The medicine may be **free.** The tax risk is **not.**

Why VAT, customs and changing trade rules are becoming operational issues for **global Managed Access Programs.**

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Consider a typical Managed Access Program (MAP). A patient in one country is approved for treatment. The medicine is manufactured elsewhere, packaged at another location, stored in a regional warehouse and delivered through a logistics partner. No commercial sale takes place.

Yet someone must still act as importer, declare a customs value, account for import VAT and retain the evidence needed to support the chosen tax treatment. If those responsibilities are unclear, or the documentation is incomplete, the result may be unnecessary cost, customs delays and disruption to patient supply.

Tax and trade are therefore no longer peripheral issues. They are becoming part of the operational reality of delivering medicines to patients.

Free of charge does not mean free of tax

Managed Access Programs (MAPs), Expanded Access Programs (EAPs) and Named Patient Programs (NPPs) rarely follow a conventional commercial supply chain. Medicines may move between manufacturers, affiliates, depots, distributors, logistics providers, pharmacies and hospitals before reaching a patient, with ownership and responsibility changing along the way.

Although supplied free of charge, these medicines can still create import VAT, customs duties, local sales taxes, fiscal representation and documentation obligations, depending on how the program is structured and the countries involved.

MAP teams do not need to become tax specialists. They do, however, need to recognize one important principle: free of charge does not mean free of tax. Decisions made during program design can have significant operational and financial consequences months, or even years later.

Europe: one program, many tax systems

The EU Single Market simplifies the movement of goods, but not VAT. Each Member State applies its own registrations, evidence requirements and reporting obligations, while the continued rollout of e-invoicing and digital reporting gives tax authorities unprecedented visibility of cross-border transactions.

For organizations operating MAPs across Europe, VAT compliance quickly becomes an operational challenge. Who owns the medicine while it is in transit? Who is registered for VAT? Who paid the import VAT and can they recover it? Is the supporting evidence complete?

The complexity increases with every country added to a program. A MAP spanning twenty countries is not navigating one European VAT system, but twenty different national implementations.

The differences can be significant.

In Germany:

A company does not need to be the Importer of Record (IOR) to recover import VAT, provided it ultimately bears the VAT cost and can provide evidence that the VAT was recharged by the CRO, CDMO or logistics provider.

In Switzerland:

However, the pharmaceutical company must be named as the Importer of Record on the import declaration or Entry Acceptance Document (EAD) to recover import VAT. A seemingly minor administrative difference can therefore determine whether substantial amounts of VAT are recoverable or become a permanent program cost.

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Even after goods have entered the EU, movements between Member States remain subject to reporting requirements. Failure to report these transfers can result in financial penalties, increased regulatory scrutiny and unnecessary compliance risk.

Why changes in US Trade Policy matter beyond the US

Changing US tariffs and trade policies are adding another layer of cost and operational complexity for life sciences companies moving products into the US. The Trump administration's IEEPA tariffs, in particular, have increased the importance of understanding precisely how products are classified and imported.

Correct Harmonized Tariff Schedule (HTS) classification can have significant financial implications, potentially affecting eligibility to recover IEEPA tariffs through the US Customs and Border Protection (CBP) ACE Importer Portal, as well as opportunities for duty drawback.

For organizations importing at scale, getting classification and recovery strategies right can translate into substantial savings and help preserve cash for future programs and studies.

But the implications extend beyond individual US shipments. Changing tariffs and trade policies are prompting life sciences companies to reconsider where products are manufactured, packaged, stored and imported.

Even where a medicine is not directly affected by tariffs, changes to the wider commercial supply chain can fundamentally alter the way a Managed Access Program operates.

A decision to relocate packaging, establish a regional distribution hub, appoint a new importer or reroute shipments may change customs valuation, VAT registrations, duty and tax recovery opportunities, and compliance obligations across multiple countries.

MAPs therefore cannot be assumed to remain unaffected simply because the medicines are supplied on a non-commercial or free-of-charge basis. As global supply chains adapt to changing trade policy, MAP supply models need to be reviewed alongside them.

The hidden cost: VAT that cannot be recovered

One of the biggest risks is not paying VAT, it is failing to recover VAT that should have been recoverable.

Import VAT on high-value medicines can be substantial, but recovery depends on having the correct registrations, documentation and evidence. If the wrong entity imports the product, the required records cannot be produced or recovery deadlines are missed, what should have been a recoverable cost becomes a permanent program expense.

Across large global programs, these losses can quickly become material.

CASE · ITALY

US $200,000

Italian VAT, unrecoverable

A US biotech selected an Italian manufacturing partner based on operational and commercial considerations, without assessing the VAT implications.

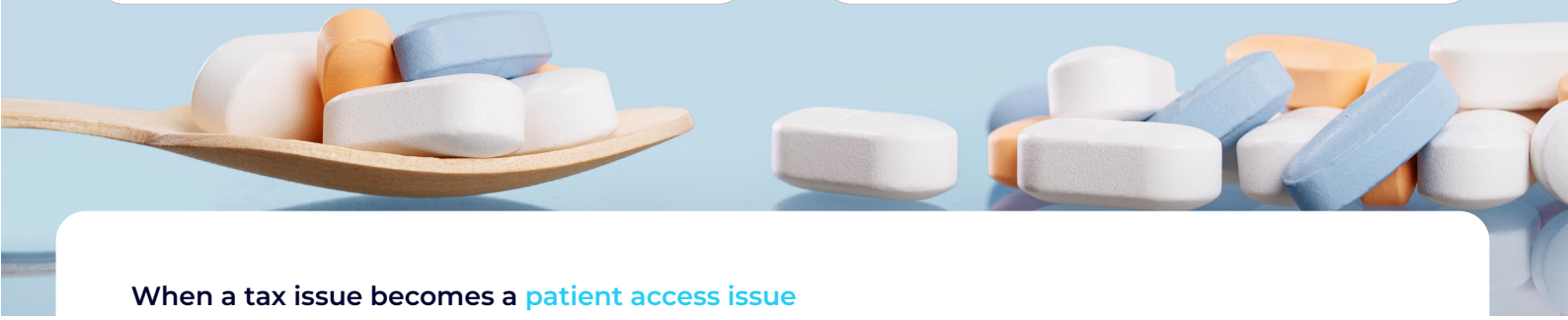
The supplier subsequently charged more than US$200,000 in Italian VAT. Because there is no VAT reciprocity agreement between Italy and the United States, the company was unable to recover the VAT, turning it into a permanent cost.

CASE · GERMANY

US $600,000

German import VAT, claim missed

Another US biotech discovered on 3 July 2025 that it had incurred more than US$600,000 in German import VAT over the previous eighteen months. Because the VAT had not been clearly itemized by its supplier, the company was unaware that it had a recoverable claim. By the time the issue was identified, the EU recovery deadline of 30 June had passed, and the opportunity to recover those funds had been lost. In both cases, money that could have been reinvested into clinical development became avoidable program cost.



When a tax issue becomes a patient access issue

The consequences extend beyond finance. A customs query may require evidence held by several different organizations. A missing document may delay customs clearance. Uncertainty over the Importer of Record may prevent a shipment from moving altogether.

Where treatment is time-critical, an administrative issue can quickly become a patient access issue.

Poor operational governance can therefore lead to:

- Irrecoverable VAT and customs costs
- Delayed customs clearance
- Disruption to treatment supply
- Increased tax and regulatory scrutiny
- Financial penalties and remediation costs
- Significant effort reconstructing historical product movements
- Reputational damage with affiliates, partners, healthcare professionals and patients

Questions every global map should be able to answer

Tax specialists determine the correct VAT treatment, but they rely on accurate operational information.

Every global MAP should be able to answer:

- ✓ Which legal entity owns the product at each stage?
- ✓ Who is the Importer of Record in each country?
- ✓ Which entity pays and may recover import VAT?
- ✓ What evidence links program approval, shipment, customs clearance and dispensing?
- ✓ What customs value has been declared?
- ✓ Where is inventory held, and under whose control?
- ✓ Can the organization reconstruct the complete product journey without relying on one person's inbox or spreadsheet?

Operational visibility is the missing link

Tax advisers can only determine the correct VAT treatment when they have a complete picture of how medicines move through the supply chain. That means understanding which suppliers are involved, how each manages importation, the contractual responsibilities between organizations, which countries are part of the transaction and, critically, which entity ultimately bears the VAT cost.

Documentation is equally important. Import declarations, invoices, proof of VAT recharge, transport records and customs documentation form the evidence needed both to recover VAT and to demonstrate compliance during a tax authority audit. Even a technically correct VAT position may be impossible to defend without complete supporting records.

The challenge is that this information is rarely held in one place. It is typically fragmented across sponsor teams, regional affiliates, CROs, CDMOs, logistics providers, finance systems, spreadsheets and email. The issue is rarely a lack of data, it's the inability to assemble a complete, auditable record quickly and with confidence.

A centralized operating platform cannot replace specialist tax advice. It can, however, provide the operational visibility, traceability and audit-ready evidence that tax, finance, supply chain and Managed Access teams need to maximize VAT recovery, reduce compliance risk and make informed operational decisions.

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Design tax into the program, not after the first shipment

Managed Access Programs are becoming larger, more international and increasingly strategic. As they scale, program design must connect regulatory approval, supply chain execution, financial governance and tax treatment from the outset.

This does not mean making every program more complicated. It means understanding where risk exists, assigning ownership clearly and ensuring every shipment generates the evidence needed to support both patient supply and financial compliance.

The organizations best prepared for changing trade rules will not necessarily be those with the largest tax teams. They will be those with complete operational visibility, clear ownership, consistent data and accessible evidence that explains the journey of every medicine from manufacture to patient.

For Managed Access teams, that visibility is no longer simply good governance. It is fundamental to protecting patient access, controlling program costs and enabling global programs to scale with confidence.

About the authors

This article was co-produced by:

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