



Pharma trade
models under pressure:
Proposed new EU Directive
could disrupt fiscal importations

Rising legal challenges in local EU courts
on fiscal importation with non-EU entities



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Proposed new EU Directive could disrupt fiscal importations

What is the challenge?

The release of EU GMP Annex 21 in 2022 defined the requirements for importation into the EU, but without clarifying the requirements for fiscal importation.

The recently proposed new EU Directive adds a new layer of complexity by explicitly prohibiting an EU WDA holder from procuring medicinal products from a wholesaler without EU WDA through financial transactions.

What is the impact on pharma?

Although this guideline is set to be enforced in 2026, local court rulings are already reflecting these requirements. Local courts are challenging fiscal importation with non-EU entities, increasing pressure on the industry.

For example:

- Pharmaceutical suppliers must possess a WDA granted by an EU member state (BVerwG 3 C 1.20).
- The Swedish Medicines Agency has contested Swiss invoicing practices at a Swedish pharmaceutical firm (Swedish Administrative Court, Decision 3084-24).



Why fiscal importation matters in pharma trade models?

Fiscal importation refers to the practice of invoicing goods from outside the EU into an EU member state, where the goods are ultimately supplied. This is a common strategic approach prevalent among multinational pharmaceutical companies operating complex, cross-border manufacturing networks. However, these companies are facing a fragmented regulatory landscape, as national legislation and judicial decisions continue to govern these matters on a country-by-country basis within the EU.

What is changing?

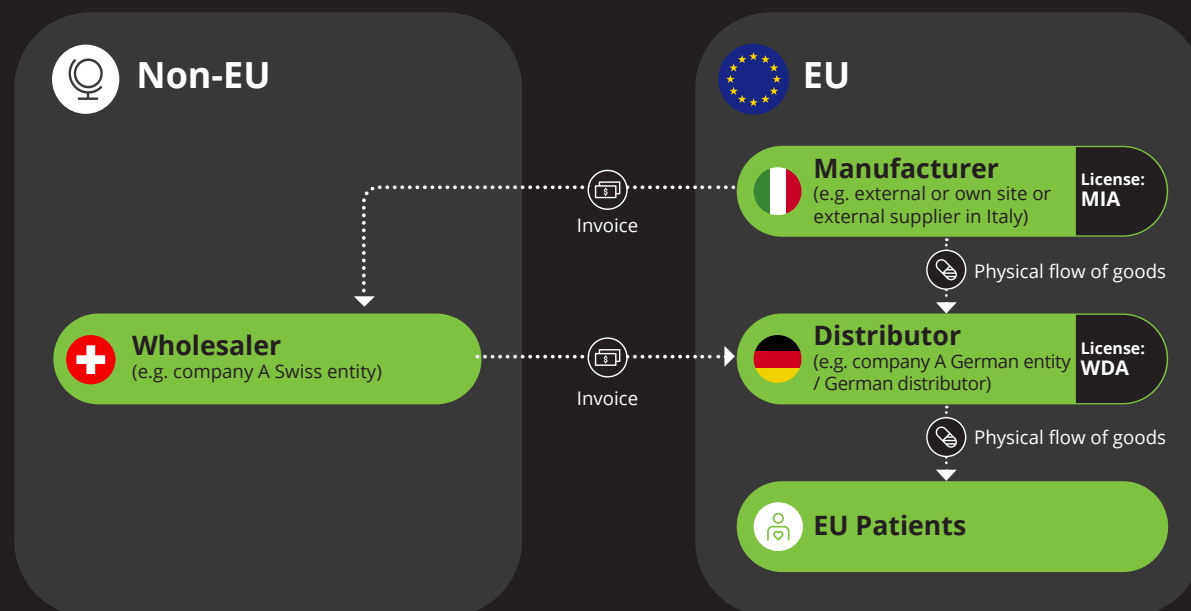
Previously focused on physical import, regulatory requirements will soon apply to financial transaction as well. For goods staying within EU borders, this means that fiscal flows involving Switzerland, UK and other non-EU countries will no longer be possible for European wholesalers.

Who will be affected?

For example, you are affected if:

- manufacturing takes place in the EU but your principal entity is outside the EU, and
- you have a hub in the EU that acts as a distributor, but invoices come from outside the EU, e.g. Switzerland.

Example of common non-EU principal entity model



We developed a Strategic Decision Framework to help you navigate in this situation

Cross functional approach

Strategic Decision Point

Tailored Multi-Disciplinary Solutions



Quality & Regulatory

Impact: Risk of findings during inspections and loss of market access.

- Identify wholesale activities qualifying as fiscal import



Supply Chain

Impact: Risk of supply chain disruptions, increased costs, and loss of customer trust.

- Map and evaluate current supply chain flows
- Identify potential short-term market interruptions



Tax & Transfer Pricing

Impact: Risk of penalties and increased scrutiny from tax authorities.

- Map new intercompany transactions under revised business model
- Evaluate functions, assets, and risks for transfer pricing adjustments
- Assess exit tax considerations and effective tax rate impact



Trade Compliance

Impact: Risk of customs delays, fines, and supply chain disruptions.

- Implement revised customs structure for EU regulation compliance
- Align commercial supply chain with VAT reporting
- Verify customs registration requirements in new jurisdictions



Legal

Impact: Risk of legal disputes, fines, and operational disruptions.

- Understand corporate law requirements for new EU entities
- Negotiate third-party contract adjustments

Strategic choice:
transform EU entity
structure or adapt
existing supply chains?



Holistic Solution:

Financial Flow Restructuring

Realign financial flows with EU-based entities

Focus Areas:

- Tax implications assessment
- Group treasury impact analysis
- Entity structure optimization
- Long-term strategic alignment

Solution Examples:

- New principal entity
- New EU trading branch
- New EU master distributor trading legal entity



Targeted Solution:

Supply Chain-Specific Adaptations

Maintain non-EU principal payment structure

Focus Areas:

- Individual supply route analysis
- Product-specific compliance approaches
- Selective organisational changes
- Balancing existing structures with compliance

Solution Examples:

- Company-specific supply chain changes

Contacts



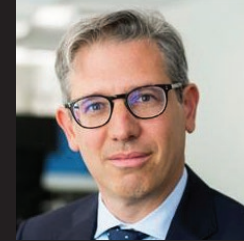
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