propharma

case study

accelerate European market access with compliant and comprehensive marketing authorization application submission

Preparedness for Marketing Authorization Application (MAA) approval ensures an efficient application process and follow-up

Placing a medicinal product in the European market requires a license for product approval. Meeting the requirements of European Medicines Agency (EMA) for an MAA is a complex task which can be costly.

If you do not have the in-house expertise and experience to tackle the multitude of required tasks such as building a Pharmacovigilance System Master File (PSMF), developing a Risk Management Plan (RMP), registering for EudraVigilance, and assigning an EU Qualified Person for Pharmacovigilance (QPPV) and a Local Person responsible for PV (LPPV) in countries where this is legally required, it can result in a delay to achieve a successful submission of your MAA. ProPharma's deep knowledge on the different aspects needed for successfully applying for an MAA and extensive EU QPPV and LPPV network, eliminates unnecessary time and effort.

Our client sought market access to Europe and requested support in MAA submission. Preparation of the RMP, set up of PV processes including its description within the PSMF as well as onboarding an EU QPPV were required milestones. So, how do you ensure a timely and effective MAA preparation for European market access?

challenge

Placing a medicinal product in the European market requires a license for product approval. To get a license the client requested support with compiling the MAA.

Modules from the MAA include administrative and prescribing information, clinical, nonclinical, and quality documentation, which all need to be submitted in line with EMA guidance and require an RMP and a summary of the PSMF. The summary of the PSMF is part of the registration dossier and must be prepared prior to submission for the MAA. Regulations require that the PSMF is signed by an EU QPPV.

To ensure the client's compliance with regulatory legislation worldwide, **it was essential to begin a global literature surveillance to identify information that could impact the risk-benefit assessment on the product and detect new safety signals for emerging safety issues**, after submission of the MAA.

Given the complexities of the various European markets, the creation of the different documents and systems and the fact that it can be difficult to source an experienced pool of EU QPPVs and LPPVs, it was important to have just one consulting partner to manage all requirements.

solution

To be compliant with EU PV legislation, all companies with applicant status in the EU must develop and maintain an RMP and a PSMF for their product(s).

ProPharma ensured that the client met all requirements in developing and maintaining their RMP to ensure the safety of the drug.

We worked with the client to develop the RMP to identify and characterize the risks of their medicinal product in a concise and efficient manner, saving them valuable time when interacting with the regulatory authorities.

We assisted in reflecting and implementing postmarketing obligations that were to be included in the RMP, by developing and reviewing educational material and risk minimization measures (RMMs).

In close collaboration with the client, ProPharma developed a PSMF, a description of the entire PV system ready for the MAA submission. In addition, we are providing an EU QPPV as well as LPPVs who work in the region on behalf of the client.

results

Our team's comprehensive understanding of the MAA submission process ultimately reduced lead time and costly delays for our client.

The first milestone to apply for the MAA licensure was completed successfully in a timely manner. In recognition of the diligent preparation of the application and ProPharma's excellent standing with the local inspectorate, the preparations for the steps after MAA approval also commenced in a timely manner.

A global literature screening was started at the time of the MAA submission, together with signal detection activities. These are based on the information already retrieved through the earlier global literature surveillance, postmarketing data in those countries where the product is already on the market as well as Health Authorities websites. These are monitored on a regular basis to **support accuracy.**

ProPharma also established the gateway for electronic submissions to EudraVigilance. This pharmacovigilance system enables the collection, monitoring, assessment, and evaluation of information related to adverse events (AEs). Marketing Authorization Holders (MAHs) are required to develop a pharmacovigilance system and provide a detailed description of it as part of their MAA.

ProPharma also provides Medical Information Contact Center services for the intake of AEs. In the interval period between MAA submission and MAA approval, EMA will be notified, as required by regulations, of AEs originating in those countries where the product is already registered.

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