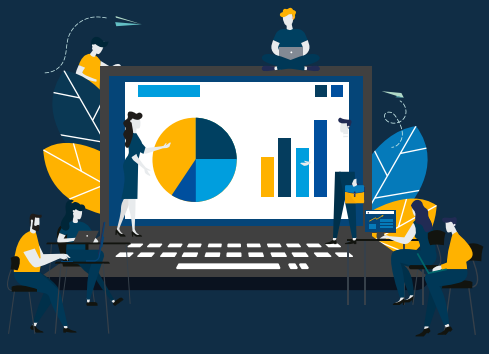
Case Study

Promotional material compliance



Our clients :

Two pharmaceutical companies sought solutions for review of promotional and non-promotional materials to ensure compliance with the European Union (EU) and national country legislation and guidelines for medicinal products.

Objective :

For BlueReg to provide a sustainable, scalable, high quality, timely and cost-effective solution for the review of promotional and non-promotional materials. To provide support for the review and approval of EU campaigns and national materials both within Europe and for rest of the world markets, submission and approval to national health authorities where applicable, implementation of relevant Standard Operating Procedures (SOPs) at the EU and / or local levels, provision of local representatives as per the market needs with delivery of specific market training as required and regulatory market intelligence to enable key business go / no go decisions to be taken for product promotion / market launches.

Challenges :

The project brief for both clients was to undertake both EU and local market reviews of promotional and non-promotional materials to ensure compliance with EU and national country codes with the following challenges :

- First product launch for both clients with no complete local affiliates set up in all European countries where market launch was planned.
- Both companies headquartered in the United States (US) with staff inexperienced in EU reviews and requirements.

- SOPs not in place at EU or national levels for material review.
- Launch planning subject to change and interest in rest of the world markets.
- Multiple stakeholders generating materials.
- Company 2 required support to cover the local representative roles in Germany (Informationsbeauftragter (Information Officer) and Belgium (Responsible for Information and Publicity (RIP)).

BlueReg support :

BlueReg provided a dedicated team of consultants with the appropriate expertise to fulfil the regulatory requirements and meet both client's expectations.

- Provided detailed country reports and overviews for markets of interest to each client covering important market considerations such as local resources required for scientific service, role of scientific service (agency submissions, signatory requirements, timelines etc), which types of materials are required to be reviewed, when can materials be distributed in the markets, congress requirements etc to enable key business go / no go decisions to be taken for product promotion / market launches.
- Provided ad hoc support for questions arising from all client stakeholders.
- Reviewed the materials (all media types) against the applicable regulations (e.g. for medicinal products, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) code of practice, European Federation of Pharmaceutical Industries and Associations (EFPIA) code of practice and national country regulations e.g. The Association of the British Pharmaceutical Industry (ABPI) UK and The National Agency for the Safety of Medicines and Health Products (ANSM) recommendations for France etc.
- Meetings held with material originators and other client stakeholders at the concept stage to explain the country specific regulations in order to improve the quality of the materials and to ensure market compliance. This was critical in the early stages when the client project teams were predominately US based and not fully aware of the detailed EU and national requirements.

- Attendance of market reviewers at concept meetings of key pieces and interdisciplinary meetings (with regulatory, medical and legal stakeholders) to ensure campaigns are compliant and the team was aware of the national differences which exist.

- Supported the creation of validation software workflows (to identify relevant stakeholders and interactions between the stakeholders) and EU and market specific SOPs.

- Regular scale up of country teams to meet high periods of demand such as market launches, congresses etc.

- BlueReg granted access to client validation software to co-ordinate and conduct multiple country reviews simultaneously.

- Worked with client stakeholders to ensure the full context of the materials were included in the validation software system to include target audience, method of distribution, provision of the full references quoted in the materials etc.

- Ensured clear and actionable market feedback was provided for every review including:

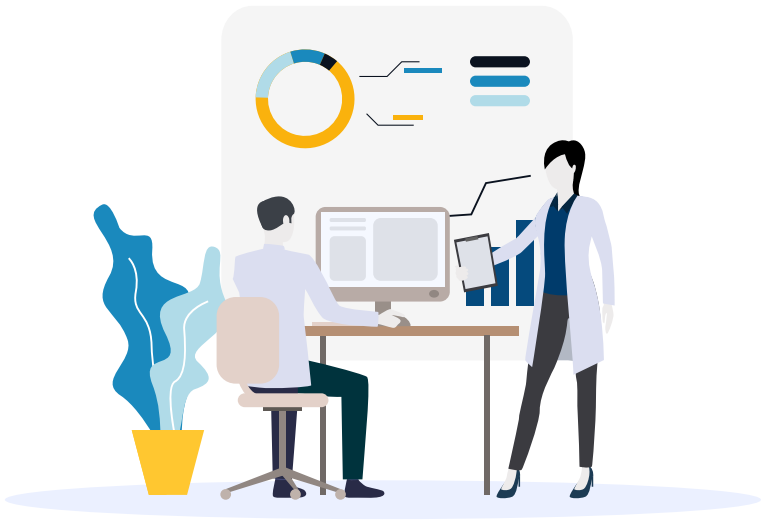
- Areas of concern / if not permissible according to local guidelines
- Suggestion of alternative wording / translation corrections
- Level of risk or consequences to continuing with the material unchanged

- In addition, for company 2 BlueReg undertook the following activities:

- Acted as local representatives in Germany (Information Officer) and Belgium (RIP) through provision of experienced and qualified local in country resources.
- Delivered local market training for sales representatives and local client teams.
- Submission of promotional materials to local Health Authorities and regulatory agencies within Europe.
- Local regulatory review, approval and certification of promotional materials (all media types) in the validation software.

- BlueReg acted as a single point of contact and coordinated the required actions in multiple markets to ensure deadlines were achieved.

- Implemented Key Performance Indicators (KPIs) to ascertain project performance such as time taken to review each material, workload per market and therapeutic area etc.



Achievements :

- Central coordination, prioritization (local national holidays, launch periods) and escalation process for concerns to ensure smooth communication for multiple client stakeholders.
- Question tracking for metrics and to ensure capitalization of responses.
- Scalable model of operation – key worldwide markets can be executed quickly with minimum lead time.
- BlueReg consultants continue to provide long term review of promotional and non-promotional materials within the validation software for both clients. Dedicated and ringfenced project teams have ensured efficiency and consistency of reviews.
- Reviews within the validation software utilise a central review model ensuring that consistent and full responses are provided for multiple markets.
- Calendar of promotional and non-promotional material release in place with both clients.
- Optimisation of the review cycles to ensure the time allocated for each review is sufficient for routine reviews balanced against expeditated reviews.
- Project scope extended to include the management of the local market product launches and regulatory support in some European countries working with the client project teams for client 1.
- For both clients, further markets were added to the project scope for promotional copy review.
- Worldwide capabilities available for review (often) at short notice and flexible to the client business needs – provision of qualified market signatories, if required.
- Project scope extended to include the management of the local market product launches and regulatory support in some European countries working with the client project teams for client
  - Reviews have been conducted to date in 77 markets.
  - In 2020, for these two clients reviews were undertaken on 2867 materials