



Australian Government

Department of Health

Therapeutic Goods Administration

Biologicals packaged or combined with another therapeutic good

Australian Regulatory Guidelines for Biologicals (ARGB)

Version 1.0, July 2018

TGA Health Safety
Regulation

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Some biologicals may be supplied with other therapeutic goods. Regulation of such products depends on whether the biological is:

- a combination product, that is a biological combined or incorporated with another therapeutic good to make a single product entity that is transplanted or injected

OR

- a multi-component packs, that is a biological individually packaged with other therapeutic goods.

Combination products

Your biological is considered to be a combination product if it is:

- ü **combined or incorporated** with another therapeutic good such that the other good may or may not act on the human body **in addition** to the biological
- ü the goods are combined and supplied for use as a single product entity that is transplanted or injected
- û **not** packaged individually to the therapeutic good.

Combination products are regulated as biologicals:

- when at least one of the components is a biological
- the other constituent/s is a therapeutic good.

The following points should be noted in determining the level of data needed to support your combination product:

- The individual therapeutic goods may have an integral part in the intended use of the final product, or one constituent may be considered an excipient in the final product.
- Generally, it is expected that the constituents would retain the intended use and function approved (if approved) for it, even when administered to patients as part of the combination product. Where the intended use or function of the individual constituents differs to the use or function already approved, additional supporting data would need to be provided to ensure safety and efficacy (if necessary).
- The quality, safety and efficacy of the individual constituents will be assessed against appropriate regulatory requirements, as well as together as a single product entity (in conjunction with a 'biological'). This single product entity will be assessed overall as a biological regardless of whether the constituent is a medicine, biological or medical device included on the ARTG separately.

Examples of combination products

1. **Biological combined with a medical device:** such as a collagen membrane coated with a layer of cells. The medical device provides a support function to ensure the cells are retained physically at the site of the defect.
2. **Biological combined with a medicine:** such as a human bone product mixed with a purified active protein, for example, recombinant Bone Morphogenetic Protein (BMP). The medicine is intended to enhance the osteoinductivity of the bone graft.



Clarification of the regulatory path for a combined biological/medical device is given in the [Therapeutic Goods \(Articles that are not Medical Devices\) Order No. 1 of 2010](#).

The following articles, or classes of articles, are declared **not to be medical devices**:

- articles incorporating tissues, cells, or substances of human origin, other than medical devices incorporating stable derivatives of either human blood or human plasma that act on, or are likely to act on, the human body in a way that is ancillary to the device
- articles incorporating viable tissues cells or substances of animal origin.

Multi-component packs

Multi-component packs maybe composite packs, kits, and system or procedure packs. Kits and composite packs are defined in the legislation under section 7B of the [Therapeutic Goods Act 1989](#). System or procedure packs are defined in section 41BF—these are regulated as medical devices.

The packs are regulated differently depending on the combination of therapeutic goods supplied with the biological.

Composite pack

- Contains two or more therapeutic goods, but does not contain medical devices.
- The goods must be for administration as a single treatment or a single course of treatment, and the components are either combined before treatment or administered in a particular sequence as part of a that treatment.
- Individual components within the pack may or may not be separately listed, registered or included.

An example of a composite pack is a vial of a biological that is lyophilised and is packaged with an ampoule or vial containing a diluent.

Kits

- Contains two or more therapeutic goods, but does not contain medical devices.
- The pack must not meet the definition of a composite pack, and must not contain any medical devices.
- The individual goods can be used independently and do not need to be combined or administered in a sequence as part of a single treatment for the product's therapeutic purpose.
- Individual components within the pack must be separately listed, registered or included.
- Will be a **medicine kit** if the biological is packaged with a medicine, and will be listed on the ARTG.
- Will be a **biological kit** if two or more biologicals are packaged together, and will be included on the ARTG.

System or procedure pack

- If the package contains a biological and any medical devices it will be regulated as a **medical device** and included as a **system or procedure pack**.
- Where the package contains a biological and other equipment used to prepare the biological, but the equipment does not meet the definition of a medical device, the pack will be regulated as a biological rather than as a system or procedure pack.



System or procedure packs are medical devices

Information on the regulation of system or procedure packs can be found in pre-market part of the [Australian Regulatory Guidelines for Medical Devices \(ARGMD\)](#).

Summary of multi-component packs

If your biological is packaged with a...	The final product will be called a...	The final product will be regulated as a...
Medicine	Medicine kit or composite pack	Listed medicine kit or biological (composite pack)
Medical device	System or procedure pack	Medical device
Biological	Biological kit or composite pack	Biological

Version history

Version	Description of change	Authors	Effective date
V1.0	Original publication incorporating new legislative changes and information previously published on the TGA website.	Biological Science Section Regulatory Guidance Team	July 2018

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Reference/Publication #D18-10607846