



With Every Patient.

CASE STUDY: USING A PA-NPP TO CREATE ACCESS FOR A CANADIAN-APPROVED PRODUCT IN EUROPE

About the Sponsor

The Sponsor is a North American pharmaceutical company developing drugs to treat rare diseases. The company is dedicated to expanding universal access to orphan drugs in order to offer affordable health solutions and effectively meet the treatment needs of patients worldwide.

The Challenge

The Sponsor had a drug that was newly approved and commercially available to patients in Canada to treat a rare genetic metabolic disorder. It wanted to maximize the potential for this product in additional territories, specifically Europe.

With little experience outside the Canadian healthcare system, the Sponsor's team did not have the knowledge to manage this in-house. The team was also aware that there was already an approved product being used to treat patients with the condition in Europe.

The Sponsor needed to find a partner who could help it understand the opportunity for its product in Europe and deliver a pathway to commercialization in this market.

Our Solution

The Sponsor decided to partner with WEP to set up a Post-Approval Named Patient Program (PA-NPP) for patients in selected European countries.

What is a PA-NPP?



PA-NPPs allow Sponsors to provide approved medicines to patients in countries where they are not yet approved or commercially available.



For more information:
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The program was designed to supply the Canadian approved medicine, on an unlicensed basis, to requesting physicians who were unable to treat their patients with the licensed competitor product. Below we have outlined how we helped set up and deliver the program, raise awareness of the product, and develop an informed market access strategy to secure approval and commercialize the product.

01

Program Set Up and Delivery

- We helped the Sponsor define the scope for its program and develop the necessary Project Plan, SOPs and supportive documentation.
- We handled all the regulatory requirements in countries in scope to ensure product could be imported and successfully cleared through customs.
- Product was stored at our UK warehousing facilities and a logistics plan was created to ensure full security and visibility along the product journey to the treating physicians.

02

Awareness Activities

- Our team of Country Managers work on-the-ground in countries across Europe and have deep local market knowledge and relationships with KOLs. This allowed them to generate awareness of the PA-NPP product.
- Through our dedicated patient advocacy support function, we engaged with local and regional advocacy groups to establish a dialogue and compliantly communicate information around the product.

03

Market Access Strategy Development

- The PA-NPP allowed us to understand the clinical need, the competitor landscape, pricing, and the potential product uptake across European countries. This helped us develop a market access strategy for commercial launch.
- Our team then supported the Sponsor through the EMA approval process and became the exclusive commercial sales partner for this product across several EU countries.