The Pharma Legal Handbook

Algeria

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

PHARMA BOARDROOM

Algeria

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Algeria.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with the Algerian Society for Regulatory Affairs & Pharmacoeconomics, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

The Algerian Society for Regulatory Affairs & Pharmacoeconomics is a non-profit organization, created on 26 October 2015 under the provisions of the Law No. 12-06 related to Associations. Its mission is to provide information and continuing education for all stakeholders in the Algerian pharmaceutical sector, and to promote research in the field of pharmaceutical regulations and HEOR.

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*** THIS REPORT WAS ORIGINALLY PUBLISHED IN OCTOBER 2019 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**
****LAST UPDATE: DECEMBER 2019**

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6 strategic missions

Promotion of research related to pharma regulations and HEOR in Algeria.

Organizing scientific events as part of continuing education for HCPs.

Providing training sessions and workshops for pharma industry professionals.

Creating an electronic portal dedicated to national and international updates.

Building a digital database related to pharma regullatory affairs and HEOR.

Participating in relevant congresses and events both in Algeria and abroad.

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

Ministry of Health, Population and Hospital Reform ("MSPRH" – "Ministère de la Santé, de la Population et de la Réforme Hospitalière") is the national regulatory authority responsible for drugs, biologicals, and medical devices for human use in Algeria.

General Directorate of Pharmacy and Health Equipment ("DGPES" – "Direction Générale de la Pharmacie et des Equipements de Santé") at MSPRH is the body responsible for reviewing, assessing, regulating and monitoring pharmaceutical products, since the MSPRH's new organizational chart implementation in 2012.

National Agency for Pharmaceutical Products ("ANPP" – "Agence Nationale des Produits Pharmaceutiques", a financially independent institution newly created under Article 223 of Health Law No 18-11, dated of 2 July 2018, will gradually replace DGPES upon its establishment. ANPP will remain under the administrative authority of MSPRH.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

Health Law No 18-11, dated of 2 July 2018, published in the Official Gazette, replacing Health Protection and Promotion Law No 85-05, dated of 16 February 1985, forms the legislative framework for all activities related to drugs, biologicals and medical devices.

a) Authorization:

- Decree No 92-284 dated of 6 July 1992, published in the Official Gazette, related to registration of pharmaceutical products for human use;
- Decree No 93-114 dated of 12 May 1993, published in the Official Gazette, modifying and completing Decree No 92-285 dated of 6 July 1992, related to authorization of pharmaceutical products manufacturing and distribution sites;
- Ministerial Decree No 116/MSP/MIN dated of 5 December 1996, published in the Ministry of Health Bulletin, fixing registration conditions for generics products;
- Ministerial Decree No 18/MSP/MIN dated 13 February 1997, published in the Ministry of Health Bulletin, fixing template of registration decision and certificate of free sale related to pharmaceutical products for human use;
- Ministerial Decree No 138/MSPRH/MIN dated of 18 October 2005, published in the Ministry of Health Bulletin, fixing timelines for assessment of registration applications related to pharmaceutical products for human use;

• Ministerial Decree No 139/MSPRH/MIN dated of 18 October 2005, published in the Ministry of Health Bulletin, fixing template of registration application forms and composition of submission dossiers;
• Ministerial Decree No 12/MSPRH/MIN dated of 16 April 2012, published in the Ministry of Health Bulletin, modifying and completing Ministerial Decree No 2479 dated of 6 November 2007, fixing homologation conditions for medical devices.

b) Pricing:

• Decree No 98-44 dated of 1 February 1998, published in the Official Gazette, fixing the caps margins applicable for production, packaging and distribution of pharmaceutical products for human use.
• Ministerial Decree No 66 dated of 11 July 2012 modified and completed, published in the Ministry of Health Bulletin, related to organization and running of the Pharmaceutical Products Pricing Committee.

c) Reimbursement:

• Interministerial Decree dated of 16 August 2003, published in the Official Gazette, creating and fixing missions, organization and running of the Pharmaceutical Products Reimbursement Committee.
• Ministerial Decree dated of 6 March 2008 modified and completed, published in the Official Gazette, fixing the positive list of reimbursed products by social security.
• Ministerial Decree dated of 6 March 2008 modified and completed, published in the Official Gazette, fixing reference tariffs for products reimbursement by social security.

3. What are the steps to obtaining authorization to develop, test, and market a product?

New drugs, biologicals and medical devices cannot be marketed unless they have been granted authorization by Ministry of Health ("registration decision" for drugs and biological, "homologation decision" for medical devices, according to article 230 of Health Law No 18-11, dated of 2 July 2018).

Applications for market authorization must be submitted to the Ministry of Health on a form specially prepared for that purpose (Form A: for generic products; Form B: for new drug products; Form D: for medical devices), accompanied by a submission dossier that includes:

- Certificate of Pharmaceutical Product issued by regulatory authorities of country of origin in the format recommended by the World Health Organization + copy of valid market authorization in country of origin (for imported products) and/or CE marking certificate (for medical devices);
- Attestation of different manufacturers and sites involved in the manufacturing, packaging, control and releasing of the product (including for Active Pharmaceutical Ingredient or API).
- Authenticated copy of GMP compliance certificate and manufacturing authorization for all sites involved in manufacturing of API(s) and finished product.

- Technical dossier in electronic format including manufacturing and quality control data, and where appropriate, non clinical and clinical data of the product + access letter to the Drug Master File restricted part;
- 05 samples of finished product (both for imported and locally-manufactured products), accompanied by original certificate of analysis + template of artworks intended to be used;
- Note for therapeutic and economic interest summarizing absolute and relative medical service, in addition to public health importance;
- FOB price attestation certified by Chamber of Commerce in country of origin (for imported products) / ex-factory price structure (for locally-manufactured products).
- Receipt of registration fees payment + change attestation (payment in convertible foreign currencies for imported products).

The authorization process generally involves:

- Preliminary examination (at the end of which, an application receipt is granted),
- Evaluation of application (including laboratory quality control tests),
- Approval or denial of application (on quality/safety/efficacy criteria + price negotiation),
- Granting of the market authorization + list price attestation.

Exceptions:
A temporary authorization for use ("ATU" – "Autorisation Temporaire d'Utilisation") may be exceptionally issued by Ministry of Health for non-registered products, when the latter are prescribed as part of the management of serious diseases in situations where there is no equivalent treatment in the national territory, and have proven their therapeutic benefit.

4. What are the approximate fees for each authorization?

The drugs, biologicals and medical devices authorization fees are fixed as part of Finance Law. Fees are payable by the person who makes the application or submit variations to initial market authorization, in local currency for locally-manufactured products, and in convertible foreign currencies for imported ones.

As at December 2019, the current authorization fees are:

- For each new application related to imported and non essential drug or biological: 1.000.000 DZD (approx. 8.350 USD);
- For each new application related to imported and essential drug or biological: 600.000 DZD (approx. 5.000 USD);
- For each new application related to locally-manufactured and non essential drug or biological: 150.000 DZD (approx. 1.250 USD);
- For each new application related to locally manufactured and essential drug or biological: 100.000 DZD (approx. 835 USD);
- For each new application related to imported medical device: 300.000 DZD (approx. 2.500 USD);