Challenges for Extra-EU products entering the European Market: A Case Study on the evaluation of Regulatory Strategy

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Expanding into the European market presents significant opportunities for extra-EU products. However, navigating the complex regulatory landscape is crucial for success. This poster highlights the key challenges faced by products, particularly those that are borderline and may fall under various classifications such as medicine products, food supplements and medical devices, and how a gap analysis can facilitate EU market entry.

Regulatory Complexity

Different Regulations: The European Union (EU) has a detailed regulatory framework that varies among member states. Regulations are directly applicable and mandatory, while directives provide guidelines that must be incorporated into national laws. For this reason, each member state might have its own regulatory practices, making market entry challenging and leading to differences in the implementation of directives.

Compliance Requirements: Companies must ensure their products meet the stringent safety, efficacy, and quality standards set by the EU. Depending on the product classification, the EU requires extensive documentation, clinical trials, and safety evaluations to comply with standards and specific product regulations.

Classification Challenges

Medicinal product: Directive 2001/83/EC defines a medicinal product as any substance or combination of substances that may be used in or administered to human beings with the aim of restoring, correcting, or modifying physiological functions by exerting a pharmacological, immunological, or metabolic action, or to make a medical diagnosis. There are several routes for obtaining marketing authorization. The assessment must include data on the quality, safety, and efficacy of medicinal products and manage pharmacovigilance activities.

Food Supplements: According to Directive 2002/46/EC, 'food supplements' means foodstuffs intended to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination. It must be ensured that these are safe for consumption and properly labeled, so the food supplement must comply with specific requirements for ingredients, health claims, and nutritional information.

Medical Devices: Regulation (EU) 2017/745 defines a medical device as any instrument, implant, reagent, material, or article intended for human use to diagnose, prevent, monitor, predict, treat, or alleviate disease or injury, modify anatomy or physiological processes, or provide information via in vitro examination. It does not achieve its main action through pharmacological, immunological, or metabolic means, but may be assisted by them. To place a medical device on the EU market, it needs a CE mark, demonstrating conformity with EU safety and performance standards. The conformity assessment involves an audit of the manufacturer's quality system and a review of technical documentation.

Case study

A gap analysis is a strategic tool that helps identify the differences between the current state of a product and the desired state required for market entry. Thorough research on EU regulations and market conditions is essential. Understanding the specific requirements for each product category can help in planning a successful market entry strategy.
A case study follows, examining the potential EU classification of a product marketed as a cinnamon-based herbal medicine by a South-East Asian company, which is indicated to alleviate gastric disorders.

- *Identify Regulatory Gaps*: The initial step involved assessing the current regulatory status of the product in its home market and compare it with EU requirements. Furthermore, the mechanism and available bibliographies on the product and cinnamon were analyzed to determine which EU categories the product might fall into. This analysis highlighted the borderline nature of the product, which could be classified either as an herbal medicinal product or a food supplement. A product that acts through a pharmacological or metabolic means cannot be classified as a medical device and for this reason this option has been excluded.
- *Evaluate Compliance Processes*: After defining the product category, it is mandatory to identify any gaps in documentation and certification that need to be addressed to meet EU regulations for that specific category. Therefore, at this stage, the necessary information for marketing products in the categories that were identified in the first step was analyzed. 1) For an **herbal medicinal product**, a complete dossier is required. For a traditional herbal medicinal product, the efficacy and safety sections of the dossier are simplified, while the quality requirements remain the same as those for herbal medicinal products. 2) For a product classified as **food supplement**, no medical claims must be made, and all ingredients must be suitable for nutritional use. Acceptable claims for food products are those intended for healthy individuals, not patients.
- *Market Readiness Assessment*: In the EU, herbal medicinal products are governed by harmonized legislation, while food supplements are subject to individual national regulations. This necessitates specific assessments and partnerships with local providers to navigate these differences effectively. Local partners can also help ensure compliance with EU legislation regarding distribution channels and responsibilities for commercializing products within the European Economic Area. As a result, a plant may be permitted in food supplements in one EU country but not in another. An initial step towards harmonization was the creation of the "BelFrIt list" a common list of plants allowed in food supplements defined by France, Belgium, and Italy, representing the most harmonized approach available. Cinnamomun cortex is reported in such list therefore it is plausible that it could be used in botanicals food supplements.
- *Develop Action Plans*: Based on the gap analysis, develop detailed action plans to address identified gaps. This includes timelines, resource allocation, and specific steps to achieve compliance and market readiness.

Conclusion

Successfully entering the European market requires careful planning and a deep understanding of the regulatory environment. By conducting a thorough gap analysis, extra-EU products can identify and address the specific challenges they face, facilitating smoother market entry and unlocking significant growth opportunities in Europe. Products that straddle multiple regulatory categories offer unique opportunities. Specialized regulatory analysis for these products can navigate classification complexities, ensure compliance and leverage their borderline market positions to drive substantial growth within the European Economic Area.

References:

1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use https://eur-lex.europa.eu/eli/dir/2001/83/oj/eng
2. Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.
3. Regulation (EU) 2017/745 of the European Parliament and of the Council