Fact Sheet: Importing Therapeutics for Clinical Trials

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Key points

If non-synthetic therapeutic goods for administration to humans in clinical trials are imported from overseas, they are considered a biosecurity risk material and require an import permit issued by the Department of Agriculture. The University of Tasmania has a valid permit for this commodity, which must be used whenever a consignment of therapeutics is imported.

Note: therapeutics imported using this permit must not be distributed, sold or used for veterinary or agricultural purposes (e.g. veterinary therapeutic use, vaccine manufacture or administration to livestock).

Process for importing human therapeutics for clinical trials

Step 1 – Importer Declaration & Permit
Using the template available here, complete and sign an Importer Declaration to accompany each consignment of therapeutics. Forward the completed Declaration to Sam Poynter, the UTAS Biosafety and Biosecurity Officer (BBO), who will then provide you with a copy of the Import Permit.

Step 2 – Consignment Dispatch
Forward a copy of the Importer Declaration and the Import Permit to the supplier of the therapeutics, and request that the documents are attached to the outside of the parcel in a transparent plastic sleeve (or equivalent). The parcel should be addressed to the location where the clinical trial is hosted.

Step 3 – Receipt
Once received, the therapeutics should be stored securely until administered under the approved conditions of the clinical trial.

Where to get help

For general enquiries, contact the BBO at biorisk.management@utas.edu.au or 6226 8349.

Biologicals Users Group (BUG) – an open-access platform for staff and students working with biological materials to share knowledge and common issues.

Institutional Biosafety Committee members may provide specific advice relating to facilities, permits, standard operating procedures and GMO dealing applications in their area.

The University has a Regulated and Hazardous Biological Materials Policy that provides information on obligations and responsibilities when working with materials of biosecurity concern.