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Water Cooler Chat

Importing Clinical Supplies into Japan

RECORDED APRIL 23, 2020

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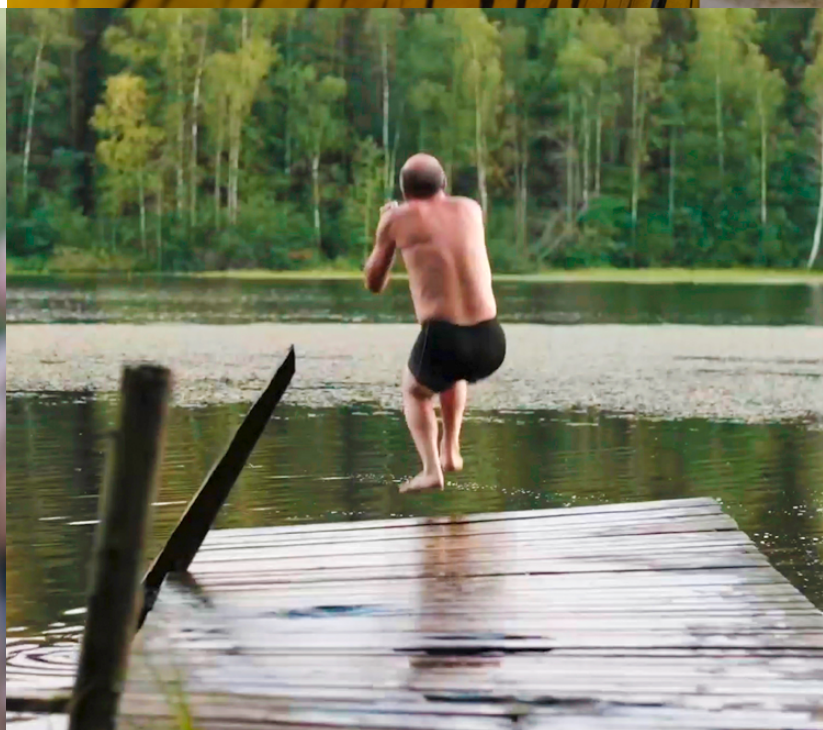


PCI Clinical Trial Services hosts a weekly virtual *Water Cooler Chat* series, where our subject matter experts host informal discussions around a number of clinical supply hot topics.

Importing Clinical Supplies into Japan

Rich Nelson, Sr. Manager, Global Logistics, recently discussed the precision with which clinical supplies and the documents accompanying their import into Japan must be prepared. Below, he covers the commercial invoice valuation of clinical kits, and clinical logistical considerations for Japan.

Importing clinical supplies into Japan requires a level of precision not seen anywhere else in the world. At first glance this may seem odd as the Japanese importation process does not include items of technical difficulty, a tedious application process, or a lengthy wait time for an import license. What it does require is a high level of formality and organization that must be followed precisely. Import attempts that do not will be delayed and sent to the back of the line.

Using a depot in Japan is highly recommended to help navigate the importation of clinical supplies. Where most countries require an exporter and an importer of record, Japan has an extra layer to the importation process, the In-Country Caretaker (ICC). The ICC represents the importer to the Japanese government, and is responsible for recovering the package upon arrival, bringing it to the customs warehouse, presenting the appropriate documents and paperwork to customs, and answering any questions the Japanese government may have. Some ICCs may also request a particular order of the documents, so that the documents are presented to the customs inspector in the correct order (according to the ICC).

These requirements therefore require that even before a shipment is even made the ICC needs to be communicating with the exporter of record, such as your clinical trial services provider or packager, to advise and agree exactly what documents need to be included with the shipment. These documents can include but are not limited to: label text, CTAs, data on the comparators, the pedigree of your materials, and your commercial invoice. Only once all documentation is prepared exactly as it has been requested, will you be given the greenlight to make your shipment.

GLOBAL DEPOT STRATEGY

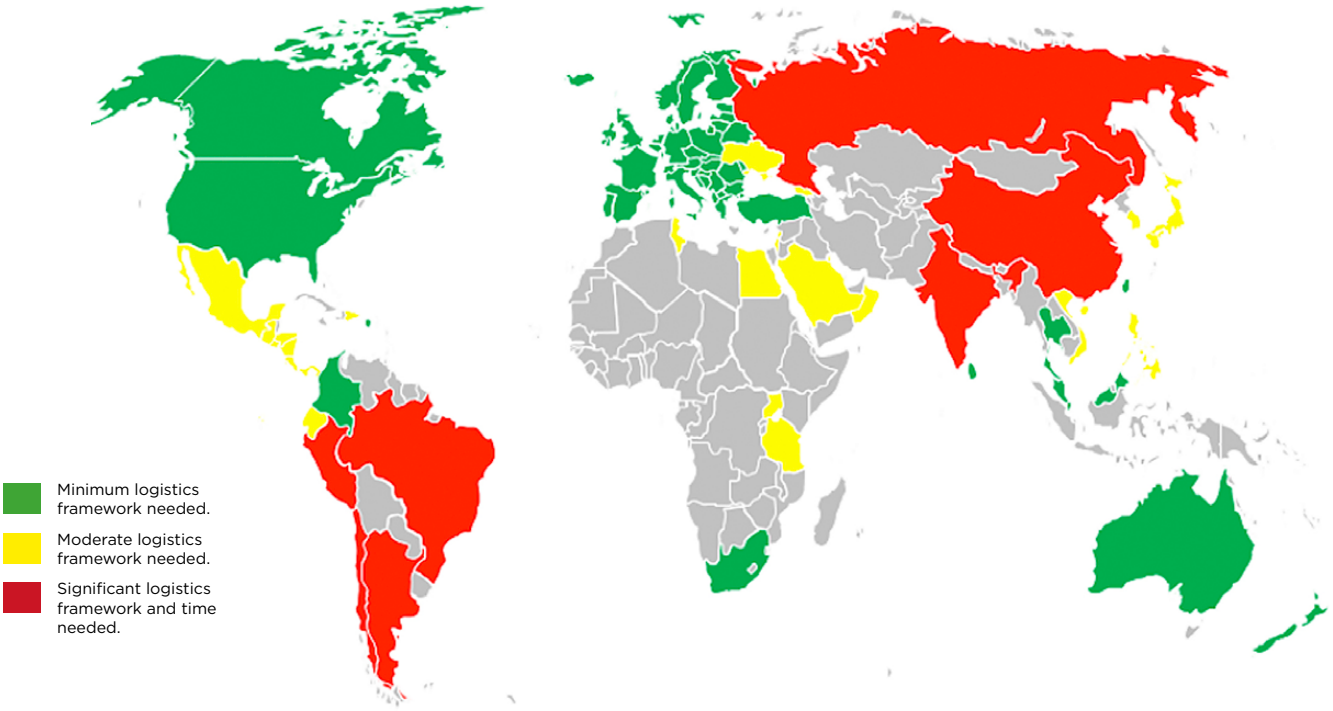
How specific does the commercial invoice accompanying the import to Japan need to be?

The commercial invoice for Japanese imports requires a high level of precision and specificity. A non-comprehensive list of items that can be found on the commercial invoice include:

- the value of the packaging
- the value of the temperature monitors
- the freight costs
- insulation system costs,
- the value of placebo and active doses in a blister card.

GLOBAL DEPOT STRATEGY

Different countries require varying amounts of logistical frameworks. Importing into Japan requires a moderate amount of logistic framework, risk-management, and takes several weeks to establish.

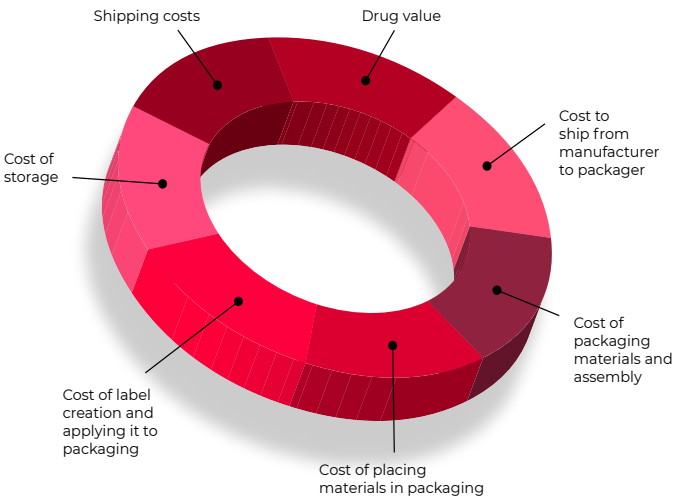


These documents are used to verify the value of each commodity specifically shown on the invoice. As the items will change on a case by case basis, it is recommended to work with your assigned ICC and your clinical packager as soon as Japan is included in your list of clinical sites.

How do sponsors typically calculate the value of the investigational drug, placebo, and direct product manufacturing conversion cost?

The valuation for Japan is also very regimented. The expectation of the value calculation is that it is as precise as humanly possible, and verifiable. A clinical trial sponsor could be asked to demonstrate how much the material cost of the IP and/or placebo were when you purchased it. While this type of request could occur anywhere in the world, the possibility of it is higher when dealing with Japan.

SINGLE KIT CONSIDERATIONS FOR JAPAN



Typical items to be considered for the value of a single kit:

- Drug value
- Cost to ship from manufacturer to packager
- Cost of packaging materials and assembly
- Cost of placing materials in packaging
- Cost of label creation and applying it to packaging
- Cost of storage
- Shipping costs

For most countries, the value of investigational drug can be thought of as the cost to replace it if it was lost. Japan requires a higher level of precision, and in some cases, proof for how much it costs to obtain the different elements that go into a single kit.

Is there a list of the paperwork involved in the importation process?

Unfortunately, this list is dependent on your product and on your study. This list could include (but is not limited to):

- CTA
- Packaging batch records
- Standard documentations

The ICC and exporter (to Japan) should be able to identify the paperwork needed for specific cases.

Are Harmonized Tariff Codes required on the commercial invoice to Japan?

Yes, commodities must be broken down line by line, such as how many placebo and active are in a blister card. Harmonized tariff codes for the placebo are required so that taxes can be assessed at the correct rates. These values would be identified by working with the ICC.

Is the valuation required on par with the EU?

It is more precise and intense than what is requested in the EU. For the EU, the valuation of the kit can be calculated by estimating how much it would cost to replace.

It should be noted that if you are shipping into other Asia Pacific countries, the information used in shipping to Japan may be shared via the ASEAN organization, so the value should be listed consistently for all nations in that region.

For Japan, there are many factors to consider such as:

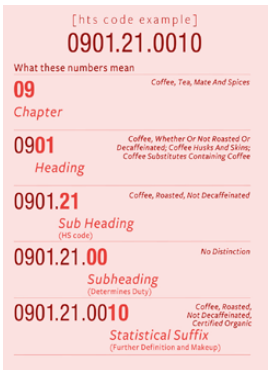
- How much has been spent on the storage of material
- How long has each different lot been stored
- How much tax had been processed against it after storage cost

Are documents required to be translated into Japanese or is English accepted?

English documents are accepted. In cases where a copy of the CTA is requested, that needs to be in Japanese – however it would originally be in Japanese, so no translation would be required.

TRIVIA

HTS: First 6 digits are the same around the world while the last four digits are country dependent. Some countries don't even have these last four digits.



Do clinical supplies being imported into Japan already need to be labeled or can the clinical label be applied in Japan?
The text of the clinical label is presented during customs, so incoming materials do need to have clinical labels. It is possible to do JIT labeling affixed at the point of distribution.

Is it preferred to use a regional depot or a local depot?
There is really no option for shipments to site from outside of the country because, in addition to the paperwork being inspected, the packaging itself is also inspected at customs. Couriers going into Japan know that they need to maintain a certain condition of the packaging. Packaging must have no damage, such as crushed corners. It must be pristine.

If shipments were going directly to a site, this pristine packaging would be difficult to maintain if it is coming directly from an international flight, and would in all likelihood be rejected by the site's principal investigator.

How are temperature-controlled products physically inspected by customs?
The bonded customs warehouse has facilities that maintain various controlled temperatures. The airlines maintain access to these facilities. If there needs to be dry ice added for example, it can be done at the warehouse. Excursions during the Japanese customs clearance process are exceedingly rare.

UK TO JAPAN DEPOT TIMEFRAME

DAY 0
Shipment to Japan requested.

DAYS 0 - 5
Shipment is physically prepared. ICC and exporter prepare import documents.

DAYS 6 - 7
Shipment in transit.

DAYS 8 - 9
Custom clearance process assuming appropriate documentation prepared.

What is the timeframe that should be allotted from identifying a shipment from the UK to being received at a depot in Japan?

Two to three weeks to deliver a shipment to a depot in Japan is standard. This includes:

- Physically preparing the shipment: 3-5 days
- In parallel, the exporter works with the assigned ICC to get the documents ready
- Transit: 1-2 days
- Custom clearance process if documentation is prepared properly: 1-2 days

Is there anything additional that should be considered for importing into Japan due to COVID-19? Added costs? More time? Restrictions?

The COVID-19 situation is affecting imports globally, and to date there are no additional Japan-specific factors that should be considered due to the pandemic. Imports generally require more time and cost more regardless of the destination country because flights are not nearly as common. Flight availability is changing timelines that the clinical supply community has become accustomed to. Now couriers need to come up with creative routings or use cargo flights. As a general rule, cargo flights will not take off until the flight is full, which means a clinical trial sponsor may have to wait several days before the clinical supply is on its way to its destination.

Who handles Japanese importation issues on behalf of the sponsor?

If a clinical sponsor is working with a partner who is also the exporter of record, the partner company should work with the ICC to fix any issues that may arise.

Importing clinical supplies into Japan requires precision. Consider using a clinical trial service provider with experience packaging and importing into Japan to avoid potential delays.

About Rich Nelson, Sr. Manager Global Logistics, PCI Pharma Services

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.

*If you are interested in learning about PCI's **Water Cooler Chat** series where our experts answer questions in real-time, please visit us **here** to see the schedule and register for this complimentary series.*