Case Study

Navigating Marketing Authorisation Transfers (MATs): Strategies for Regulatory Compliance

This case study explores key strategies for successfully navigating Marketing Authorization Transfers (MATs). Understanding the regulatory landscape is essential to ensuring compliance and minimizing risks during the transfer process.

Scenario

The biopharmaceutical industry has been one of the most active sectors for mergers and acquisitions (M&As), with companies consistently pursuing strategic deals to drive growth, enhance competitiveness, and optimize portfolios. Compared to other industries, biopharmaceutical firms have executed a higher number of M&As over the past few decades, benefiting both large and small players.

A critical component of these transactions is the , a regulatory requirement to ensure that medicinal products remain compliant under the new ownership structure. MATs also arise during therapeutic portfolio realignments, as companies seek to streamline operations and maximize market potential.

Upon completion of the MAT process, the rights and responsibilities of the original Marketing Authorization Holder (MAH) for a specific medicinal product are officially transferred to the new MAH on a specified date, ensuring seamless regulatory continuity.

Large-Scale MAT Execution

In a landmark transaction, two globally established multinational corporations (MNCs) entered into an agreement to transfer a portfolio of consumer healthcare products to a newly formed joint venture. This complex process involved the transfer of over 10,000 MATs across multiple markets.

SEQOVA played a pivotal role in ensuring the success of these transfers, providing end-to-end support from strategy development to execution. Our team collaborated closely with stakeholders to navigate regulatory complexities, mitigate risks, and ensure a seamless transition of marketing authorizations.

Rationale for outsourcing the MAT process

Companies often choose to outsource MAT processes to ensure efficiency, compliance, and expertise. The key reasons include:

- Regional Presence & Regional Expertise - Understanding diverse country-specific regulations is crucial for a smooth MAT execution.

- Regulatory Affairs Expertise - Specialized knowledge in MAT processes, regulatory tools, and compliance ensures minimal disruptions.
- Challenges in Short-Term Team Setup - Setting up an in-house team for a short period (1–2 years) is resource-intensive and impractical.

By outsourcing, companies gain access to specialized talent, streamlined processes, and operational flexibility while maintaining compliance.

Strategies Deployed for the Project

Successful MAT execution requires a structured approach, involving both **technical** and **non-technical** considerations.

Technical Strategies

- ✓ **Portfolio Decisions** – Selecting the products to transfer.
- ✓ **Timeline Planning** – Defining the transfer duration based on regulatory and resource requirements.
- ✓ **MAT Execution Strategy** – Structuring the transfer using grouping, work-sharing, waves, or phases.

Non – Technical Strategies

- ✓ **Resource Allocation** – Determining the required team size.
- ✓ **Talent Identification** – Engaging regulatory experts with the right skill set.
- ✓ **Team Setup** – Hiring, onboarding, and training staff.
- ✓ **Document Verification** – Ensuring submission documents are complete and available.
- ✓ **Process Development** – Establishing SOPs, work instructions, QC processes, checklists, issue logs, and internal/external communication channels.
- ✓ **RA Tool Compliance** – Ensuring regulatory tools meet industry standards.
- ✓ **Feedback Mechanism** – Setting up regular client feedback surveys.

MAT Planning Considerations

Regulatory teams must evaluate multiple factors when planning MATs to ensure compliance and smooth execution. Key Considerations:

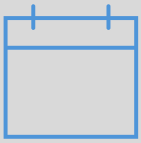
PRE-MAT SUBMISSION REQUIREMENTS

- The new MAH must appoint a **local contact person/entity** to interact with the Health Authority, manage product complaints, and oversee pharmacovigilance (PV) activities.
- Compliance with **country-specific regulatory requirements** is mandatory before establishing the local affiliate.

ESTABLISHING A REASONABLE MAT IMPLEMENTATION DATE

- Both MAHs must collaborate to select an appropriate date, considering **regulatory approvals, product supply continuity, and patient access** to therapy.

SELECTING THE MAT SUBMISSION DATE

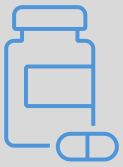


- Submission timelines vary by country. In some regions, MAT is treated as a **variation filing**, while in others, a simple **notification to the Health Authority (HA)** suffices.
- Some countries grant same-day approvals, while others follow extended review timelines.
- If the product launches with a common package, the submission date must align with the **common implementation date** across multiple markets.

ENSURING A COMPLETE MAT PACKAGE

- MAT applications must be compliant with **national regulatory requirements** to avoid delays.
- Regulatory experts must accurately interpret country-specific guidelines to prepare an **acceptable and complete MAT submission**.

UPDATING PRODUCT ARTWORK



- Labels require updates due to MAT.
- New **artwork files** should be prepared in advance, ensuring compliance with local regulations before finalizing packaging post-approval.

DETERMINING THE BATCH RELEASE & SALES TRANSITION DATE

Regulations differ regarding old batch sales post-MAT approval

- Some countries allow existing batches to remain on the market until expiry.
- Others impose a **defined grace period** (e.g., **six months in Sweden, one year in Switzerland, two years in Denmark**).

ESTABLISHING A NEW PHARMACOVIGILANCE (PV) SYSTEM

- The new MAH must comply with global and local **good pharmacovigilance practices (GVPs)**.
- Appointment of a **Qualified Person for Pharmacovigilance (QPPV)** and, if required, a **Local Person for Pharmacovigilance (LPPV)** is mandatory.
- Some countries require submission of the **Summary of Pharmacovigilance System Master File (sPSMF) variation** before MAT submission, while others mandate it before approval (e.g., **Italy requires a PSMF submission before MAT submission**).

Conclusion

Marketing Authorization Transfers (MATs) require strategic planning, regulatory expertise, and operational efficiency, especially given the varying guidelines across Europe. SEQOVA's expertise has helped partners overcome these complexities, ensuring smooth transitions, regulatory compliance, and business continuity.