Loucif+co

BUSINESS LAW BOUTIQUE

PHARMACEUTICAL SECTOR WHAT HAS BEEN ACHIEVED OVER THE PAST 4 YEARS ?

Algiers, 23 April 2024



Key points

- A review of achievements almost four years after the adoption of the government's action plan to boost the pharmaceutical sector.
- Major developments since the adoption of the plan: increase in local production, reduction in imports, expansion of the industrial fabric and diversification of supply.
- Export strategy: measures taken to boost pharmaceutical exports, particularly to Africa.
- Promotion of research and innovation: draft decree to promote clinical trials, research and innovation.
- Advances in digitalisation, with the introduction of a dedicated digital platform by the Ministry for Industry and Pharmaceutical Production, aimed at guaranteeing the availability and traceability of medicines and combating illicit commercial practices.

Almost four years have passed since the Government adopted its action plan to boost the pharmaceutical sector. This period has been marked by a series of initiatives aimed at ensuring the availability, quality and accessibility of pharmaceutical products, while at the same time strengthening the national industry.

In this newsletter, we look at the key achievements and trends in this strategic sector.

Achievements

In December 2023, the Minister for Industry and Pharmaceutical Production presented a comprehensive review of the action plan to promote the pharmaceutical sector to the Health, Social Affairs, Labour and Vocational Training Committee of the People's National Assembly. As a reminder, the action plan adopted in July 2020 comprised four strategic areas:

- Ensuring the continuous availability of essential pharmaceutical products.
- Establishing a regulatory framework to ensure quality, efficacy and safety.
- Ensuring economic accessibility of pharmaceutical products to all citizens.
- Elevating the national pharmaceutical industry to a strategic sector that generates wealth.

Major developments

Since the adoption of the plan, several significant developments have been observed:

1. Increase in local production: The policy focusing on local manufacturing has borne fruit, with the national market coverage rate for locally manufactured pharmaceutical products reaching 68%, well on track to achieving the target of 70% by the end of 2024.

Loucif+co

BUSINESS LAW BOUTIQUE

- Import reduction: A 40% reduction in the import bill in 2022, indicative of the transition towards self-sufficiency. Initiatives such as the launch of local insulin production have reduced the import bill by almost €100 billion in 2023.
- **3.** Expansion of the industrial base: The new regulations now open access to manufacturer status not only to establishments with their own production facilities, but also to those subcontracting one or more manufacturing stages to other manufacturers.

This development has led to the involvement of more than 200 local companies in pharmaceutical production, demonstrating the diversification and strengthening of the sector. These include 189 production sites and 14 companies operating on a subcontracting basis.

Concurrently, the number of medicines registered in the national nomenclature of pharmaceutical products, as part of local production, has reached 3,327 out of the 4,544 registered medicines, representing a coverage of 73%. This increase of 300 medicines since August 2022 reflects the progress made in national medicine production.

These advancements in local production can be attributed in particular to the introduction in 2008 of a measure suspending imports of pharmaceutical products when they are locally manufactured.

4. Supply diversification: The approval of projects focusing on the production of anti-cancer drugs also reflects the desire to meet the specific health needs of the population.

Export strategy

Algeria is also seeking to boost its pharmaceutical exports, particularly to Africa. To encourage this expansion, several measures have been undertaken, including:



- 1. Relaxation of foreign ownership rules in export companies: Foreigners may engage in export activities up to 100%, while the remaining activities in the pharmaceutical sector remain subject to the 49/51% rule, limiting foreign ownership in Algerian entity capital to 49%.
- 2. Export rate consideration in price setting.
- 3. Freedom in setting export prices above local regulated prices.
- 4. Simplification of procedures for registering products for export.

Promoting research and innovation

As part of the promotion of clinical studies and research and development, the Ministry for Industry and Pharmaceutical Production has introduced provisions to encourage clinical research and innovation in the pharmaceutical industry.

The conduct of technical studies is subject to authorization by the health minister and must be conducted by an authorized sponsor. A draft decree is reportedly being prepared to streamline procedures.

Loucif+co BUSINESS LAW BOUTIQUE

Digitalisation and traceability

The sector has recently made significant progress in the area of digitisation.

In order to guarantee the availability of medicines and ensure their traceability, as well as to combat illegal commercial practices such as monopolies and concurrent sales, the Ministry for Industry and Pharmaceutical Production has set up a dedicated digital platform.

The Ministry's digital platform currently consolidates data relating to production and reception programmes, as well as import programmes. It also collects weekly stock declarations from producers and importers, as well as quantities distributed for pharmaceutical products.

Should you have any inquiries or require legal assistance, do not hesitate to reach out. We would be delighted to assist.

CONTACT:



Rym Loucif Partner Loucif+co

19, Rue des Pins, 16035 Hydra, Algiers, Algeria Email : <u>rloucif@loucif-law.com</u> T. (Algiers): + 213 (0)5 52 58 28 93 T. (Algiers): + 213 (0)7 70 07 21 16 T. (Paris): + 33 (0)6 29 27 13 34

This newsletter is a free, periodical electronic publication edited and published for clients and business associates. The newsletter is strictly limited to personal use by its addressees and is intended to provide non-exhaustive, general legal information. The newsletter is not intended to be and should not be construed as providing legal advice. The addressee is solely liable for any use of the information contained herein and the law firm shall not be held responsible for any damages, direct, indirect or otherwise, arising from the use of the information by the addressee