AzurBio

Case study

Navigating Marketing Authorization for Homeopathic Medicinal Products with Indication in France

Goal:

Obtain a Marketing Authorization in France for a homeopathic medicinal product with therapeutic indication, distributed under a brand name, ensuring compliance with Directive 2001/83/EC and French national requirements, while optimizing timelines and dossier quality.

The challenges

Regulatory Framework

According to Directive 2001/83/EC, homeopathic medicinal product ("HMP") is **any medicinal product prepared from substances called homeopathic stocks** in accordance **with a homeopathic manufacturing procedure** described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States.

Homeopathic medicinal products with therapeutic indication appearing on the labelling cannot use the simplified registration procedure (Article 14(1) of Directive 2001/83/EC). In France, they require a marketing authorization under Article 16(2) of Directive 2001/83/EC and in accordance with the principles and characteristics of homeopathy as practiced in France, as defined in Article R.5121-28-5 of the French Public Health Code.

National Rules

France applies specific adaptations for preclinical and clinical data, which differ from other EU countries. For a homeopathic medicinal product subject to marketing authorization, the applicant is exempt from providing all or part of the results of pharmacological, toxicological, and clinical trials when they can demonstrate, through detailed reference to published literature recognized **within the tradition of homeopathic medicine practiced in France,** that **the homeopathic use** of the medicinal product, or its constituent homeopathic stocks, **is well established and ensures complete safety.**

Specificity of Homeopathic Medicines

The branded specialties often combine several homeopathic stocks and claim indications, posology, and target population. The dossier must reflect traditional use and homeopathic principles while meeting pharmaceutical quality standards.

The justification of the homeopathic use consists of a **well-developed rationale for the justification of the homeopathic use of each stock and their dilution,** based on the available bibliographical documentation.

Evidence Requirements

Marketing authorization is conditional upon the existence of documentation demonstrating **the homeopathic nature and the tradition of use in France** for the claimed indication.

This includes bibliographic data such as monographs, materia medica, classical homeopathic texts, documented traditions, and recent publications.

Quality Issues and Specificities

As with all medicinal products, the marketing authorization application dossier for homeopathic medicines must include a quality module; however, this module is adapted to the specific characteristics of homeopathic medicinal products.

In homeopathy, the active substances can be either the stock or its dilutions/triturations. The stock can be processed as well as unprocessed raw material. Therefore, homeopathic medicinal products may contain large numbers of active substances or combinations of them, from both synthetic and natural origin (including botanical, zoological, human and mineral).

The quality section of the marketing authorization application dossier must therefore include the specific elements particular to homeopathic medicinal products; i.e., information on the starting material, including raw materials, homeopathic stock(s), and intermediates up to the final dilution(s) (or triturations) to be incorporated into the finished product.

Procedural Constraints

Mutual Recognition or Decentralized Procedure is not applicable when national rules under Article 16(2) are used.

Steps

Regulatory Strategy

Confirm eligibility of the homeopathic medicinal product for MA with therapeutic indication under Article 16(2) and French national provisions.

Submission & Follow-up

Respond to ANSM questions, manage variations, ensure pharmacovigilance compliance.

Dossier Preparation

- Administrative documents (CTD Module 1).
- Quality documentation (CTD Modules 2.3 & 3): raw material, starting material for homeopathic preparations (stock), potentisations (dilutions/triturations), drug product.
- Nonclinical Overview adapted to homeopathy (CTD Modules 2.4 & 4), including bibliographic evidence of safety.
- Clinical Overview adapted to homeopathy (CTD Modules 2.5 & 5), including bibliographic evidence of the traditional homeopathic use.
- Patient Information compliant with French-specific labelling rules, including patient leaflet adapted to self-medication.

Outcome:

The product obtained national MA in France, enabling commercialization with therapeutic indications under a brand name. The tailored strategy avoided unnecessary conventional trials, reduced regulatory risk, and ensured dossier robustness.

Benefits of the Partnership with AzurBio:

- **Expertise in Homeopathic Regulations:** Mastery of EU and French frameworks, including Article 16(2) adaptations.
- **Access to AzurBio's proprietary homeopathy database,** built over years of expertise, containing materia medica, provings, bibliographic references, and handbooks. This resource, combined with our expertise, ensures robust, well-documented submissions.
- **Operational Efficiency:** Streamlined dossier preparation.
- **Risk Mitigation:** Anticipation of national requirements and avoidance of procedural pitfalls.
- **Strategic Advantage:** Faster market access compared to companies unfamiliar with homeopathic regulatory nuances.

Conclusion:

Marketing homeopathic medicinal products with indication in France requires specialized expertise in both European law and homeopathic practice. By leveraging AzurBio's experience, companies can achieve compliance, optimize timelines, and maintain therapeutic integrity in a highly complex domain.