HERMS WHITE PAPER | NOVEMBER 2026

Pharmaceutical Product Registration in the UAE

How EDE Marketing Authorisation Works

HERMS Consultancy DMCC

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How EDE Marketing Authorisation Works

The UAE has consolidated pharmaceutical regulation under one federal body. According to the Emirates Drug Establishment (EDE), it was established on 29 September 2023 and is the federal authority responsible for regulating medical and pharmaceutical products, including medical devices, blood derivatives, stem cells, medicated cosmetics and veterinary medicines.

Who registers pharmaceutical products in the UAE?

EDE is the single federal regulator. Marketing authorisations, establishment licensing and pharmacovigilance services sit with EDE, taking over functions previously handled by the Ministry of Health and Prevention (MOHAP).

How are EDE services accessed?

EDE services are digital-first and accessed online. UAE PASS is used for authentication on several services.

How long is a marketing authorisation valid?

EDE's service page states that marketing authorisation certificates are issued for five years or for the validity it grants.

Is a pharmacovigilance officer required?

Marketing Authorisation Holders apply to EDE to approve and register their Qualified Person for Pharmacovigilance (QPPV).

What companies should do now

• Confirm that company, manufacturer and product records are correctly reflected under EDE.

• Review renewal dates and variation plans against current EDE procedures.

• Verify the status of your local QPPV and pharmacovigilance system documentation.

• Monitor EDE legislation and guideline updates, which are published on its portal.

How HERMS supports

HERMS acts as a regulatory partner for companies entering or operating in the UAE: company and manufacturer registration, dossier preparation, submission management, renewals and variations, and pharmacovigilance support.

References

EDE – About Us: https://www.ede.gov.ae/en/home

EDE – Issuance of Marketing Authorization: https://www.ede.gov.ae/en/w/issuance-of-marketing-authorization-for-a-drug-or-biopharmaceutical-product

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Drug registration timelines by country

GCC central registration through the Gulf Health Council

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Linked references and further reading

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