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Your Roadmap to European Drug Approval: The Complete Solution

Introduction

Bringing a pharmaceutical product to market in Europe is a complex and highly regulated process. From securing Marketing Authorization (MA) to ensuring ongoing compliance, companies must navigate a web of requirements across the European Economic Area (EEA) countries and the UK. ProPharma's comprehensive suite of solutions offers a seamless pathway for pharmaceutical companies seeking access to the European market.

This guide outlines how ProPharma can act as your trusted partner for Marketing Authorization Holder (MAH) responsibilities, ensuring full compliance while enabling your commercial success.

The European Regulatory Landscape: A Quick Overview

To sell medicinal products in Europe, companies must:

- Obtain a **Marketing Authorization (MA)** for each product.
- Appoint a European-based **Marketing Authorization Holder (MAH)**.
- Maintain **pharmacovigilance, quality, reimbursement**, and **regulatory** obligations post-approval.
- Navigate country-specific requirements across the EEA and UK.

This system ensures product quality, safety, and efficacy for European patients but can create significant operational burdens if companies aren't well equipped to adhere to the requirements.

A Step-by-Step Roadmap

Successfully entering and staying in the European market requires careful planning and expert execution at every stage. This roadmap breaks down the complex process into six clear, manageable steps, ensuring your product remains compliant and competitive.

Step 1: Initial Regulatory Strategy & Gap Assessment

- Evaluate your current regulatory status and identify compliance gaps.
- Design a tailored roadmap leading to European market entry.

Step 2: Appointment of MAH Partner

- ProPharma can assume the legal role of MA Applicant and MAH.
- Transition regulatory dossiers and pharmacovigilance systems.

Step 3: Establishment of Quality and Pharmacovigilance (PV) Systems

- Set up Qualified Person responsible for Pharmacovigilance (QPPV), Local Person responsible for Pharmacovigilance (QPPV), and Pharmacovigilance System Master File (PSMF).
- Establish a global safety database, adverse event case management, literature search process, and risk management plan.
- Ensure supply chain readiness and GMP compliance.
- Set up Manufacturing Import Authorization (MIA) and Qualified Person (QP) declaration for your submission.

Step 4: Pricing and Reimbursement Planning

- Assess pricing and reimbursement environments in target countries.
- Develop and submit Health Technology Assessment (HTA) dossiers on a European level (EU HTA) and in target countries.
- Engage with European and national pricing and reimbursement authorities to secure access.
- Strategize for optimal pricing while addressing parallel trade and reference pricing dynamics.

Step 5: Ongoing Compliance Management

- Lifecycle management of authorizations.
- Pharmacovigilance and regulatory reporting.
- Batch certification and QP oversight.

Step 6: Market Expansion & Continuous Support

- Support additional MAs as your portfolio grows.
- Stay ahead of regulatory changes with proactive monitoring.

Why Choose ProPharma as Your MAH Partner?

ProPharma offers a **single point of contact** for all MAH-related responsibilities in Europe. The solutions include:

1. Comprehensive MAH Services

ProPharma can serve as your legal MA Applicant and MAH, applying for and holding the authorization on your behalf in full compliance with European regulations, or provide support and management for MAH responsibilities where needed, without acting as the legal MA Applicant or MAH.

Services include:

- **Regulatory oversight** for the full life cycle across the EEA and UK.
- Ensuring compliance with relevant European and national legislation.
- Managing product lifecycle activities including variations, renewals, and line extensions.

2. Pharmacovigilance System Oversight

ProPharma provides a robust PV system across all four phases of the product lifecycle – ranging from the clinical and pre-submission stages, through submission and approval of marketing authorisation, to the post-approval product launch phase.

3. Qualified Person (QP) Services

ProPharma offers QP services for **batch certification** and **QP Declarations** to ensure Good Manufacturing Practice (GMP) compliance:

- Batch release for both **commercial** and **investigational** medicinal products.
- QP Declarations for API/DS manufacturing sites.
- Oversight of supply chains and manufacturing/importation activities.

4. Regulatory and Quality Compliance

ProPharma's experts handle:

- GMP/GDP inspections and audits.
- Manufacturing and Importation Authorisation Holder (MIAH) requirements.
- Support for serialization, anti-counterfeiting measures, and product recalls.

5. Pricing and Reimbursement Strategy

Navigating pricing and reimbursement is critical for successful market access in Europe. ProPharma helps you:

- Engage with European regulatory authorities through the preparation and active participation in Joint Scientific Consultations (JSCs).
- Prepare Joint Clinical Assessment (JCA) dossier in parallel with the centralized EMA market authorization application.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.
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- Understand national pricing and reimbursement systems across EU/EEA countries and the UK.
- Develop a market access strategy aligned with your commercial goals.
- Prepare national dossiers for health technology assessment (HTA) submissions.
- Engage with payers and pricing authorities to secure optimal pricing and reimbursement terms.
- Anticipate challenges with parallel trade and reference pricing mechanisms.

Our team ensures your product achieves not only regulatory approval but also the commercial viability and market readiness needed for success in diverse European markets.

6. Tailored Solutions for Your Product Portfolio

Whether you have commercial products, investigational medicinal products (IMPs), or both, ProPharma can scale services to meet your needs:

- **Commercial Products**: Comprehensive MAH and QP oversight.
- **IMPs**: Dedicated IMP QP services for clinical trials.

The ProPharma Advantage

- **Global Reach, Local Expertise**: Coverage in all 30 EEA countries and the UK.
- **24/7 Pharmacovigilance and Regulatory Support.**
- **Experienced QPs** with deep knowledge of EU GMP requirements.
- **Seamless Integration and Project Management** with your global operations.
- **Risk Mitigation**: Avoid compliance pitfalls and penalties.

Ready to Navigate European Drug Approval with Confidence?

With ProPharma as your MAH partner, you can focus on your core mission: bringing life-changing therapies to patients. Let ProPharma handle the challenges of the European regulatory landscape and manage compliance, pharmacovigilance, and batch certification.

Contact us to discuss your European market entry. propharmagroup.com/contact-us/

About ProPharma

For the last 25 years, ProPharma has improved the health and wellness of patients by providing advice and expertise that empowers biotech, med device, and pharmaceutical organizations of all sizes to confidently advance scientific breakthroughs and introduce new therapies. With deep domain expertise in regulatory sciences, clinical research solutions, quality and compliance, pharmacovigilance, medical information, FSP solutions, and digital transformation, ProPharma offers an end-to-end suite of fully customizable consulting solutions that de-risk and accelerate our partners' most high-profile drug and device programs. For more information about ProPharma, please visit propharmagroup.com.