Five strategies to optimise clinical trial customs tax in Europe

As the global clinical trial supply and logistics market continues to grow to support increasing pharma R&D, there is a resulting demand to drive down cost in the supply chain.

April 2022

OXIMIO

The VAT and customs implications of clinical trials are commonly overlooked, as the focus is largely on product sourcing requirements, temperature control, local regulatory requirements and decentralized trial setup. Taking a tactical approach can significantly reduce VAT and customs challenges, making the budget stretch further. This article addresses key considerations for VAT across Europe in the supply chain, in addition to five key cost optimisation takeaways.

How VAT and duties appear in the budgets of clinical trials

It is essential to factor in VAT and customs implications when managing clinical trials. Based on our recent survey, CMOs, CROs and Sponsors do not tend to budget for country-specific customs payments. Only a few respondents confirmed that they have relevant budget lines in their clinical demand planning models. Most of the companies treat Customs VAT and Duties as pass-through costs and consider them as inevitable expenses.

What is claimable/non-reclaimable per country

Customs VAT can usually be reclaimed in the EU and the UK (if a relevant EORI number is used for clearance). EU residents can reclaim via the 'EU VAT Refund' and through the '13th Directive Claim'. Importantly, only sponsors owning the product are eligible for the reclaim procedure (IoRs and CROs cannot officially apply for the reclaim). In non-EU (EAMA) countries, Customs VAT is normally absorbed into a cost and cannot officially be reclaimed. The sponsor companies may include these local costs in their investment VAT and offset it via the tax balance.

Even though VAT may not be officially reclaimed, some countries provide full exemption to VAT related to the importation of Investigational Medicinal Products, like Malta.

How reclamation works

Procure tax documentation

Your internal accounting prepares VAT reclamation

File tax documentation with government

Claims must be submitted by June 30th the following year*

Receive VAT refund from government

Reclamation takes an average of 4 to 6 months*

* May vary by country

EORI Number and registration is required.

Duty and VAT per country

We can divide European countries into three main groups:

1. **Countries with High Tax Regime (15-25%):** Bulgaria, Croatia, Denmark, Germany, Lithuania, Slovakia, Slovenia, Moldova, United Kingdom

2. **Countries with Moderate Tax Regime (7-15%):** Austria, Czech Republic, Estonia, France, Finland, Italy, Latvia, Turkey, Serbia, Bosnia & Hercegovina, North Macedonia

3. **Countries with Simpli ied Tax Regime (less than 7%):** Cyprus, Greece, Georgia, Hungary, Ireland, Luxemburg, Malta, Portugal, Spain, Sweden, Ukraine, Israel

Bottlenecks, and how to resolve them

If customs payments are not budgeted and planned for properly, they can be an extreme burden on the sponsor's cash flow at the time of site initiation and for large bulk shipments. A review of the country's requirements can lead to potential changes in its selection and supply chain.

Five key strategies to optimise costs:

1. Choice of port of entry
2. On-demand supply
3. Decentralized courcing
4. Value adjustment
5. Later stage corrections

1. Choice of port of entry

You can influence the rate that applies by carefully assessing the port of entry. For example, if 19% is applied in Germany vs 5% in Hungary, that already delivers 14% economic value.

2. On-demand supply

The strategy includes the setup of multiple packaging providers being able to act as regional distribution hubs. The distribution sites can drive efficiency via using bonded depots as well as pooling some IMP from various protocols and at the same time having expedited timelines and being closer to the demand. Some countries provide advantages for doing packaging and labelling in their countries – and Spain is one of the examples – they may provide tax advantages once the imported products are not considered as finished forms.

3. Value adjustment

This approach is based on adjusting the value of IMP to a lower rate if legally possible in the country of destination. For example, lowering the cost of the comparator to the registered price in the country of a destination rather than the cost of sourcing (which can be higher).

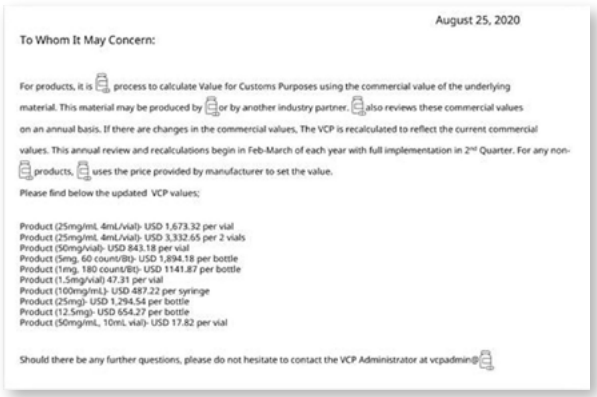
Another good option is to apply the nominal value of the product. For example, have an unblinded depot where placebo is shipped at its nominal value.

4. Late-stage correction

If the cost of the production (manufacturing and labeling) reduces from phase 1 to phase 3, the value of IMP can be corrected accordingly. If unused IMP is used in another trial, it can influence the sums paid at customs.

5. Cost reduction case study

Managing VAT correctly – legally but wisely - can bring an advantage. Here is an example of the actual email to customs from an Oximio sponsor client. They implemented our optimisation strategies, resulting in a significant cost reduction for their R&D department.



August 25, 2020

To Whom It May Concern:

For products, it is [redacted] process to calculate Value for Customs Purposes using the commercial value of the underlying material. This material may be produced by [redacted] or by another industry partner. [redacted] also reviews these commercial values on an annual basis. If there are changes in the commercial values, The VCP is recalculated to reflect the current commercial values. This annual review and recalculations begin in Feb-March of each year with full implementation in 2nd Quarter. For any non-[redacted] products, [redacted] uses the price provided by manufacturer to set the value.

Please find below the updated VCP values:

Product (25mg/mL 4mL/vial)- USD 1,673.32 per vial
Product (25mg/mL 4mL/vial)- USD 3,332.65 per 2 vials
Product (50mg/vial)- USD 843.18 per vial
Product (5mg, 60 count/Bt)- USD 1,894.18 per bottle
Product (1mg, 180 count/Bt)- USD 1141.87 per bottle
Product (1.5mg/vial) 47.31 per vial
Product (100mg/mL)- USD 487.22 per syringe
Product (25mg)- USD 1,294.54 per bottle
Product (12.5mg)- USD 654.27 per bottle
Product (50mg/mL, 10mL vial)- USD 17.82 per vial

Should there be any further questions, please do not hesitate to contact the VCP Administrator at vcpadmin[redacted]

Summary

Rapid growth in the clinical trial supply and logistics market has highlighted customs and tax complexities for VAT across Europe in the supply chain. It is essential that CMOs, CROs and Sponsors consider customs and VAT implications when transporting patient medications to cross-border sites. With the correct planning using the five key strategies outlined above, unnecessary spending can be mitigated.

For further guidance on how to manage customs and VAT in the supply chain, read our 'Customs Toolkit for IMP VAT requirements in the EU' here