AliraHealth

EU Supply Integrity Guidelines

A summary of strategies pharmaceutical companies can adopt to minimise the negative impact of parallel trade on their business.

June 2021

For more information:

Introduction

PURPOSE OF THE DOCUMENT

This report outlines the **key components of a successful distribution strategy** that pharmaceutical companies can adopt to **minimise the negative impact of parallel trade on their patent-protected medicines.**

In addition to improving financial performance, a sound and well-implemented distribution strategy can significantly reduce the risks that diversion brings to patient access and health outcomes, while also protecting prescriber confidence and company reputation.

This document aims to help companies that are setting up a European Distribution capability as well as companies seeking to increase the efficacy and performance of their current arrangements.

WHAT IS PARALLEL TRADE?

Parallel Trade is defined in this report as **the parallel distribution between countries with different prices outside the manufacturer's designated distribution channels**.

In the pharmaceutical industry, parallel trade takes place in many global markets, with particular prevalence in the European Economic Area. The European Union Treaty protects the principle of free movement of products across countries. This allows parallel traders to exploit price differentials for profit.

The European Competition Law, together with guidelines and a study of numerous landmark European court cases, set out the principles and practices that a pharmaceutical company is—and is not—allowed to deploy to protect its commercial interests, safeguard patients, and support other stakeholder interests.

ACKNOWLEDGMENT

Across the pharmaceutical industry, there is a wide range of approaches—and success—to the way distribution is managed in Europe. We are grateful for **the contributions of several leading industry practitioners for their insights and experiences in creating this report**.

GENERAL ASPECTS

Effective distribution is critical: Suboptimal management has widespread consequences

Key takeaway: While price differentials in innovative medicines improve patient access and equity across Europe, these benefits are quickly eroded when the distribution is not effectively managed.

Evaluating the efficacy of your distribution strategy in Europe is key—and the impact goes beyond just financial results:

- **Financial performance:** Medium-to-large pharmaceutical companies can experience annual opportunity costs in the range $10m to $100m from unwanted and suboptimum parallel trade levels.
- **Pharmaceutical access and company reputation:** Patient access in key markets may be compromised by diversion, potentially negatively impacting their therapy outcomes, the prescriber's confidence, and the overall brand reputation.
- **Organization commitment:** Too little governance and transparency, as well as a focus on country sales rather than patients, can lead to parallel trade compromising a company’s integrity when it comes to aligning rewards with value added.

GENERAL ASPECTS

How to create an effective European distribution management strategy

Key takeaway: Successful companies are clear about what leads to success—it takes HQ driving priorities and initiatives, supported by high competence at the local level.

An effective strategy demands the following key elements:

- **Initiative and sound governance at HQ,** powered by dedicated resources to outline the market dynamics and shape key decisions in supply chain and performance management.
- **Distribution management in key exporting markets** that is competent, operates effectively, and responds dynamically to challenges.
- **Performance measurement and incentive management** that recognises the complexities of benefits in different markets and where issues need to be managed.
- **A thorough and holistic price strategy in pre-launch** phase to pre-empt any issues and mitigate risks from the outset.

Key Elements in EU Distribution Management

CORPORATE STRATEGY

Audience: General Manager, Europe
Regional Chief of Finance

1. **Allocate and empower dedicated resources**
2. **Secure internal stakeholder commitment to broad, long-term benefits of success**
3. **Understand the legal perimeters**
4. **Closely monitor the market to prioritise and react dynamically**

DISTRIBUTION EXECUTION IN CRITICAL MARKETS

Audience: Supply Integrity Director
European Trade Director
European Commercial Director

5. **Know real demand**
6. **Safeguard patient supply**
7. **Choose the right distribution model**
8. **Advise affiliates on execution**

LAUNCH & PRICING STRATEGY

Audience: Market Access & Pricing Director
General Manager, Europe
Regional Chief of Finance

9. **Design effective price corridors and apply best practices at launch**
10. **Avoid price management pitfalls**

KEY ELEMENTS OF **CORPORATE STRATEGY**

Allocate and empower dedicated resources

Key takeaway: Company leadership must empower dedicated resources at the HQ level to evaluate current distribution management, create clear a clear benefit analysis, and deliver proposed changes to influence key functions and affiliate companies.

Evaluating Excellence in distribution management transcends analytics and big-data management. It requires knowledge of distribution alongside a broad skill set that includes well-developed diplomatic and negotiation skills.

Successful companies agree—the complexity of this task requires dedicated resources endorsed by leadership to influence decisions on the management of supply and the way local affiliates align this to the patient demand. Key elements of an effective approach include:

> **Systematic reconciliation** of third-party sales data with in-market demand.

> **Company reporting systems** that reflect both in-market and third-party sales.

> Established protocols to **implement and maintain supply management schemas with precision.**

> **Commitment of the affiliates** to actively support the distribution strategy.

KEY ELEMENTS OF **CORPORATE STRATEGY**

Secure internal stakeholder commitment to broad, long-term benefits of success

Key takeaway: Affiliates in exporting countries must be committed to measuring market demand at the patient level as part of their performance discussion.

At first, tasking affiliates with ownership of how much is sold—and to whom—can be daunting. Selling too much undermines sales elsewhere in the organisation in the form of parallel trade, while selling the "right quantity" to each wholesaler requires a high level of market knowledge that the local affiliate may not have at the outset.

Securing the commitment of these internal stakeholders requires:

- **Performance management that's based on in-market patient demand and alignment of third-party sales.** This might be a marked change for a local affiliate previously focused on third-party sales only.
- **Managing sales in a new way that ensures continuity of supply to the market.** This requires a sound understanding of local regulations, current practices, and the application of Competition Law.

KEY ELEMENTS OF **CORPORATE STRATEGY**

Understand the legal perimeter

Key takeaway: Sound knowledge of Competition Law, along with local regulations and practices, can guide and reshape the distribution model and the amounts supplied to the market.

Competition Law sets the perimeters within which pharmaceutical companies can take action to optimise the distribution in a market and bring the supply amount closer to patient demand.

EU Competition Law makes clear distinctions between agreements a pharmaceutical company may have with a wholesaler or distributor in a market, and the unilateral actions it can take to optimise supply.

Having the right advice can make a significant difference, and this usually comes from those with a sound understanding of how the pharmaceutical distribution market works—which differs between countries.

Training company management and customer-facing associates in Competition Law issues is key if diversion-related problems are to be resolved in the correct way.

KEY ELEMENTS OF **CORPORATE STRATEGY**

Closely monitor the market to prioritise and react dynamically

Key takeaway: Sustaining alignment between patient demand and supply to individual wholesalers in multiple EU markets requires multisource data and analysis to be channelled effectively and efficiently across the organisation.

Transparency on sales versus demand is essential.

Sometimes the costs of oversupply needs to be weighed against the costs and feasibility of alternative distribution models. Direct-to-pharmacy distribution can be critical to a successful strategy.

Precision plays a key role to a successful outcome. For example, a decrease in oversupply to a market from 15% to 10% results in a 33% reduction in the financial impact. For larger companies, a reduction of 1% in sales across all export markets can deliver close to a $10m impact.

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KEY ELEMENTS OF **DISTRIBUTION EXECUTION IN CRITICAL MARKETS**

Know real demand

Key takeaway: Knowing the quality of your data on in-market demand—and validating it with alternative sources—can be key to successful outcomes.

Possible in-market data-quality issues can compromise a good distribution strategy. Take steps to validate data quality, or at least estimate its accuracy. In many markets, independently-produced reimbursement data and other measures of consumption are available. Knowing how the data is sourced and what percentage of the market is covered can help assess its accuracy.

Secure a good algorithm: The key objective is to ensure that supply is closely aligned to real demand. It's a fallacy to always assume increasing supply will reduce shortages—sometimes the opposite occurs. Therefore, the algorithms developed to map supply to demand play a vital role in effective supply management, and a poor algorithm can exaggerate both shortages and excess supply.

Sampling may help: Parallel import market sampling often sheds light on the situation and can expose an issue, although sampling usually cannot substitute having a reliable measure of demand in the key markets.

KEY ELEMENTS OF **DISTRIBUTION EXECUTION IN CRITICAL MARKETS**

Safeguard patient supply

Key takeaway: Measuring pharmacy-service levels and patient adherence to the therapy can be used as a proxy for assessing the robustness of supply.

Patient supply is of paramount importance. Interruptions to supply and inconvenience in collecting prescriptions can quickly impact medication compliance and negatively affect patient outcomes and therapeutic efficacy. This can also undermine the prescriber's confidence in a product.

Set up a process to track and respond to incoming pharmacy complaints and to be as objective and systematic as possible in measuring shortages. A few phone calls from pharmacies—perhaps in one area—can be resolved without increasing supply to the whole country.

Consulting services offering analysis of de-identified e-prescription data can be effective in measuring interruptions to supply and verify whether patients and pharmacies are experiencing supply interruptions. These services are becoming increasingly valuable in safeguarding patient supply and providing critical information to resolve recurring issues.

KEY ELEMENTS OF **DISTRIBUTION EXECUTION IN CRITICAL MARKETS**

Choose the right distribution model

Key takeaway: The choice of distribution strategy at launch has a critical impact in the occurrences of diversion-related distribution issues in later stages.

A common oversight is avoiding evaluating the optimal distribution model at the time of launch and instead supplying all orders to all wholesalers. It's often only realized too late that supplying all orders to wholesalers delivers suboptimal results.

Choosing the right distribution model can have many benefits to the success of the launch—even beyond how the problems of diversion are managed. Better understanding of prescribing, market penetration, and the way customers view and adopt a new product, can be invaluable to the early launch insights and success.

KEY ELEMENTS OF **DISTRIBUTION EXECUTION IN CRITICAL MARKETS**

Advise affiliates on execution

Key takeaway: Optimal distribution in a key market means that the supply sent to each wholesaler is just slightly more than local demand.

Regular reconciliation of market data and supply levels should provide a clear picture of the optimal supply level a country needs to meet the actual local demand.

Inaccurate information about wholesaler market shares can lead to greater allocations, resulting in higher levels of diversion and operational problems to resolve patient shortages.

HQ and local affiliates need to collaborate closely to resolve early issues that can surface when first executing a supply management strategy. Just increasing allocations—particularly where there is no improvement to patient supply—signals the need to reassess how the supply is managed.

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KEY ELEMENTS OF **LAUNCH & PRICING STRATEGY**

Design effective price corridors

Key takeaway: Price corridor design before launch can anticipate diversion issues—giving a company the opportunity to explore alternative distribution models, rather than having to resolve suboptimal distribution situations post-launch.

For yet-to-launch products, proactive measures around price corridor design are effective in reducing the negative impacts of diversion.

Alira Health highly recommends preparing a full market access and pricing strategy for medicines that are in Phase III. External reference-pricing models are primary tools for success in analyzing the willingness to pay by several EU countries. This can inform the design of a narrow price corridor, considering pack-price differences across countries.

KEY ELEMENTS OF **LAUNCH & PRICING STRATEGY**

Avoid price-management pitfalls

Key takeaway: Changing prices in key countries could have repercussions on other countries, according to price-reference practices.

Mature products that have been launched following a commercial strategy might end up with a wide price corridor and uncontrolled discounts across the chain.

Price differences enhance parallel trade and impact revenue—and if managed reactively—can increase revenue leakage.

Company-wide price-governance design and the creation of a price-approval committee are the first steps to controlling pricing.

Creating an operational pricing department and enhancing pricing management is necessary to contain price differences among countries. The preparation of business cases for each price change that includes external reference pricing and product-flow impact is essential for correct price management.

10 Alira Health success factors

Commitment for leadership

Dedicated resources with influence in the organization

Company-wide price governance

A proactive price strategy driven by parallel trade considerations

A system for optimising market supply integrated into the supply planning and order management processes

Sound data with integral analysis and reporting

Sampling data from importing countries and using analytics to confirm sources

Compliance and training to ensure personnel apply the right tools in the right way

Performance metrics and incentives to secure employee commitment to the organisation’s wider objectives

Qualified legal support

OUR ADVICE

A weakness in just one or two areas can compromise the entire strategy

Rarely can a company achieve success in EU distribution management without being competent in at least 8 of our 10 success factors.

The Data Provider Network for Alira Health

Alira Health relies on an extensive network of local partners to gather sell-out and sell-in data from the most relevant European countries.

- **Automated data collection from points-of-care**
- **High projection reliability**
- **Longitudinal dimension available**
- **Growing network**

The Industry Expertise of Alira Health

Alira Health experts bring industry expertise to reconstructing and managing parallel-trade dynamics through a holistic approach that embraces pricing strategies, competition regulations, supply- and distributor-management, and data procurement and analysis.

MARKET ACCESS AND PRICING

- Expertise in pricing and price-corridor definition
- Experience in price reference modeling and strategy development
- Industry experience in proactive and reactive measures to parallel trade

EU COMPETITION & SUPPLY MANAGEMENT

- Operational experience and distribution know-how to improve distribution in critical markets
- Knowledge of best distribution practices in all key EU markets
- Expertise in setting up parallel-trade governance at HQ level
- Knowledge of EU Competition Law and compliance expertise to assess and manage risk from third-party arbitrage

DATA ANALYTICS

- Partnerships with providers for gathering robust sell-out and sell-in sales data
- Access to databases for pricing and parallel distributor notifications
- Experience in modelling and reconstruction of distribution flows to highlight the full extent of parallel distribution flows
- Capability to develop business analytics tools that integrate internal supply data and third-party data sources
- Consulting expertise that includes key opinion leaders
- Extensive local networks for the provision of country-specific data

OUR TEAM OF **EXPERTS**

FILIPPO BENETTI, PHD

Manager, Advanced Analytics

Filippo Benetti, PhD, is a physicist and data scientist with experience in real-world data application in the healthcare industry.

After working on digital projects at Deloitte Italy, Filippo spent more than a year as Data Manager in the largest rehabilitation hospital network in Italy, leading a project for patient-data acquisition and activation.

At Alira Health, he leads the practice of Advanced Analytics, developing innovative methodologies rooted in machine learning and big data to support pharmaceutical clients in defining marketing and supply-chain optimisation strategies based on real-world evidences. His team also integrates the Alira Health strategy and M&A practices with data management and mathematical modelling capabilities.

Filippo earned his degree in nanomaterials for medical applications at the University of Trento.

> Contact Filippo

MARK INIGO-JONES, MA, MSC

EU Distribution Expert

Mark Inigo-Jones, MA, MSc, is an expert in pharmaceutical distribution management with more than 19 years of hands-on experience in big pharma and, more recently, small pharma. As Head of European Trade at Novartis, Mark developed and implemented the distribution strategy across all European countries. He has extensive experience in changing the distribution model in many countries as well as detailed country knowledge on allocation systems.

Mark's hallmark is performance: in his time at Novartis, he brought about the highest percentage reduction in parallel trade among peer companies. He attributes this success to the analytics and the governance- and performance-management systems implemented and endorsed by European leadership.

In addition, Mark holds a master's degree in European competition law and has extensive experience in managing the compliance aspects of distribution. He developed all the training materials and trained the Novartis and Sandoz legal-functions teams during his time at Novartis. He also worked closely with internal and external law firms to assess the compliance of new distribution models.

NEREA BLANQUÉ, MSC

Vice President, Market Access

Nerea Blanqué is one of Alira Health's Vice Presidents of Global Market Access and Pricing. She has designed pricing strategies for the launches of several strategic products and successfully negotiated prices with authorities in several EU countries. Nerea has experience in global price corridor setting, global value dossier design/messages, and local adaptations. She has managed several cross-company parallel trade projects.

Nerea holds a BSc and MSc in Pharmacy from the University of Barcelona, a research diploma in immunology from Háskoli Islands, and a post-graduate degree in Business consulting from Glamorgan University in Wales, as well as a senior-executive program PDD from IESE Business School in Barcelona. She currently coordinates and gives market access and pricing classes in a master's program at the Biotechnology Business institute.

> Contact Nerea

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