

Proposed EU Pharma Package: How Croatia Unlocks 2 Years of Extended Market Exclusivity

Croatia: The Strategic Gateway to Extended EU Exclusivity

Why Croatia Matters for Your EU Launch:

Croatia is a **strategic access point** for meeting the new EU Pharma Package's requirements.

- **Goal:** Secure the proposed 2 years of extended exclusivity across the EU.
- **Method:** Must launch and supply in *all* Member States within 2 years of MA.
- **Hurdle:** HZZO (Croatian Health Insurance Fund) is the sole public payer.

The Croatian Launch = EU Exclusivity Insurance.



Step 1: Regulatory Approval (HALMED)

The Gatekeeper:

The Agency for Medicinal Products and Medical Devices (HALMED) handles regulatory MA .

The Pathway:

- Croatia follows **EU Procedures**: Centralized Procedure (CP), Mutual Recognition (MRP) , and Decentralized Procedure (DCP).
- **Focus**: Must establish product Quality, Safety, and Efficacy.
- MA must be secured before starting the HZZO pricing process.

Step 2: Reimbursement & Pricing

Securing a Spot on the National Lists

After MA, apply to the HZZO Committee for Medicines.

Key Criteria:

- **Therapeutic Value:** Clinical benefit vs. current care
- **Public Health Importance:** Value to the national population
- **Budget Impact:** Financial consequences for the HZZO

The Lists:

1. **List A (Basic):** 100% HZZO coverage (no patient co-payment).
2. **List B (Supplementary):** Partial coverage (patient co-payment required).

Pricing Controls: The EPR and IPR Pillars

Croatia employs dual pricing controls to manage pharmaceutical spending:

1. External Price Referencing (EPR)

- HZZO sets the **Maximum Wholesale Price** by benchmarking against reference EU countries.

2. Internal Price Referencing (IPR)

- Sets reimbursement ceilings based on the **cheapest comparable product** within the therapeutic group.

High-Cost Levers:

- **Managed Entry Agreements (MEAs):** Confidential rebates to manage budget impact.
- **"Especially Expensive Medicines" (PSL):** High-cost therapies (oncology, biologics) are funded via a **separate budget** to protect hospital funds.

Strategy: Croatia for EU Advantage

Maximize Your European Exclusivity

The proposed EU Pharma Package incentivizes wide market coverage:

- **Incentive:** 2 additional years of RDP(Regulatory Data Protection).
- **The Problem:** Coordinating 27 national launches in 2 years is complex.
- **The Solution: Croatia.** Its centralized system makes it a priority target for rapid P&R filing.

Strategic Takeaway: Leverage expert knowledge for a rapid, successful Croatian entry to tick the launch box and protect billions in revenue in the large EU markets.