Fact Sheet

Meet Pre-Launch Regulatory Requirements Across the Globe

Ensure compliance with diverse regulatory frameworks with IQVIA Market Authorizations and Labelling Solutions

The challenges

Regulatory submissions for marketing authorization applications are challenging due to strict, evolving regulations and deadlines set by local authorities. Companies must navigate language and cultural differences, ensuring compliance and effective communication with diverse regulatory bodies. Delays in translating and submitting documents can lead to non-compliance and rejection. These challenges are exacerbated by the need for high-quality, timely translations that meet specific regulatory standards and guidelines.

The approach and outcomes

Successfully navigate the entire regulatory landscape to ultimately achieve the marketing authorization for your product with our modular and customizable solutions:

MARKET AUTHORIZATION LANGUAGE SUITE

- **Common Technical Dossier/Document (CTD):** Demonstrate the safety, quality and efficacy of your product with specific information depending on the region
- **Product Information (PI):** Ensure your marketing authorization application adheres to local regulatory guidelines, reducing the risk of non-compliance and improving the chances of approval

MULTILINGUAL LABELLING SOLUTIONS

- **Labelling:** Maintain patient safety by providing clear and consistent translation for labels in every language and region, while addressing cultural and linguistic differences

Ensuring a seamless and efficient process with IQVIA's comprehensive regulatory coverage

- **IQVIA's unique regulatory compliance expertise:** End-to-end regulatory affairs solutions and experts, along with regulatory expert linguists (largest in-house linguist pool in the industry)
- **IQVIA's AI and machine translations:** proprietary engines trained with clinical data, as well as best of breed selection of the latest technologies in the market to maximize the quality depending on the content type
- **Customizable regulatory workflows** (e.g. EMA and Swissmedic) and rapid turnarounds for different marketing. **Compliance with regulatory requirements** via customized translation memories and term bases

The IQVIA difference

IQVIA end-to-end regulatory affairs and lifecycle management solutions provide you with regulatory strategy, labeling, publishing, and intelligence solutions supported by our data and technology, from early drug development through submissions and post-registration.

CONTACT US

To learn more about how IQVIA Language Solutions can help you navigate multilingual regulatory submissions, contact us at ruyana.dassu@iqvia.com

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