

SPECIAL TOPIC

Drug Products: Generate cash flow advantages on the import tax (VAT) by making use of a fiscal representative

Neither a non-EU nor an EU company that have a VAT registration can easily use the VAT transit rule when importing drug products. This means that VAT has to be paid on imports of goods from outside the EU. Of course, this VAT can be reclaimed via the next monthly or quarterly VAT declaration. However, this means a cash flow disadvantage because import VAT needs to be pre-financed. Thus companies located in non-EU countries (e.g. Switzerland, USA, South America, Russia, etc.) planning to import their drug products into EU states should take into consideration to be represented by a fiscal representative for purposes of VAT (Value Added Tax).

That saves these companies, which do not have their own offices in the EU (e.g. in Germany), the administrative effort of VAT registration and thus the associated declaration obligations. Fiscal representation in Germany is possible under Art. 22a Value Added Tax Act (UStG) for companies located abroad which conduct business in Germany exclusively free of VAT, and for which no input tax amounts can be deducted. The company based abroad must not have its domicile, its registered office, its top management or a branch office either in Germany.

Customs



clearance



Tax-free



deliveries

There are several options, goods imported from a third country and having as their final destination another EU country apart from Germany can be handled:

- **Option 1:** Customs clearance is effected in Germany, whereby exemption from import VAT is applied for; after customs clearance, the goods are dispatched for delivery directly as tax-free intra-community supply to other EU countries
- **Option 2:** Drug products in a first step are being transferred into an Inward Processing procedure (*Aktives Veredelungsverfahren*) in order to get executed the release for the EU market by a Qualified Person; subsequently the goods can be directly dispatched as tax-free intra-community deliveries to other EU countries or, alternatively, transferred into a Bonded Warehouse situation, waiting for further treatment

What are the functions of a fiscal representative?

The fiscal representative has to fulfil as its own obligations the obligations of the company domiciled abroad, which the latter would have to fulfil pursuant to VAT legislation.

1. It submits a VAT declaration for the calendar year which summarizes the overall tax basis.
2. The fiscal representative is also required to submit a Summary Report by the 10th day after expiry of a calendar year to the Federal Central Tax Office (*Bundeszentralamt für Steuern*), unless it has exemption in a certain situation.
3. The fiscal representative is required to fulfil the general recording duties pursuant to Art. 22 UStG.

SUMMARY: Fiscal representation is an attractive option for companies that are not VAT registered in the country of the first point of entry into the EU. The fiscal representative takes over all duties with regard to VAT, customs and INTRASTAT filing.

The foreign company can enter the EU market without worrying on customs, statistical and VAT regulations. It is ensured that the foreign company is 100% compliant to EU tax requirements!

Benefits

- No VAT registration necessary
- Higher degree of compliance, the fiscal representative takes care of all requirements
- Client can concentrate on its core business
- Consignee receives goods as intra-Community delivery, no additional activities required at place of destination
- No expertise on EU customs, VAT and statistical legislation required
- Cash flow advantage due to payment of VAT at the place of destination

How can Glatt Pharmaceutical Services support these companies?

Our tailored logistic services exactly include the needed solutions to address the challenges of EU-Imports together with further offerings for marketed products and clinical trials materials, such as:

- Warehousing (15 – 25°C, 2 – 8°C, -25°C, -80°C)
- Cross-docking services
- Bonded Warehouse Services
- „Pre-Wholesale“ activities for marketed drug products
- High-speed commissioning (“Pick-by-Voice”)
- Multicarrier-Shipping System
- “Order-to-cash-Service”
- Organization of the distribution logistics for clinical trials
- Specialties / Premium Services:
 - Comparator sourcing for clinical trials
 - Blinding of clinical trial medication
 - Secondary packaging of clinical trial medication
 - Unpacking, Re-Packing of authorized drugs, (Re-) Labelling
 - Import of Human and Veterinary drug products into the EU, including customs clearance, optimized handling of import turnover taxes and customs duties
 - Fiscal representation services
 - Batch Certification / Release of drug products (authorized drugs, clinical trial medication) by a Qualified Person
 - Project Management

Interested to get more Information? Please get in touch with us: