ALMAC

Partnering to Advance Human Health

Brochure

Tailor-made Product Launch Solutions

Balancing speed with precision, our flexible suite of offerings provides you with a reliable, effective, and expert approach to support the successful and timely introduction and launch of your new product and market penetration into new territories.

Key considerations for a successful product launch

Our dedicated product supply team are experts in navigating market requirements and supporting client partners to successfully launch their orphan / niche drug products. They have extensive practical experience of launching pharmaceutical products into the marketplace and manage a multidisciplinary project team in quality, packaging design, regulatory and distribution, ensuring milestones are met and that your market entry strategy is successful.

By integrating all of your pharmaceutical and distribution needs for your pharmaceutical product launch into a single supply team as early as possible, you will minimise your effort and maximise your return.

Pre-submission

QP Declaration & Site of Release

Nominating a Qualified Person (QP) for the release of your drug product is essential when submitting your Marketing Authorisation Application (MAA).

Our experienced QPs can act as an extension of your team, putting in place relevant quality agreements between all manufacturing sites and taking responsibility for product quality and market release.

Packaging Design

From your first English mock-up when filing to full component design, our regulatory and operational expertise ensures that you develop a compliant and functional pack from the outset.

Submission

Named Patient Supply / Early Access Programmes

As your product launch is being extended country by country, our Named Patient Supply process facilitates further market penetration.

Country Groupings / Blue Box

By providing guidance on country groupings for regional packs, we minimise your stock holding and maximise flexibility.

Artwork Origination
Generating print-ready artwork in-line with current pharmaceutical packaging and artwork legislation ensures minimal revisions upon submission, aiding with approval timelines.

Shipment Validation
Designing a configuration tailored to your product ensures that your valuable drug product reaches the end user in optimum condition.

EU Import Testing
Ensuring compliance with Directive 2001 / 83 / EC: Article 51; all pharmaceutical products manufactured outside Europe must be analysed in line with the specification outlined in the product's MAA upon entry into the EU.

Product Tax Status
By examining and understanding the supply chain process in advance, the correct tax procedures can be established to minimise exposure to VAT and duty.

Approval, launch & ongoing commercial supply

Product Ordering
Receiving orders directly from registered pharmacists and clinics, via Almac's secure 24 / 7 web-based Product Order Portal (POP), dedicated email or multilingual telephone or fax, enables a shorter, more flexible drug product supply chain.

QP Release
Our dedicated team of experienced QPs ensures that your product is certified as suitable for release in line with requirements of EU Good Manufacturing Practices (GMP) and your marketing authorisation.

Serialisation
Providing full serialisation / aggregation and 2D matrix barcoding solutions to GS1 standards facilitates traceability of your product throughout the manufacturing and distribution supply chain.

Product Distribution to Pharmacy
Your product is delivered directly to the pharmacy within 24 hours of the order being received – providing a simplified supply chain.

Product Invoicing
We offer client invoicing, monitoring, and reporting of customer payments, as well as debtor follow-up and account management to ease your financial administration burden.

Dedicated Logistics
To make the distribution process as simple as possible, we can also assist with the management of all necessary import/export documentation and customs clearance. Almac Pharma Services has known Consignor Status from the Irish Aviation Authority providing a smooth expediting process.

- QP Declaration & Site of Release
- Packaging Design

- Named Patient Supply
- Country Groupings (Blue Box)
- Artwork Origination

- Shipment Validation
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- **QP Release**
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Our product launch experience

20+
Product launches p.a.

>20%
of launched EU approved orphan drugs p.a

25,000
Shipments p.a.

2000+
Packaged SKUs

65
Commercial products processed

60
Countries

almacgroup.com

Get in touch

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