Arriello

From development to market.
Faster. Better. Smarter.

Leveraging local knowledge for an urgent renewal submission.

Streamlining the creation and execution of a Regulatory Affairs strategy.

Client type:
Pharmaceutical.

Geography:
United Kingdom.

Lifecycle stage:
Post-marketing.

Service area:
Regulatory Affairs.

Summary.

- GAP analysis, submission strategy, documentation, local liaison.
- Urgent deadlines and missing key documents for a Marketing Authorization required the faster, better, smarter, approach that Arriello clients know and trust.
- An effortless renewal submission strategy.

Challenges.

A few challenges presented themselves that required immediate action:

Renewal date submissions. We were already six weeks past the required renewal submission date. Urgent action for negotiation with the authorities was required.

Dossier documentation. Locally, a specific document called the "Normative Document" was required which referred to the quality section of the dossier which was not available from the client. Plus, within the dossier, missing updates from the life cycle maintenance further added to the challenge ahead.

Samples availability. Marketing Authorization covered four different strengths, with one already marketed. With renewal submission deadlines looming, everything required urgent action and negotiation with the authorities.

Solution.

We quickly negotiated with authorities and established a regulatory submission strategy, complete with critical milestones. Once this was ready, samples of the marketed product were submitted to the health authority.

During the assessment of the marketing authorization renewals, we also advised our client on supply initiatives to ensure that enough stock remained available to patients.

In parallel, we sourced the missing Normative Document from the local authority and ensured the dossier was updated in line with all the regulatory strategy milestones.

We assisted the client with a complete list of renewal requirements (Regulatory Intelligence support) and evaluated the client dossier against industry requirements with the help of our local partner, who checked the dossier against national requirements to ensure full local compliance. We knew a dossier gap analysis would identify and correct gaps in time to complete a full dossier update.

Faster. Better. Smarter.

Knowledge and expertise go a long way in being able to react faster to challenges. Our advantage in being able to access the local requirements and missing documentation expedited a smart regulatory submission strategy. Providing **solutions that work in the real world** is always better for clients, efficiency and streamlined solutions. Sometimes client's requests (i. e. urgent submissions) show just how we work smarter, going beyond to add further value such as market stock coverage, in order to overcome any hurdle.

For our client, this **resulted in on-time submissions** with the desired effect on market authorization, and an effortless collaboration with Arriello from start to finish.

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About us.

Arriello is a leading consultancy and solutions provider of risk management and compliance services to the pharmaceutical industry. We've been making the development-to-market process faster, better, and smarter since 2008.

Our global services span the product life cycle from Clinical to post-submission Regulatory Affairs and Pharmacovigilance, Quality Assurance and Auditing, and innovative automation solutions.

Headquartered in Ireland, with operations across Europe, we consult and create solutions across the EU, North America, LATAM, CIS, MENA, Asia, and South Africa.

With our extensive global network, decades of combined experience and ISO:9001 certification, we are a trusted partner primarily to pharmaceutical and biotech companies.

Our valued clients rely on our ability to deliver, however complex their requirements, through our proven expertise, global coverage, and technology.

ISO 9001 certified

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