

Case study

Coordinating Local RA & PV Support Across 18 EU/EEA Countries

OUTCOME HIGHLIGHTING



300
Marketing
Authorizations



100+
Individual
Dossiers



18
EU/EEA
countries



Local RA, PV,
QA and PRLS
support



Biosimilar oncology,
CNS generics and
women's health products

OVERVIEW

A client preparing for market launch needed coordinated local Regulatory Affairs and Pharmacovigilance support across multiple EU/EEA countries, with short timelines and complex national requirements.

CHALLENGE

The client required LCPPV, LCPRA, LCPQA and PRLS services, alongside local regulatory expertise to support market launch. The project involved more than 300 Marketing Authorizations and 100+ individual dossiers, with short timelines for NCA submissions, unclear local guidance, and the need for country-specific support.

OUR APPROACH

1

Pre-Launch Meetings:

Definition of expectations, strategy and timeline, as well as cross functional discussions.

2

Gap Analysis:

Assessment of requested local roles and the latest approved product information for compliance with requirements, Braille certificate, artworks design, national codes, prioritization with regard to business strategy, target markets, Power of Attorney, supply chain, and commercial packaging.

3

Strategy:

Analysis of priority actions, required countries and roles, allocation of relevant experts. Development of a rapid launch plan focusing on business objectives; target markets, supply chain and commercial packaging. Development of action items and timelines to achieve milestones.

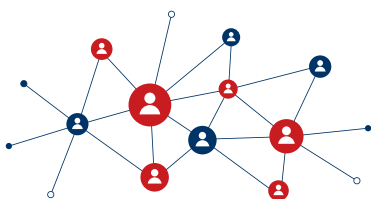
4

Execution:

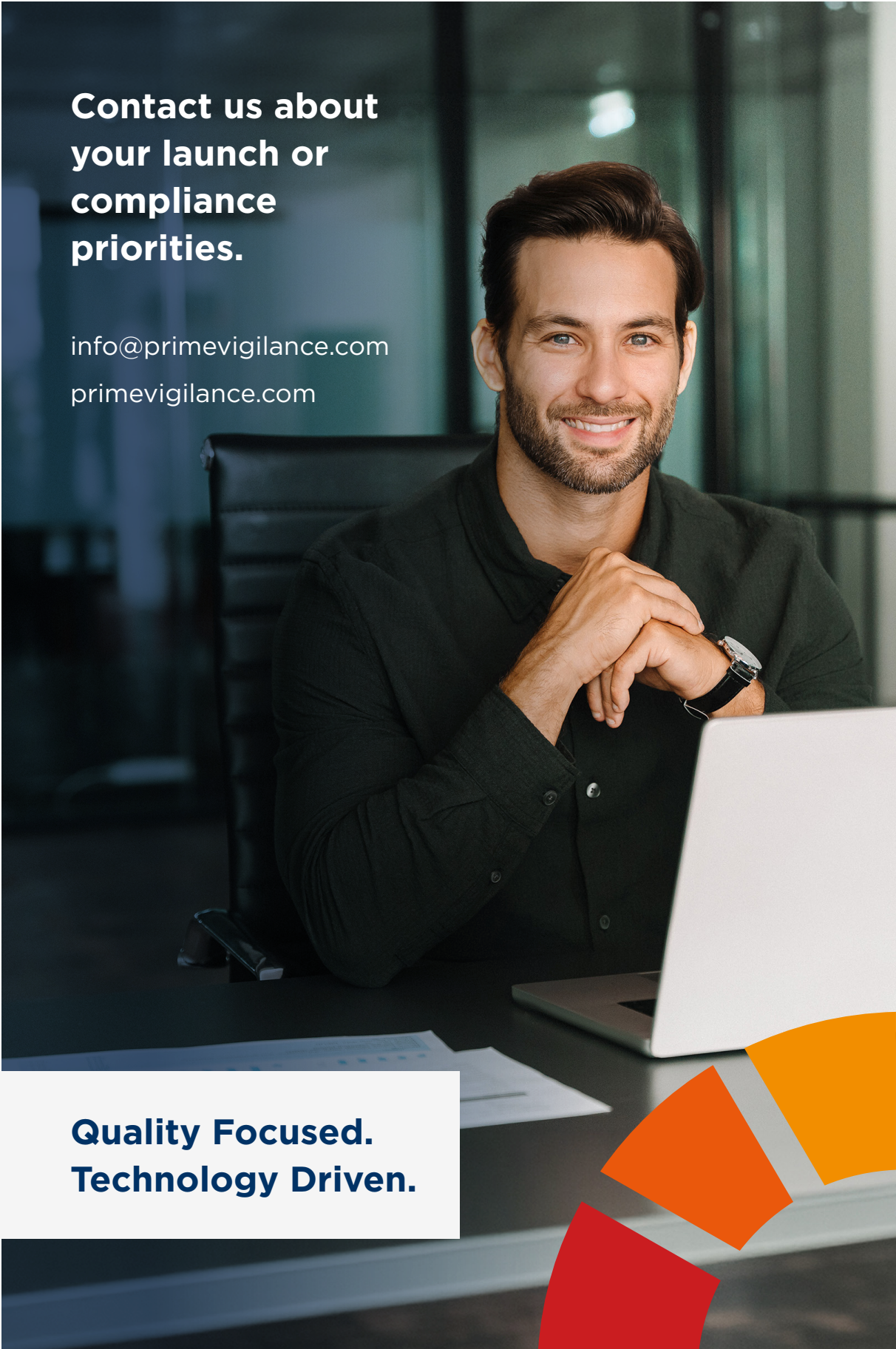
Flexible approach to meet the urgent request via fully competent resources. Setting up the network of LCPs and PRLs in a timely manner as per client needs.

OUTCOME

Products were successfully launched within the agreed timeline. PrimeVigilance also created efficiency by aligning services already provided to affiliated stakeholders, including the MAH and distributor.



One coordinated local network to support a compliant, time-sensitive market launch.



**Contact us about
your launch or
compliance
priorities.**

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**Quality Focused.
Technology Driven.**