VERISTAT

Successful SwissMedic Marketing Authorization Application for an Oncology Therapy

Background

A biopharmaceutical company sought to extend market access for its oncology therapy to Switzerland, following successful Marketing Authorization (MA) approvals in the European Union and the United Kingdom. Having partnered with the client on those earlier submissions, Veristat was engaged to prepare and submit the SwissMedic MAA.

Challenge

The Swiss submission required adaptation of the existing EU dossier to incorporate changes made during the EU MA review and to meet SwissMedic's national requirements. Our goal was to ensure alignment with Swiss-specific administrative, labeling, and technical requirements while preserving the scientific integrity and structure of the approved EU dossier.

PROJECT OVERVIEW

SUBMISSION TYPE
- Initial Marketing Authorization Application (MAA)

REGION
- Switzerland

THERAPY AREA
- Oncology

REGULATORY AUTHORITY
- SwissMedic

GLOBAL SERVICES PROVIDED
- Regulatory Strategy
- Medical Writing
- Labeling
- eCTD Publishing
- Submission Management
- Project Management

PREVIOUS SUBMISSIONS
- EU and UK MAAs prepared, submitted and managed by Veristat through approval and post approval maintenance.

Our Solution

Drawing on our prior experience with the EU and UK submissions, we applied a coordinated, cross-functional approach to deliver the Swiss MAA efficiently and compliantly.

- **Regulatory & Medical Writing Support:** Veristat EU-based medical writers reviewed and updated the Module 2 summaries based on the approved EU MA, ensuring alignment with SwissMedic expectations and specifications.
- **Module 1 Development:** Our regulatory experts compiled the Swiss national Module 1, including labeling, administrative documents, and region-specific forms.
- **Publishing & Submission:** Our publishing team completed eCTD compilation, quality control, and electronic submission through SwissMedic's portal, ensuring technical compliance and data integrity.
- **Global Collaboration:** The submission was led by our Regulatory Project Lead based in Basel, supported by regulatory colleagues in Spain, and publishing and medical writing specialists in the U.S. and Europe, enabling efficient global coordination and real-time problem-solving.

Outcome

The initial MAA was successfully submitted and accepted by SwissMedic. The achievement reflects our ability to leverage prior submission experience, apply region-specific regulatory knowledge, and deliver fully compliant dossiers that meet the expectations of local authorities.

From first time approvals to regional expansions, our cross-functional teams help clients navigate complex requirements and confidently achieve regulatory milestones.

About Veristat

If you've faced missed deadlines or slow progress, talk to Veristat. We have a proven record of accelerating clinical development programs with the expertise to navigate the complex path to marketing authorization efficiently. Partner with experts who understand the value of speed without compromising quality. From first-time approvals to regional expansions, our cross-functional teams help clients meet regulatory milestones with confidence.

Reach out to us to learn more. veristat.com ›