ALMAC

Partnering to Advance Human Health

Case Study

Pack Design for EU Orphan Drug Launch

Almac delivers EU ultra-orphan drug launch for US client in Almac designed primary and secondary packaging format.

Pack Design for EU Orphan Drug Launch

As the client company was US based, its experience of the EU marketplace and the key quality, packaging and supply chain requirements was limited. Accordingly, the client recognised the importance of partnering with an experienced, full service CMO to guide them through the complexities of the submission/commercialisation process towards a successful launch of their product. With detailed project discussions taking place at Almac's UK headquarters and following a successful site audit, Almac was selected and named as the client company's site of release on their product MA application.

The client company chose to utilise Almac's full suite of expert launch services, including EU import analysis, packaging design and artwork origination, primary and secondary packaging, QP release and distribution of their drug product direct to pharmacies, via Almac's in-house 3PL services.

Challenges

Product

Treating an ultra-orphan indication (patient population of <1 in 50,000), meant pack requirements were extremely low, resulting in very small country specific batch sizes. To facilitate maximum stock flexibility, it was essential that the packs, and the means by which they were to be processed, allowed for Just-In-Time (JIT) processing.

Taking advice from Almac, the client implemented a regionalised packaging approach, grouping markets into multi-language/country packs, helping minimise stock holding whilst maximising its flexibility to meet the demands of smaller markets without committing stock to orders that may never arise.

The product also posed challenges; it was temperature and moisture sensitive, requiring specialist handling in a low RH environment, and also required high-barrier protection.

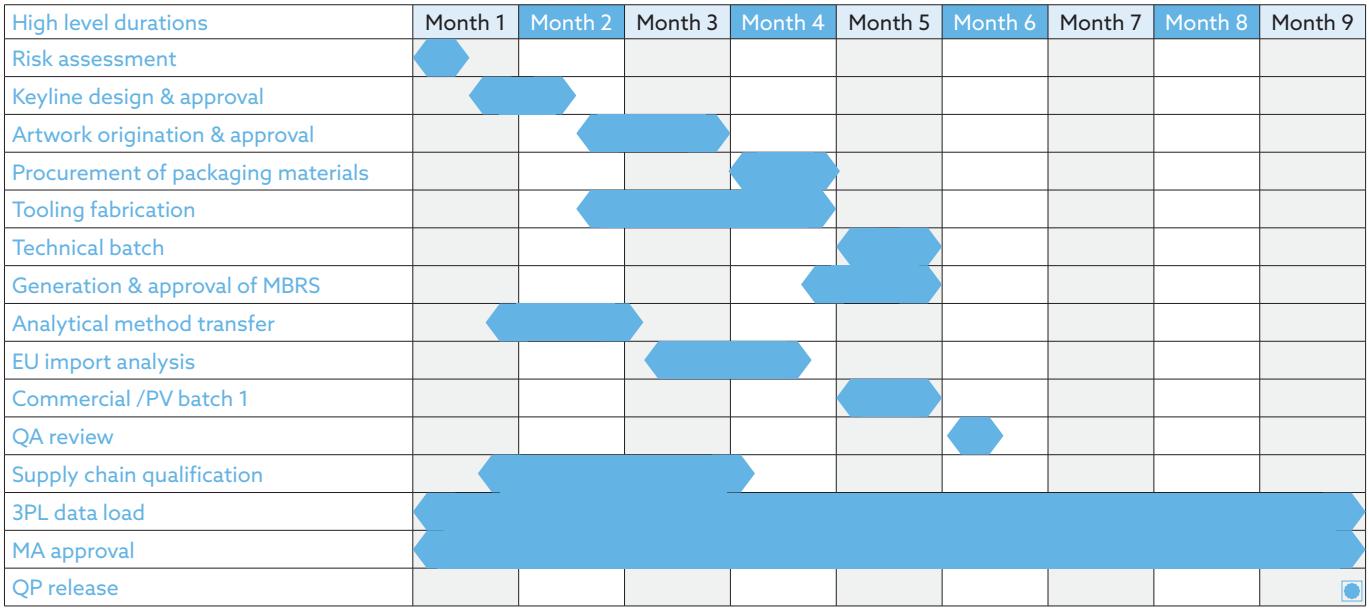
Packaging

Almac's Packaging Design & Artwork team worked with the client to design an innovative blister/wallet* pack format which met all the product and patient needs including:

1. Patient Compliance - as a treatment for a chronic condition, patient compliance was critical.
2. Size - although treatment required multiple doses per day, the client required the monthly pack to be pocket-sized, which resulted in a complex blister/wallet design. The pocket-sized wallet also restricted the artwork 'real estate,' as in the 'white space' for country-specific details, such as blue boxes, serialisation data etc.
3. Safety - the wallet design had to be child-resistant/ senior-friendly.

Timelines

Almac typically works with client companies approximately 12 months prior to an MA approval. However, in this case, the client's ultra-orphan drug product qualified for accelerated regulatory assessment which resulted in an aggressive launch timeline of 9 months.



*Westrock Dosepak

Almac's Solution

Packaging Hurdles

The Almac product launch team comprising personnel from Engineering, Product, QA and Validation, as well as Artwork/ Packaging Design, was tasked to ensure the pack concepts produced were not only fit for purpose, but could be assembled by a viable, robust, validatable and cost-effective process.

The first activity required was the completion of a Failure Modes & Effects Analysis (FMEA), which looked at all factors that could affect the drug product. These factors included:

- Regulatory/legal requirements
- The effects of patient non-compliance
- Senior-friendly & child resistance options
- End-user profile (trained professional in clinic/hospital or patient in home)
- Drug Value vs Material Cost
- Sustainability of the chosen materials
- Environmental conditions (effect of exposure to heat, light & moisture)
- Physical factors (susceptibility to knocks & bumps)

Once the FMEA was completed, it was clear that, due to the moisture sensitivity and patient compliance requirements, the primary pack format should be a blister and the secondary pack format a wallet. Prototypes of two different pack designs were manufactured and provided to patient groups for review. Once the patient feedback had been received, the preferred option was trialled in some of the client's Phase III studies. This approach allowed for further patient feedback, with a view to making any required changes ahead of the commercial launch.

Project Management

Central to the successful launch of the client company's product was the coordination and management of all launch activities by one of Almac's experienced Product Supply Managers, who led the multi-disciplinary team to secure a timely launch.

Following Almac's standard project management process, the Product Supply Manager generated:

1. Communication matrix that defined roles, responsibilities and provided contact details of each member of the team.
2. Documentation matrix that defined roles and responsibilities for generating, reviewing and approving GMP documentation.
3. Comprehensive live project plan that specified key deliverables and timelines.

The detailed project plan was paramount in driving weekly conference calls, across three time zones, and ensured the entire project team was kept informed of the project status and key next steps, to guarantee a successful product launch, upon MA approval.

Results

In less than nine months from MA submission, the team met the project requirements to develop a bespoke pack format for the ultra-orphan drug product and successfully launch the product onto the European marketplace within 48 hours of MA approval.

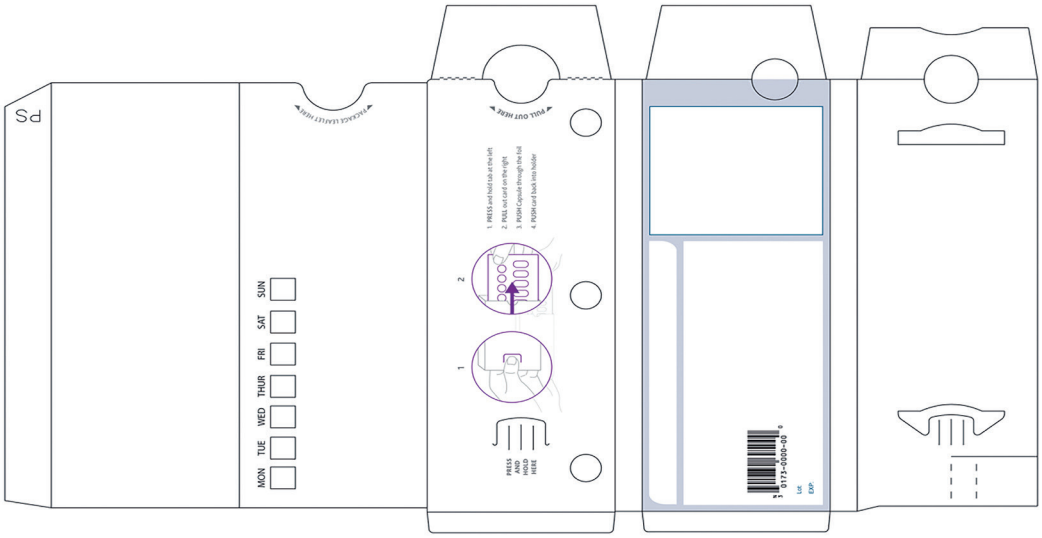
The final pack design was a 2 x bi-weekly Aclar blister format, sealed into a monthly wallet pack. Aclar was selected as the base material due to the high level of protection provided. This was second only to Alu:Alu, which proved to be 50% larger during pack design trials, which would have meant that a monthly "pocket pack" would not have been possible.

Facilitating the ultra-orphan indication, the requirement for flexible stock holding and JIT processing, the Aclar blisters did not contain any market-specific print, which meant that an entire batch could be blistered in a single operation and stored as blank bulk blisters, until required. Secondary packaging into market-specific wallets could then take place on-demand, to meet the individual needs of the EU regions.

Upon MA approval and receipt of orders via Almac's 3PL system, country-specific packs were processed, dispatched and with the specialist pharmacies across Europe within 48 hours.

Key Takeaways

- The EU market is extremely complex - 31 regulatory bodies, 24 languages etc
- Initiate the launch process as early as possible, particularly with regard to pack design
- Keep the pack format & supply chain simple
- Strong project management is essential to meet strict regulatory / launch timelines
- Leverage experience where possible



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GET IN TOUCH

UK
Almac Group
(Global Headquarters)
22 Seagoe Industrial Estate
Craigavon
BT63 5QD
United Kingdom

pharmaservices@almacgroup.com
+44 28 3836 3363

US
Almac Group
2661 Audubon Road
Audubon
PA 19403
United States of America

pharmaservices@almacgroup.com
+1 610 666 9500