



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

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Partnering to Advance Human Health

Brochure

Tailor-made Product Launch Solutions

Just like clockwork!

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.

PRE-SUBMISSION



- QP Declaration & Site of Release
- Packaging Design

SUBMISSION



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

SUBMISSION



- Shipment Validation
- EU Import Testing
- Product Tax Status

APPROVAL, LAUNCH, & ONGOING COMMERCIAL SUPPLY



- Product Ordering
- QP Release
- Serialisation
- Product Distribution to pharmacy
- Product Invoicing