For A Healthier Africa
AFRiSUMMIT
2nd - 5th November 2025
Hilton Grand Nile Hotel, Cairo - Egypt

الوكالة الوطنية للمواد الصيدلانية
Agence Nationale des Produits Pharmaceutiques

People's Democratic Republic of Algeria
Ministry of Pharmaceutical Industry
National Agency for Pharmaceutical Products

Changes in the regulatory framework for medical devices in Algeria

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Agenda

Introduction & General Background

- Algeria, which is in the process of developing its healthcare system, is strengthening its regulatory framework for medical devices to ensure safety, efficacy and innovation.

- The medical device sector represents a growing share of the Algerian pharmaceutical market.

- The ANPP plays a central role in the regulation and approval of these products, namely:

✓ National body responsible for ensuring that medical devices comply with quality and safety requirements: regulation, health safety and compliance of medical devices.
✓ Technical and regulatory processing of approval applications
✓ Documentary and scientific evaluation of files
✓ Laboratory testing

This presentation highlights the key regulatory developments for 2023-2025.

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Current regulatory framework

- Law 18-10 on medical devices (adopted in 2018, gradually being implemented).
- Implementing decrees defining the specific procedures for registration and control.
- Classification of devices according to their risk (class I to IV).
- Manufacturers' obligations: technical documentation, clinical evidence, ISO 13485 certification.

Key regulatory changes for 2023–2025

- Introduction of a national electronic system for registering and tracking medical devices (ANPP platform).
- Strengthening of requirements for post-market surveillance and health vigilance.
- Establishment of clear deadlines for approval decisions (target: 90 days).
- Increased transparency requirements for reporting device-related incidents.

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Here is the list of the latest AIMs published (introduction of the principle of interdependence, strengthening of communication and coordination between stakeholders, definition of the national medical device vigilance system with clear responsibilities for all stakeholders).

1. Interministerial Order of 10 September 2025, corresponding to 17 Rabie El Aoual 1447, relating to the framework for the principle of regulatory trust and mutual recognition in relation to pharmaceutical products and medical devices.

2. Interministerial decree of 10 September 2025, corresponding to 17 Rabie El Aoual 1447, on coordination and communication regarding the regulation of pharmaceutical products and medical devices.

3. Interministerial decree of 10 September 2025, corresponding to 17 Rabie El Aoual 1447, on the organisation and operation of the national pharmacovigilance and medical device vigilance system.

Official texts available

Decree/Decision/ Order / Note	Date / Reference	Content
Note to pharmaceutical establishments for medical devices – No. 06/MIPP/ANPP/DG/NOTE/2025 (online appointment booking for submission of approval applications)	30 January 2025 updated on 30/09/2025	Introduction of an online appointment system for submitting approval applications.
Provisional marketing authorisation (PMA)	10th of February 2025	The ANPP allows non-approved medical devices to obtain a marketing authorisation (ACP) valid for one year, subject to the provision of GMP/BPF certificates, free sale certificates, etc.

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Ministerial Order (6 February 2025) establishing the terms and conditions for the exceptional and derogatory marketing of non-approved medical devices.	**06/02/2025**	**Allows for the exceptional marketing of non-approved devices, subject to certain conditions.**
Draft executive decree amending Executive Decree No. 20-324 of 22 November 2020 on the procedures for the approval of medical devices	January 2023	This project provides for a 24-month extension for devices that have not yet been approved in order to maintain supply to hospitals.
Note to pharmaceutical establishments for medical devices — Note No. 04/MIPP/ANPP/DG/NOTE/2024	12 March 2024	Door on medical device vigilance obligations under Law 18-11 of 2 July 2018

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Note No. 09 concerning pharmaceutical establishments for medical devices	**1st April 2024**	**Status, responsibility, formalities for establishments related to medical devices.**

Approval process: simplifications and developments

- Complete digitisation of the approval file via the new ANPP platform.
- Possibility of interactive exchanges with assessors to speed up the procedure.
- Implementation of a priority system for innovative and urgent devices.
- Harmonisation with international practices to facilitate access to the Algerian market.

Risk management and post-marketing vigilance

- Establishment of a national active vigilance system.
- Enhanced collaboration with healthcare professionals for incident reporting.
- Continuous analysis of safety data and updating of product information.
- Development of risk management training courses for industry stakeholders.

Alignment with international standards

- Gradual implementation of ISO 13485 and ISO 14971 standards for quality management and risk management.
- Collaboration with the WHO and harmonisation with European MDR regulations.
- Active participation in African regulatory networks to share experiences and best practices.

challenges encountered and solutions considered

Challenge	Solution
Complexity of procedures for small local businesses.	Establishment of a one-stop shop and personalized support services.
Lack of local clinical data.	Encouraging national clinical studies in partnership with hospitals.
Strengthening the technical capacities of evaluators.	Continuing education programs and international exchanges.

Outlook for the sector in Algeria

- Development of a local manufacturing and innovation ecosystem.
- There are 111 local manufacturers, but not many manufacturers of high-tech devices.

- Encouraging public-private partnerships to accelerate access to technologies. Digital health is experiencing estimated annual growth of 7.6%.

- Integration of connected medical devices into the regulatory framework.

Make Algeria a regional hub in North Africa for medical devices.

Algeria's ranking in the field of medical devices

In the Maghreb: Algeria leads in terms of regulation and approval capacity, ahead of Morocco and Tunisia, thanks to its advanced institutional infrastructure and recent reforms.

In the Arab world: Algeria ranks among the top three countries in terms of regulatory framework for medical devices, with strong momentum towards integration with international standards.

In the Mediterranean: Algeria is progressing rapidly and beginning to catch up with countries such as Egypt and Turkey thanks to its efforts in digitalization and technical training.

Globally: Mid-level ranking, with clear ambitions to move upmarket through local innovation, international cooperation and rapid adoption of European ISO and MDR standards.

Conclusion & Call for regional cooperation

- Regulatory updates aim to enhance safety and innovation.
- Regional collaboration is key to harmonizing standards and facilitating trade.
- Invitation to share experiences at Afrisummit to build a dynamic African market.
- The ANPP remains committed to supporting the sustainable development of medical devices in Algeria.

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