Regulatory Review of Promotional Materials for an EU-based Pharmaceutical Company Across 60+ Global Markets

This comprehensive case study delves into the challenges, objectives, solutions, and achievements of a regulatory review project undertaken by a mid-size pharmaceutical company across the European Union (EU), Asia-Pacific (APAC), Latin America (LATAM), and the Middle East

Situation

The regulatory landscape governing pharmaceutical promotional and non-promotional materials is complex, particularly for pharmaceutical companies operating across diverse regions.

A pharmaceutical company was striving to achieve compliance with the EU, national regulations, and developing markets (APAC, LATAM, and the Middle East) for their 2,000+ promotional and non-promotional materials across 60 countries. The customer sought a comprehensive, scalable, cost-effective solution to address the complexities of international regulations, varying market needs, and the challenge of coordinating across multiple vendors. IQVIA's support covered materials ranging from sales aids and brochures to website content, social media posts, press releases, medical education resources, journal articles, direct-to-consumer advertising, scientific presentations, posters, and patient education materials.

The primary objectives of the project were:

MATERIAL COMPLIANCE:	GLOBAL APPROVAL FACILITATION:	SOP ESTABLISHMENT:	LOCALIZED EXPERTISE:	INFORMED DECISION-MAKING:
Ensure that all promotional and non-promotional materials adhere to the stringent EU and national legislation and guidelines of each country. Also ensure that promotional and non-promotional materials are meticulously aligned with the prevailing labeling requirements and pertinent local guidance for each country under consideration.	Streamline and support the review and approval processes for EU-wide campaigns and national materials in each targeted country.	Establish comprehensive Standard Operating Procedures (SOPs) at the EU and local levels, ensuring a consistent and standardized approach to the review process.	Provide dedicated local representatives with market-specific training, facilitating accurate and localized compliance.	Deliver precise and up-to-date regulatory market intelligence to enable well-informed business decisions in a rapidly evolving landscape.

Challenge

The customer was facing the following operational challenges:

VENDOR MANAGEMENT AND CENTRALIZATION:
Managing multiple vendors, lacking a centralized approach, and the oversight and administrative burden on the central headquarters team.

LOCAL AFFILIATE COVERAGE:
The absence of local affiliates posed a strategic hurdle while customizing the materials for markets.

SOP IMPLEMENTATION:
The strategic objective of refining operational efficiency was hindered by an absence of SOPs for material review, necessitating a focused effort on local SOP development and integration.

STAKEHOLDER COORDINATION AND EFFICIENCY:
Inefficiencies due to lack of coordination among numerous stakeholders responsible for generating materials.

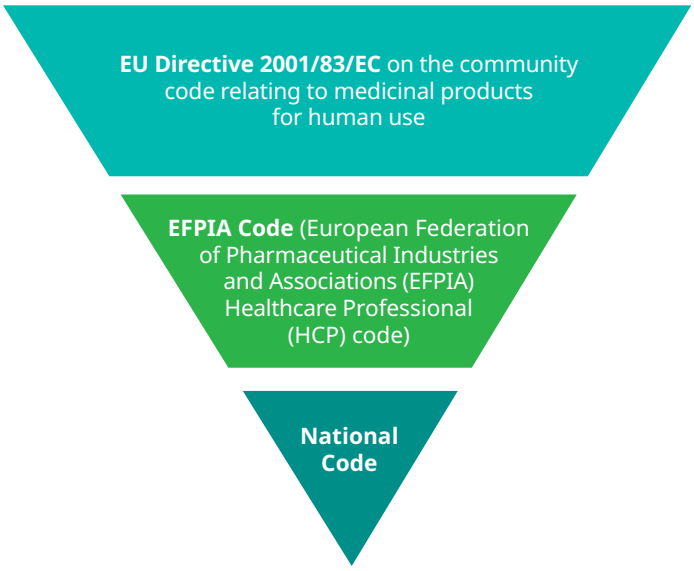
DIGITAL COMPLIANCE:
With the rise of digital marketing, pharmaceutical companies face the challenge of ensuring their online promotional materials meet regulatory standards.

Solution

To overcome the challenges, IQVIA embarked on a comprehensive strategy. IQVIA assembled a dedicated team of regulatory experts with a deep understanding of the EU and national regulations. The project involved extensive collaboration, including concept meetings with material originators, interdisciplinary discussions, and market-specific training. Workflows were created to streamline the review process, and market-specific SOPs were established to ensure consistent and compliant reviews. The project also expanded to manage local market product launches and provide regulatory support in European countries and emerging markets.

IQVIA provided training on EU Directive 2001/83/EC on the Community code relating to medicinal products for human use, the EFPIA Code, and applicable EFPIA Member Associations' national codes and any other applicable (local) internal policies, procedures, and laws.

Figure 1: Top-down training approach from global codes to national codes



An intelligence-driven approach was also adopted to ensure the customer and reviewers were on top of the national requirements of each country. Countries varied in terms of submission requirements to national regulatory authorities, the inclusion of prices in promotional materials, and the necessity of local approvers.

IQVIA established a dedicated digital compliance team that focused on the unique challenges presented by digital promotional materials. This team worked with the marketing and regulatory teams to ensure that digital content was compliant, e.g., direct-to-consumer promotion on social media.

Table 1: Cross-country comparison of promotional material requirements across the regions

REQUIREMENT	UK	IRELAND	POLAND	SPAIN	FRANCE	GERMANY	ITALY	BELGIUM	PORTUGAL	SAUDI ARABIA	UAE	EGYPT
Submission of promotional material to national RA before release	Yes, but only for special situations	No	No	No for the national RA, but it needs to be submitted to the HA of the autonomous region	Yes	No	Yes	Yes	No, but within ten days after the distribution, on an online form	Yes, for material directed to HCP	Yes, for HCP and consumer	Yes, for HCP and consumer
Price in promotional material?	Yes	No	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes
Local approver required for promotional material?	Yes- either a UK-registered medical doctor or pharmacist	No	No	Yes	Yes	Yes, MAH information officer	Yes	Yes, the Responsible Person for Pharmaceutical Information	No	No	No	No

Results

- **Material evaluation and regulatory compliance:** IQVIA conducted a comprehensive review of over 2,000 diverse media materials, meticulously reviewing them in accordance with relevant regulations, encompassing standards set out by organizations like IFPMA, EFPIA, and national country guidelines. This stringent review process ensured the alignment of materials with established legal and regulatory frameworks.
- **Tailored market engagement:** To foster meticulous market compliance, IQVIA organized concept meetings, bringing together material originators and stakeholders. These sessions served as pivotal opportunities to delve into country-specific regulations, enhancing material quality and reinforcing adherence to distinct market norms.
- **In-depth market insights:** The provision of detailed country reports proved indispensable for informed decision-making, particularly in go/no-go determinations pertinent to product promotion and market launches. These insights equipped customers with the knowledge to navigate sophisticated market landscapes effectively.
- **On-demand support:** The responsive nature of IQVIA's support system was exemplified through its provision of ad hoc assistance.
- **Structured frameworks and scalability:** IQVIA was pivotal in structuring the operational architecture. This encompassed supporting the development of comprehensive workflows and SOPs tailored for the EU and emerging markets. Moreover, the scalability of country teams during peak demand periods, such as market launches and congresses, was instrumental in ensuring consistent and quality-driven operations.

- **Actionable insights and improvement:** IQVIA's review process extended beyond compliance verification. It enriched the process by offering clear, actionable feedback. This feedback encompassed not only regulatory observations but also constructive suggestions, including alternative wordings and translation corrections.
- **Defined roles and responsibilities:** The pivotal factor in achieving smooth coordination among the various teams was the establishment of clear and specific roles and responsibilities within the scope of the review for each group member.

Table 2: Roles and responsibilities of teams involved in different stages of promotional material review

ROLE	RESPONSIBILITIES
 Medical affairs reviewer	• Review for technical/medical/scientific accuracy. • Review against the listed references, where study data from a trial are summarized in the material. • Check the appropriateness of messages from a medical perspective and substantiation for all claims. • Ensure the proper language is used for the materials. • Check the correct use of references, imagery, and figures.
 Regulatory affairs reviewer	• Check against SmPC to ensure the claims or messages are consistent with the terms of the product approval. • Review to ensure that all statements are consistent with the approved indication. • If applicable, conduct the HA submission of the notification. • Be aware of current regional and local regulations or guidance impacting advertising and promotions by monitoring the regulatory environment.
 Marketing reviewer	• Assure that only approved regional claims are used locally. • Assure that the regional-level approved version of the material is referenced in the local approval process. • Ensure all final versions of the printed material have a unique material identification reference number. • Review for adherence to the current revision of brand guidelines. • Ensure the submission contains accurate product information and is aligned with marketing strategy. • Check the correct use of brand and company trademarks and service marks. Consult with Brand Protection/Trademarking where applicable. • Verify the quality of final material from a language and look perspective.
 Legal reviewer	• Assess the legal risk of various issues related to promotional materials. • Advise of legal sufficiency of claims substantiation. • Evaluate the implicit and explicit messages of claims to assess whether they have the potential to mislead or confuse. • Trademark attorney/paralegal: check the accurate use of brand and company trademarks and service marks, if applicable..
 Healthcare/commercial reviewer	• Ensure customer-facing items are compliant with the Health Care Compliance Policy.

Conclusion

The efficacy of a strategic approach is evident in the successful regulatory review of promotional and non-promotional materials across diverse global markets. The project effectively ensured compliance with intricate regulations by addressing challenges through centralized coordination, customized market engagement, and actionable feedback. Moreover, establishing well-defined roles and responsibilities bolstered seamless collaboration among teams. The project's accomplishments are underscored by its provision of valuable market insights, ad hoc support, and the implementation of scalable operational frameworks.

IQVIA's regulatory team played a pivotal role, supporting the review of over 2,000 promotional materials across 60+ markets. As the scope of work expanded dramatically, it encompassed materials ranging from sales aids and brochures to website content, social media posts, press releases, medical education resources, journal articles, direct-to-consumer advertising, scientific presentations, posters, and patient education materials. This comprehensive endeavor ensured regulatory compliance, and significantly influenced material efficacy and market launch strategies.

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