Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Excluded Goods Order No.1 of 2011

Guideline for Items 4(o), 4(p), 4(q) and 4(r)

Version 1.1, March 2013

TGA Health Safety Regulation

New Items in the Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 in relation to products of human origin

Item 4(q): Exclusion of goods manufactured and used in medical practice

The Order provides in this Item a description of HCT obtained during medical procedures that are part of medical practice and not regulated by the TGA.

This means that it is not necessary for:

- the HCT manufactured and used in the circumstances referred to in the Item to be included in the Australian Register of Therapeutic Goods; or
- the person manufacturing or producing the HCT to have a licence under Part 3-3 of the Act

Item 4(q) of the Order specifically excludes from TGA regulation HCT that are:

i. collected from a patient who is under the clinical care and treatment of a medical practitioner registered under a law of a State or an internal Territory; and

ii. manufactured by that medical practitioner, or by a person or persons under the professional supervision of that medical practitioner, for therapeutic application of a single indication and in a single course of treatment of that patient by the same medical practitioner, or by a person or persons under the professional supervision of the same medical practitioner.

This provision reflects the Australian Health Ministers' Conference (AHMC) agreement that single surgical procedures and medical practice should not be regulated by the TGA.

Products (goods) covered by item 4 (q)

The Item only covers HCT that are collected from a patient and used in that same patient. That is, the products are ONLY for autologous use. An example is the use of veins from a patient's limb(s) for grafts in cardiac bypass surgery. It should be noted that only the tissue (vein in this example) itself is excluded from the definition of therapeutic goods. Equipment and materials that are used for the manufacture of the product may still be therapeutic goods to which the Act and Regulations apply and thus subject to regulation by the TGA.

Single medical practitioner and single patient

A registered medical practitioner must have prime responsibility for the clinical care of his/her patient throughout the course of treatment in which the HCT products are used for the Item to apply. If the medical practitioner cannot assure ongoing responsibility for clinical care of that patient and oversight of the HCT, then the products will not come within the Item and thus may be subject to regulation by the TGA.