

Case Study

Marketing Authorisation Holder Transfer for 60 MAAs



Our client:

Is a global pharmaceutical and biotechnology company specialising in the research, development and marketing of medicines and vaccines for immunology, oncology, cardiology endocrinology and neurology.

Objective:

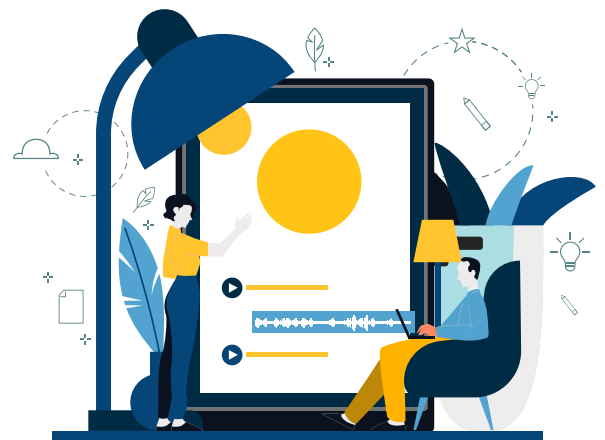
To publish and submit a Marketing Authorisation Holder transfer to ANSM for 60 Marketing Authorisations in National, MRP and DCP Procedures.

Introduction:

BlueReg was asked by the Client to perform the eCTD publishing and submission of a MAH Transfer for 60 different Marketing Authorisations registered through National, MRP and Decentralised Procedures. The submission had to be done in one single package via CESP to the French ANSM.

The publishing of the MAH sequences required prior upload of all existing eCTD lifecycle sequences for all concerned products into the BlueReg publishing system:

- 26 Products / 60 Marketing Authorisations
- Import of 924 existing eCTD Lifecycle Sequences



Challenges:

The Publishing Team had to face multiple challenges:

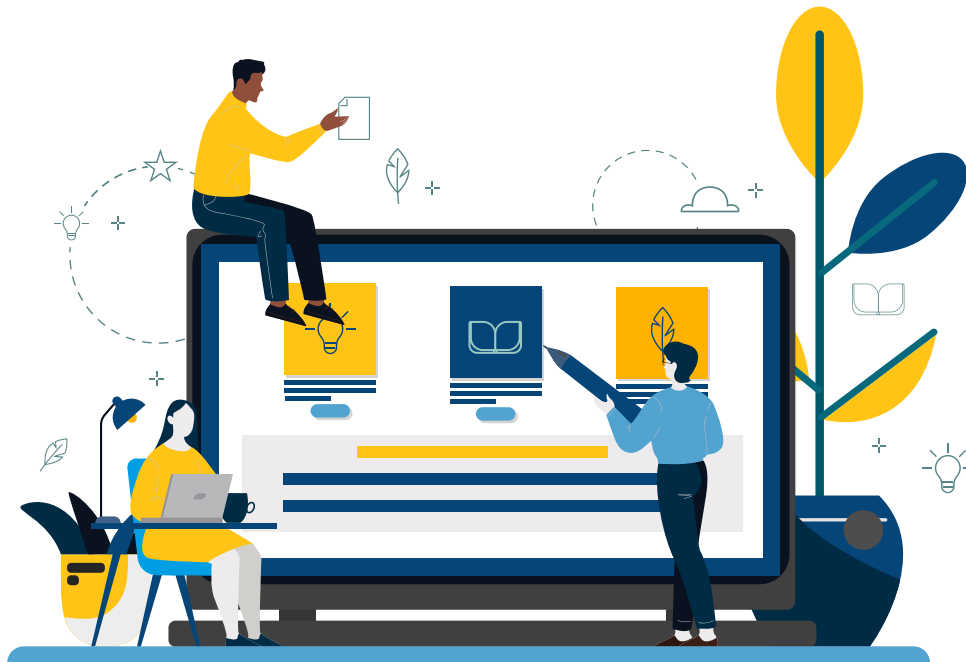
The COVID-19 pandemic:

- Project “on hold” for several months (ANSM requested to report the project due to pandemic situation)
- Upload of additional sequences into the publishing tool (resulting from the period the project was on hold)
- Project Management / Management of resources (due to postponed project)

Technical constraints while importing existing eCTD lifecycle sequences into the publishing tool:

- Huge sequences
- Time-consuming upload
- Corrupted / incomplete sequences during file transfer

Coordination with the Client to receive eCTD sequences published by another external partner last minute prior to MAH transfer sequence



BlueReg Support:

A BlueReg project team was assigned to perform the following steps in close collaboration with the Client:

- Define the content of the MAH transfer sequence.
- Agree on the submission requirements to ANSM.
- Coordinate the receipt of all existing eCTD lifecycle sequences / resolve any technical issues on existing sequences.
- Upload of existing eCTD lifecycle for all products into BlueReg's publishing tool.
- Ensure timely publishing of the MAH transfer sequences in eCTD format and their technical validation (26 sequences in total).
- Perform CESP submission to ANSM for all products (1 single submission).

Achievements:

- Successful import of all 924 existing eCTD sequences in BlueReg's publishing tool
- Publishing and submission timelines met
- ANSM approval of MAH transfer without any questions

