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Legal Obligations of Pharmaceutical Products as Guarantees for Consumer Protection

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Abstract---In the context of product liability rules, pharmaceutical manufacturers have several key obligations, including informing consumers, ensuring product safety, and providing guarantees against hidden defects. They must also comply with established production standards and norms. However, manufacturers' responsibility is heightened in the case of pharmaceutical products, given their significant impact on human health and safety.

Keywords---manufacturer, civil liability, obligations, pharmaceuticals, consumer.

Introduction

Due to the complex nature of pharmaceutical products and the associated health and safety risks, lawmakers and the judiciary have devoted considerable attention to safeguarding consumers against the inherent power imbalance between them and manufacturers. This has been achieved through the establishment of a legal framework that imposes several fundamental obligations on manufacturers. These include informing consumers of the specifications and potential risks of medications, guaranteeing against hidden defects and ensuring products conform to applicable scientific and regulatory standards. These obligations demonstrate a commitment to fostering consumer confidence in pharmaceutical products and ensuring they are circulated within a legally responsible framework.

Problem statement:

To what extent are these obligations effective in providing consumers with actual protection against the knowledge and technical imbalance with pharmaceutical manufacturers? Additionally, how successfully

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have lawmakers balanced regulating these obligations with preventing risks and mitigating their effects when they occur?

Chapter One: Preventive Obligations for Consumer Protection Against Pharmaceutical Products

Due to the unique nature of pharmaceutical products, which are characterised by their complex composition and potential dangers to human health, lawmakers have established a set of preventive obligations for pharmaceutical manufacturers. These obligations aim to minimise potential risks before the product reaches consumers. The two main obligations are the obligation to inform (Section One), which ensures consumers are fully aware of a drug's characteristics, usage and side effects, and the obligation to comply (Section Two), which requires manufacturers to provide drugs that meet scientific and regulatory standards.

Section One: The Obligation to Inform in the Pharmaceutical Field

Scientific advancements in product manufacturing necessitate the enforcement of this obligation[1]. Due to technological developments impacting all areas of life, particularly in the medical field, and the unique nature of pharmaceutical products, it is essential that consumers have the right to be informed when purchasing medications. This right serves two purposes: first, to empower consumers with knowledge[2] (Subsection One), and second, to enable them to use the product correctly, avoiding misuse and consequent harm (Subsection Two).

Subsection One: Definition of the Obligation to Inform

Law No. 04-02, dated 23 June 2004, outlines the rules applicable to commercial practices[3] and is one of the key texts through which the Algerian legislator enshrined the obligation to inform, as a means of protecting the weaker party and enhancing transparency in transactions. Article 8 defines the obligation to inform as follows: 'A legal obligation that precedes the conclusion of the sale, whereby the intervenor informs the consumer about the nature of the product being sold, providing honest and truthful information about its features and any risks arising from it.'

Pharmaceutical products have a unique status due to the continuous human need for them. Therefore, while the obligation to inform is a fundamental pillar of consumer protection, it is of particular importance in the realm of pharmaceuticals, especially medications. Information regarding pharmaceutical products is crucial in ensuring the effectiveness of the product and the safety of consumers[4].

The obligation to provide information is explicitly stated in Article 194 of the Health Protection and Promotion Act, which states: 'Medical and scientific information regarding pharmaceutical substances and medical supplies used in human medicine is mandatory. This information must be accurate, verifiable and consistent with the published medical and scientific research data."

Pharmaceutical manufacturers and other specialised stakeholders in medical promotion are responsible for providing medical and scientific information, as well as advertising, relating to pharmaceutical substances and medical supplies used in human medicine.

As set out in the aforementioned article, the obligation to inform in the pharmaceutical field has a distinct nature in terms of its mandatory nature, adherence to accuracy and verifiability, and the

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1- There are multiple terms that indicate the obligation to inform. Some scholars refer to this obligation as the 'obligation to enlighten', while others call it the 'obligation to disclose' or 'inform'.

2- Youcef Zahiya Houria, 'The Obligation to Disclose as an Element of Ensuring Consumer Safety', Critical Journal of Law and Political Sciences, Faculty of Law, University of Mouloud Mammeri, Tizi Ouzou, Issue 02, 2009, p. 56.

3- Official Journal (J.R.) No. 41, published on 27 June 2004 and amended and supplemented by Law No. 10-06, dated 15 August 2010 (J.R. No. 46, published on 18 August 2010).

4- Mer Sihem, 'Drugs and the Specificity of Obligations Imposed Within Its Scope', Legal Studies, Centre for Insight Research, Consulting and Educational Services, Algeria, Issue 18, August 2013, p. 18.

necessity of aligning with and complying with scientific data and ongoing research in the pharmaceutical and medical fields[5].

The scope of the obligation to inform in the pharmaceutical sector goes beyond the essential information required by general civil law principles[6]. For instance, Article 352, paragraph one of the Civil Code stipulates[7] that the buyer must have sufficient knowledge of the item sold, which is deemed sufficient if the contract includes a description of the item and its essential characteristics, enabling its identification.

Additionally, Article 12 of the Ministerial Decree of 30 October 2008, which specifies the technical specifications for the import of pharmaceutical products and medical supplies for human use, outlines the information to be included on the inner and outer packaging of drugs. Article 13 further stipulates that usage instructions must be included within the package of the pharmaceutical product.

Subsection Two: The Content of the Obligation to Inform

The obligation to inform arose from the serious nature of the product, which can be attributed either to its inherent characteristics or to the complexity of its use. Often, these two factors coexist in a single product, as is the case with medications. This makes it challenging for an ordinary person to understand how to use complex or hazardous products correctly[8].

Against this backdrop, the Algerian legislator has intervened, mandating that all stakeholders must inform consumers of all product-related information. According to Article 17 of the Consumer Protection[9] and Fraud Suppression Law: 'Every stakeholder must inform the consumer of all information related to the product they offer for consumption, whether through labelling or any other appropriate means.'

Manufacturers must provide consumers with the necessary information on how to use the medication, since consumers are ultimately the users of the product[10]. As a specialist who is or should be knowledgeable about the product's components and the risks it poses, the manufacturer has two duties towards the consumer.

1. The First Duty: Instructions for Use

The manufacturer must provide guidance on the essential characteristics of the drug, including how to use it, how many doses to take, how much to take per dose, when to take it, and how to administer it[11]. This helps to avoid risks arising from incorrect usage.

If consumers deviate from the prescribed method of use and the intended purpose of the medication (often outlined in leaflets attached to the packaging), they are responsible for their actions and the manufacturer is not liable for any resulting harm[12]. However, if a consumer uses the drug as directed

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5- Article 10 of Executive Decree No. 12-203, which concerns the rules applied in the field of product safety, states: 'Producers, importers and service providers must provide consumers with all the necessary information to enable them to avoid potential risks associated with the consumption and/or use of the product or service throughout its normal life or reasonable expected lifespan...' However, Article 3 of the same decree excludes medical devices and chemical products that are subject to specific legislative and regulatory provisions. This indicates that medicine, as a chemical product, does not fall under the provisions of this decree.

6- Source: Mer Sihem, 'Drugs and the Specificity of Obligations Imposed Within Its Scope', Legal Studies, p. 20.

7- It states: 'The buyer must be sufficiently informed about the subject of the sale. Knowledge is considered sufficient if the contract includes a description of the sale and its essential characteristics so that it can be recognised...'

8- Amazouz Latifa, 'The Seller's Obligation to Provide Information as a Subsidiary Obligation to the Obligation of Delivery', Algerian Journal of Legal, Economic and Political Sciences, Faculty of Law, University of Algeria, Issue 3, 2009, p. 96.

9- Law No. 09-03 concerning consumer protection and combating fraud, amended and supplemented by Law No. 18-09 dated 10 June 2018 (J.R. No. 35), published on 13 June 2018.

10- Hamadi Saliha, 'The Responsibility for Pharmaceutical Products', Master's Thesis in Private Law, Faculty of Law, University of Aboubakr Belkaid, Tlemcen, 2011/12, p. 17.

11- Mer Sihem, 'Drugs and the Specificity of Obligations Imposed Within Its Scope', p. 20.

12- Akrim Mahmoud Hussein Al-Badwi, 'The Obligation to Disclose as a Means of Ensuring Safety', Al-Rafidain Journal of Law, Vol. 1, Issue 24, 2005, p. 9.

but still suffers harm due to failing to take necessary precautions, merely stating the method of use is not sufficient to guarantee consumer safety.

2. The second duty: warning of risks

The manufacturer has an obligation to alert users to the potential risks associated with the medication and the necessary precautions to avoid these risks, not just to state how to use the medication. This obligation to warn complements the obligation to provide[13] usage instructions.

The duty to warn involves detailing side effects, such as advising allergy sufferers against taking penicillin, warning heart patients about certain medications and cautioning against leaving the medication within reach of children[14]. This is achieved by highlighting all the precautions patients must take when using the medication.

Under Article 41 of Executive Decree No. 13-378, the Algerian legislator stipulated the necessity of warning about the risks of using products. This article defines the conditions and procedures related to consumer information[15]. It states: 'Information regarding the precautions for using non-food products must include warnings about the associated risks, according to their nature and intended use.'

Information about the risks associated with medications is provided through printed labels affixed to the packaging, which include all relevant data about the drug, such as its manufacturing and expiry dates and its components. This information is also provided in the package insert, which outlines the indications for use, possible side effects and other necessary information, taking into account the form and nature of the drug[16].

In this context, we present a case that was heard by the French Court of Cassation and summarise it as follows: A woman (Ms M) visited her doctor for treatment for severe obesity after childbirth and was prescribed the drug 'L'Isoméride'. A few days later, she developed pulmonary hypertension, necessitating surgery.

She filed a lawsuit against the manufacturer of 'L'Isoméride', Ardix, but the court acquitted Ardix of the charges on the grounds that it had provided all the necessary information about 'L'Isoméride' in the package insert, which clearly outlined the risks for people with severe obesity.

However, the French Court of Cassation held the treating physician liable for breaching his obligations by prescribing the medication despite being aware of the potential dangers it posed to the patient's health[17].

Subsection Two: The Obligation of Warranty in Pharmaceuticals

A warranty is an important means by which consumers can compel the seller to deliver a sound, defect-free product. However, the modern concept of a defect is now based on product safety and the risks associated with its use.

First: The obligation to guarantee against hidden defects

Similar to the French and Egyptian legislatures, the Algerian legislator has not defined hidden defects, but has specified the conditions that must be met for a hidden defect to warrant a guarantee.

Article 379 of the Civil Code outlines the criteria for hidden defects: the absence of qualities guaranteed by the seller at the time of delivery to the buyer; or a defect in the sold item that reduces its value or utility for its intended purpose.

13-Muhammad Ahmed Al-Ma'adawi, 'Civil Liability for Dangerous Product Actions (Comparative Study)', Dar Al-Jami'a Al-Jadida, Alexandria, 2007, p. 226.

14-Ahmad Al-Said Al-Zaqrd, 'The Medical Prescription (Ticket) Between Legal Concept and Civil Liability of the Pharmacist', Dar Al-Jami'a Al-Jadida, Alexandria, 2007, p. 135.

15- J.R. No. 58, dated 9 November 2013 and published on 18 November 2013.

16-The information that constitutes the identity card of pharmaceutical products does not include information related to pharmacy science, treatment or scientific publications, but rather the drug leaflet, which includes information on the drug's expiry date, potential adverse effects of consumption, side effects and conditions under which it should not be used. For more details:
Source: Hannouz Mourad and Khadir Mohammed, Elements of Pharmaceutical Law (For the Use of Pharmacy and Law Professionals), Office of University Publications, Algeria, 2000, p. 84.

17- Cass., Civ. 1, 24 January 2006, No. 02-16648. Available at: www.legifrance.gouv.fr. Visited on 20 May 2016.

A product defect can be defined as either a flaw that damages or destroys the item (materially), or a defect that affects the item's characteristics in such a way that it becomes unfit for its intended use (functionally). This definition is similar to that of a defect in the item itself.
A product defect may originate from its design and composition or from its manufacturing process, which may involve the omission or disregard of necessary technical standards during production. Additionally, a defect may arise if adequate precautions are not taken during design, assembly, preparation for consumption, storage, packaging, display or usage to prevent or warn of potential harm.

1. Conditions for hidden defects warranting a guarantee:

For a claim regarding hidden defects to be accepted, certain general conditions must be met. We will address these conditions and how they apply to the civil liability of the manufacturer for drug-related damages.
The defect must have existed at the time of delivery, as referred to in Article 379 of the Civil Code, which states that the defect must have been present 'at the time of delivery'. Therefore, the manufacturer is not liable for defects that appear after delivery of the drug to the consumer, especially if the consumer has failed to follow usage instructions, which may render the product defective.
The defect must also reach a level of severity that could potentially exacerbate the user's illness.
- The defect must be hidden, meaning the consumer could not easily detect it when purchasing[18] the drug.
- The consumer must be unaware of the defect. If the buyer proceeds with the purchase while being aware of the defect and does not speak up about it, this indicates acceptance of the product in its current state and constitutes a waiver of the right to seek a guarantee[19]. This is supported by Article 379, paragraph two of the Civil Code, which states: 'However, the seller shall not be liable for defects of which the buyer was aware at the time of sale, or which they could have discovered by examining the product as a reasonable person would.'
Given the serious risks they may pose to consumers' lives, it is unreasonable to expect them to accept existing defects in medication. However, when it comes to hidden defects, it is necessary to distinguish between professional buyers and ordinary consumers. For the latter group, a defect is considered hidden if they lack the technical means to identify or recognise it[20]. In contrast, the former can more easily identify defective pharmaceutical products as specialists.

2. Provisions of the Guarantee

The harmed party must prove the existence of a hidden defect in the medication that caused the damage. This involves demonstrating the conditions necessary to guarantee the defect. To obtain compensation for all damages incurred — more than just those caused by the defect, particularly in the case of defects in medical products and drugs[21] — the harmed party must prove that the manufacturer was aware of the defect when the medication was placed on the market.
However, the judiciary has ruled that manufacturers must compensate for damages arising from defects in the items they produce, regardless of their awareness of these defects[22]. Courts have likened manufacturers to bad-faith sellers due to their professional expertise and presumed knowledge of defects in sold items. Consequently, manufacturers are liable for all damages incurred by the buyer[23].

18- Youcef, Fatiha, 'Consumer Protection in the Field of Pharmacy', Algerian Journal of Legal, Economic and Political Sciences, Faculty of Law, University of Algeria, Part 30, Issue 1, 2002, p. 61.
19- Mohammad Sabri Al-Saadi, 'The Clear Explanation of the Civil Code (Sale and Exchange Contracts: A Comparative Study of Arab Laws)', Dar Al-Huda for Printing, Publishing and Distribution, Algeria, 2008, p. 384.
20- Bensouissi, Khira, 'Pharmaceutical Work', Legal Conference Journal, Issue 1, 2013, p. 178.
21- Ousama Ahmed Badr, 'Guaranteeing the Risks of Medical Products (Comparative Study)', Dar Al-Jami'a Al-Jadida, Alexandria, 2005, p. 143.
22- Jaber Mahjoub Ali, 'Ensuring Consumer Safety from Damages Arising from Defects in Sold Industrial Products (A Study in Kuwaiti Law and Egyptian and French Laws)', Part One, Journal of Rights, University of Kuwait, Issue 1, January 1981, p. 221.
23- Civ. 1re, 19 January 1965, D. 389; RTD civ. 1965. 665. Available at: http://fiches.dalloz-etudiant.fr/droit-prive [Accessed 19 February 2015].

Hidden defects in medication cannot be revealed by conventional means, which makes them challenging to detect, regardless of whether the user is a professional. Therefore, the obligation to provide a guarantee is even more critical here, as we are dealing with a defect that can be considered more than just hidden.

Second: the obligation to ensure safety

The obligation to ensure safety is a concept born out of necessity. It arose from the occurrence of damage that was not covered by existing legal texts at the time[24]. This prompted legal scholars to seek solutions, while the judiciary aimed to keep pace with continuous scientific and technological advancements and address the legal issues they produce.

The obligation to ensure safety means that every product must provide guarantees against all risks that could affect consumers' health and safety or harm their material interests. Stakeholders must compensate individuals or property owners for any harm caused by defects, or face the penalties prescribed by law[25].

This obligation is a subsidiary contractual obligation requiring the professional debtor to protect people's health and safety from all risks[26]. Sometimes, a product may be free from defects yet still possess inherent dangers that could suddenly harm the consumer's health or property[27].

The judiciary has recognised this obligation, which legislators have adopted to guarantee the rights of victims by providing compensation for damages, even if these damages arise from causes that science does not yet understand[28].

For example, the Aix-en-Provence Court of Appeal ruled that the dangerous nature of pharmaceutical products and their potential contamination with disease-causing viruses establishes the manufacturer's liability, which cannot be dismissed due to a lack of knowledge about these viruses, given that they could not be detected using the scientific and technological capabilities available at the time the drugs were produced[29].

Manufacturers have a duty to ensure the safety of their products and to avoid harming consumers' lives or health[30]. Under Article 10 of the Consumer Protection and Fraud Suppression Law, the Algerian legislator emphasised the necessity of ensuring the safety of products placed on the market. Article 9 of the same law also states that products must not endanger consumer health, safety or interests.

Pharmaceutical products are characterised by their complexity and risk, and are essential for human health. Consequently, manufacturers and sellers are obliged to guarantee their safety during consumption[31]. Article 11, paragraph 1 of the amended Consumer Protection and Fraud Suppression Law stipulates that 'every product offered for consumption must meet the legitimate expectations of consumers regarding its nature, type, origin, essential characteristics, composition, necessary components, identity, quantity, usability and risks arising from its use'.

24- Fatak Ali, 'Consumer Protection and the Impact of Competition on Product Safety Assurance', 1st edition, Dar Al-Fikr Al-Jami'i, Alexandria, 2014, p. 194.

25- Fatak Ali, 'Consumer Protection and the Impact of Competition on Product Safety Assurance', Previous Reference, p. 196.

26- Philippe Le Tourneau, 'The Responsibility of Sellers and Manufacturers', Dalloz, Paris, 1997, p. 24.

27- Jaber Mahjoub Ali, 'Ensuring Consumer Safety from Damages Arising from Defects in Sold Industrial Products', Previous Reference, p. 212.

28- Mer Sihem, 'The Producer's Obligation for Safety: A Comparative Study', Master's thesis submitted for the Master's degree in Private Law, Faculty of Law, University of Aboubakr Belkaid, Tlemcen, 2008/09, p. 29.

29- Mohammad Raed Mahmoud Abdu Al-Dalal, 'Civil Liability of Pharmaceutical Producers for Defects in Pharmaceutical Products (Comparative Study)', Master's thesis submitted for the Master's degree in Private Law, Faculty of Law, University of the Middle East, 2011, p. 23.

30- Diden Bouazza, 'Market Circulation of Drugs in Consumer Law', Algerian Journal of Legal, Economic and Political Sciences, Faculty of Law, University of Algeria, Issue 3, 2008, p. 210.

31- Abdel Rahman Hadibi, 'Civil Liability for Drug Circulation', Master's thesis submitted for the Master's degree in Law, Contract and Liability Branch, Faculty of Law, Ben Aknoun, University of Algeria 1, 2011/12, p. 35.

Although there is no direct contractual relationship between consumers and manufacturers, consumers can hold manufacturers accountable for their obligation to ensure the safety of pharmaceutical products[32].

The assessment of a drug's safety is tied to its development, which is subject to strict regulatory frameworks that are regularly enhanced due to the increasing demand for safety[33].

Manufacturers must stay informed about developments in pharmaceutical science, and their responsibility extends beyond the scientific knowledge available when the drug is first marketed. They must keep abreast of all newly identified risks in order to prevent and mitigate harmful effects. The pharmaceutical industry is fundamentally research and development-based[34].

Relying solely on the scientific knowledge available at the time of manufacturing is insufficient[35]; manufacturers remain liable and must be vigilant regarding potential future risks, particularly for products related to human health and safety[36].

Third: the obligation of compliance in pharmaceuticals.

The law requires manufacturers to ensure that all products on the market comply with specifications, do not pose risks to consumers and provide the necessary health and safety, while also meeting legitimate consumer demands. This can only be achieved if these products conform to agreed or legislated standards[37].

Within the framework of the amended Consumer Protection and Fraud Suppression Law, the Algerian legislator defined compliance as follows: 'The response of every product intended for consumption to the conditions contained in technical regulations and to its health, environmental, safety and security requirements.'

The obligation of compliance aims to fulfil consumers' legitimate desires. To this end, the Algerian legislator established the principle of product compliance through Articles 11 and 12 of the aforementioned law, indicating that compliance has two aspects:

1. Respect for source requirements: The specific nature of each product varies depending on its source.
2. Conformity to mandatory specifications: Products and services must comply with mandatory rules outlined in laws and regulations, as well as professional standards and practices.

Thus, compliance is governed by a set of rules.

- Preventive rules: These aim to ensure compliance and exclude from the market those products that do not meet the requirements specific to each product, based on its source and quality. For instance, the production, packaging, storage and presentation to consumers of pharmaceutical products, which are derived from chemical and natural substances, requires high-level techniques.
- Repressive rules: These apply in cases of non-compliance through two legal[38] means: standardisation and control.

The aforementioned article emphasises the specificity of the obligation to inform in the pharmaceutical field, highlighting its mandatory nature and the need for information to be accurate, verifiable and aligned with scientific data and ongoing research in the pharmaceutical and medical fields.

The obligation to comply extends from the production phase to the delivery phase.

32- 'The Responsibility of the Pharmaceutical Manufacturer'. Available at: http://www.juripole.fr/memoirels/prive/sandrine.husson/partie2, accessed 19 February 2015.

33- Blandine Fauran, 'Health Products: Precaution, Prevention and Risk Management in the Field of Medicine'. The Need for Rationalised Application', Health Law, No. 6, Dalloz, 2010, p. 1115.

34- Shahat Gharib Shalghami, 'The Specificity of Civil Liability in the Field of Medicine', Dar Al-Nahda Al-Arabiya, Cairo, 2008, p. 26.

35- Muhammad Al-Qutub, 'Civil Liability Arising from Drug Damages', Previous Reference, p. 97.

36- Article 1386-10: 'The producer may be liable for defects even if the product was manufactured in accordance with the rules of the art or existing standards, or if it was subject to administrative authorisation.'

37- Za'abi, Ammar. 'Consumer Protection from Damages Resulting from Defective Products'. Thesis submitted for the Doctorate in Law (Business Law Specialty), Faculty of Law and Political Science, University of Mohamed Khider, Biskra, 2012/13, p. 79.

38- Ridwan Qarwash, 'The compliance of products and services with legal specifications and standards as a guarantee for consumer protection in Algerian law', Academic Journal of Legal Research, Faculty of Law and Political Science, University of Abderrahmane Mira, Bejaia, Year Five, Volume 9, Issue 1, 2014, p. 233.

- During production: According to Article 1115-7 of the French Public Health Code, products must conform to the pharmaceutical formula under which the manufacturer obtained authorisation, complying with all the necessary specifications and undergoing all the required controls. This reflects the fact that the obligation to comply with regulations during drug production involves the manufacturer guaranteeing pharmaceutical quality, meaning adherence to the required chemical and constitutional formulas.

During delivery: The pharmacist must provide the medication listed on the prescription exactly as it is written. They cannot dispense an alternative to the medication listed on the prescription or exercise their authority to determine the strength or efficacy of the drug[39].
In a case presented before the French judiciary, the criminal judge found the pharmacist liable, even though the medication had been dispensed in accordance with the prescription, on the basis of the obligation to provide advice and guidance. Therefore, merely dispensing the medication as per the prescription is not enough to exempt the pharmacist from liability.
Manufacturers are obliged to ensure the safety of the drugs they produce, but cannot guarantee their effectiveness or success in treatment. Instead, they must provide drugs that comply with established scientific principles and are agreed upon by the prescribing physician.
Legal scholars and judges argue that, in this case, the manufacturer only has an obligation of means; they are not responsible for ensuring that the drugs they market achieve complete healing. They are only required to conduct the necessary studies, research, tests and analyses to verify safety, as it is impossible to impose an obligation on the manufacturer to guarantee absolute efficacy given that drugs may be ineffective or not yield the desired results due to a patient's specific condition[40].
The Court of Appeal in Poitiers confirmed that producers and sellers of pharmaceutical products are only obliged to take care when it comes to the therapeutic efficacy of the swine flu vaccine, provided that it complies with the scientific specifications in place at the time of production. Similarly, the Paris Court ruled that a drug manufacturer 'does not guarantee the therapeutic efficacy of the products it produces or sells in all cases'[41].
The Algerian legislator has emphasised the necessity of compliance in the pharmaceutical field, as stipulated in Article 193 bis of the Health Protection and Promotion Law, which states that 'pharmaceuticals and medical supplies used in human medicine are subject to quality and compliance control, in accordance with applicable legislation and regulations'[42].
This is further confirmed by Article 193 bis 1 of the same law, which states: 'No pharmaceutical product ready for use, nor any medical supplies used in human medicine, may be marketed unless they have previously been monitored and certified as complying with the elements of the registration or approval file.'

Conclusion

Given the direct and vital impact of these products on human health and physical safety, the study of the obligations of drug manufacturers is of great importance. Medicines are not ordinary consumer goods; they are hazardous products that require manufacturers to adhere to strict legal obligations regarding manufacturing, composition, distribution and providing information about side effects.
Manufacturers are therefore obliged to ensure the safety and efficacy of their products, as well as to inform consumers of potential risks and ensure compliance with all scientific standards and criteria.

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[39]- André Demichel, 'Pharmacy', Rép.pén. Dalloz, 1996, p. 11.
[40]- Ahmad Al-Said Al-Zaqrd, 'The Medical Prescription (Ticket)', Previous Reference, p. 116.
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Therefore, defining the scope of these obligations and how they are monitored is crucial for balancing the interests of patients as consumers with the need to encourage innovation in the pharmaceutical industry. This necessitates enclosing these obligations within a stringent legal framework that ensures the highest levels of public health protection.

In light of the above, we present the following suggestions:

Firstly, it would be advisable for the Algerian legislator to enact a law that regulates the prevention of drug hazards. Under this law, the responsibility of the drug manufacturer would be subject to its provisions, thus avoiding the need for them to be subjected to the civil liability system under general rules.

Secondly, it would be beneficial for the Algerian legislator to establish a special guarantee fund for incidents related to the consumption of pharmaceutical products, ensuring that harmed consumers receive appropriate compensation in cases where liability is not established.

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