APCER LIFE SCIENCES
Together for better health

CASE STUDY

Efficiently navigating the regulatory submission landscape

Therapeutic area: Multiple therapies

Product type: Drugs

Geography: EU

Product life cycle stage: Post-approval

About the Client

A leading generic pharma company with experience across the therapeutic segments of cardiovascular (CV), central nervous system (CNS), gastrointestinal system, diabetology, paediatrics, and oncology with advanced research and development (R&D) capabilities and a global presence.

Business Challenge

The company encountered delays in Article 57/XEVMPD submissions for their medicinal products registered in the UK. The primary reasons for this delay were:

- lack of resources,
- lack of knowledge of regulatory intelligence, and
- lack of information regarding some of the approved products in the region.

They had an urgent requirement of streamlining Article 57/XEVMPD submissions in order to maintain regulatory timelines for their products.

Overview - Regulatory submission & Importance of XEVPRM

- The ongoing submission of product data for medicines by marketing-authorisation holders (MAHs) is a legal requirement from Article 57(2) of Regulation (EC) No. 726/2004, as amended by Regulation (EU) 1235/2010 and Regulation (EU) 1027/2012. This eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) through the EudraVigilance database by European Medicines Agency (EMA) has undergone several changes and enhancements since its inception in the year 2005. Initially it was optional, however, since July 2012, MAHs are required to submit information about new marketing authorisations granted after 2 July 2012.
- Currently, MAHs are obliged to maintain the submitted medicinal product information and notify the EMA of any newly authorised medicines or variations to the terms of the marketing authorisation using eXtended EudraVigilance Product Report Message (XEVPRM) format. The aim of the data submission is to establish a complete inventory of all medicines authorised for human use in the European Economic Area (EEA), including medicines authorised centrally via the EMA and those authorised at national levels via the National Competent Authorities, those authorised at national levels via the National Competent Authorities.

Solution

The MAH sought support from APCER Life Sciences to streamline XEVMPD submissions. APCER helped clear the backlog and ensured smooth XEVMPD submissions within sought timelines by adhering to the following:

Collaboration with MAH

Secured prerequisite information from EMA

Established standard processes

Enabled integrated systems to help clear backlog

Ensured smooth XEVMPD submissions

Outcome

- Restored compliance.
- Successful submission of XEVPRM.
- Streamlined the process of subsequent submissions.

Our Regulatory Affairs Capabilities

Regulatory consulting and execution services with an experienced team of CMC writers and reviewers.

Regulatory and scientific team with **extensive experience** in preparing regulatory documents throughout the product life cycle.

Publication and submission of electronic dossiers in different countries, such as the US, the European Union, the United Kingdom, and Canada.

High-quality deliverables consistently meeting or exceeding client and regulatory expectations.

Custom and fully compliant solutions to meet ever-changing regulatory requirements.

APCER LIFE SCIENCES | Together for better health
Part of APC Group

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2022, and ISO 27701:2019 certified company.

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120 • UK: (+44) 208 326 3220 • Asia: (+91) 79 6677 8600

For Business enquiries, please email at: marketing@apcerls.com
For General enquiries, please email at: info@apcerls.com