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Water Cooler Chat

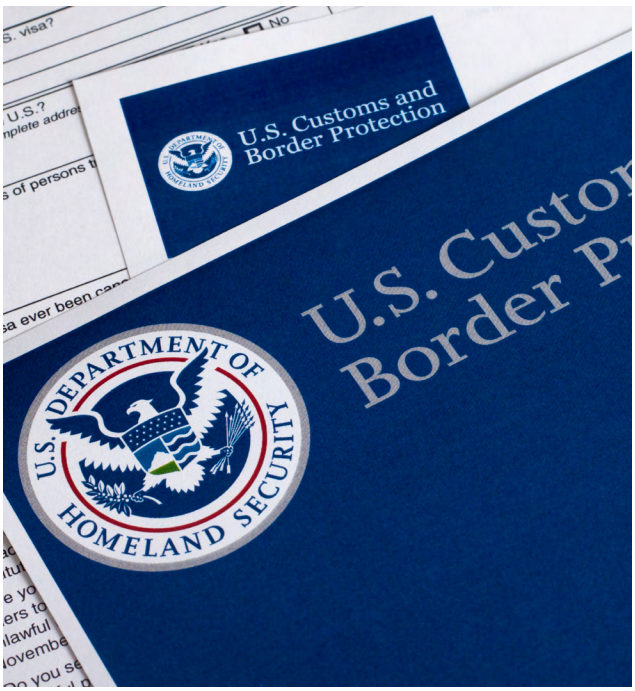
Customs Material Valuation in the US and Europe

YOUR BRIDGE BETWEEN LIFE-CHANGING THERAPIES AND PATIENTS

PCI Clinical Trial Services hosts a weekly virtual ***Water Cooler Chat*** series, where our subject matter experts host informal discussions around a number of clinical supply hot topics.

Customs Material Valuation in the US and Europe

Gavin Morgan and Rich Nelson, PCI's Senior Managers of Global Logistics, recently discussed how to effectively calculate clinical material valuation and the impact of using these valuations within the US and Europe. In this article, we cover the six methods used to calculate customs valuation, VAT/Duty implications and calculations, as well as the delays, material destruction or fixed penalty notices that can be caused by inaccurate valuations.



When biotech and pharma companies transport investigational medical products (IMPs) internationally, they are often required to pay import fees. These taxes are based on the shipment's value; however, determining that value can be challenging. Paradoxically, while these goods are not actually being sold, governments consider each shipment a sale.

As always, the goal is to value these items accurately. Estimating too high can increase a company's customs obligation. Estimating too low can have short- and long-term tax ramifications. To further complicate matters, every country has a different tax rate.

A few years ago, companies could assign a nominal value (for example, $1) to shipped IMPs, but that approach is no longer valid. Also, if customs officials question an assigned value, that could raise red flags, and they may assign a new value. If the company does not agree to the new valuation, the shipment may have to be destroyed.

Sometimes customs officials will hold a shipment while value is being sorted out. However, with tight trial deadlines and temperature-controlled shipments, even a relatively small delay can have profound consequences. As a result, it is critically important for companies to assign accurate values in advance, so items can clear customs rapidly and without mishap.

How to Assign Value

There are six acceptable ways to value imported goods *(See Calculating Customs Valuation chart below)*. Some of these methods only rarely apply to IMPs. However, it is good to understand the complete framework.

Method 1: Transaction Value
If the product has been purchased, for customs purposes, that price is its value. Even after a clinical trial label is attached, goods purchased for $100 should be valued at that price. This method may apply to ancillary supplies – other than drug or placebo – which have often been purchased and have a definite price.

Method 2: Value of Identical Goods
In some cases, customs officers may assign a value based on "identical" goods. Even though it's an IMP, and not marketed, they may research the actual trial. If there is an equivalent agent on the market in that country, that drug's value could be applied to the IMP. This approach can potentially generate high values, and correspondingly high taxes, particularly if the import is an oncology drug.

Method 3: Value of Similar Goods
This approach is not commonly used. Customs officials may look for a match in similar goods. For example, another company may have imported a related item or the importing company may have performed a previous trial with a similar drug.

Method 4: Selling Price
Since these goods are not being sold, this method does not apply.

Method 5: Production Cost of the Goods
Assessing production cost is generally the most relevant approach. This figure is also the replacement value for these materials and will generally include the cost to produce the actual drug, as well as the packaging.

Using replacement value works well because the invoice is consistent with the insurance coverage. It would be awkward to claim $20 per kit for customs and $100 for insurance.

One way to head off any possible customs issues is to create a document that outlines all production costs: raw materials, making the product and packaging, kitting all supplies, etc.

	Calculate on the basis of...	Try the next method if...
Method 1	The transaction value - the price payable to the seller	There has been no sale of goods
Method 2	The customs value of identical goods, produced in the same country as your imports	There are no identical goods
Method 3	The customs value of similar goods, which must be: produced in the same country, able to carry out the same tasks and commercially interchangeable	There are no similar goods
Method 4	The selling price of the goods (or identical or similar goods)	There are no sales of the goods
Method 5	The production cost of the goods, including the cost of any materials, manufacturing and any other processing used in production	This production cost information is unavailable
Method 6	Reasonably adapting one of the previous methods to fit unusual circumstances	N/A

Calculating the customs valuation upfront keeps everybody on the same page. The importer of record uses the customs invoice to apply for an import license. If no queries are raised, that valuation should continue throughout the trial.

Method Six: Adapting Previous Method

Sometimes, method five can produce an invoice that is still quite high. Clinical trial materials can be expensive to make, and even more so when producing small amounts. If that drug is commercialized, those costs will come down significantly.

Taxation agencies around the world understand a drug's unit price will go down during the product's life cycle, and companies can make estimates based on those future costs. They can declare that, when higher volumes come into play, these items will be cheaper to produce. Estimating the mass-produced product can cost approximately 33% of the IMP and will often get through customs without raising any red flags.

Sometimes, different countries require different valuations. For whatever reason, one particular country may not accept the price on the invoice. There may be a similar product comparison in that country. Unfortunately, when this happens, there is not much a company can do to overcome it.

UK Issues: Value Added Tax

Every country has different tax rates. In the UK, the Value Added Tax (VAT) is 20%. Some European countries are higher. This really comes into play when valuing placebos.

While there is no actual duty on pharmaceutical products in the UK and other countries, placebos are classified as a food product, which has a different commodity code and incurs a 12.8% duty. The rates may vary, but this is a common practice in the European Union.

In a hypothetical scenario, a company is importing a $100,000 shipment *(See Chart: UK VAT/Duty Calculations below)* and that includes both active drugs and placebos. Unless the company breaks out the quantity of active vs. placebo in the invoice, the broker must declare the entire shipment is placebo.

As a result, that 12.8% duty would apply to the full $100,000 shipment. However, by breaking out these two items, the company can save $15,000 on this particular lot. The invoice could call out a thousand kits, and break down 800 active kits and 200 placebos within the shipment. This approach

TIPS FOR ASSIGNING A NEW VALUE

Sometimes, a value estimate can go down. That's great, but it can also be tricky. If a product is imported at $200, but six months later it comes in at $150, customs agents may take note of the discrepancy. Companies need to anticipate these objections, documenting why production costs have gone down. Another approach is to adjust how the product is packaged. Even a slight change in the product description, such as different label text or new kitting, can make the new value acceptable.

Shipment 1 Product description: Active and/or Placebo	Shipment 2 Product description: Active only
Total Value = $100,000 Placebo (2106909260) is liable to 12.8% duty= $12,800 VAT is Duty amount ($12,800) + invoice value ($100,000) x 20% = $22,560	Total Value = $100,000 Active pharma (3004900000) is duty free VAT is $100,000 x 20% = $20,000
Total Import cost = $35,360	Total Import cost = $20,000

should not interfere with the study blinding, as depots are generally unblinded to the study.

It's also important for companies to know that, while other import taxes can be reclaimed in the UK, duty cannot.

U.S. Issues: De Minimis Value

Until relatively recently, companies importing IMPs into the U.S. could use a de minimis value, such as $1. There's no advantage to doing this because, if importers use the correct harmonized tariff code, the U.S. does not assess taxes against inbound pharmaceuticals. Also, FDA regulations classify placebos as drugs.

In addition to being unnecessary, de minimis or inaccurate values can cause dramatic consequences down the line. If the drug hits all its end points and is eventually commercialized, it's going to have actual, retail value.

As a result, the customs paperwork will assess a much larger value, say $100. However, customs agents may look at the earlier $1 valuation and wonder why it changed so drastically. Particularly, as noted earlier, when the cost of goods should go down when production is scaled up.

Interestingly, even though no taxes would have been assessed on these imports, companies can be fined for tax evasion and other fees. They can also lose the right to import or export. This is not a hypothetical situation – it has happened to packaging companies, clinical research organizations and others.

In addition, this is not solely a U.S. issue, and it's valuable to remember that customs officials from different countries communicate regularly. If a company sends a product to the Ukraine at $1 and sends the same product to Russia at $100 five years later, they could face a significant tax bill, long after the initial shipment has been forgotten. .

ABOUT OUR PCI CLINICAL TRIAL SERVICES STAFF MEMBERS

Gavin Morgan, Senior Manager, Global Logistics
Since 2009, Gavin has been leading the clinical distribution team at PCI's Bridgend facility. His main responsibilities include the overseeing of all activities associated with UK imports along with supporting the full supply chain of clinical trial supplies including the selection and management of 3rd party couriers and depots. Gavin has over 20 years of experience within the clinical trial industry, with a focus on the distribution of clinical materials globally.

Rich Nelson, Senior Manager, Global Logistics
Rich Nelson has over 15 years of clinical and commercial distribution and logistics experience. In his current position at PCI, Rich works with clients to provide seamless global distribution for their investigational drug products, ensuring cost-effective and time-efficient delivery throughout the clinical trials process. Rich has a B.A in Criminal Justice and Law Enforcement from Monmouth University.

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