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WHITE PAPER

The Key Steps to Becoming a Marketing Authorisation Holder in Europe & the UK

Abstract

This white paper provides a guide to becoming a Marketing Authorisation Holder (MAH) in Europe/the UK.

The European Medicines Agency (EMA) plays a pivotal role in regulating the pharmaceutical industry across the European Union (EU) and European Economic Area (EEA), while the UK MHRA plays an equally pivotal role in regulating the UK's pharmaceutical industry. Pharmaceutical/Biotechnology companies looking to launch treatments in the European and UK markets must navigate complex regulatory landscapes. This white paper provides a comprehensive overview of the process, highlighting where regulatory and product development organisational support can play a role thus empowering potential MAHs to navigate the regulatory landscape with confidence.

Introduction

The European and the UK pharmaceutical markets are amongst the largest and most regulated in the world. An MAH is responsible for obtaining authorisation to market medicinal products within the EU/EEA and UK. The UK's withdrawal from the EU means that separate regulatory processes now apply to the EU/EEA and the UK, necessitating careful planning and regulatory compliance.

MAH - a highly responsible position

Being an MAH is a highly responsible position; the MAH is legally accountable for the quality, safety, and efficacy of the medicinal product, throughout the product's lifecycle. The MAH has responsibilities as outlined in Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and Good Pharmacovigilance Practice (GVP). The MAH is obliged to meet the requirements of its status as MAH including maintaining the Marketing Authorisation (MA), and informing the relevant authorities when needed, for example, of safety information. Certain MAH activities may be outsourced, but the overall responsibility cannot be delegated.

What are the key steps required for a successful Marketing Authorisation?

The EMA, along with national authorities of EU/EEA member states and the UK MHRA oversee the authorisation and supervision of medicinal products. The EMA has 3 procedures for obtaining EU marketing authorisations: centralised, decentralised and mutual recognition. Understanding these procedures is fundamental to navigating the regulatory landscape.

Step 1 - Consult with a Regulatory expert

Before initiating the Marketing Authorisation Application (MAA) process, experienced regulatory experts that are familiar with the EU and UK regulatory frameworks are required to provide guidance on the requirements and processes for obtaining MAs and to help identify any potential challenges or obstacles.

Step 2 - An established presence in the EU

To submit an MAA in the EU/EEA or UK, the Applicant needs to have registered companies in those regions. When "establishing an entity" in the EU/EAA and/or the UK, it is not enough to simply have a shell company. As MA Applicant or MAH, there must be processes and procedures in place to enable compliance with the relevant GMP, GDP and GVP legislation. There needs to be a series of standard operating procedures (SOPs) in a Quality Management System (QMS), also employment of personnel with relevant training and experience, systems to manage change controls, traceability and stock management, and adequate safety procedures. This represents a significant investment, both in terms of finance and time. Some companies may need to wait until they have submitted their MAA to obtain the further investment that will allow them to set up a company in Europe. In this case, a company may choose to obtain support from an organisation that can temporarily act as the MAH – such as TMC.

Although the MAH remains legally accountable for all MAH responsibilities, smaller companies will have some of the activities required to market a medicine performed by external partners. This might include manufacturing, distribution, safety database management etc. In 2022 the EMA published "Reflection paper on Good Manufacturing Practice and Marketing Authorisation Holders". This guide recognises that MAHs may have many aspects being outsourced. Even if outsourced, the MAH still retains responsibility for all activities and measures put in place to ensure overall control and compliance.

Step 3 - Preparing for application

Before submitting an MAA, extensive and meticulous preparation is essential. This includes compiling all data gathered from preclinical and clinical trials, product manufacturing and quality and patient safety etc., and compiling comprehensive documentation in line with Common Technical Document (CTD) guidelines and where a smaller company may also need support from a third-party product development organisation, such as TMC.

Step 4 - Submission and review

The application submission involves detailed documentation related to quality, safety, and efficacy. The EMA, national EU Agencies and MHRA all assess the application's compliance with regulatory standards. Close collaboration with regulatory authorities and effective communication by the sponsor regulatory team are crucial during this phase.

Post-Marketing Obligations

Once authorised, an MAH is responsible for ongoing pharmacovigilance activities to monitor and report adverse reactions and ensure product safety. Additionally, postmarketing commitments such as periodic safety update reports (PSURs) and risk management plans (RMPs) must be fulfilled. MAHs must adapt to changes throughout the product lifecycle, including variations to existing authorisations, renewals, and modifications to packaging, labelling and formulations. Compliance with evolving regulations is vital to maintaining authorisation.

Role of Regulatory Consultants:

Given the intricate nature of the regulatory landscape, engaging with experienced regulatory consultants such as TMC can offer invaluable support, ensuring accurate interpretation of regulations and efficient application processes. Examples of where they can provide support are:

- Helping companies submit their MAA earlier. A company may establish their own legal entities during or shortly after the MA assessment, outsourcing the initial MAH role. Licences may be quickly and efficiently transferred to the company's own legal entity at the right time so that the correct party is the MAH (and identified on the pack!) at launch.
- When a company acquires a medicinal product asset which includes EU and/or UK licences, but where the company doesn't yet have an MAH capable entity in those regions.
- For companies who need to get an approval but are not yet ready to launch the product and who may divest after approval.

Conclusion

Becoming an MAH presents challenges: navigating complex regulatory requirements, managing international variations, adapting to evolving guidelines etc. Legal, financial and logistical aspects must also be carefully managed.

Becoming a Marketing Authorisation Holder in Europe and the UK is a multifaceted journey that demands meticulous planning, adherence to regulations, and ongoing commitment to product quality and safety.

Disclaimer:

This white paper is intended to provide general information and should not be considered as legal or professional advice. Regulatory requirements are subject to change and readers are encouraged to consult relevant regulatory authorities and experts before making decisions related to becoming a Marketing Authorisation Holder in Europe and/or the UK.

Relevant Legislation:

Directive 2001/83/EC

EMA/419571/2021 Reflection paper on GMP and Marketing Authorisation Holders.

EU GMP Guidelines, Regulation No. 1252/2014, Directive 2094/EC

About TMC

TMC was founded nearly 25 years ago and is a global product development and clinical research organisation - a CRO with a difference. Utilising a unique business model, TMC's activities are performed by over 900 mature, highly experienced personnel that are subject-matter industry experts, located in over 70 countries. TMC supports pharma/biotech companies that are developing innovative, often life-saving, treatments for niche, rare and orphan diseases. By hand-picking operational teams to match the needs of every project, TMC provides tailored solutions and world-class support that responds uniquely to its clients' requirements..

To learn more about TMC and our focused solutions visit **www.tmcpharma.com** or email us directly at **info@tmcpharma.com**.

+44 1252 842255

info@tmcpharma.com

tmcpharma.com

/tmc-pharma-services-ltd

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