

## CASE STUDY: THE VALUE OF WORKING WITH WEP TO PROVIDE EARLY ACCESS IN FRANCE

### Background

A European biopharmaceutical company (Sponsor) inherited an Expanded Access Program (EAP) when it acquired an infectious disease medicine from a major American pharmaceutical company. The original program had been set up and managed by WEP, to supply the investigational drug to patients who were unable to enroll in the active clinical trial in the U.S. only.

Recognizing WEP's global experience in the EAP space, along with our established infrastructure, WEP was chosen to maintain the program and expand its scope internationally.

This was a direct result of the WEP Market Access team partnering with the Sponsor to understand its global development and commercialization goals, and provide tailored guidance on how the EAP could evolve to offer long-term strategic value. WEP has since made the drug available to patients worldwide.

### Challenge

Early Access to promising new medicines that address areas of high unmet clinical need in France falls into a structured set of schemes. WEP has significant experience initiating and delivering Early Access programs in France and recommended setting up a Autorisation d'accès compassionnel (AAC) for the infectious disease medicine.

Below, we outline the value of working with WEP on this type of program.

## Why WEP

01

### Regulatory, Project Management and Market Access Expertise

One of WEP's key advantages in France is our deep knowledge of all the access pathways and the AAC specifically, developed through our work with representatives in the French National Agency for Medicines and Health Products Safety (ANSM) across multiple medicines, disease areas and stages of clinical development.

- We helped the Sponsor understand key roles and responsibilities for all stakeholders under the AAC, including management of unsolicited physician requests, hospital ordering, supply chain and importation, data collection, turnover submissions and payments.
- WEP led interactions with the ANSM, preparing and submitting the AAC dossier, Therapeutic Use Protocol (PUT-SP), and Pharmacovigilance/Data Collection Plan.

#### Key takeaway:

Drawing on our deep expertise with France's Early Access Schemes, we helped the Sponsor secure approval for a program that enabled French patients to access this important medicine through a dedicated regulatory pathway to regulations.

02

### Establishing a Value-Driven Program

Under France's AAC framework, companies can choose to charge for the investigational product. As such, we advised the Sponsor to set a price for the drug to generate early revenue while maintaining access for eligible patients and fulfilling data collection and overall management of the access program.

Based on our knowledge of pricing mechanisms in France, and our understanding of the Sponsor's future commercial objectives, we helped the Sponsor establish a compliant pricing strategy, balancing revenue with equitable patient access and future commercialization goals.

### **Key takeaway:**

WEP understands how to design programs that drive strategic value for Sponsors. France AAC schemes can generate revenue ahead of commercial launch, which can be used to offset program costs and fund further R&D, thereby accelerating the advance of new therapies.

## **03**

### **Expert Program Delivery**

As the program in France is delivered through a standalone regulatory pathway, with mandatory data collection and invoicing for product supplied, it requires a dedicated cross-functional delivery team. This team is made up of our Market Access team, with local expertise in France, our global Project Management team overseeing patient request management and product supply; and a dedicated French Project Manager who supports key stakeholder interactions in France to ensure successful implementation.

### **Key takeaway:**

At WEP, we can seamlessly integrate France access programs into global access solutions such that the Sponsor receives a consistently high level of customer service and patients have access in all countries in scope.

## **Conclusion**

At WEP, we provide robust access solutions that can scale and flex as patient and physician demand evolves over time. By combining strategic thinking, country-specific regulatory expertise, and best-in-class project management, WEP has enabled efficient and compliant early access for patients in France.