

FISCAL IMPORTATION

OF MEDICINAL PRODUCTS AND THE ROLE OF THE QUALIFIED PERSON:

A BELGIAN REGULATORY PERSPECTIVE

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1. Introduction and Regulatory Context

In the pharmaceutical supply landscape, multinational companies frequently separate the physical movement of medicinal products from their financial and invoicing flows. Products may be manufactured, certified, and stored entirely within the European Union, yet purchased through financial transactions originating from entities established outside the EU, often in Switzerland, the United States, or other third countries. This divergence between physical and financial flows creates a regulatory classification issue that has significant compliance consequences in Belgium.

Since 21 August 2022, the requirements described in Annex 21 of The Rules Governing Medicinal Products in the European Union, Volume 4 — EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use have been in force. This guideline, alongside the Belgian Law of 25 March 1964 on medicinal products for human use, forms the cornerstone of Belgium's regulatory framework on importation.

The Federal Agency for Medicines and Health Products (FAMHP/AFMPS) has issued an authoritative interpretation of these rules specifically addressing so-called 'fiscal importation' - a scenario that catches many multinational pharmaceutical organisations off guard. This divergence has historically been viewed as a purely commercial and tax matter but the financial flow is now a primary regulatory criterion: inspectors follow the money, not merely the goods. This blog examines the concept of fiscal importation, the Qualified Person's (QP) dual role in such contexts, and the compliance pathways available to affected entities.

2. What is Fiscal Importation?

2.1 The AFMPS Definition

Fiscal importation is a concept that, until recently, received limited regulatory attention. The AFMPS defines it as follows:

"Fiscal importation" refers to the "paper-based" purchase of medicinal products that have not physically left the territory of the European Union (EU), from an entity established outside the EU. The acquired medicinal products are then "imported" for fiscal purposes in order to be placed on the EU market.

In practical terms, this means that when a Belgian entity whether a wholesaler (affiliate, or distribution company) purchases medicinal products from a non-EU supplier, even if the goods themselves never leave EU territory, that transaction is considered an importation for regulatory purposes and requires as such Manufacturing and Importation Authorization (MIA) licenses.

2.2 The Dual Definition of Importation

The key to understanding fiscal importation lies in the AFMPS interpretation of what constitutes an 'import'. Rather than limiting the definition to the physical crossing of EU borders, the AFMPS — pursuant to Article 12bis, §1, paragraph 5 of the Law of 25 March 1964, and Article 88(1) of Regulation (EU) 2019/6 on veterinary medicinal products — takes the position that importation encompasses two distinct triggers:

1. Physical movement: Medicinal products physically cross the EU external border from a third country into EU territory, or
2. The act of purchasing: the legal acquisition of medicinal products from a Belgium entity established outside the EU, regardless of whether the goods physically move across borders.

This dual interpretation is the defining characteristic of fiscal importation and represents one of the most consequential regulatory positions issued by the AFMPS in recent years.

3. Legal Framework and Applicable Guideline

Legal Instrument	Key Relevance to Fiscal Importation
Law of 25 March 1964 — Art. 12bis, §1, para. 5	Belgian primary law—requires MIA for importation; fiscal importation included.
Directive 2001/83/EC — Arts. 40–52, 51	EU manufacturing/importation authorisation; QP batch release obligations.
Regulation (EU) 2019/6 — Art. 88(1)	Extends importation definition to include purchase act (veterinary medicines).
EU GMP Annex 16 (Since 15 April 2016)	GMP requirements for QP confirmation and certification responsibilities for commercial medicinal product.
EU GMP Annex 13 (Since 08 Dec 2017)	GMP requirements for QP confirmation and certification responsibilities for investigational medicinal product.
EU GMP Annex 21 (since 21 Aug 2022)	GMP requirements for importation from third countries; QP responsibilities.
EU GDP Guidelines 2013/C 343/01	Defines 'acquire'/'purchase'; WDA scope limited to EU-authorised sources.

4. The WDA / MIA Divide: Compliance Consequences

4.1 What a WDA Holder May and May Not Do

A Wholesale Distribution Authorisation (WDA) is granted to entities engaged in the wholesale distribution of medicinal products within the EU. Under the AFMPS interpretation and EU GDP guidelines, a WDA holder:

- May source medicinal products from other authorised wholesalers, importers, or manufacturers established within the EU;
- May NOT purchase medicinal products from a company located outside the EU, even if those products have never left EU territory; and
- May NOT obtain medicinal products manufactured and QP-certified within the EU from a non-EU entity, regardless of where the goods are physically located.

This has been confirmed in the AFMPS published guidance, which states explicitly that an authorised wholesaler is not permitted to purchase medicinal products from a company located outside the EU, regardless of whether the products have physically left EU territory.

4.2 When a Manufacturing and Importation Authorisation (MIA) is Required

When the fiscal importation criteria are met (i.e., a Belgian entity purchases medicinal products from a non-EU entity) that entity must hold a Manufacturing and Importation Authorisation (MIA). The MIA extends the regulatory scope of the holder to include importation activities and carries with it the obligation to appoint a Qualified Person responsible for batch certification.

The MIA requirement applies irrespective of the fact that the products were manufactured and QP-certified within the EU. The determining regulatory factor is the legal origin of the transaction, not the physical location of the goods at the time of purchase.

5. Follow the Money and ownership of the goods: Financial Flow as Regulatory Evidence

5.1 Why Financial Flows Matter

In a conventional GDP inspection, auditors examine the physical supply chain: manufacturing site authorisations, QP batch release documentation, cold chain compliance, warehouse GDP certificates, and delivery records. In fiscal importation inspections that include GMP and GDP activities, also known as GMDP, the inspector applies an additional and equally rigorous lens: the financial transaction chain.

The AFMPS position is that the integrity of the distribution chain — as required by Article 12bis — cannot be assessed solely by looking at where goods travel physically. It must also be assessed by following where money flows: which entity issues the invoice, which bank account receives payment, which company is named as the contractual seller, and what the legal character of that company is.

This means that an inspection readiness programme for a Belgian pharmaceutical entity operating in a multinational structure must include full documentation of the following financial flow elements:

- The identity and country of establishment of the invoicing party (seller)
- The bank account details — country of the bank, legal owner of the account, and IBAN
- The direction of intercompany (IC) payments and their settlement destination
- The legal relationship between the invoicing entity and any parent company established outside the EU
- SAP or equivalent ERP records confirming ownership transfer points and the entity holding title to goods at each step
- Transfer pricing documentation and intercompany agreements that reflect the financial structure

5.2 The Payment Destination Test

A critical practical test applied during AFMPS inspections, and increasingly during corporate compliance reviews, is the payment destination test. The question is simple but determinative:

“When the Belgian entity settles its purchase invoice, in which country or which entity country owning the bank account does the money ultimately land, and to whom does it belong?”

If the payment is made to a non-EU bank account held by or for the benefit of a non-EU parent company, this constitutes strong prima facie evidence that the legal acquisition was made from a non-EU entity, irrespective of how the invoicing chain is structured at intermediary levels. The presence of an EU branch or EU-registered intermediary within the transaction chain does not, in itself, alter this assessment where the economic benefit of the transaction ultimately flows to a non-EU entity.

Similarly, where the funds are transferred to an EU-based bank account operated through an EU branch, but the account itself is legally owned or controlled by a non-EU entity, this may also constitute prima facie evidence that the legal acquisition was made from a non-EU entity.

In both cases, this is the fact pattern that triggers the fiscal importation classification.

5.3 ERP Audit Trail Requirements

Inspectors examining financial flows will request access to or extracts from the company's ERP system (typically SAP) to verify:

- Which legal entity is listed as the vendor in the purchase order for the Belgian entity
- Which legal entity's bank account details are populated in the payment run
- Which legal entity is credited in the intercompany reconciliation
- Whether ownership of the goods (inventory title) in the system is held by an EU or non-EU entity prior to the sale to the Belgian affiliate

6. The Branch vs. Subsidiary Distinction: The Most Consequential Legal Difference

6.1 Why This Distinction is Regulatory-Critical

Of all the structural elements that determine whether a supply arrangement constitutes fiscal importation, the distinction between a branch and a subsidiary of a non-EU parent company is the most consequential — and the most frequently misunderstood. Many pharmaceutical companies assume that because their European operational entity is physically located within the EU and holds

EU regulatory authorisations, it qualifies as an EU entity for purchasing purposes. This assumption is legally incorrect when the entity is a branch rather than a separately incorporated subsidiary.

6.2 What is a Branch?

A branch is not a separate legal entity. It is a registered extension of its parent company, operating under the parent's legal personality. Key characteristics of a branch that are determinative for fiscal importation analysis:

- A branch has no independent legal existence — it is the parent company operating in another jurisdiction under a different trading name and registration number.
- Contracts entered into by a branch are legally binding on the parent company — not on the branch itself as a distinct entity.
- Invoices issued by a branch are, in legal terms, invoices from the parent company.
- Payments made to a branch's bank account are, in legal terms, payments to the parent company. Even if the bank account is in an EU country (e.g., Austria), the legal beneficiary of that payment is the non-EU parent (e.g., Switzerland).
- The branch has no independent share capital, no separate balance sheet recognised in its home jurisdiction as a distinct legal person, and cannot hold assets in its own name independently of the parent.

6.3 What is a Subsidiary?

A subsidiary is a separately incorporated legal entity; a company registered under the laws of an EU Member State, with its own legal personality, share capital, balance sheet, and contractual capacity. Key characteristics relevant to fiscal importation:

- A subsidiary is legally distinct from its parent company, even if the parent holds 100% of its shares.
- Contracts and invoices from a subsidiary are the obligations of the subsidiary as an independent legal person.
- Payments to a subsidiary are made to a legally EU-established entity, even if the subsidiary subsequently pays dividends or transfers funds to a non-EU parent.
- A subsidiary may hold a WDA or MIA in its own name and exercise those authorisations as a legally autonomous entity under EU pharmaceutical law. However, attention is required, as in certain EU jurisdictions a branch may also be permitted to hold a WDA, depending on the applicable national legal framework.

6.4 The Regulatory Consequence: Branch = Non-EU Entity for Purchasing Purposes

The AFMPS position, grounded in the AFMPS published guidance and consistent with the dual-trigger importation definition, is that when a Belgian entity purchases medicinal products from a branch of a non-EU company established within the EU, that transaction is a purchase from a non-EU entity. The branch's EU location does not transform the legal character of the transaction.

This is illustrated clearly in the following comparison:

Structural Element	Branch of Non-EU Parent (e.g., Austria or Dutch Branch of a Swiss or third country parent company)	EU Subsidiary (e.g., Austrian or Dutch or Belgium — 100% owned by Swiss or third country parent company)
Legal personality	None — extension of the parent company	Separate EU legal entity
Contracts / invoices	Binding on the parent	Binding on EU subsidiary independently
Payment recipient (legal)	Parent company (even if bank account is in EU country e.g. the Netherlands or Austria) Parent company	EU Subsidiary or EU entity
Bank account beneficiary		EU Subsidiary or EU entity
WDA / MIA holder	Authorisation held in name of the branch under the parent's personality YES — purchase is from a non-EU entity	Authorisation held in name of EU subsidiary (e.g. Belgium entity) as independent entity
Fiscal importation triggered?	NO — MIA required	NO — purchase is from an EU-established entity
WDA sufficient for Belgian affiliate?		YES — if Austrian or Dutch subsidiary or entity holds WDA or MIA

The practical consequence is significant; let's imagine an Austrian or Dutch branch of a Swiss parent that performs EU QP batch certification and release, holds a manufacturing licence (MIA/GMP certificate), and operates a GMDP-compliant manufacturing and warehouse, which is nonetheless a non-EU entity for the purpose of determining whether a Belgian affiliate's purchase from it constitutes fiscal importation.

6.5 The VAT Registration Number Does Not Determine Entity Status

A common misconception is that an EU VAT number assigned to a branch is indicative of EU entity status for regulatory purposes. A branch may hold a German, Austrian, or Dutch VAT number without being a separate EU legal entity. The VAT number reflects tax registration in the Member State — it does not confer independent legal personality. Inspectors and regulatory assessors look at the corporate law status of the entity, not its tax registration.

Similarly, the location of the goods (e.g., warehouse in Germany or France) or the location of QP certification activities (e.g., performed by a QP employed by the Austrian or German branch) does not determine the legal character of the purchasing transaction. The relevant question remains: with whom did the Belgian entity contract, and what is that contracting party's legal character?

7. Detailed Financial Flow Analysis

7.1 The Financial Flow that triggers a Fiscal Importation (Example)

The following flow represents the fact pattern that triggers fiscal importation classification. It is based on the structure identified in a Belgian pharmaceutical affiliate operating under a WDA, where the financial flow revealed a Swiss connection:

Step F1 Manufacture	Goods manufactured and QP-certified within the EU (e.g., Austria, Germany, France). Physical goods are always EU and manufacturing activities remain within the EU.. QP batch release performed under Directive 2001/83/EC.
▼	
Step F2 IC Invoice	Intercompany invoice issued by [Austria Branch of Swiss parent entity] → Belgian Affiliate (Belgian entity). Invoice header shows Austrian or Dutch address and EU VAT number — but legal seller is the Swiss parent via its branch.
▼	
Step F3 Purchase Order	Belgian affiliate issues purchase order to the Austria Branch. In SAP, the vendor record shows the Austrian branch, but: - the bank account populated for payment is a Swiss IBAN (CH...). The economic beneficiary is a Switzerland parent entity. - The bank account populated for payment is a Austrian IBAN (AT...) but the bank account is own by a Switzerland parent entity. In the case, an intercompany invoice is generated to wire the money in Switzerland.
▼	
Step F4 Payment	Belgian affiliate transfers payment from Belgian bank account → Swiss bank account (IBAN CH...) in settlement of the Austria Branch invoice or to an account own by the swiss parent company. Money leaves Belgium and arrives in Switzerland. This is the decisive compliance trigger for a FISCAL IMPORTATION.
▼	
Step F5 IC Settlement	The non EU-parent entity (e.g. Swiss parent) records the receipt as revenue from its Belgian market operations. The economic loop closes in Switzerland — a non-EU country. Therefore a FISCAL IMPORYATION.

Regulatory conclusion: Regardless of the physical location of the goods, the QP certification location, or the EU VAT number of the branch, this financial flow constitutes fiscal importation under Article 12bis, §1, paragraph 5 of the Law of 25 March 1964. The Belgian entity requires a Manufacturing and Importation Authorisation (MIA).

7.2 The Financial Flow (Intra-EU Model) not classified as a Fiscal importation (Example)

The following flow represents the model confirmed by the AFMPS for an intra-EU transaction where all physical, purchasing and payment flows remain within EU-established legal entities:

Step F1 Manufacture	Goods manufactured and QP-certified within the EU. QP batch release performed in a EU country by an EU-incorporated subsidiary. Manufacturing activities remain within the EU.
▼	
Step F2 Ownership	Goods are owned by one or multiple EU entity during each transaction.
▼	
Step F3 Invoice	Intercompany invoice or invoice issued by EU entity to another EU entity. Invoice header shows EU address and EU VAT number — and legal seller is the EU parent entity or EU entity.
▼	
Step F4 Payment	Belgian affiliate perform the payment to an EU entity or EU parent company. The economic beneficiary is a EU parent entity and EU subsidiary or EU branch of a EU parent entity. The bank account is located in Europe.
▼	
Step F5 IC Settlement	The EU parent company records the receipt as revenue generated from its Belgian market operations. In such a scenario, the economic loop effectively closes within the European Union. Conversely, where the EU entity holding legal ownership of the product (which may be located outside Belgium but within the EU) subsequently transfers the proceeds to a non-EU parent company, the economic benefit ultimately accrues to the non-EU parent. In that case, the economic loop may be considered to close outside the EU, even though the payment itself was not made directly from Belgium to the non-EU parent company.

Regulatory conclusion: in this case, the Belgium flow is fully intra-EU transaction where all physical, purchasing and payment flows remain within EU-established legal entities.

8. The Qualified Person in Fiscal Importation

8.1 Standard QP Obligations under EU GMP Annex 21

In a conventional importation scenario, the Qualified Person of the MIA holder bears responsibility for certifying that each batch of imported medicinal product has been manufactured, tested, and controlled in accordance with GMP standards at least equivalent to EU requirements. This includes verifying the manufacturing site authorisations, batch documentation, and — where no mutual recognition agreement exists — performing or confirming independent testing in the EU.

8.2 QP Certification and EU Centralised Marketing Authorisations (MA)

Where the medicinal product is authorised via the centralised EU procedure under Regulation (EC) No 726/2004, QP certification must be conducted in accordance with Annex 16 of EU GMP Guidelines, which specifically addresses the certification by a QP and batch release of medicinal products. The QP certifying the batch for EU market release must confirm compliance with the terms of the MA and any applicable post-authorisation commitments.

In fiscal importation scenarios involving MA products, the interplay between Annex 16 (QP certification) and Annex 21 (importation) requires particular attention, especially where the QP

certifying the batch and the MIA holder performing the importation are different legal entities; a common structure in multinational group arrangements.

8.3 The QP for Fiscal Importation: Scope of Responsibility

Where fiscal importation is confirmed and the Belgian entity obtains an MIA, a Qualified Person must be designated under the MIA. In the context of fiscal importation — where the goods have not physically crossed an EU border and have already been QP-certified for EU market release or not — the role of the QP under the MIA has a specific and distinct scope compared to conventional physical importation.

The MIA-holding QP responsible for fiscal importation must verify and certify:

1. That the medicinal products subject to fiscal importation have been manufactured in accordance with GMP standards at least equivalent to EU GMP, or in the case of EU-manufactured goods in full compliance with EU GMP.
2. That each batch has been QP certified by a Qualified Person established within the EU, either under the relevant EU manufacturing/import authorisation or under the Belgian MIA. In the latter case, the Belgian entity performs both the EU QP certification and the fiscal certification, thereby avoiding duplication of QP release activities in another Member State (e.g. Italy). In all cases, the certification must be fully documented, traceable, and readily available for inspection.
3. That the supply chain from which the products are sourced is fully authorised and that no supply chain integrity gaps exist between the manufacturing site and the point of fiscal importation.
4. That the financial acquisition from the non-EU entity has been documented, that all relevant intercompany and contractual agreements are in place, and that these agreements reflect compliance with Article 12bis.
5. That a complete and audit-ready paper trail exists linking the financial transaction (fiscal importation) to the physical supply chain, QP certification, and batch documentation.

8.4 QP / RP Dual Oversight in Fiscal Importation Structures

The dual oversight structure, QP for GMP batch certification/fiscal importation and RP for GDP compliance, is a defining feature of complex multinational pharmaceutical supply chains operating with fiscal importation in Belgium.

Role	Responsibility	Regulatory Basis
QP (EU batch release)	Certifies each batch of medicinal product prior to EU market release. Verifies GMP compliance, batch documentation, MA conformity. May be employed by the manufacturer, MAH, or another authorised entity.	Art. 51, Directive 2001/83/EC; EU GMP Annex 16
QP for fiscal importation (MIA holder)	Certifies the importation activity itself — verifying that the fiscal importation complies with MIA scope, supply chain integrity, and that the non-EU entity's products meet EU standards. Signs the importation certification.	EU GMP Annex 16, Chapter 7; Art. 12bis Belgian Law; MIA conditions
RP (Responsible Person — GDP)	Ensures GDP compliance of the distribution activities of the Belgian entity. Oversees the quality management system, storage, transport, deviation management, and supplier qualification.	EU GDP Guidelines 2013/C 343/01; Belgian Royal Decree

These three roles may be held by different individuals or, in smaller organisations, may be combined in one or two persons, subject to competency and workload considerations. It is essential that the quality management system clearly documents who holds each role, what their specific responsibilities are in the fiscal importation context, and how oversight interactions between QP (batch certification and fiscal importation and release), and RP (GDP with 3PLs, transport and Customers) are managed.

9. Conclusion

Fiscal importation is one of the most operationally impactful regulatory developments in Belgian pharmaceutical distribution in recent years. The AFMPS position is unambiguous: purchasing medicinal products from a non-EU entity, regardless of whether those products ever physically leave EU territory, constitutes importation under Belgian law and requires an MIA.

The Qualified Person for fiscal importation plays a critical and distinct role: not merely certifying product quality, but certifying the integrity of a complex cross-border supply chain in which physical flows and financial flows diverge. The QP/RP dual oversight structure must be clearly defined, documented, and embedded in the quality management system.

Companies operating in Belgium with multinational supply chains should urgently review their financial flow structures against the AFMPS interpretation. The physical compliance of the supply chain (including QP-certified batch release, MAH oversight, and GDP-compliant logistics) does not itself resolve a fiscal importation compliance gap. The legal origin of the purchasing transaction is the determining regulatory criterion.

Each batch must be QP certified by an EU-established Qualified Person under the applicable MIA framework, including Belgian MIA where relevant. In such cases, the Belgian entity may perform both EU QP certification and fiscal importation release, avoiding duplication of QP release activities in other Member States (e.g. Italy). All certification must be documented, traceable, and inspection-ready.

QP Pro Services holds an MIA enabling the execution of EU QP certification, physical and fiscal importation activities when required, ensuring regulatory compliance and controlled financial flow alignment within a your company framework.

Proactive engagement through appropriate MIA structuring or financial flow alignment remains the only sustainable response. AFMPS requirements are enforceable, actively inspected, and not open to interpretation.

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