Navigating the complexities of VAT and customs in the life sciences industry

Some of the most complex supply chain models can be found in the life sciences sector. Drugs under development frequently travel through multiple countries, undergoing separate and distinct processes as part of the manufacturing and clinical trial phases. Increasingly, pharmaceutical companies are expanding their clinical trials and product distribution channels into emerging markets. This trend often carries with it increased customs and VAT cost and complexity.

Once drugs are developed and approved (or, in some cases, even before they are approved) getting them to market often means storing them in multiple locations to make them available for immediate use by hospitals and consumers. Pharmaceutical and life sciences companies often struggle to understand their obligations and processes from a VAT and customs perspective. Missing out on opportunities for available relief, delayed VAT registrations and required documentation can lead to indirect tax cost and potential interest and penalties. In many cases, a careful and proactive review of the supply chain can help reduce or avoid these unforeseen VAT and customs costs and help streamline the related compliance burden.

Inaccurate product valuation for drugs in the sourcing phase can lead to costly delays

VAT and customs considerations factor into every stage of the supply chain, from sourcing products and raw materials for a newly developed drug all the way through to introducing it to the market. The sourcing phase is often when companies encounter their first challenges in navigating differing export and import requirements of the country, or countries, from which they are procuring their raw materials or through which they are moving goods. The inability to accurately set a value – and substantiate it – for the components of a drug that has not been created, approved or sold in the open market can make this process extremely difficult and open the door for costly delays and even assessments for customs purposes. For example, in the case of the clinical trial, or manufacturing of new drugs, there is generally no change in ownership as the drug moves through respective countries and undergoes a process in each. The lack of a sale means the importer cannot use the preferred method of customs valuation – the transaction value – and creates additional administrative reporting burdens.
Administrative burdens associated with manufacturing reliefs can outweigh the cost savings

After the sourcing phase, manufacturing begins – often with entities in several countries adding “value” to the production of the drug. During this development phase of the supply chain, the drug, or some form of it, may move across multiple borders, typically triggering import duties and VAT at each stop.

Finished pharmaceutical products and certain chemical intermediates are often not subject to customs duties under the World Trade Organization Agreement on Trade in Pharmaceuticals, as part of the zero-for-zero initiative. However, raw materials used for research and development, manufacturing and clinical trials are frequently dutiable, adding customs costs that must be considered part of the overall production cost.

If the company is not registered for VAT in each jurisdiction, this VAT may become a cost. In many cases, the VAT and customs duties are paid by the logistics provider and expensed by the pharmaceutical or life sciences party receiving the invoice. However, the VAT may be refundable (even without a VAT registration in some cases) or potentially could have been avoided.

What should businesses consider?

Did you consider the impact of VAT on your business?
- Pricing and budgeting
- Product design
- Business model
- Contracts and other business documents
- Customer and vendor renegotiation
- Training

Can you properly account for and manage VAT?
- Revenue
- Costing
- Profitability
- Cash flow
- Forecast
- Accounting
- Reporting

What are the enhanced compliance requirements for VAT?
- Invoice compliance management (issuance and verification)
- VAT filing compliance management
- Internal control management
- Policies, guidelines, manuals

Can your systems adapt?
- Business operating systems
- Accounting system
- Related interfaces
- Internal control system
- Tax management system

Several reliefs are available to companies importing and exporting goods. Short-term reliefs such as VAT deferment arrangements (offered in many countries throughout the world) allow companies to import goods into those countries without having to pay the VAT at the time of import. As an example, in the UK The VAT applicable to all goods imported in the calendar month is due 15 days after the month ends. This allows companies to import goods and make just one payment a month. The Netherlands has a specific license that enables the importer to defer payment at the time of import and instead account for VAT by self-assessing in the Dutch VAT return. Pharmaceutical entities typically have full VAT recovery and can reclaim this VAT in the same return (so that no payment to tax authorities arises). This brings significant cash flow benefits for companies importing goods through the Netherlands and many other countries with similar postponed VAT accounting regimes.
With imported goods that will later be exported, a regime such as inward processing relief (IPR) allows the deferment of both VAT and customs duties. In Mexico, for example, the IMMEX program (formerly maquilaadora program) provides for duty deferral on the temporary import of goods and, in some cases, duty waivers for products that are later exported from Mexico. Recent amendments to the Mexican legislation require that IMMEX companies obtain a certification from the tax authorities or file a customs bond covering the potential VAT payments on temporary imports. Operating within a free trade zone, as is commonly done in China, enables manufacturers to import raw materials destined to undergo manufacturing into products for export without triggering a VAT or customs duty payment upon import. The administrative requirements for taking advantage of these regimes, however, can be so restrictive that some companies choose to pay the VAT, wait for the refund and absorb the customs costs, rather than go through the required documentation and processes.

Centralization of product classifications and origin determinations can provide efficiency and cost savings

In addition to VAT considerations, customs and other government authorities rely on product classification and origin information as the basis for import duties, taxes and controls. Each time the developing drug moves across a border, it requires a classification and origin assignment. While classification rules are largely harmonized for most countries, the process is highly technical and requires significant expertise about the product and the jurisdictions into which it moves. In the case of biotech and pharmaceutical companies, chemists and engineers are often required to help manage this process. The potential for redundancy, lack of consistency and inaccuracies in properly classifying a product has led many businesses to outsource this function or to consolidate their classification process into a center of excellence (COE). With the harmonization of classification codes, many companies find they can leverage efficiencies when consolidating and centralizing the classification process. Similarly, companies gain efficiencies by centralizing origin determination, particularly with regard to free trade agreements (FTAs) and other special tariff treatment programs. In this case, even where differences in the rules exist, processes to conduct the analysis can be similar. Getting a new drug to the point of distribution is a milestone for a pharmaceutical or biotech company. While this phase brings further complexities, many regimes or reliefs are available to help offset cost and streamline the compliance burden.

The COE model – streamlining internal processes to meet import/export requirements

![Diagram](image-url)

**Value**
- Reduce costs by assigning classifications for multiple jurisdictions in a single (or limited) touch manner
- Free up current resources to work on business support or other more value-added activities

**Control**
- Global visibility
- Quality, consistency and increased certainty of tariff classification determinations
- Improved documentation
- Risk management

**Efficiency**
- Consistent processes
- Appropriate technology
- Skilled and experienced people
- Increased service levels for business users
- Language resources no longer an issue

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Many companies choose to warehouse their drugs in a location convenient to large pockets of their client base. This can allow customers to manage their inventory efficiently and in a cost-effective manner and can prevent them from essentially having to warehouse large quantities of product to enable prompt fulfillment of client orders. In the absence of any concessions offered in the relevant jurisdiction, this typically requires registering in each jurisdiction where the drug is stored. Some EU countries offer various warehouse options (e.g., consignment stock, call of stock) that allow an entity to transport a product into their jurisdiction and store it until it is required – or “called” – by the final customer. This frequently relieves an entity from registering in a jurisdiction. The storage of goods in a customs warehouse defers the payment of both VAT and customs duties until the products are needed, offering cash flow benefits and reducing the number of required VAT registrations (and the consequence cost of VAT compliance).

**Identifying and accessing needed data is vital**

The breadth and timing of transactions across multiple jurisdictions and entities often necessitate the use of an Enterprise Resource Planning (ERP) system and the automation of a company’s financial or tax system. Many companies employ an ERP system as well as a tax engine to help manage the complexities associated with the movement of goods between countries and multiple indirect tax registrations and rates. With expansions or changes in global footprint, companies may have to make significant updates to properly track products and materials through the supply chain and stay up-to-date on changes in taxability and rates.

The use of data analytics can also help companies identify where costs are arising and evaluate and structure their supply chain for maximum efficiency and cost savings. Reviews of this data can, and often do, result in significant refunds.

**Conclusion**

Advancing a new drug to the point of distribution is a milestone for a pharmaceutical or biotech company. Throughout the life cycle of a drug’s production and deployment, indirect tax risks and opportunities must be evaluated for their impact on the overall business strategy and final product cost. In structuring the supply chain, companies should consider specific country regimes and available reliefs and evaluate whether consolidating or outsourcing functions such as product classifications would be beneficial. A proactive supply chain review and planning process can help offset costs and streamline the compliance burden, particularly in the highly complex biotech and pharmaceutical sectors.

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**How EY can help**

EY has a globally integrated team of subject-matter professionals capable of providing a full spectrum of services to help clients manage their global trade function, including:

- Import/export classification assignments
- Free trade agreements (FTAs)
- Special trade programs qualification analysis
- Export “restricted party” screening
- Global VAT reviews
- Supply chain mapping and modeling
- Compliance services
- Controversy assistance
EY is a global leader in assurance, tax, transaction and advisory services. The insights and quality services we deliver help build trust and confidence in the capital markets and in economies the world over. We develop outstanding leaders who team to deliver on our promises to all of our stakeholders. In so doing, we play a critical role in building a better working world for our people, for our clients and for our communities.

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How EY's Global Life Sciences Sector can help your business
Life sciences companies – from emerging start-ups to multinational enterprises – face new challenges in a rapidly changing health care ecosystem. Payers and regulators are increasing scrutiny and accelerating the transition to value and outcomes. Big data and patient-empowering technologies are driving new approaches and enabling transparency and consumerism. Players from other sectors are entering health care, making collaborations increasingly complex. These trends challenge every aspect of the life sciences business model, from R&D to marketing. Our Global Life Sciences Sector brings together a worldwide network – more than 7,000 sector-focused assurance, tax, transaction and advisory professionals – to anticipate trends, identify their implications and develop points of view on responding to critical issues. We can help you navigate your way forward and achieve success in the new ecosystem.

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