TMC Commercial

CASE STUDY

Accelerating European market entry with TMC's end-to-end regulatory and drug commercialisation support

Background & Objectives

A US-based biopharmaceutical company had acquired an asset for a rare, inherited metabolic disorder, which was already approved in the EU and US. In the US, the client could take over commercialisation immediately upon acquisition. However, the client lacked EU local regulatory infrastructure and was unaware of the critical requirements for European distribution and licensing.

As a global pharma services company with extensive European regulatory expertise and specialist knowledge, TMC Commercial stepped in as the client's trusted partner to gain early market access into Europe.

Challenges & Solutions

Despite having a commercially ready product, the client encountered a fundamental regulatory roadblock: in Europe, if you do not hold a valid wholesale distribution licence (WDL), you cannot buy, sell or distribute a medicinal product.

Many biotech and pharma companies would assume they could immediately commercialise their drug in Europe as they had done in the US. However, without a legal presence, full regulatory oversight and **appointing a local Marketing Authorisation Holder (MAH),** they risked:

- **Losing their European marketing authorisation** (due to inactivity or non-compliance).
- **Delays of 12+ months** to set up local infrastructure or find the right regulatory partners.
- Failing to provide timely access to patients in critical need.

TMC Commercial supported the client by:

Preparing and submitting the Marketing Authorisation Transfer procedures and Acting as their UK and EU MAH

- Taking on full legal responsibility for the product in Europe
- Overseeing all regulatory, compliance and pharmacovigilance activities

Providing a QPPV and pharmacovigilance oversight

- Appointing a QPPV for EU/UK
- Managing safety reporting, risk management plans and signal detection

Handling regulatory strategy and lifecycle management

- Maintaining and updating the client's dossier throughout the product lifecycle
- Ensuring compliance with EU/UK regulations, even post-Brexit

Enabling commercialisation in weeks, not months

- Collaborating with a distribution partner with an existing WDA
- Coordinating a compliant route to market, avoiding typical 12-month delays

Offering full medical information support

- Setting up a dedicated medical information service for GPs to contact TMC
- Facilitating rapid response and patient access to the rare disease drug in collaboration with the client

Ensuring inspection-ready compliance

- In January 2025, TMC underwent an inspection by HPRA (Ireland's regulator) and received no critical findings — demonstrating TMC's commitment to quality, compliance and operational excellence.

Outcome

Many companies assume launching in Europe requires setting up local operations, lengthy timelines and multiple partners.

But there's a faster, compliant alternative.

Through TMC Commercial's integrated support model, the client was able to:

- **Retain and activate their European licence,** avoiding regulatory lapse.
- **Launch and distribute their rare disease product across Europe** within just a few months — not a year.
- **Ensure safe and timely access for patients**, with trusted medical support available to GPs.
- **Operate in full compliance** with all EU and UK regulatory requirements, without needing to build internal infrastructure.

TMC Commercial provided the complete turnkey solution.

TMC Commercial provides flexible, full-service drug commercialisation solutions in the EU and UK — giving late-stage and commercial-ready biotech and pharma companies the opportunity to build their own commercial presence without needing to out-licence to a partner. We also have the specialist expertise to act as an MAH, either as a temporary bridge or long-term solution.

Contact TMC Commercial today at connect@tmcpharma.com to see how we can help you commercialise your asset in the EU and UK — quickly and confidently.