

Title: RegWeb supports Mid-Sized Pharma Manufacturers with Regulatory Review of Promotional Materials in European Market

Client Background:

One of the mid-sized pharma companies needed to ensure regulatory compliance for their promotional and non-promotional materials in Eastern European (EEU) markets. The company, headquartered in Western Europe, faced several challenges, including:

- Navigating EEU reviews and requirements for the first time
- Lack of local affiliates in EEU and emerging markets
- Coordination between multiple stakeholders involved in material generation
- Need for local representative roles in Hungary and Poland.
- Constant monitoring of new regulations and guidelines, to ensure company is always in compliance.



Project Scope:

The project's primary objective for the client was to perform comprehensive local

market reviews of promotional and non-promotional materials to ensure compliance with EU and local national country codes in the 12 EEU Countries. The goal was to facilitate successful product promotion and market launches in the region.

These materials included print and digital advertisements, brochures, posters, websites, and social media content for promotional purposes.



Approach:

RegWeb assembled a team of highly experienced and knowledgeable professionals for promotional material review for its compliance with global and local Regulatory requirements. The team conducted thorough regulatory and medical reviews of all materials, ensuring compliance with relevant regulations, such as the IFPMA code of practice, EFPIA code of practice, and national country regulations.

RegWeb also organized meetings with promotional material creators and other client stakeholders during the concept stage to explain the specific regulations in each country. This helped to enhance



material quality and ensure market compliance, as the client project teams primarily operated from Western Europe and US and were unfamiliar with detailed EEU national requirements.

RegWeb regulatory experts provided detailed country reports and overviews for the targeted markets, covering critical market considerations such as local resources required for scientific service, the role of scientific service, types of materials subject to health authority review, distribution timelines, congress requirements, and more. These insights facilitated crucial decision-making for product promotion and market launches.

RegWeb's local experts also provided submission support in countries Regulatory agencies at national levels as required.

RegWeb served as the primary point of contact and efficiently managed the necessary tasks across multiple markets to meet all deadlines.

Achievements:

- RegWeb **efficiently coordinated** the review process for multiple client stakeholders, ensuring seamless communication and timely completion of review across various markets.
- **Key Performance Indicators (KPIs)** were implemented to measure project

performance, including review time per material, workload per market, and therapeutic area, among others.

- RegWeb **acted as local representative** in Hungary and Poland for launch support.
- The sponsor added further markets to the project scope for promotional copy review.
- **RegWeb's worldwide capabilities** allowed for swift execution of reviews at short notice, catering to the clients' specific business needs.
- Value addition by creating a complementary database of regional requirements.

Conclusion:

RegWeb provided effective regulatory support to the mid-size pharma company, ensuring compliant reviews of promotional and non-promotional materials across EEU markets. The dedicated team of consultants, along with the defined workflows and work-instructions contributed to consistent and efficient reviews, facilitating successful product promotion and market launches.

RegWeb constantly monitored new regulations and guidelines, so that rest assured that client is always in compliance.





How RegWeb can Support You?

We offer a comprehensive range of services tailored to meet your needs, ensuring compliance with international congress requirements and local regulations. RegWeb provides a wide range of regulatory and technical support services to help you navigate the ever-changing regulatory landscape. Our team of experts can provide you with

integrated packages of services or customized ad-hoc assistance, depending on your needs. We are committed to helping you maintain your competitive edge by providing you with the knowledge and resources you need to comply with the local regulations.

Our Services:

- **Global coordination and oversight:** A dedicated project manager ensures that projects are completed on time and to a high standard, with clear KPIs and metrics.
- **Expert review:** A team of experienced consultants reviews and validates promotional materials for compliance with global and local regulations.
- **Local support:** A worldwide network of local partners provides services such as local signatories and training.
- **Work-instructions and workflows:** RegWeb can help you set up, train on procedures and workflows for promotional material review and validation.
- **Submission to regulatory agencies:** RegWeb can submit promotional materials to regulatory agencies at the national level as required.
- **Build, own, operate and transfer:** RegWeb believes in creating value added transferable services to ensure clients are benefitted at the end of project.

For more information, please contact us

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