

# PRODUCT INFORMATION FOR MARKETING AUTHORIZATION APPLICATION (SMPC, PIL, AND LABELING)

**CLIENT PROFILE:** A Czech pharmaceutical service provider offering a comprehensive suite of services that ensure seamless market access and regulatory compliance for pharmaceutical companies.



## OBJECTIVES

To translate Product Information (**Summary of Product Characteristics (SmPC)**, **Patient Information Leaflets (PIL)**, and **Labeling**) from English into Portuguese to submit a Marketing Authorization Application.

## APPROACH

**1. Translation Plus Review:** After the initial translation, a native linguist experienced in pharmaceutical translation conducted a thorough review of the materials. This ensured both linguistic precision and technical accuracy.

**2. Consistency with Regulatory Standards:** Implemented a rigorous quality assurance mechanism to ensure that the translated materials aligned with QRD guidelines, MedDRA and EDQM terminology, blue box requirements, and other national criteria.

**3. Feedback from National Authority:** Post delivery, the documents underwent an assessment by the national authority. Feedback and amendments proposed by the authority were promptly implemented to ensure the materials met all regulatory standards.

## BENEFITS

### 1. Regulatory Compliance

The translated documents are linguistically and scientifically accurate and align perfectly with regulatory requirements, making them ready for submission.

### 2. Enhanced Patient Safety

Both healthcare professionals and patients are well-informed, thereby reinforcing the safety of the medicinal product.

### 3. Client Satisfaction

By offering accurate translations and additional support, the client was able to ensure maximum satisfaction for their pharmaceutical customer, bolstering their reputation in the industry.

## AT A GLANCE

### CHALLENGES

- Meeting the detailed requirements of pharmaceutical translations, especially considering specific mandates like QRD and blue box.
- Integrating feedback from national authorities within a tight deadline.

### BENEFITS

- Efficient regulatory submissions due to translations that are compliant with all necessary guidelines and feedback.
- Increased patient engagement and safety through transparent, accessible product information.



**Need a medical translator or writer?**  
**I'm Your Portuguese Patient Partner**  
[www.anasofiacorreia.com](http://www.anasofiacorreia.com)  
[ana@anasofiacorreia.com](mailto:ana@anasofiacorreia.com)