

# Expanding a pharmaceutical portfolio into Europe isn't a simple “copy-paste” from the US or Canada



From FDA / Health Canada logic to **Europe's multi-layered regulatory framework**



# There is no such thing as a single European regulator

## Europe doesn't operate as a single regulatory system

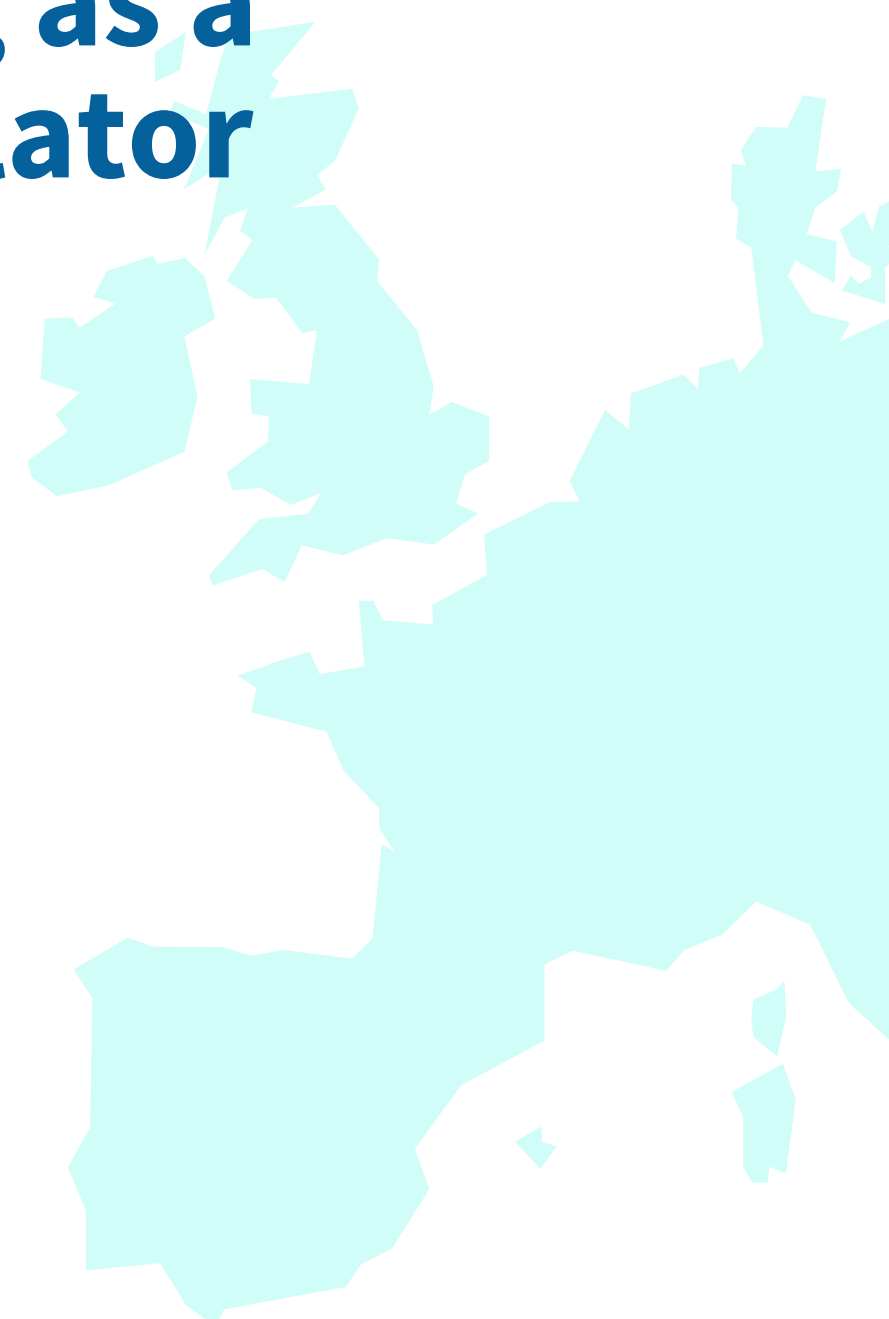
In the **US and Canada**, companies are used to a **more centralized model**:

- FDA in the United States
- Health Canada in Canada

In **Europe**, the landscape is **more complex**:

- The EMA coordinates certain procedures at the EU level
- National Competent Authorities (NCAs) still play a key role
- The strategy depends on the product type and the regulatory pathway

**Entering Europe means understanding when decisions are centralized, and when they're not**



# The authorization pathway matters more than it seems

## Not all medicines follow the same approval pathway

In the EU, companies need to assess which procedure best fits their product.

- Centralised Procedure
- Decentralised Procedure
- Mutual Recognition Procedure
- National Procedure

This affects:

- Timelines
- Country Launch Strategy and Sequence
- Operational complexity
- Life-cycle Management strategy

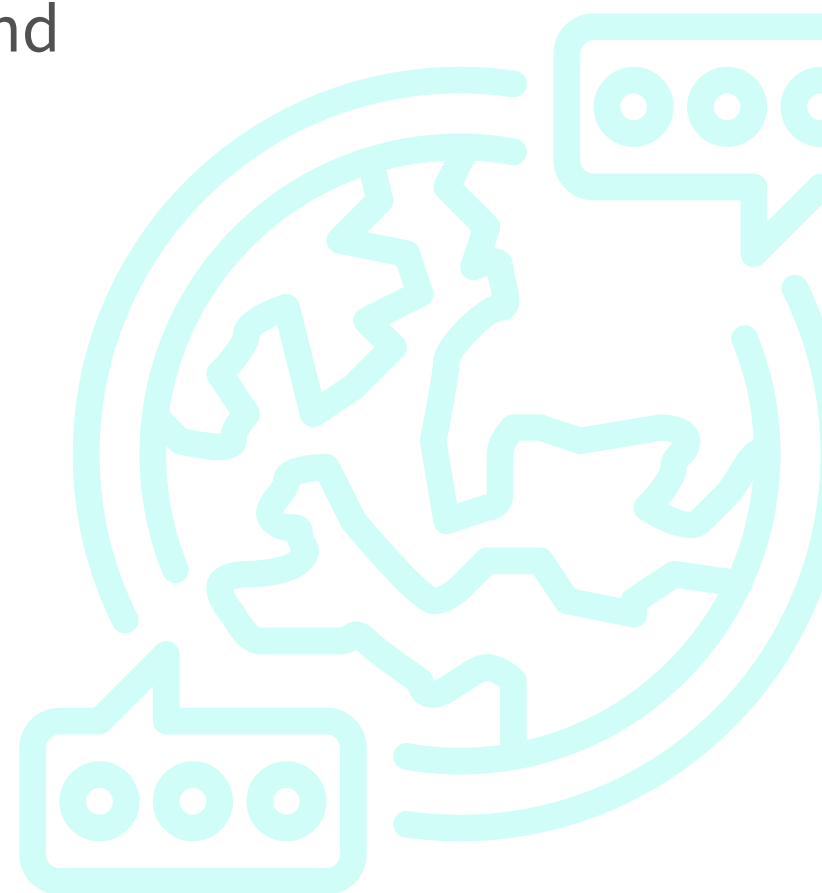


# Europe requires local adaptation, even after approval

Compared with the more uniform North American approach, Europe requires additional layers of adaptation.

- Language requirements
- Multi-country labeling and packaging
- National implementation differences
- Pharmacovigilance, local representation, and post-approval obligations

**Having a Marketing Authorisation (MA) in Europe doesn't mean operating the same way in every country**



# Regulatory approval does not equal market access

For US and Canadian companies, this is a critical distinction:

**In Europe, approval is only one part of the equation.**

This includes:

- HTA / value assessment
- Pricing and reimbursement
- National (or sometimes regional)
- Negotiations
- Different access timelines across countries

**To succeed in Europe, Regulatory and Market Access strategies must be aligned from day one**

# Post-approval maintenance is more complex than many expect

## In Europe, approval is just the beginning. Ongoing compliance is key

For many US and Canadian pharmaceutical companies, one of the biggest surprises comes after approval:

**The complexity of life-cycle management in Europe.**

This often involves:

- Managing variations across multiple markets
- Ongoing pharmacovigilance obligations
- Renewals, PSURs, and regulatory maintenance
- Coordinating CMC, labeling, and artwork changes across countries



**Approval**

# Your Trusted Partner

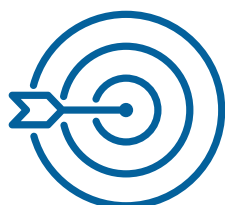
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