

## CASE STUDY

# Local Expertise, Local Knowledge: MAH in Bosnia and Herzegovina



## The Challenge


Our client, a global over-the-counter pharmaceutical company with an expansive international presence and a portfolio of time-sensitive seasonal products, initially engaged **Clinres—a ProPharma company**—for regulatory and pharmacovigilance (PV) services. At that time, supply chain activities—including planning, interdepartmental coordination, and logistics—remained the responsibility of the client’s internal teams.

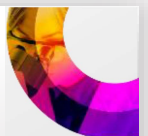
However, this separation of functions proved insufficient in **Bosnia and Herzegovina**, a market with strict and complex local regulatory requirements. Several compounding challenges emerged:

- **Regulatory Readiness Gap:** Internal stakeholders underestimated the timelines required to obtain local approvals necessary for product import and distribution.
- **Suboptimal Interdepartmental Communication:** Key planning teams within the client organization operated in silos, leading to misaligned timelines and missed submission deadlines.
- **Delayed Stock Planning:** Inadequate foresight and delayed inventory coordination resulted in the inability to meet the country-specific launch requirements.
- **Market-Specific Risks:** Given the highly seasonal nature of the product, missing the launch window meant forfeiting an entire year’s revenue in this market—posing a serious financial and reputational risk.

Without localized expertise and tighter coordination, the client faced an urgent and high-stakes situation with limited time to correct course.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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# Clinres: Acting as Marketing Authorization Holder and Strategic Partner

Recognizing the urgency of the situation, **Clinres acted as the Marketing Authorization Holder (MAH)** for the client's product in Bosnia and Herzegovina. This allowed us to take on full regulatory responsibility and act on behalf of the client in all interactions with national health authorities.

With over 15 years of MAH experience, and as part of **ProPharma**, Clinres brought integrated regulatory expertise, local presence, and global standards to the table. This alignment enabled a seamless response that spanned both regulatory and operational dimensions—bridging the client's internal gaps and delivering rapid, locally compliant solutions.

## The Solution


To address the client's critical launch challenges, the Clinres team implemented a proactive, multi-pronged approach:

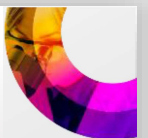
- **Direct Manufacturer Engagement:** We established communication with the manufacturing site to reprioritize production and expedite batch readiness.
- **Accelerated Sample Submission:** Product samples were submitted to the local Health Authority well in advance of full-batch shipment to the EU warehouse, enabling regulatory review to begin immediately.
- **Stakeholder Alignment:** Clinres coordinated across all parties—including the client's internal teams, manufacturing, logistics, and local distributors—to ensure synchronized execution.
- **Health Authority Engagement:** Formal meetings with local authorities were arranged to provide full product context, present the complete dossier, and request accelerated assessment in accordance with local guidelines.
- **Strict Compliance and Transparency:** All actions were carried out in full alignment with national legal and ethical standards, emphasizing thorough documentation and collaborative dialogue with regulators.

This level of coordination was only possible due to our role as MAH and our understanding of both local regulations and the client's internal structure.

“ Proactive communication is key to solving challenges quickly. ”

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## The Results

Clinres' decisive and coordinated intervention enabled the client to **secure all necessary local approvals** in time to meet the critical seasonal market window. Key outcomes included:

- **3-month lead time reduction**, compared to internal projections
- **On-time product availability**, despite earlier delays
- **Preservation of full annual revenue** in the Bosnian market—a **high six-figure EUR value**
- **Reinforced trust** from global supply and marketing teams in regional execution

What initially appeared to be a lost opportunity was transformed into a success story—delivering not only regulatory compliance but also commercial rescue. The client later shared that Clinres' role “**restored the confidence of global supply and marketing teams in regional execution**,” underscoring the value of having a proactive, well-connected local partner with the capability to act beyond a support function.

### Improve the Health and Safety of Patients

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory goals are met, business objectives are achieved, and patient health and safety is improved.

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