmacist is required to inform the competent services of the ministry responsible for the pharmaceutical industry for the cancellation of his decision to exercise, and the modification or withdrawal of the approval.

In this case, a new technical director pharmacist is appointed within a maximum period of fifteen (15) days.[162]

4.2) Missions of the technical director pharmacist and the assistant pharmacists of the pharmaceutical wholesale distribution establishment:

The technical director pharmacist and the assistant pharmacist of the pharmaceutical wholesale distribution establishment are responsible for ensuring that each operation wholesale

[159] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 14.

[160] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 15.

[161] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 17.

[162] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article11.

distribution of pharmaceutical products or medical devices is carried out, in accordance with the laws and regulations in force and in compliance with good distribution practices.[163]
They must have a contract with the pharmaceutical establishment and carry out their activity, full time, in the pharmaceutical establishment.[164]

The technical director pharmacist assisted in the exercise of these functions by one or more assistant pharmacists, particularly for pharmaceutical establishments.[165] He can only delegate some of his tasks to them.
The names of assistant pharmacists must be declared to the competent departments of the ministry responsible for the pharmaceutical industry.

In the case of a multi-site pharmaceutical establishment, each secondary site must have at least one assistant pharmacist with a delegation of the missions of the technical director pharmacist, a copy of which is sent to the competent departments of the Ministry responsible for pharmaceutical industry. [166]

For the replacement periods, the assistant pharmacists are granted the same powers and missions as those attributed to the technical director pharmacist and exercise them effectively for the duration of the replacement.[167]

The technical director pharmacist can share his missions for all stages of distribution with the assistant pharmacist.
Any sharing of missions between the technical director pharmacist and the assistant pharmacist must be defined in a document formally accepted by all parties.
This document must detail the missions concerning the compliance of wholesale distribution operations of pharmaceutical products and medical devices with good distribution practices.[168]

The missions of the technical director pharmacist and assistant pharmacists:

The technical director pharmacist as well as the assistant pharmacists of the pharmaceutical establishment ensures the application of the technical and administrative rules, as well as the rules of good wholesale distribution practices.

[163] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 3.
[164] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article9.
[165] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 2.
[166] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 5.
[167] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 8.
[168] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 4.

In this context, they are responsible, in particular:
— To ensure compliance with the rules of good wholesale distribution practices.
— To ensure compliance with health and safety rules.
— Ensure the maintenance and archiving of documentation.
— To monitor the conditions of supply and storage of pharmaceutical products and medical devices, as well as the procedures for preparing and shipping orders.
— Monitoring the sales operations of pharmaceutical products and medical devices.
— To implement internal audits and self-inspections.
— To inform and train the personnel under their responsibility.
— Report any anomaly noted to the competent departments of the ministry responsible for the pharmaceutical industry.
— To ensure the management and monitoring of products with narcotic and/or psychotropic properties in accordance with the legislation and regulations in force.[169]

For the technical director pharmacist, He must:
— Inform the competent departments of the ministry responsible for the pharmaceutical industry of any anomaly relating to the application of the technical and/or administrative rules noted during the performance of their duties.[170]

The technical director pharmacist must be able to exercise his authority and have the resources and responsibilities necessary to accomplish his missions.[171]

For export establishment, the Ministry has not yet drawn up the decree setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists.

IV Other occupations:

With the diversity of knowledge and training of the pharmacist, he comes to occupy various jobs within the pharmaceutical industry, these jobs do not exclusively require the profile of a pharmacist, and we mention some of them below:

Production director:

The production manager implements the product production strategy on an industrial site according to the objectives, in compliance with regulations and quality, health and safety rules,

[169] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 6.
[170] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 10.
[171] Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 7.

costs and planned deadlines. He supervises and leads the production teams. He coordinates his activities in relation to the quality, logistics and industrial organization departments. He can be a pharmacist or an engineer.[172]

Production and/or packaging manager:

The manufacturing and/or packaging manager implements the production strategy in a given sector in compliance with regulations and quality, health and safety rules, cost environment and planned deadlines. He can be a pharmacist or an engineer.[173]

Control laboratory manager:

The control laboratory (or quality control) manager defines and implements quality control techniques in order to verify the quality of products and services in compliance with health and safety regulations and rules.[174]

Health visitor:

The medical visitor is the main interface with the medical profession at the time of sale. He is responsible for promoting and selling products, answering customer questions. It draws up its sectorial action plan based on national and regional objectives. He may be a pharmacist, doctor or biologist or just have a business or marketing background.[175]

Range leader:

The line manager develops the Marketing Strategy for a product, a product line or a group to ultimately increase turnover and profitability; he implements the Marketing action plan for the product(s) entrusted to him. He leads a team of product managers, training and coordinating them. He has a marketing or sales background.[176]

Regional director:

The regional director is at the level of the regions, he is responsible for applying the business strategy of the company at his level. He leads the team of pharmaceutical visitors. He also has the role of competitive intelligence and makes retry all the information collected by the medical visitors to his superiors. He can be a doctor, pharmacist or other scientific background.[177]

Pharmaceutical visitor:

The pharmaceutical representative has the same role as the traditional medical representative, he is responsible for promoting and selling products, answering customer questions. It draws up

[172] https://www.leem.org/index.php/referentiels-metiers/directeurrice-de-production
[173] https://www.leem.org/referentiels-metiers/responsable-de-fabrication-etou-de-conditionnement
[174] https://www.leem.org/referentiels-metiers/responsable-laboratoire-de-controle
[175] http://www.leem.org/article/mise-en-concurrence-pour-lobservatoire-de-l-information-promotionale, "Competition for the Observatory of Promotional Information
[176] Hubert. K, Function: marketing product manager, Towards the mastery of business tools and skills 6th edition (2013), Dunond.
[177] https://www.leem.org/referentiels-professions/directeurtrice-regionale

its sectorial action plan based on national and regional objectives. He can be a pharmacist, doctor or biologist or just have a commercial or marketing background, but can only intervene for self-medication products sold by the pharmacist.[178]

Marketing director:

The marketing director designs and leads the marketing strategy and ensures compliance with national, European and international regulations. As he coordinates and animates the marketing team. He can be a doctor, a pharmacist or with a marketing or sales background.[179]

[178] http://www.leem.org/article/mise-en-concurrence-pour-lobservatoire-de-l-information-promotionnelle
[179] https://www.leem.org/referentiels-professions/directeurtrice-marketing

Practical part:

I. Study objective:

As part of our thesis on "the role of the pharmacist in the pharmaceutical industry", we are carrying out a study based on a questionnaire intended for the technical director pharmacist and the assistant pharmacists. This study aims to clarify the tasks, missions and responsibilities of the pharmacist in pharmaceutical companies.

II. Material and method :

The survey is done online for TD pharmacists and assistant pharmacists in different wilayas of Algeria. And the questionnaire was distributed by online dissemination and by travel and direct contact with pharmacists at the level of their work establishments.

II.1- Survey period:

The survey was carried out from 25-05-2022 to 02-08-2022.

II.2-Type of study:

The study method used for carrying out the survey is the qualitative study based on a questionnaire.

II.3-Study population:

Our study was addressed to two populations: for technical director pharmacists, and for assistant pharmacists.

The questionnaires were distributed online in Facebook groups of industrial pharmacists. And also by direct contact with them.

A total of 5 responses were collected, 3 DT pharmacists and 2 Assistant pharmacists in different wilayas.

II.4- Description of the questionnaire:

The questionnaire includes 33 questions, 31 open questions and 2 closed questions. The open question allows pharmacists to express their opinions.

The questionnaire is based on 3 parts:

1st part: personal information

2nd part: questions for technical director pharmacists.

3rd part: questions intended for the technical director pharmacists and the assistant pharmacists.

The questionnaire is divided into 18 parts, each part contains a regulatory text, and these questions are formed from this text.

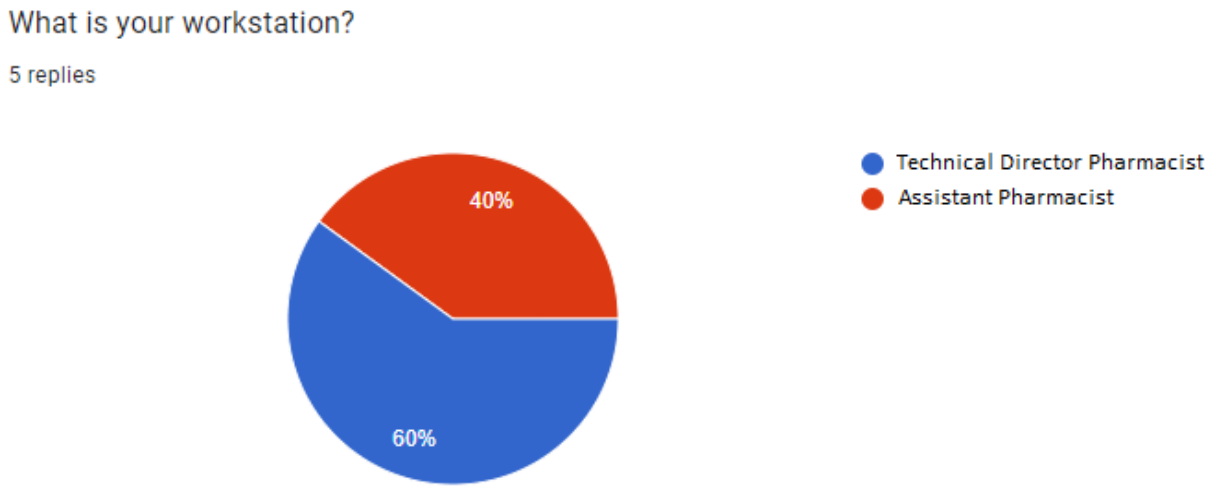
*** all the regulatory texts are obtained from the Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical manufacturing establishment.**

III. Results and interpretations:

The questions:

1- Personnel:

1. What is your occupation?

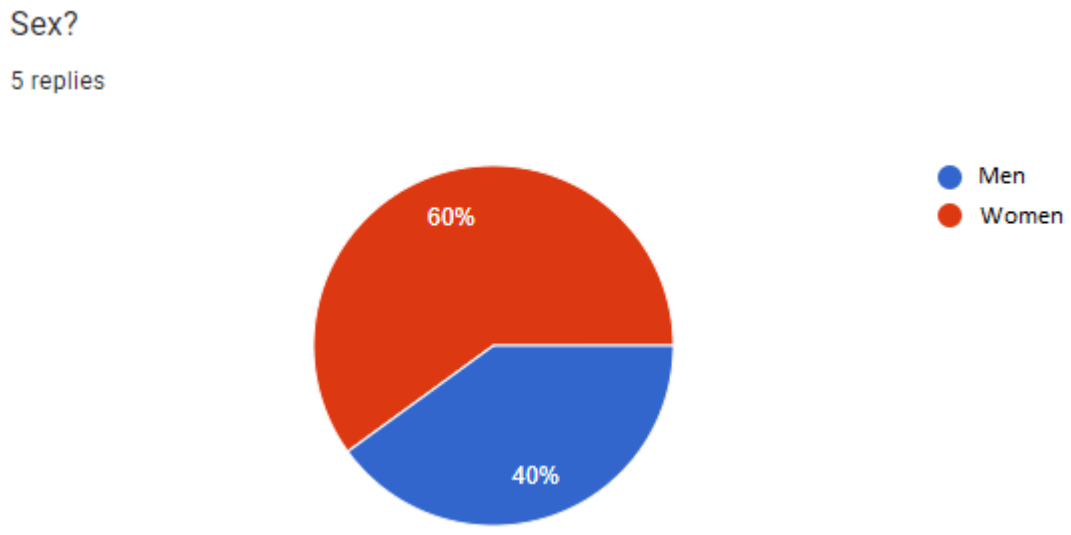


2. What establishment do you work for?

5 answers
SPA VITAL CARE
Saidal
Saidal
Pharmaghreb Laboratories
EURL TABUK ALGERIA

The population contains 3 technical director pharmacists and 2 assistant pharmacists, one of the 3 TDs works in an establishment specializing in medical devices. And the others work in establishments specializing in drugs.

3. Sex?



4. Age?

5 answers
- 29
- 30
- 31
- 32

- 37

5. Please mention all the positions within your establishment that must be occupied by a Doctor of Pharmacy.

5 answers
- Pharmacist Technical Director and Assistant of the Technical Director
- Technical director and assistant pharmacist
- Assistant pharmacist / production pharmacist / quality assurance /
- TD Assistant Pharmacist, QA Manager, QCL Manager, Production Manager
- SC / QC / QA / PRD

The Ministry of Pharmaceutical Industry requires only two positions to be occupied by a pharmacist in the pharmaceutical establishment, which are TD pharmacist and assistant pharmacist. Some establishments only require the profile of doctor of pharmacy in positions other than the two determined by the ministry.

6. Write a short description of each position held by the pharmacist

3 answers
- Assistant pharmacist: within the technical department, he assists the technical director in his tasks.
Production pharmacist: he ensures the smooth running of drug manufacturing operations, he reports to the production manager.
Quality insurer: he ensures the application of the rules during the manufacture of the drug.
- Each position has its own tasks
- Management and middle management

2- Pharmacist Technical Director

I- Regulatory text

Article 4: "to ensure that initial and continuous training programs are implemented and kept up to date."

7. Do you have the ability to optimize these training programs? If so, what is your optimization source?

3 answers
- Yes, according to an internal training procedure
- Yes, my source is BPF, GMP, ISO standards
- Yes, BPF / ICH / EudraLex / WHO / SUPAC

According to the answers. TD pharmacists are required to continuously optimize training programs. The sources of these optimizations are different.

II- Regulatory text

Article 8: "The number of assistant pharmacists is set according to the number of staff"

8. Do you find that the number of assistant pharmacists in relation to the number of staff is sufficient to assist you?

3 answers
- Yes

- In our case yes
- Yes

The technical director pharmacists find that the number of assistant pharmacists in relation to the number of staff is satisfactory and sufficient to assist them.

III- Regulatory text

Article 4: "to designate the assistant pharmacists, in collaboration with the management of the establishment. He informs the competent services of the ministry responsible for the pharmaceutical industry of their absences or their resignation"

9. For you, what are the criteria of choice and qualities most sought after in candidates?

3 answers
- Freshly graduated, serious, presentable, motivated.
- It is the seriousness and the sense of responsibility.
- Basic knowledge of BPF, sense of responsibility and analysis.

Each institution has its own selection criteria when recruiting assistant pharmacists.

10. What platforms do you and your HRs use to recruit new assistant pharmacists?

3 answers
- Emploitic, Linkdin.
- Emploitic.
- EMPLOITIC / LINKED IN.

We observe that pharmaceutical establishments use online platforms for the recruitment of pharmacists, mainly two platforms which are: EMPLOITIC and LINKEDIN.

IV- Regulatory text

Article 4: "— to report to the directors of the establishment any obstacle or limitation to the exercise of its missions.
— to inform the competent services of the ministry responsible for the pharmaceutical industry of any disagreement relating to the application of the technical and administrative rules which opposes it to an administrative or supervisory body".

11. Does the second regulatory text designate the protocol to be followed systematically after the failure to eliminate these obstacles at the level of the establishment?

3 answers
- Yes it is a responsibility of the TD to declare to the MIP service any disagreement
- Yes
- Nope

Two responses affirm that the second regulatory text is a complement to the first text. One response disagreed with this statement without giving an illustration.

V- Regulatory text

Article 4: "to participate in the deliberations of the administrative or supervisory bodies of the pharmaceutical establishment, when these deliberations concern or may affect the exercise of the missions under its responsibility, listed in this order."

12. Given that your missions are multiple and affect several parts of the company, who is supposed to have the authority and the good faith to judge that these deliberations are likely to affect the exercise of the missions for which you are responsible?

3 answers
- It is up to the TD to judge whether these deliberations affect his missions, which are defined in the Official Journal.
- The CEO.
- General Director.

We observe a variety of responses on a delicate point.
Each establishment has a mechanism for judging the need for the presence and participation of the TD pharmacist in the deliberations of the administrative or supervisory bodies.

VI- Regulatory text

Article 4: "to ensure that a pharmaceutical quality management system is applied and respected".

13. Is this system dictated by your establishment? By what authority is it validated?

3 answers
- Yes, validate by ANPP
- Yes, QA
- Yes; MIP

All the answers state that it is the pharmaceutical establishment that provides the quality management system.
We notice diversity in the identification of the authority that validates this system.

14. Are you supposed to be able to modify/optimize it? If so, what are your sources?

3 answers
- Yes, it is the Quality Assurance department that takes care of it, sources for example ISO standards
- Yes
- Guidelines / BPF / WHO

The TD pharmacist is required to continuously optimize the quality management system. The sources of these optimizations differ, but generally obtained from national and international standards.

VII- Regulatory text

Article 4: "to participate in the development of the research and development program".

15. What are the establishment objectives when developing an R&D program? Give examples.

2 answers
- Have new products in order to satisfy market needs and with good prices and better quality.
- Develop quality products to contribute to the treatment of patients; develop antihypertensives by combining three active ingredients.

Respondents gave examples of the objectives of their establishment's R&D programs.

16. Of these targeted programs, which are the most likely that the DT pharmacist should participate in?

2 answers
- All.
- Having public health objectives.

All DT pharmacists answered that they participate in all R&D programs.

VIII- Regulatory text

Article 4: "to submit to the competent departments of the Ministry responsible for the pharmaceutical industry, the provisional program for the import of raw materials and packaging items".

17. Does this program have to be accompanied by documents and statistics from the market that explain and justify the import program?

3 answers
- Yes, are detailed in the note published by the MIP on August 17, 2021.
- Documents concerning the company itself (production forecast, production status of the previous year, etc.).
- Yes.

The provisional import program must be accompanied by documents and statistics, as detailed in the note published by the MIP on August 17, 2021.[180]

3- Technical director pharmacist and assistant pharmacist:

IX- Regulatory text

Article 2: "The technical director pharmacist is responsible for ensuring that each batch of pharmaceutical product or medical device is manufactured and controlled, in accordance with the legislation and regulations in force and in compliance with the requirements set out in the decision to registration or approval decision."

18. What leads to the triggering of control or does it occurs periodically? What is its frequency?

4 answers
- Controls are carried out: before, during and after the manufacturing process for each batch of finished product.
- Each manufactured batch must be checked before its release.
- The control is done on each batch.
- Each batch is controlled according to the registration dossier and BPF.

The answers are similar; some are more detailed than others.

19. 2- Which state body ensures compliance with these regulations in force and by what means?

4 answers

[180] https://www.miph.gov.dz/fr/provisional-programmes-of-import-exercise-2022/

- Ministry of Pharmaceutical Industry and National Agency for Pharmaceutical Products through inspections
- ANPP/technical-regulatory control of each batch released. Periodic sampling of batches released on the market is controlled by ANPP. Periodic audits of accredited quality control laboratories
- ANPP, MIP
- ANPP, sample analysis

The answers are similar. The ANPP and the MIP are the state bodies responsible for ensuring compliance with these regulations.

X- Regulatory text

Art 11: "The technical director pharmacist practicing in an establishment manufacturing innovative therapies must justify specific titles and work in these fields of activity or be assisted by a person justifying this competence."

20. Please give examples illustrating these titles and specific work in the different fields of activity.

3 answers
- Not applicable
- I never participated in this
- N / A

None of the responders had come across these specific jobs.

XI- Regulatory text

Article 3: "Any sharing of missions between the technical director and the personnel occupying positions of responsibility, relating to the conformity of a batch must be defined in a document formally accepted by all the parties. This document must detail the missions concerning the compliance of the batch with good manufacturing practices and the registration or approval decision."

21. What governance model is applied to ensure both the sharing and decentralization of tasks and the individual aspect of responsibility?

3 answers
- Everything must be the subject of a written procedure which begins with the descriptive job of the assistant, the TD must always check the work of his assistant in order to assume his responsibility as the only validator.
- The job descriptions of each manager.
- Governance day.

Only one response clearly explained the governance model.

XII- Regulatory text

Article 4: "To ensure that the transport conditions guarantee the proper preservation, integrity and safety of pharmaceutical products and medical devices or related inputs"

22. Are there well-defined and well-known standards or checklist for judging these conditions of transport as valid/invalid?

4 answers

- Yes during the reception operation, the TD shares a checklist with the storekeeper concerning several points: Appearance, color, integrity of the order ....., temperature readings. These checklists are specific to each establishment (internal management).
- In the case of temperature-sensitive products, the product will be accompanied by temperature monitor to give the history of the conditions undergone by the product.
- N / A
- Yes, monitors and transport validations.

The answers mention that the checklists contain several types of tests: organoleptic and tests requiring equipment

23. Are there protocol tests when there are transport modifications/optimizations?

4 answers
- Yes and there is also a contract which clearly defines the different requirements.
- Yes, the distribution centers must be informed by the summary of product characteristics (SPC) of the product.
- N / A.
- Yes, revalidations.

In case of modifications/optimizations, the tests of the protocol are systematically done according to 3 answers, the 4th answer is not clear.

XIII- Regulatory text

Article 4: "to ensure that self-inspections are carried out at regular intervals, according to a pre-established program and that the necessary corrective and preventive measures are put in place"

24. What types of self-inspections are you responsible for?

4 answers
- Storage warehouse inspection, sales department inspection (sales operation)
- Self-inspection of production workshops, Quality control laboratory
- Internal audit
- LI and LII internal audit

The answers mention the various self-inspections carried out at the level of the establishment. Those for which TD pharmacists and assistant pharmacists are responsible.

XIV- Regulatory text

Article 4: "to report to the national pharmaceutical products agency any placing on the national market of a drug or medical device that it considers to be falsified, within the meaning of the legislative and regulatory provisions in force, of which it ensures the manufacturing"

25. Have you ever encountered a similar situation before?

3 answers
- Nope
- Nope
- Yes

One of the responders encountered a counterfeit product.

26. Do you (your establishment) have a vigilance and screening program to detect these counterfeit products? If yes, please illustrate.

3 answers
- Nope
- We have a materiovigilance manager who monitors and collects all incidents related to the use of the products we market.
- Yes, inform the competent authorities.

Each establishment deals differently with the problem of counterfeit products.

XV- Regulatory text

Article 4: "to justify, at any time, that the products manufactured comply with the characteristics which they must meet and that the manufacturing pharmaceutical establishment has carried out the necessary checks"

27. How to justify that the manufactured products comply with the required characteristics and that the necessary checks have been carried out?

4 answers
- By Batch Analysis Certificate.
- The technical director and the sub-director of the quality control laboratory certify with a certificate of analysis comprising all the necessary checks.
- Product specification sheet
- Check all documentation and audit departments with unexpected prawns.

The justification, according to the respondents, is done by documentation.

28. What guarantees the reliability of the latter with the ministry?

4 answers
- Technical documentation
- The quality control laboratory is accredited by ANPP so they are guaranteed
- Validation of the QCL by the ANPP
- Existing data integrity

According to these responses, reliability is guaranteed by the establishment's quality control laboratory, accredited by the ANPP, through the development of technical documentation.

XVI- Regulatory text

Article 4: "to declare to the competent departments of the Ministry responsible for the pharmaceutical industry expired products, incinerated products and provisional production programs"

29. The development of the provisional production program is done at the level of supply chain management by the "demand planner" (also called sales forecaster). Do you attend Sales & Operations (S&OP) meetings?

4 answers
- Yes
- Nope
- Yes
- Yes

All TD pharmacists answered yes, the assistant pharmacist who answered this question denied being present at these meetings.

30. In your opinion, does the sales forecaster have to be a pharmacist to adapt well to the seasonality and volatility of the pharmaceutical products and medical devices market or is only the commercial profile sufficient for this task?

4 answers
- It is not a requirement that he be a pharmacist.
- By a market Access who can be a pharmacist doctor or veterinarian with training in marketing and sales.
- Not necessarily but preferred.
- Not necessarily.

All the answers agree that it is not an obligation but rather a preference for sales forecasters to be pharmacists.

XVII- Regulatory text

Article 4: "to declare, on a weekly basis, to the competent services of the Ministry of the Pharmaceutical Industry the stock status of pharmaceutical products"

31. Is this declaration made at the "miph.gov.dz" site provided by MIP?

2 answers
- Yes
- Yes

The weekly declaration of the state of stock is made at the site level "miph.gov.dz" by affirmation of all the answers.

32. Do you have access to see the stock statuses of competing companies to better understand the status and needs of the market in order to facilitate the development of forecast production/import programs?

3 answers
- Nope.
- No, it's confidential.
- Nope.

According to all the answers the stock status of competing companies is confidential.

XVIII- Regulatory text

Article 11: "The technical director pharmacist working in a radiopharmaceutical product manufacturing establishment must have appropriate training on the aspects of the quality management system specific to this type of medicine and radiation protection skills or be assisted by a person with these skills".

33. Are there centers in Algeria that guarantee such training and are they valid? If so, please tag them.

3 answers
- Nope.
- I don't know about this.
- Nope.

According to the answers, it was concluded that there are no training centers on radiopharmaceuticals in Algeria to their knowledge.

Discussions:

In our study, we target pharmacists within the establishments specifically the TD pharmacists and the assistant pharmacists with a view to their essential place in the establishment in accordance with the legislation provided by the MIP, to understand precisely the missions of these two positions on the field. The choice was towards different establishments with different pharmaceutical activities and which produce drugs and medical devices. It was noted that the majority of this population are young pharmacists.

The answers of our study are useful to clarify certain points which were not perfectly clear in the official journal, after the census and the analysis of the answers we concluded the following:

About the deliberations of the administrative or supervisory bodies of the pharmaceutical establishment and the judgment on the susceptibility of these deliberations, whether or not they affect the exercise of the missions of the TD pharmacist.
According to the results obtained, the establishments treat this crucial point differently; some see that it is preferable to make this judgment by the general manager. Others see that the TD pharmacist is responsible for this judgment.
We see that this judgment must be made only by the TD pharmacist, since he is the only one who can make such judgment to guarantee that the decisions taken during these deliberations do not pose any risk to public health.

Pharmaceutical establishments provide the quality management system. The validating authority defers this between the establishments as concluded from the results. The application of this system is one of the missions of TD pharmacist, and the keeping of the optimization of the latter in continuation up-to-date, using multiple sources mainly the national and international standards.

One of the missions of the TD pharmacist is to ensure the manufacture of batches in accordance with the legislation and regulations in force and in compliance with the requirements set out in the registration decision or the approval decision.
This assurance is done by controls carried out before, during and after the manufacturing process for each batch of finished product. The authorities which ensure compliance with these regulations are the MIP and the ANPP through inspections, technical-regulatory controls and the analysis of samples.
QCL under the supervision of the TD pharmacist carries out the controls and attests to them by the batch analysis certificate; the ANPP accredits the document provided by QCL.

The TD pharmacist's missions are so vast that he cannot accomplish them alone; the MIP has given him the power to share his missions with all personnel occupying positions of responsibility relating to the conformity of a batch, so that the TD pharmacist ensures both the sharing and decentralization of tasks and the individual aspect of responsibility. It must be the subject of a written procedure which begins with the descriptive job of the assistant and always checks the work of his assistant in order to assume his responsibility as the sole validator.

The TD pharmacist is required to ensure that the transport conditions guarantee the proper storage, integrity and safety of pharmaceutical products and medical devices or related inputs. To ensure this mission, he follows, in collaboration with the storekeeper and the store team, protocol tests affecting several points: Appearance, color, integrity of the order, temperature reading. Each establishment has its own checklists for each product.
All changes to transport conditions must comply with the internal requirements of the establishment, and be subject to protocol tests to be revalidated.

The assistant pharmacists aim to help the TD pharmacist to accomplish his missions. The number of assistant pharmacists is fixed by the MIP in relation to the number of staff, proving to be satisfactory for all responders.
The recruitment process is done in collaboration between the management of the establishment and the TD pharmacist on these two sites LINKEDIN and EMPLOITIC. Each establishment has its own selection criteria.

The provisional import program must be accompanied by documents and statistics, as detailed in the note published by the MIP on August 17, 2021

The provisional production programs must be declared to the competent services of the ministry responsible for the pharmaceutical industry by the TD pharmacist. The development of these programs is done at the level of supply chain management by the sales forecaster who does not have to be a pharmacist but rather a preference to adapt well with the seasonality and volatility of the market for pharmaceutical products and medical devices.
TD pharmacists are expected to attend sales and operations (S&OP) meetings, unlike assistant pharmacists who are not concerned to attend these meetings.

Since the encounter with falsified products is rare, pharmaceutical establishments do not have very vigilant or rigorous protocols to detect these products.

When R&D programs are carried out with its different objectives in pharmaceutical establishments. The TD pharmacist is required to participate in all programs with public health objectives.

The sample of our study had never encountered the manufacture of advanced therapy. Regarding the manufacture of radiopharmaceuticals, the MIP required training to deal with these

dangerous substances, according to our study, there are no training centers on these products in Algeria.

The declaration of the stock status of pharmaceutical products is done weekly by the TD pharmacist on the site “miph.gov.dz”. The inventory status of competing companies is confidential.

The TD pharmacist is required to continuously optimize the training programs. The sources of these optimizations differs, but generally obtained from the national and international norms.

Conclusion:

Pharmacy is a multidisciplinary science so it allows pharmacists to access different professional fields (laboratory, hospital, retail and industry). The pharmaceutical industry represents an enormous field which can host several occupations for a pharmacist to exercise his abilities.

As final year students, we encounter the crossroads of finding the best career that matches our personal skills. Through our years of study, we have tried to collect as much information as possible in our society (students, former colleagues of the company) but the industrial field has always remained a mystery for us and we were unable to collect enough information with available sources to paint a clear picture of the professional background, so we have done this work in the hope of providing clarity not only for ourselves but also for other students and recently graduated pharmacists.

The recent creation of the new separate ministry has made it possible to improve the pharmaceutical industry and has succeeded in initiating progress, particularly on the legislative level. This step was our guide that led us to collect a significant amount of information that helped us to accomplish our work and deepen our knowledge to solve the lack of information among students.

One of the key elements that we discover through our work is the implication of legislation in this area. The pharmacist is required to have a perfect knowledge of the laws to be able to exercise his functions in an appropriate manner.

The technical director pharmacist has a large number of missions whose tasks must be delegated to assistant pharmacists so that he can properly and fully assume his responsibility in relation to the regulations in force.

Bibliographic references:

(1) Edge of the 11 Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the pharmacist technical director and pharmacist assistants of the pharmaceutical manufacturing establishment. Article 2.

(2) Hamadi A.: "Towards a systemic approach to governance: the case of access to medicines in Algeria", Doctoral thesis in economics, University Lille 1, 2013, p. 97.

(3) Ziani F.: "Analysis of drug consumption in Algeria: case of the wilaya of Sétif", thesis of magister in economics, A.MIRA University of Bejaia, 2010, p.64.

(4) Hamadi A, op.cit, p. 97.

(5) https://www.socothyd.com/new/reseau.php.

(6) Belhacene O. and Ferfera MY. : "The contrasting effects of the involvement of foreign laboratories in the Algerian pharmaceutical industry", Algeria, International Colloquium, Fifty years of experience in State-Economy-Health development, 2014, p.55.In:https:// www.ajol.info/index.php/cread/article.

(7) http://www.saidalgroup.dz.

(8) Hamadi A, op, cit, p98

(9) Official Journal of the Algerian Republic n°16 of 18/04/1990.

(10) Official Journal of the Algerian Republic n°34 of 11/08/1990.

(11) Official Journal of the Algerian Republic n°64 of 10/10/1993.

(12) Belhacene O. and Ferfera MY.: op.cit. p.56.

(13) Official Journal of the Algerian Republic n°53 of 12/07/1992.

(14) Order n°46 of the Minister of Health of 07/10/1998.

(15) CNOP. : "Issues and perspectives of the pharmaceutical environment in Algeria", Paris, 2008, p.2.

(16) Joint-stock company resulting from the restructuring of the three PHARMS, created on September 24, 1997.

(17) http://www.saidalgroup.dz.

(18) https://www.saidalgroup.dz/qui-sommes-nous/

(19) Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 2.

(20) Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 3.

(21) Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 7.

(22) Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 4.

(23) Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 7.

(24) Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 5.

(25) Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 6.

(26) Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 7.

(27) Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry. Article 4.

(28) Executive Decree No. 20-271 of 11 Safar 1442 corresponding to September 29, 2020 setting the powers of the Minister of the Pharmaceutical Industry. Article 8.

(29) https://www.miph.gov.dz/fr/le-ministere/organigramme/
(30) Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry.
(31) Executive Decree No. 20-273 of 11 Safar 1442 corresponding to September 29, 2020 on the organization and operation of the general inspectorate of the Ministry of the Pharmaceutical Industry. Article 3.
(32) Executive Decree No. 20-273 of 11 Safar 1442 corresponding to September 29, 2020 on the organization and operation of the general inspectorate of the Ministry of the Pharmaceutical Industry. Article 4.
(33) Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry. Article 2.
(34) Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry. Article 3.
(35) Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry. Article 4.
(36) Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry. Article 5.
(37) Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry. Article 6.
(38) Executive Decree No. 20-272 of 11 Safar 1442 corresponding to September 29, 2020 on the organization of the central administration of the Ministry of Pharmaceutical Industry. Article 7.
(39) Business economics by Abderraouf MTIRAOUI- P 04
(40) Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 3.
(41) Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 5.
(42) Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 2.
(43) Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 6.
(44) Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 8.
(45) Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 7.
(46) Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 9.
(47) Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 10.
(48) Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 11.
(49) Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 12.
(50) Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 13.
(51) Department of Blida- 2019-2020- Dissertation Title: Drug marketing strategy and plans: Typical marketing plan for a locally produced generic by –Alili Mohamed El Amine, Arabji Youcef and Benmiloud Mohamed Nossair- Figure 2.
(52) Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 14.

(53) Executive Decree No. 21-82 of 11 Rajab 1442 corresponding to February 23, 2021 relating to pharmaceutical establishments and the conditions for their approval. Article 15.
(54) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the elements of the application file for approval of the pharmaceutical manufacturing establishment, the procedures for processing the file as well as the list of substantial modifications. Chapter 1.
(55) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the elements of the application file for approval of the pharmaceutical manufacturing establishment, the procedures for processing the file as well as the list of substantial modifications. Chapter 2.
(56) Order of 9 Rabie Ethani 1443 corresponding to November 14, 2021 setting the elements of the application file for the approval of the operating pharmaceutical establishment, the procedures for processing the file, as well as the list of modifications of a substantial nature. Chapter 1.
(57) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the elements of the application file for approval of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices, the procedures for processing the file as well as the list of modifications substantial. Chapter 1.
(58) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the elements of the import pharmaceutical establishment approval application file, the procedures for processing the file as well as the list of substantial modifications. Chapter 1.
(59) GUIDE TO GOOD MANUFACTURING PRACTICES, Anfel Bouarrata.
(60) Executive Decree No. 22-247 of Aouel Dhou El Hidja 1443 corresponding to June 30, 2022 relating to the rules of good manufacturing practice for pharmaceutical products for use in human medicine. Chapter 1.
(61) Executive Decree No. 22-247 of Aouel Dhou El Hidja 1443 corresponding to June 30, 2022 relating to the rules of good manufacturing practice for pharmaceutical products for use in human medicine. Chapter 2.
(62) Executive Decree No. 20-325 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the registration procedures for pharmaceutical products. Chapter 2.
(63) Executive Decree No. 20-325 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the registration procedures for pharmaceutical products. Chapter 2, Section 1.
(64) Executive Decree No. 20-325 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the registration procedures for pharmaceutical products. Chapter 2 Section 2.
(65) University of Batna 2. Department of Pharmacy Module: Industrial Pharmacy (5th year) -Dr. Ouahab Ammar- Marketing authorization (3.1. Registration process in Algeria).
(66) Executive Decree No. 20-325 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the registration procedures for pharmaceutical products. Chapter 2, Section 2.
(67) Executive Decree No. 20-325 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the registration procedures for pharmaceutical products. Chapter 2, Section 3.
(68) Executive Decree No. 20-324 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the procedures for the approval of medical devices. Chapter 2.
(69) Executive Decree No. 20-324 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the procedures for the approval of medical devices. Chapter 2, Section 1.
(70) Executive Decree No. 20-324 of 6 Rabie Ethani 1442 corresponding to November 22, 2020 relating to the procedures for the approval of medical devices. Chapter 2, Section 2.
(71) http://www.saidalgroup.dz.
(72) Belhacene O.et Ferfera MY.: op.cit., p.65.
(73) https://www.pasteur.dz/fr/presentation/histoire.
(74) https://www.socothyd.com/new/reseau..php
(75) http://www.pch.dz
(76) https://www.biopharmdz.com/index.php
(77) https://merinal.com/about-us.html

(78) http://bekerlaboratoires.com/
(79) Belhacene O.and Ferfera MY. op.cit, p 63.
(80) Les cahiers du cread n°107-108 2014 THE CONTRASTING EFFECTS OF THE INTERVENTION OF FOREIGN PHARMACEUTICAL LABORATORIES IN THE ALGERIAN SECTOR OF THE PHARMACEUTICAL INDUSTRY by Ouerdia BELLAHCENE and Mohamed Yassine FERFERA
(81) http://www.novonordisk.dz/about-novo-nordisk/novo-nordisk-algeria.html,
(82) Art 249 of law n°18-11 of July 02, 2018.
(83) The National Pharmaceuticals Agency: A Dark Future. April 15, 2018 by SN
(84) http://www.anpp.dz/presentation.html
(85) https://www.ich.org/page/history
(86) https://www.ich.org/page/mission
(87) https://www.fda.gov/about-fda/fda-history
(88) https://www.fda.gov/about-fda/what-we-do#mission
(89) EMEA becomes EMA 14th December 2009
(90) https://www.ema.europa.eu/en/about-us/history-ema
(91) https://www.iracm.com
(92) Guillaume VDR. : "Can we defend the pharmaceutical industry", p 102.
(93) ICH Guidelines.
(94) https://www.interpharma.ch
(95) Abecassis PH. and Coutinet N.: Op.cit., p. 116.
(96) https://www.inserm.fr/dossier/medicament-developpement/
(97) https://www.msdmanuals.com.
(98) P PAURICHE, F.RUPPRECHT op.cit., p. 9.
(99) LEEM. : Op.cit., p.47.
(100) LEEM. : Economic report, Op.cit., p.44
(101) Pinel J.: “Counterfeit and sub-standard medicines: a life-threatening situation”, p 6.
(102) Young people, chemistry and life sciences. : “The pharmaceutical industry and biotechnologies”, Educational dossier produced as part of the conference programme, p6.
(103) Amendment of Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.
(104) Pauriche P. and Rupprecht F.: op.cit, p 12.
(105) https://www.efpia.eu/about-medicines/development-of-medicines/intellectual-property/supplementary-protection-certificates/
(106) Public Health Code (article L.5211-1).
(107) https://www.ordre.pharmacien.fr/Les-pharmaciens/Le-metier-du-pharmacien/Fiches-metiers/Officine/Pharmacien-titulaire-d-officine
(108) https://www.ordre.pharmacien.fr/Les-pharmaciens/Le-metier-du-pharmacien/Fiches-metiers/Etablissements-de-sante/Pharmacien-hospitalier
(109) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article11.
(110) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article12.
(111) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article13.
(112) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article14

(113) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article15

(114) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article16

(115) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article18

(116) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article17

(117) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article2

(118) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article3

(119) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article5

(120) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article 4

(121) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article6

(122) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article7

(123) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article9

(124) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article8

(125) Order of 11 Dhou El Kaâda 1442 corresponding to June 22, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the pharmaceutical manufacturing establishment. Article10

(126) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article12

(127) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article15

(128) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article 13

(129) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article 14

(130) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article16

(131) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article11

(132) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article3

(133) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article9

(134) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article2

(135) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article5

(136) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article8

(137) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article4

(138) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article6

(139) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article10

(140) Order of 15 Joumada El Oula 1443 corresponding to December 20, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the import pharmaceutical establishment. Article7

(141) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article12.

(142) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article15.

(143) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article13.

(144) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article14.

(145) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article16.

(146) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article 11.

(147) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article3.

(148) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article9.

(149) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article2.

(150) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article5.

(151) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article8.

(152) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article4.

(153) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article6.

(154) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article7.

(155) Order of 25 Rabie Ethani 1443 corresponding to November 30, 2021 setting the missions and qualifications of the technical director pharmacist and assistant pharmacists of the operating pharmaceutical establishment. Article10.

(156) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article12.

(157) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 13.

(158) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 16.

(159) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 14.

(160) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 15.

(161) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 17.

(162) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article11.

(163) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 3.

(164) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article9.

(165) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 2.

(166) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 5.

(167) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 8.

(168) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 4.

(169) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 6.

(170) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 10.

(171) Order of 27 Safar 1443 corresponding to October 5, 2021 setting the missions and qualifications of the technical director pharmacist and the assistant pharmacists of the pharmaceutical establishment for the wholesale distribution of pharmaceutical products and medical devices. Article 7.

(172) https://www.leem.org/index.php/referentiels-metiers/directeurrice-de-production

(173) https://www.leem.org/referentiels-metiers/responsable-de-fabrication-etou-de-conditionnement

(174) https://www.leem.org/referentiels-metiers/responsable-laboratoire-de-controle

(175) http://www.leem.org/article/mise-en-concurrence-pour-lobservatoire-de-l-information-promotionale, “Competition for the Observatory of Promotional Information

(176) Hubert. K, Function: marketing product manager, Towards the mastery of business tools and skills 6th edition (2013), Dunond.

(177) https://www.leem.org/referentiels-professions/directeurtrice-regionale

(178) http://www.leem.org/article/mise-en-concurrence-pour-lobservatoire-de-l-information-promotionnelle

(179) https://www.leem.org/referentiels-professions/directeurtrice-marketing

(180) https://www.miph.gov.dz/fr/provisional-programmes-of-import-exercise-2022/

Abstract:

The pharmaceutical industry is one of the strategic economic sectors in the world. The pharmacist is a key element of this industry and participates in all the different activities from the research phase to the marketing phase.

This work is a descriptive study of the pharmaceutical industry filed in Algeria. And the significant contribution of the pharmacist in the latter. With its different roles in many periods of the life cycle of drugs and medical devices. The purpose of which is to clarify and better understand this contribution and the determination of the missions and objectives of each job a pharmacist occupies.

This practical study allowed us to understand the execution of missions by the technical director pharmacist and his assistants on the field of work, and also how to delegate his tasks and how to coordinate with his assistants to share his duties while keeping his responsibilities.

Résumé:

L'industrie pharmaceutique est l'un des secteurs économique stratégique dans le monde. Le pharmacien consiste un élément clés de cette industrie et participe dans tous les différentes activités dès la phase de recherche jusqu'à la commercialisation.

Ce travail est une étude descriptive de l'industrie pharmaceutique déposée en Algérie. Et l'apport non négligeable du pharmacien dans ce dernier. Avec ses différents rôles dans de nombreuses périodes du cycle de vie des médicaments et des dispositifs médicaux. Dont le but est de clarifier et de mieux comprendre cet apport et la détermination des missions et objectifs de chaque poste que le pharmacien occupe.

Cette étude pratique nous a permis d'appréhender l'exécution des missions par le directeur technique pharmacien et ses assistants sur le terrain de travail, et aussi comment déléguer ses tâches et comment se coordonner avec ses assistants pour partager ses tâches tout en gardant ses responsabilités.

الملخص:

تعتبر صناعة الأدوية من القطاعات الاقتصادية الإستراتيجية في العالم. الصيدلي هو عنصر أساسي في في هذه الصناعة ويشارك في جميع الأنشطة المختلفة من مرحلة وصولا إلى مرحلة التسويق.

هذا العمل عبارة عن دراسة وصفية لصناعة الأدوية في الجزائر. والمساهمة الكبيرة للصيدلي فيهذاالأخير. مع أدوارها المختلفة في فترات عديدة من دورة حياة الأدوية والأجهزة الطبية والغرض منها هو توضيح هذه المساهمة وفها بشكل أفضل وتحديد مهام وأهداف كل وظيفة يشغلها الصيدلي.

أتاحت لنا هذه الدراسة العملية فهم تنفيذ المهام من قبل المدير الفني الصيدلي ومعاونيه في مجال العمل ، وكذلك كيفية تفويض مهامه وكيفية التنسيق مع مساعديه لتقاسم واجباته مع الحفاظ على مسؤولياته.