Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Understanding rules for boundary and combination products

Guidance to help sponsors figure out if their therapeutic goods are medicines, biologicals, or medical devices.

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Purpose

These guidelines discuss key concepts that will assist manufacturers and sponsors understand which regulatory pathways and requirements will apply to boundary and combination products depending on how they are categorised.

The examples provided are a revised list of common boundary and combination products, and the category under which they are likely to be regulated.

This information is for guidance purposes only. It does not address every aspect of the relevant legislation.

Refer to the Legislation and legislative instruments or contact us through the contact details mentioned in the guidance to ensure all relevant legislative requirements are met.

Legislation

Therapeutic Goods Act 1989

Therapeutic Goods (Excluded Goods - Hand Sanitisers) Determination 2020

Therapeutic Goods (Excluded Goods) Determination 2018

Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020

Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023

Therapeutic Goods (Biologicals—Specified Things) Instrument 2021

About this guidance

The TGA regulates therapeutic goods as defined in Section 3 of the *Therapeutic Goods Act 1989* (the Act) which generally fall under the following categories:

- Medicines as defined under Section 3 of the Act,
- Biologicals as defined under Section 32A of the Act,
- Medical devices as defined under Section 41BD of the Act, and
- Other therapeutic goods (OTGs) which include goods like tampons and disinfectants.

Products that fall under these categories have different regulatory pathways and requirements.

See Products we regulate for more information about these categories and other products that we regulate.

Appendix A contains definitions and concepts used for regulating of therapeutic goods.

Using the online tool Is my product a therapeutic good? to work out if your product is a therapeutic good, and if so, the category of therapeutic good.

Some products may have attributes of two or more categories with different intended actions or effects and the appropriate regulatory pathway is not immediately obvious. These are referred to as '**boundary products'**.

Some products contain more than one type of therapeutic good with more than one therapeutic action or effect and are referred to as '**combination products'.**

This guidance has been developed to help manufacturers and sponsors understand which requirements and regulatory pathways apply to boundary and combination products in Australia.

We discuss key concepts and provide examples and case studies to show how boundary and combination products are regulated.

This information is provided for guidance only. It should not be relied on to address every aspect of the relevant legislation.

You should get independent legal advice to make sure everything is legal.

Boundary products

'**Boundary products**' are therapeutic goods that:

- have some of the attributes of two or more categories of regulated goods, and
- are products for which the appropriate regulatory pathway is not immediately obvious.

Regulation of boundary products

We regulate boundary products depending on the:

- principal therapeutic effect of the product,
- the therapeutic claims; and
- intended use mentioned on the product information or advertising materials.

Based on the factors below, we regulate products that incorporate or administer medicinal substances as either medical devices or medicines:

- which component or ingredient of the product provides the most important therapeutic effect of the product,
- what the principal therapeutic effect achieved is, when used consistently with the manufacturer's intended use, and
- the primary mode of action of the product in achieving its therapeutic effect and how it relates to the definitions of medicine, biological and medical device.

Some factors can influence the determination of principal therapeutic effect, including:

- actual therapeutic effect of the product and scientifically demonstrated action, verifiable in humans through clinical study findings,
- therapeutic claims made for the product, including any made on:
    - websites
    - linked helplines
    - testimonials
    - publications
- the context in which the claims are made, and the overall presentation,
- the labelling, packaging or package inserts, pamphlets and promotional literature including any pictures or graphics,
- product names and branding can also be deemed to be implicit claims,
- advertisements, including those appearing in “advertorials”, on television, other media and the Internet, and
- the product form (capsule, tablet, injection etc.) and how it is supposed to be used.

Medicinal products

The action of a **medicinal product** is typically achieved by pharmacological, chemical, immunological, or metabolic means.

For example, substances used for diagnostic purposes (in vivo diagnostics) usually act chemically and are regulated as medicines.

> Appendix A explains the concept of pharmacological, immunological, and metabolic means.

Medical devices

The principal intended action of **medical devices** is typically achieved by physical means. This includes:

- mechanical action,
- impervious, physical barrier only protecting the surface it is directly applied to,
- replacement of, or support to, organs or body functions, and
- measurement or monitoring body or its physiological functions.

Therapeutic goods that are chemical substances and exert their therapeutic effect through local or systemic chemical means are generally not medical devices. In most cases, the principal mode of action is metabolic or pharmacological.

Examples of boundary products

A product can contain medicinal substances that act on the body in an ancillary way. This includes herbal material and plant extracts. Depending on the intended therapeutic action, these substances may be regulated as medicines.

Alcohol swabs

- Alcohol swabs with antiseptic claims will probably be regulated as medicines due to the claims.
- Swabs with no claims other than cleaning skin will likely be regulated as medical device.

Nasal decongestion

- Products that use physical means to penetrate, clear and wash nasal blockages and loosen mucus are likely regulated as medical devices.
- Nasal decongestion products that contain an active ingredient and clear the nasal blockages by pharmacological means will likely be regulated as medicines.

Eye lubricating products

- Products that are only intended to lubricate the eye are likely regulated as medical devices.
- Eye lubricating products that have pharmacological components intended for antiseptic effect are likely regulated as medicines.

Disinfectants

- Liquid, spray, wipe, or aerosol intended to be used for disinfecting medical devices are likely regulated as medical device.
- Commercial grade disinfectant for surfaces other than medical devices or skin with a specific claim of killing bacteria will be likely regulated as an OTG.

Combination products

Products with components that have more than one therapeutic effect can potentially fit within more than one category of therapeutic goods are commonly referred to as ‘combination products’.

Combination products can commonly be:

- medicine - medical device combinations - medical devices that incorporate, or are used to administer a medicine,
- biological – medical device combinations - biologicals presented as a combination product with a medical device component (i.e., integrated with the medical device), such as a metal stent coated with a matrix and endothelial cells,
- biological – medicine combinations - biologicals presented as a combination product with a medicine component.

Regulation of combination products

The principal therapeutic effect for the product determines what type of therapeutic good the product is and how it is regulated. Like boundary products, the regulation of combination products may also depend on other factors such as therapeutic claims and intended use mentioned on the product or in advertising.

Medicine - medical device combinations

Medical devices that incorporate or are used to administer medicine are regulated as either medical devices or as medicinal products, depending on the **primary intended purpose of the product**. These combinations may be in the form of:

- **Medical devices used to administer a medicine** that is supplied separately will be likely regulated as medical devices. For example, syringes marketed empty, medicine spoons, and droppers. These products are usually supplied empty.
- **Medicines co-packaged with or contained within the same pack as the medical device** where the medicine component is responsible for the primary intended purpose of the product

will be likely regulated as medicines. The device component is intended to be used to measure or administer the medicine within the pack. For example, paracetamol oral liquid and its measuring syringe or a cup.

- **Medical devices used for administering medicines** where the device and the medicine component forms a single **integral product** will likely be regulated as medicines. The product must not be re-usable or refillable. For example, epinephrine auto-injectors, and pre-filled asthma inhaler.

> 'Integral' is usually taken to mean a single component product. However, there may be circumstances where this could apply to two elements that are packaged together and combined into one product immediately prior to administration to the patient.
>
> The relevant Essential Principles of Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002 apply with respect to safety and performance for the device component (for example, a syringe component of a pre-filled syringe). The device component does not need a separate ARTG entry, unless supplied separately.

- Medical devices incorporating a medicine as an integral part will likely be regulated as medical device. These are products that:
    - meet the definition of a medical device, and
    - incorporate, as an integral part, a substance, that:
        - if used separately, would be considered a medicine, and
        - is liable to act upon the body with action ancillary to that of the other functions of the medical device.

- 'Medicine' in this context includes but is not limited to substances that may be medicines, including herbal medicines (herbal material and plant extracts) and substances derived from human blood or blood plasma. For example, heparin-coated catheter. The safety, quality, and efficacy of the medicinal substance may be assessed by the relevant Branch of the TGA.

> Medicine device combinations may be covered by System or procedure packs. Refer to our System or procedure packs for further guidelines.

Biological combination products

Combination products will likely be regulated as biologicals when at least one of the components is biological and other components are therapeutic goods.

Combination products are biological products that are:

- 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,
- the goods are combined and supplied for use as a single product entity that is transplanted or injected, and
- not packaged individually to the therapeutic good.

> See guidance on Biologicals packaged or combined with another therapeutic good.

Biological - medical device combinations

Biological products presented as combination with a medical device component (i.e., integrated with the medical device) are regulated under the Biologicals Regulatory Framework and included in the ARTG as a biological. It is the constituents of the combination product that define the product as a biological, rather than the mode of action or principal therapeutic effect.

For example, metal stent coated with a matrix and endothelial cells will be regulated Biologicals Regulatory Framework. The device (i.e., the metal stent itself) will be assessed according to medical device regulatory requirements but will not be included in the ARTG separately.

Biological - medicine combinations

Biological products presented as combination product with medicine component are regulated under the Biologicals Regulatory Framework and included in the ARTG as a biological.

For example, a human bone product mixed with purified active protein such as recombinant Bone Morphogenetic Protein (BMP). The medicine (BMP) is intended to enhance the osteoinductivity of the bone graft.

> Adding a substance can change the product's principal therapeutic effect, changing the product's category of therapeutic good.

See Appendix B for case studies of regulatory pathways with multiple therapeutic effects.

Summary

This document focuses on boundary and combination products and how they are regulated in Australia.

The information in this document is for guidance only. It should not be relied on to address every aspect of the relevant legislation.

It is best to read this in conjunction with information on the TGA website such as guidance documents, decision making tools, and links to our assessment processes.

More information

You can consult the TGA if you are unsure about your product's category or regulatory pathway. Email the following areas for information:

- Prescription Medicines - info@tga.gov.au
- Over-the-counter medicines - OTC.Medicines@health.gov.au
- Medical Devices - devices@tga.gov.au
- Biologicals - bloodandtissues@tga.gov.au
- TGA info - info@tga.gov.au

This guidance focuses on boundary and combination products. For information on related topics see:

- Food-Medicine Interface Guidance Tool
- Complementary medicine interface (includes guidance on cosmetic-medicine interface)

- Excluded goods orders, determinations and specifications
- Biological products regulated as a therapeutic good, but not as a biological
- Biological products that are exempt or excluded from TGA regulation
- Disinfectants, sterilants and sanitary products

Appendix A

Concepts and terms

Medicine

Medicines are defined in Section 3 of the Act as therapeutic goods that are represented to achieve or are likely to achieve their principal intended action by:

- pharmacological
- chemical
- immunological, or
- metabolic means
- in or on the body of a human.

Medical device

Medical devices are defined in Section 41BD of the Act. Medical devices:

- are used in, for, or in relation to humans
- have therapeutic benefits
- generally, have one or more of the following characteristics:
    - have a physical or mechanical effect on the body
    - are used to record patient images for diagnosis or monitoring
    - are used to measure or monitor functions of the body
    - are used for prediction, prognosis, diagnosis, or monitoring of diseases or conditions
    - are used to guide treatment.

They can include components with:

- pharmacological
- immunological
- metabolic means as ancillary (secondary and assistive) functions.

Additionally, certain types of products may be explicitly declared as being or not being medical devices. These declarations are used to clarify the status of particular therapeutic goods or a category of therapeutic goods.

Biological

Biologicals, defined in Section 32A of the Act, are therapeutic goods comprising, containing, or that are:

- derived from human cells or human tissues
- certain other products comprising or containing live animal cells, tissues, or organs.

- Biologicals entered into the ARTG are classified into one of four regulatory classes.

The Secretary may declare specific therapeutic goods to either be or not be a biological. Goods declared to not be a biological are regulated by the TGA as either a medicine or a medical device. Refer to Therapeutic Goods (Biologicals—Specified Things) Instrument 2021 for further information.

Other therapeutic goods

Other therapeutic goods are therapeutic goods that do not fit the definition of a medical device, medicine or biological. These products are either:

- regulated under Chapter 3 of the Act as listed therapeutic goods, or
- are exempt from entry in the ARTG.

Examples include sterilants, disinfectants, tampons, and menstrual cups.

Sterilants and disinfectants are regulated in a variety of ways depending on the intended purpose as detailed in:

- the instructions for use
- labelling
- promotional material.

Specific information and guidance are available at Disinfectants, sterilants and sanitary products.

Differentiating terms

The terms listed below are important to understand and help differentiate between product type.

A therapeutic good is likely to be a medicine if its principal intended action is by:

- pharmacological,
- immunological
- metabolic

means in or on the body of a human.

The term *in or on the body of a human* includes actions upon:

- all components of the human body itself
- microbial flora
- pathogenic organisms.

Extracorporeal blood that is in continuous circulation with the body is considered a part of the body.

Principal intended action refers to the main mechanism of how a product exerts its therapeutic effect. This allows discrimination between types of therapeutic goods. The principal intended action must be scientifically plausible, considering:

- the intended clinical indications for the product
- how physiological or pathological processes are affected.

The principal intended action must be a verifiable and desirable therapeutic effect.

Key therapeutic actions that discriminate between types of therapeutic goods are:

'Pharmacological means[1]' is an interaction between:

- a substance or its metabolites (typically at a molecular level), and
- a constituent of the human body
    - that results in initiation, enhancement, reduction or blockade of physiological functions or pathological processes.

Examples of constituents of the human body include, amongst others:

- cells and their constituents including:
    - cell membranes
    - intracellular structures
    - RNA
    - DNA
    - proteins, for example, membrane proteins
    - enzymes
- components of extracellular matrix, foreign objects and organisms that are within or on the body
- components of blood
- components of body fluids.

Examples of action via pharmacological means:

- interaction between a ligand (for example, agonist, antagonist) and a receptor
- interaction between a substance and membrane lipids
- interaction between a substance and components of the cytoskeleton
- interaction between a substance and a pathogenic organism.

'Immunological means' is:

- an action initiated by a substance or its metabolites on the human body
- mediated or exerted (that is, stimulation, modulation, blocking, replacement) by cells or molecules involved in the functioning of the immune system, such as:
    - lymphocytes
    - toll-like receptors
    - complement factors
    - cytokines
    - antibodies

Examples of action via ‘immunological means’ include:

- modulation of an immune response (for example, suppressing, blocking, activating, enhancing)
- replacement, reconstitution or introduction of natural or modified immune cells or molecules
- triggering an immune response against the targeted tissues, cells or antigens by immune-specific recognition
- targeting action of other linked or coupled substances.

Examples of substances acting via immunological means:

- vaccine
- tetanus anti-serum
- monoclonal antibodies
- anti-venom
- C1 esterase inhibitor.

Products with immunological recognition as a principal intended action are medicines. This is because immunological recognition used to target or direct the effects of linked or coupled substances is not an ancillary[2] action.

'metabolic means[1]' is an action of a substance or its metabolites that involves an alteration in the function of the human body by stopping, starting, changing the rate, extent or nature of a biochemical process.

The biochemical process can be physiological or pathological.

The term ‘biochemical processes’ refers to reactions in the human body such as:

- anabolic and catabolic reactions
- transport of substances between compartments.

An interaction with a known receptor is not a prerequisite for the metabolic means of action.

Examples of action via ‘metabolic means’ include:

- the movement of water due to active transport of electrolytes mediated by, for example, Na/K ATPase pumps
- inhibition of endogenous enzymes, including the digestive enzymes
- inhibition of absorption of any substance in the alimentary or respiratory tracts
- altering the electrolyte balance, including pH and osmolality, of the serum or other body compartment or cavity.

The Australian Register of Therapeutic Goods (ARTG)

The ARTG is the public database of therapeutic goods that can be legally supplied in Australia. Medical device sponsors must have their product in the ARTG unless the product is exempt from ARTG inclusion, excluded from regulation by TGA or otherwise approved. The ARTG database is publicly accessible and includes the following:

- registered goods
- listed goods
- medical devices
- biologicals

Registrable and listable goods

Registrable and listable goods are regulated under Chapter 3 of the Act. Registrable goods undergo a more rigorous evaluation of their quality, safety and efficacy, before being entered into the ARTG, than listable goods.

Medical devices

Medical devices are regulated under Chapter 4 of the Act and can be entered into the ARTG if their manufacturers:

- comply with the Essential Principles for safety and performance
- have applied appropriate conformity assessment procedures or undergone comparable overseas regulator pathways
- meet certain other requirements.

Exempt goods

Some therapeutic goods can be made exempt from selected regulatory requirements. For example, a therapeutic good could be made exempt from requiring entry in the ARTG. Exemptions are detailed in legislation and can include associated conditions.

Example conditions:

- notification to the TGA before supply
- reporting of adverse events after supply
- allowing of inspection of manufacturing facilities by the TGA.

Exemptions from the inclusion provisions of medicines and biologicals are published in Schedules 5 and 5A of the Regulations (exempt goods). Exemptions for medical devices are published in Schedule 4 of the MD Regulations.

Sponsors can identify applicable exemptions for products once the type of therapeutic good is known:

- medicine
- medical device

- biological
- other therapeutic good.

Note: Sponsors must comply with all conditions of applicable exemptions.

Excluded goods

The Secretary may declare that particular goods are not therapeutic goods. These goods are called Excluded goods and are not regulated by TGA. Information on Excluded Goods is available at Excluded goods orders, determinations and specifications.

Supply of 'unapproved' therapeutic goods not in the ARTG

Products not included in the ARTG are referred to as unapproved therapeutic goods and these can be legally supplied in Australia through several different pathways. These unapproved products may include medicines or medical devices, including medical cannabis and vaping products containing nicotine, and can be accessed under the following pathways depending on various factors including the needs of particular people or circumstances of use.

- Special access scheme
- Authorised prescribers
- Personal Importation Scheme
- Clinical trials
- Accessing medicines during a medicine shortage

These schemes cannot be used to facilitate the commercial supply of therapeutic goods.

Appendix B

Case studies of products with more than one therapeutic effect

Patches of bandages

The product is a **medicine**. This is because the principal therapeutic effect could only relate to the medicine. The adhesive patch provides the mode of administration of the active therapeutic ingredient. An antimicrobial medicated wound dressing intended principally for use as a barrier to protect a wound or damaged skin and hence promote healing is a **medical device**.

A medicine-impregnated patch that adheres to healthy skin to deliver the medicine trans dermally in itself is not intended to have any therapeutic effect on the skin, although it could cause a local reaction. The therapeutic claims made only relate to systemic effects of the medicine.

An irrigation solution with an added microbicide

A sterile, physiological solution with an added microbicidal substance that is intended to be used for irrigation of a part of the body is a **medicine**. In this case, the principal therapeutic effect is to reduce the clinical risk of infection at the site of a contaminated or infection-prone wound.

A similar solution that does not include a microbicide is a **medical device**. This is because its principal therapeutic effect is achieved through facilitating physical removal of objects and substances at the site of use.

A substance to fill a space between bone fragments that contains a medicine to stimulate bone growth

A matrix (not of human cell or tissue origin) principally used as a bone void filler achieves its effect by acting as a scaffold for bone formation, without physiological stimulation of bone growth or cellular infiltration is a **medical device**.

Adding a substance that stimulates bone growth changes the product's principal therapeutic effect. In this case, the matrix administers a medicine to the anatomical site. This medicine helps with fusion of bones. The principal intended action is achieved pharmacologically through stimulation of bone growth making this product a **medicine** rather than a medical device.

A matrix of human cell or tissue origin is **biological.**

A bone cement incorporating an antibiotic

A cement for fixation of joint replacement systems in bone is a medical device

Incorporation of an antibiotic to reduce the risk of infection does not alter the principal therapeutic effect of the cement, which is to fix a prosthesis to bone, thereby reducing pain or increasing functionality; the antibiotic has an important, but clearly ancillary effect in reduction of the risk of local infection.

This product is a **medical device**. The addition of an antibiotic does not affect the product’s principal therapeutic action of acting as a physical adhesive mechanism.

Should a similar product, incorporating an antibiotic, be intended to be used to treat or prevent an infection, whilst not being used to fix a prosthesis to bone, its principal therapeutic effect has changed and consequently, the product is a **medicine**.

Decisions on whether and how to enter products in the ARTG are made by the lead program although assessments may take place across the TGA.

Examples of boundary and combination products and their product category

Below is a list of some boundary and combination products and the most appropriate regulatory category likely applicable. The list includes products intended for therapeutic use only.

This page will be updated to include further products and clarification as required. Discussions are underway about the regulation of head and body lice products, moisturisers and emollients, and toothpastes. The page will be updated once a decision has been finalised.

Absorbable, with shape, used in surgery

Tissue adhesives (may include cyanoacrylates, fibrin-based adhesives).

Product category: Medical Device

Rationale: Principal intended action is primarily achieved by physical means even though they may attach by chemically crosslinking to tissues, which is ancillary action.

Absorbable, without shape, used in surgery

Visco-elastic fluids such as intraocular visco-elastic fluids and synovial (animal origin) visco-elastic fluids.

Product category: Medical Device

Rationale: Act by physical means to protect tissues from trauma by providing lubrication, cushioning, and maintaining space between tissues. Absorption by metabolic means is ancillary action.

Absorbable implants

Collagen injections

Product category: Medical Device

Rationale: Principal intended action of smoothing out wrinkles achieved by adding volume, absorbing water, and providing structural support. Resorption of the filler by metabolic means is ancillary action.

Hyaluronic acid injections (when used as filler or lubricant)

Product category: Medical Device

Rationale: Principal intended action of smoothing out wrinkles achieved by adding volume, absorbing water, and providing structural support. Resorption of the filler by metabolic means is ancillary action.

Skin mesh products derived from human tissue such as collagen cellfree extracellular matrices

Product category: Biological

Rationale: As per section 32A (1)(a)(i) of the *Therapeutic Goods Act 1989* (the Act).

Antiseptics, disinfectants, cleaners, soaking solutions

For use on skin

Antiseptic 'wipe' or sponge

Product category: Medicine

Rationale: For products containing antiseptics, the targeting and killing of microorganisms is achieved through pharmacological action and regulated as medicine.

Moist swab (with antiseptic claim)

Product category: Medicine

Rationale: For products containing antiseptics, the targeting and killing of microorganisms is achieved through pharmacological action and regulated as medicine.

Moist swab (with no claims other than cleaning the skin)

Product category: Medical Device

Rationale: For products containing antiseptics, the targeting and killing of microorganisms is achieved through pharmacological action and regulated as medicine.

Fabric dressing with antiseptic (unless primary intended action is to deliver the antiseptic)

Product category: Medical Device

Rationale: Those products without an antiseptic claim achieve their principal intended action through physical means and regulated as medical device. See Understanding regulation of disinfectants, sterilants and sanitary products.

Antibacterial hand sanitisers

Product category: Medicine

Rationale: Antibacterial hand hygiene products that claim to kill specific organisms and/or are to be used in hospital settings. For more information see Hand sanitisers: Information for manufacturers, suppliers and advertisers.

Hand sanitisers that meet the requirements of the specified excluded goods determination

Product category: Excluded

Rationale: As per the Therapeutic Goods (Excluded Goods-Hand Sanitisers) Determination 2020.

For use on inanimate objects (hard or soft surfaces)

Hospital grade or household/ commercial grade disinfectant that do not make specific claims*

Product category: Other therapeutic good (exempt)

Rationale: See Understanding regulation of disinfectants, sterilants and sanitary products.

* Virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity are known as "specific claims". More information can be found in the Disinfectant Claim Guide.

Hospital grade or household/ commercial grade disinfectant that make specific claims* to kill microorganisms

Product category: Other therapeutic good (exempt)

Rationale: See Understanding regulation of disinfectants, sterilants and sanitary products.

Disinfectant and sterilant gases

Product category: Excluded

Rationale: As per Schedule 1, Item 5 of the Therapeutic Goods (Excluded Goods) Determination 2018.

Ostomy appliance detergents, deodorisers

Product category: Excluded

Rationale: As per Schedule 1, Item 5 of the Therapeutic Goods (Excluded Goods) Determination 2018.

Body 'cleaning' and irrigation substances

Bulk forming laxatives (including ispaghula husk and methylcellulose)

Product category: Medicine

Rationale: Hydrophilic function by chemically attracting and sequestering extra water in stools.

Osmotic laxatives (including lactulose and polyethylene glycol)

Product category: Medicine

Rationale: Soften stools by osmotically increasing the amount of water in the intestinal lumen by pharmacological or metabolic means.

Gastrointestinal detoxifier

Product category: Medicine

Rationale: Chelating compound that acts through metabolic effect in the gut.

Enema solutions for rectal administration of medicine

Product category: Medicine

Rationale: Principal intended action is primarily achieved by pharmacological or metabolic means of the medicine. Actions achieved by physical means (for example, water pressure) are ancillary actions.

Douches, including kits for therapeutic use

Product category: Medical Device

Rationale: Physically remove debris using water based solutions. See System or procedure packs.

Unmedicated, physiological solutions for irrigation such as prefilled saline syringe - catheter, flush syringe, eye irrigation solution, isotonic saline for nasal irrigation)

Product category: Medical Device

Rationale: Principal intended action of irrigation is achieved by physical means (mechanical rinsing), even if there are additives in the solution that are not medicines with ancillary action for example, preservatives.

Solutions for irrigation that incorporate active ingredient, such as substances with an antimicrobial action

Product category: Medicine

Rationale: Products containing medicinal substance, achieving the principal intended action primarily by pharmacological or metabolic means, for example killing microorganisms and reducing infection risk. The solution is for delivering the medicine and considered ancillary action.

Activated charcoal used internally

Product category: Medicine

Rationale: Principal intended action is achieved by metabolic means and regulated as medicine.

Hypertonic saline for inhalation

Product category: Medicine

Rationale: Inhaled hypertonic saline increases mucus clearance by osmotically increasing water content and disrupting ionic bonds in mucus. The principal intended action is not through physical means.

Hypertonic eye drops

Product category: Medicine

Rationale: Hypertonic eye drops reduce swelling in the eye by osmotically drawing out water.

Body fluid replacements and nutrients

Blood substitutes and plasma expanders

Product category: Medicine

Rationale: These are of two main types:

- Crystalloids (such as saline solution) increase both intravascular and interstitial blood volume by decreasing osmotic pressure.
- Colloids contain larger insoluble molecules that exert osmotic pressure which draws fluids inward, to increases blood volume.

Peritoneal dialysis solutions and substances prepacked for their preparation

Product category: Medicine

Rationale: Works primarily by altering the concentration of chemical and biological substance within the body and regulated as medicine.

Haemofiltration solutions

Product category: Medicine

Rationale: Works primarily by altering the concentration of chemical and biological substance within the body and regulated as medicine.

Haemodialysis solutions not in direct contact with blood that is, other side of membrane (in-vitro)

Product category: Medical Device

Rationale: Concentrates for haemodialysis that are not intended to be used in direct contact with the blood are regulated as medical device.

Apheresis solutions

Product category: Medical Device

Rationale: Non-invasive product with principal intended action primarily achieved through physical means such as physical separation.

Contact lens care products

Contact lens cleaning, disinfecting, rinsing or hydrating solutions

Product category: Medical Device

Rationale: Products specifically to be used for disinfecting, cleaning, rinsing or hydrating contact lenses are specified as medical devices as per Schedule 1, Item 5 of the Therapeutic Goods (Medical Devices - Specified Articles) Instrument 2020.

Wetting agents

Product category: Medical Device

Rationale: Products specifically to be used for disinfecting, cleaning, rinsing or hydrating contact lenses are specified as medical devices as per Schedule 1, Item 5 of the Therapeutic Goods (Medical Devices - Specified Articles) Instrument 2020.

Hydrating agents

Product category: Medical Device

Rationale: Products specifically to be used for disinfecting, cleaning, rinsing or hydrating contact lenses are specified as medical devices as per Schedule 1, Item 5 of the Therapeutic Goods (Medical Devices - Specified Articles) Instrument 2020.

Comfort drops

Product category: Medical Device

Rationale: Products specifically to be used for disinfecting, cleaning, rinsing or hydrating contact lenses are specified as medical devices as per Schedule 1, Item 5 of the Therapeutic Goods (Medical Devices - Specified Articles) Instrument 2020.

Soft contact lens lubricants

Product category: Medical Device

Rationale: Products specifically to be used for disinfecting, cleaning, rinsing or hydrating contact lenses are specified as medical devices as per Schedule 1, Item 5 of the Therapeutic Goods (Medical Devices - Specified Articles) Instrument 2020.

Hard contact lens lubricants

Product category: Medical Device

Rationale: Products specifically to be used for disinfecting, cleaning, rinsing or hydrating contact lenses are specified as medical devices as per Schedule 1, Item 5 of the Therapeutic Goods (Medical Devices - Specified Articles) Instrument 2020.

Diagnostic imaging or similar agents

Diagnostic imaging or similar agents (in vivo)

For use in conjunction with:

- Positron emission tomography Medicine
- Computerised axial tomography
- Nuclear magnetic resonance imaging
- Ultrasonography
- X-ray imaging
- Radionucleotide scanning

Product category: Medicine

Rationale: In vivo imaging agents injected, ingested, or otherwise instilled into the body are declared to not be medical devices as per Schedule 1, Item 6 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Agents injected, ingested, or otherwise instilled into or applied to the body for use in device therapy, such as in vivo imaging agents

- laser fluorescent dyes

- fluorescein ocular drops/strips
- injectable fluorescein
- laser/UV light activated agents
- lithotripsy imaging agents

Product category: Medicine

Rationale: In vivo imaging agents injected, ingested, or otherwise instilled into the body are declared to not be medical devices as per Schedule 1, Item 6 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Dyes or markers used to identify or to mark normal anatomy

For example, surgical marker pen to mark planned incision, identification of normal anatomy of the eye.

Product category: Medical Device

Rationale: Dyes and stains (that do not contain a medicine) for identification of normal anatomy are regulated as medical devices.

Dyes used to identify damaged, or tissue affected by pathological processes

For example, dye or tracer used for sentinel node biopsy, dye used to identify corneal abrasion).

Product category: Medicine

Rationale: Dyes and stains used to identify damaged tissue affected by pathological processes (diagnostic purposes) are considered medicines. For example, dyes used for identification of a corneal lesion or a sentinel lymph node

In vitro diagnostic (IVD) goods

That incorporate material of human origin

Product category: Medical Device

Rationale: IVD medical devices and in-house IVD medical devices are specified to not be biologicals as per Schedule 2, Item 3 of the Therapeutic Goods (Biologicals - Specified Things) Instrument 2021. See In vitro diagnostic (IVD) medical devices.

Breath test for Helicobacter pylori co-packaged with labelled urea

Product category: Medical Device

Rationale: IVD medical devices and in-house IVD medical devices are specified to not be biologicals as per Schedule 2, Item 3 of the Therapeutic Goods (Biologicals - Specified Things) Instrument 2021. See In vitro diagnostic (IVD) medical devices.

Diagnostic goods for in vivo use

Labelled urea for *Helicobacter pylori* test

Product category: Medicine

Rationale: Principal intended action is achieved by immunological, pharmacological or metabolic means.

Allergen skin tests such as scratch test and patch test

Product category: Medicine

Rationale: Principal intended action is achieved by immunological, pharmacological or metabolic means.

Tartaric acid for testing patient reflex cough

Product category: Medicine

Rationale: Products may contain a device component, but the action is ancillary as the device components are used for delivering or applying the medicine. These are not IVD medical devices as the test sample is not taken out of the body

External use products (for therapeutic use only)

A product without intended therapeutic use is not a therapeutic good.

Emollient and moisturising preparations

Product category: Medical Device

Rationale: Principal therapeutic action is through providing a protective barrier from the external environment to keep moisture in or out and has a therapeutic intended purpose.

Emollient and moisturising preparations containing an active ingredient

Product category: Medicine

Rationale: The product is intended to treat skin irritation or lesions through pharmacological, metabolic, or chemical means.

Skin adhesive and adhesive enhancers

Product category: Medical Device

Rationale: Holds products against the skin using physical force, even though they may attach by crosslinking chemically.

Extra-corporeal therapies

Immunoadsorption columns including charcoal activated and those using monoclonal antibodies

Product category: Medical Device

Rationale: Principal intended action is primarily achieved through physical means such as adsorption and physical separation.

Haemoperfusion columns

Product category: Medical Device

Rationale: Principal intended action is achieved through physical means such as adsorption and physical separation.

Anticoagulant used on human blood that is in continuous circulation with the body

Product category: Medicine

Rationale: Principal intended action is primarily through pharmacological or metabolic means.

Perfusion circuit with heparin

Product category: Medical Device

Rationale: Principal intended action is achieved through physical means and heparin results in ancillary action.

Hard-tissue scaffolds

Hard-tissue scaffolds that primarily act by physical means

Such as:

- hydroxyapatite (with or without collagen)
- calcium phosphate (with or without collagen)
- coral
- bioglass
- cartilage repair systems incorporating non-human derived tissue

Product category: Medical Device

Rationale: Principal intended action is achieved through structural support for subsequent tissue grown and repair.

Cartilage repair systems incorporating human tissue

Product category: Biological

Rationale: The product has tissues derived from humans and is regulated as per section 32A (1)(a)(i) of the Act.

Haemostatic agents

Haemostatic agents that primarily act by physical means

For example, collagen, cellulose, gelatines, polysaccharides, matrices, sealants, and adhesives.

Product category: Medical Device

Rationale: Principal intended action is primarily achieved by physical means through:

- Absorbing water from blood,
- Forming a matrix structure to allow/promote platelet aggregation, and
- Adhering to tissue or bone to form physical barrier blocking blood flow.

Collagen can also activate platelets by pharmacological means, this is considered ancillary action.

Haemostatic agents that primarily act by augmenting the coagulation cascade

For example, thrombin and fibrin sealants.

Product category: Medicine

Rationale:

- Thrombin chemically converts soluble fibrinogen in blood plasma into insoluble fibrin in response to triggers such as vessel wall injury.

- Fibrin sealant is formulation of human thrombin, human fibrinogen and antifibrinolytic inhibitor that delays clot degradation (synthetic aprotinin) which upon mixing, mimics a physiological clot.

See Multi-component packs in Biologicals packaged or combined with another therapeutic good.

Gingival retraction cords coated with adrenalin or astringent

Product category: Medical Device

Rationale: Principal intended action of retracting tissue is achieved by the cord; added components aid this effect therefore have an ancillary effect.

Dentistry products with aluminium chloride used for haemostasis

Product category: Medical Device

Rationale: Principal intended action is primarily achieved through physical effect on the protein coagulation and are regulated as medical device.

Lubricants and gels

Electrode gels

Product category: Medical Device

Rationale: Principal intended action is achieved through physical means by reducing electrical resistance and by conducting the signal for diagnostics such as Electroencephalogram (EEG), Electrocardiogram (ECG) and Electrophysiology (EP) examinations.

Lubricants represented for therapeutic use

Product category: Medical Device

Rationale: Principal intended action of reducing damage due to friction is achieved through physical means. For example, substances intended to facilitate the passage of a medical device within the human body or between bodily structures, such as the surfaces of a joint or between eyelid and eyeball or to lubricate the surface of the eye.

Lubricants with spermicide/virucide

Product category: Medicine

Rationale: Principal intended action is achieved by the spermicide/virucide through pharmacological means. Lubricant is used as a delivery mechanism.

Vaginal gel such as those that maintain Potential of hydrogen (pH) balance

Product category: Medicine

Rationale: Principal intended action is metabolic, altering the chemistry of a part of the body.

Artificial tears for use with/without contact lenses (unmedicated)

Product category: Medical Device

Rationale: Act by physically protecting the eye through lubrication. Absorption by the body through metabolic means is ancillary action.

Artificial saliva

Product category: Medical Device

Rationale: Principal intended action is by physically providing lubrication to moisten and prevent mechanical trauma.

Medical gases

Oxygen and other medical gases (except cryogenic gases, gases for mechanical use, and sterilant gases)

Product category: Medicine

Rationale: See Medicinal gases guidance.

Sterilant gases

Product category: Excluded

Rationale: Disinfectant and sterilant gases are excluded as per Schedule 1, Item 5 of the Therapeutic Goods (Excluded Goods) Determination 2018.

Oxygen – chemical generators

Product category: Medicine

Rationale: Declared to not be medical devices as per Schedule 1, Item 4 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Gas used as a diagnostic such as gas mixtures for pulmonary function testing devices

Product category: Medicine

Rationale: In vivo imaging agents injected, ingested, or otherwise instilled into the body are declared to not be medical devices as per Schedule 1, Item 6 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Oxygen concentrators

Product category: Medical Device

Rationale: It is an apparatus that increases the concentration of oxygen by physical means.

Gases for mechanical use on humans

For example, to expand a body cavity or create a tamponade.

Product category: Medical Device

Rationale: Insufflation gases for the abdominal cavity or laparoscopic and endoscopic procedures intended exclusively for minimal access surgery with a physical mode of action (e.g., inflation).

Compressed gases when used as a power source for a medical device

Product category: Excluded

Rationale: As per Schedule 2, Item 4 of the Therapeutic Goods (Excluded Goods) Determination 2018.

Multi-component packs

Comprises of kits, composite packs, system or procedure packs and surgical loan kits. Kits and composite packs are defined under section 7B, and System or procedure packs contain medical devices are defined under section 41BF of the Act.

Composite packs and kits do not contain medical devices. Refer to guidance on system or procedure packs and Biologicals packaged or combined with another therapeutic good for more information.

Composite pack containing medicine

Product category: Medicine

Rationale: Composite packs containing medicine are regulated as medicine, even if they contain biologicals.

Composite pack not containing medicine (biologicals only)

Product category: Biological

Rationale: Composite packs containing biologicals only (no medicine) are regulated as biologicals.

Kits containing medicine

Product category: Medicine

Rationale: Kits containing medicine are regulated as medicine, even if they contain biologicals.

Kits not containing medicine (biologicals only)

Product category: Biological

Rationale: Composite packs containing biologicals only (no medicine) are regulated as biologicals.

System or procedure packs (SOPPs)

Product category: Medical Device

Rationale: SOPPs must include a medical device or an in vitro diagnostic (IVD) medical device and depending on its intended purpose may also include medicine, biologicals, other therapeutic goods or goods that are not considered to be therapeutic goods. First aid kits are also regulated as SOPPs as they include device components.

Surgical loan kit

Product category: Medical Device (Exempt)

Rationale: Surgical loan kits are not SOPPs. They ONLY contain medical devices. All goods in a surgical loan kit must already be included in the Australian Register of Therapeutic Goods (ARTG) (hence why the kit is exempt)

Oral products

The Therapeutic Goods Administration (TGA) is responsible for regulating oral hygiene products such as toothpastes that are medicines or claims to have therapeutic use.

Oral Hygiene products are ‘therapeutic goods’ if they:

- Do not meet the relevant requirements of the Therapeutic Goods (Excluded Goods) Determination 2018,
- Contain ingredients that are under the Poisons Standard, or
- Make a therapeutic claim.

Dental bleaches and whiteners

Product category: Excluded

Rationale: As per Schedule 1, Item 3 of the Therapeutic Goods (Excluded Goods) Determination 2018.

Oral hygiene products such as dentifrices, mouth wash and breath fresheners for the care of the teeth and mouth

Where they:

- do not contain any substance included in the Poisons Standard or
- contain benefits/ claims only related to oral hygiene and/or prevention of tooth decay)

Product category: Excluded

Rationale: As per Schedule 2, Item 6 of the Therapeutic Goods (Excluded Goods) Determination 2018.

Salivation stimulation lozenge containing active ingredient

Product category: Medicine

Rationale: Principal intended action of stimulating saliva production is primarily through pharmacological or metabolic means. These products usually contain an active ingredient that specifically stimulates salivation.

Products used to cleanse dentures such as dental cleansing solutions and brushes for cleaning dentures

Product category: Medical Device

Rationale: These are accessories to a medical device (dentures) and are regulated as medical device. This is independent of their mode of action. See Schedule 1 Item 5 of the Therapeutic Goods (Medical Devices - Specified Articles) Instrument 2020.

Other lozenges with therapeutic use

Anti-snoring dissolvable lozenge and other substances

Such as dissolvable oral strip, and throat spray/rinse that have active ingredient

Product category: Medicine

Rationale: Products that have active ingredient and the therapeutic effect is achieved by pharmacological, immunological or chemical means are regulated as medicine. Products may have physical action such as lubrication but that will be an ancillary action.

Throat lozenge to relieve sore throat and/or aid decongestion that have active ingredient

Product category: Medicine

Rationale: Products that have active ingredient and the therapeutic effect is achieved by pharmacological, immunological or chemical means are regulated as medicine. Products may claim to have a physical action such as lubrication but that will be an ancillary action.

Incorporating both a medicine and a medical device

Condom with spermicide or virucide

Product category: Medical Device

Rationale: Principal intended action is primarily achieved through physical barrier, spermicide or virucide is ancillary action.

Catheter coated with heparin or antibiotic

Product category: Medical Device

Rationale: Principal intended action is primarily achieved through physical means, heparin or antibiotic coating has an ancillary action.

Bone cement with antibiotic

Product category: Medical Device

Rationale: Provides structural support and physical adhesion, the antibiotic has an ancillary action.

Active implantable medical device lead, steroid-eluting

Product category: Medical Device

Rationale: Principal intended action is primarily achieved through physical means, steroid has an ancillary action.

Cardiac stent/lead, medicine-eluting

Product category: Medical Device

Rationale: Principal intended action is primarily achieved through physical means, medicine has an ancillary action.

Intra ocular lens, heparin coated

Product category: Medical Device

Rationale: Principal intended action is primarily achieved through physical means, heparin has an ancillary action.

Products such as tubing and catheters to carry blood, albumin coated

Product category: Medical Device

Rationale: Principal intended action is primarily achieved through physical means, albumin has an ancillary action.

Copper intra uterine contraceptive device

Product category: Medical Device

Rationale: Copper primarily works through physical action resulting in contraception.

Hormone-eluting intra uterine contraceptive device

Product category: Medicine

Rationale: Hormone delivered by the intra uterine device results in contraception by pharmacological/metabolic means. The intra uterine device acts as a delivery mechanism.

Dental cement with antibiotic/adrenalin

Product category: Medical Device

Rationale: Principal intended action is to provide structural support and bind to the teeth, which is through physical means. Antibiotic and adrenalin have ancillary action.

Dressings impregnated with medicinal product whose primary purpose is as a wound protectant

Product category: Medical Device

Rationale: Principal intended action of the dressing is to protect the wound by physical means, the pharmacological action of the impregnated medicine is ancillary action.

Warming plasters (adhesive) containing capsaicin (capsicum oleoresin or capsicum extract) or mustard packs

Product category: Medicine

Rationale: “Warming” sensation is achieved by pharmacological or metabolic means and are regulated as medicine.

Inhaler device – with medicine, nonrefillable

Product category: Medicine

Rationale: Products that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose). As per Schedule 1, item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Vapes containing a medicine (nicotine or cannabis), non-refillable

Product category: Medicine

Rationale: Products that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose). As per Schedule 1, item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Inhaler device – refillable, supplied separately to medicine

Product category: Medical Device

Rationale: Product is used for delivering the medicine and is not intended to form a single integral unit with the medicine. The medicine is typically sold separately. See

- Vaping hub and
- Reclassification of medical devices that administer medicines or biologicals by inhalation.

Vapes – refillable, supplied separately to medicine

Product category: Medical Device

Rationale: Product is used for delivering the medicine and is not intended to form a single integral unit with the medicine. The medicine is typically sold separately. See

- Vaping hub and
- Reclassification of medical devices that administer medicines or biologicals by inhalation.

Contact lenses – medicated for hypersensitivity

Product category: Medical Device

Rationale: The medicine for hypersensitivity is ancillary to the contact lenses, which achieve the principal intended purpose by affecting light refraction.

Pre-filled or pre-loaded devices intended to deliver a medicine

Syringes prefilled with a medicinal product (other than prefilled with sterile water/saline for catheter inflation)

Product category: Medicine

Rationale: Articles that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) are declared not to be medical devices as per Schedule 1, Item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Transdermal patch

Product category: Medicine

Rationale: Articles that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) are declared not to be medical devices as per Schedule 1, Item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Intravenous nutrition etc. bags (filled)

Product category: Medicine

Rationale: Articles that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) are declared not to be medical devices as per Schedule 1, Item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Parenteral nutrition bags (filled)

Product category: Medicine

Rationale: Articles that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) are declared not to be medical devices as per Schedule 1, Item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Peritoneal dialysis bags (filled)

Product category: Medicine

Rationale: Articles that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) are declared not to be medical devices as per Schedule 1, Item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Oxygen and medical gas containers (filled) or delivery units

Product category: Medicine

Rationale: Articles that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) are declared not to be medical devices as per Schedule 1, Item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Internal sponge, membrane or similar for delivery of spermicide or Sexually transmitted disease (STD) virucide

Product category: Medicine

Rationale: Articles that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) are declared not to be medical devices as per Schedule 1, Item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Styptics (pencils, wool etc.)

Product category: Medicine

Rationale: Articles that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) are declared not to be medical devices as per Schedule 1, Item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Analgesic plasters

Product category: Medicine

Rationale: Articles that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) are declared not to be medical devices as per Schedule 1, Item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Medicated paste bandages

Product category: Medicine

Rationale: Articles that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) are declared not to be medical devices as per Schedule 1, Item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Corn/callus removal pads with medication

Product category: Medicine

Rationale: Articles that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) are declared not to be medical devices as per Schedule 1, Item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Unfilled or unloaded devices intended to deliver a medicine

Blood bags (that contain and deliver an anticoagulant/preservative)

Product category: Medical Device

Rationale: Products used for delivering medicine and is not intended to form a single integral unit with the medicine are medical devices. The medicine is typically sold separately.

Blood bags without anticoagulant/preservative

Product category: Medical Device

Rationale: Products used for delivering medicine and is not intended to form a single integral unit with the medicine are medical devices. The medicine is typically sold separately.

Preservative solutions for use in blood bags

Product category: Medical Device

Rationale: Products used for delivering medicine and is not intended to form a single integral unit with the medicine are medical devices. The medicine is typically sold separately.

Intravenous nutritional etc. bags (unfilled)

Product category: Medical Device

Rationale: Products used for delivering medicine and is not intended to form a single integral unit with the medicine are medical devices. The medicine is typically sold separately.

Parenteral nutrition bags (unfilled)

Product category: Medical Device

Rationale: Products used for delivering medicine and is not intended to form a single integral unit with the medicine are medical devices. The medicine is typically sold separately.

Peritoneal dialysis bags (unfilled)

Product category: Medical Device

Rationale: Products used for delivering medicine and is not intended to form a single integral unit with the medicine are medical devices. The medicine is typically sold separately.

Oxygen and medical gas containers (unfilled)

Product category: Medical Device

Rationale: Products used for delivering medicine and is not intended to form a single integral unit with the medicine are medical devices. The medicine is typically sold separately.

Tissue replacements of biological origin

'Manufactured' from human tissue

Product category: Biological

Rationale: As per section 32A (1)(a)(i) of the Act.

‘Manufactured’ from animal tissue and rendered non-viable

Product category: Medical Device

Rationale: Product is a medical device as it incorporates non-viable tissue.

Products that comprise or contain live animal cells, tissues or organs

Product category: Biological

Rationale: As per Schedule 1, Item 1 of the Therapeutic Goods (Biologicals - Specified Things) Instrument 2021.

Direct transplants

Product category: Excluded

Rationale: As per Schedule 2, Item 4C of the Therapeutic Goods (Excluded Goods) Determination 2018.

Blood products

Product category: Medicine

Rationale: Blood and blood components including haematopoietic progenitor cells and plasma derivatives are regulated as medicines. See blood and blood components.

Tissue storage and transport solutions

In-vitro fertilisation media

Product category: Medical Device

Rationale: The primary intended action of storage is achieved through physical means and are regulated as medical devices. Actions achieved by active ingredient such as nutrients, antibiotics and anticoagulants will be ancillary. Products such as ex-vivo cell culture media or in-house solutions used in manufacturing of commercialised cell therapy products are not regulated as medical devices. See Australian regulatory guidelines for biologicals.

Other storage and transport solutions containing ingredients of animal origin

Product category: Medical Device

Rationale: The primary intended action of storage is achieved through physical means and are regulated as medical devices. Actions achieved by active ingredient such as nutrients, antibiotics and anticoagulants will be ancillary. Products such as ex-vivo cell culture media or in-house solutions used in manufacturing of commercialised cell therapy products are not regulated as medical devices. See Australian regulatory guidelines for biologicals.

Other storage and transport solutions containing ingredients of non-animal origin

Product category: Medical Device

Rationale: The primary intended action of storage is achieved through physical means and are regulated as medical devices. Actions achieved by active ingredient such as nutrients, antibiotics and anticoagulants will be ancillary. Products such as ex-vivo cell culture media or in-house solutions used in manufacturing of commercialised cell therapy products are not regulated as medical devices. See Australian regulatory guidelines for biologicals.

Topical compounds and products with therapeutic use

Compound or solution for removal of warts by burning or freezing

Product category: Medical Device

Rationale: Extreme temperature (hot or cold) resulting from heat transfer causing cell death is a physical means of action.

Topical nail treatment solutions containing antibacterial or antifungal ingredients

Product category: Medicine

Rationale: Principal intended action is primarily achieved through pharmacological means by antibacterial or antifungal ingredient. May also contain ingredient that creates a physical barrier to exclude the micro-organism which will be considered as ancillary action.

Topical nail treatment solutions without antibacterial or antifungal ingredients

Product category: Medical Device

Rationale: Products intended to treat infected nails by creating a physical barrier to protect from micro-organisms are regulated as medical devices.

Vascular access products

Vascular access device locking solution that incorporate active ingredient such as an anticoagulant or antibiotic

Product category: Medical Device

Rationale: Locking solutions use physical means (take up space) to maintain patency between infusions, prevent blood coagulating within the vascular access device, and prevent blood reflux. Active ingredients are considered ancillary.

Weight loss treatment - ingested

Ingested weight loss treatments that occupy space in the stomach and are not absorbed

Product category: Medical Device

Rationale: Weight loss treatments such as capsules that expand in the stomach act by physical means as they create a feeling of satiety by occupying space.

Ingested weight loss treatments that affect absorption of food

Product category: Medicine

Rationale: If it affects absorption of calories in the gastrointestinal system by metabolic means.

Other products that have therapeutic use

Ocular endotamponades such as gases and silicone oils

Product category: Medical Device

Rationale: Products introduced into vitreous cavity for creating a physical tamponade are regulated as medical device.

Sodium alginate-based products for reflux

Product category: Medicine

Rationale: They have a metabolic effect, altering the chemistry of gastric contents.

Therapeutic Sunscreens

Product category: Medicine

Rationale: Non-exempt sunscreens are required to be listed under section 26A of the Act or registered under section 25 of the Act. See Australian regulatory guidelines for sunscreens.

Lithotripter

Product category: Medical Device

Rationale: Principal intended action of breaking kidney stones to aid removal is achieved by physical means using high energy shock waves.

Dissolution agent used with lithotripter

Product category: Medicine

Rationale: Principal intended action of dissolving kidney stones to aid removal is achieved by pharmacological or metabolic means such as alkalisation of the urine.

Gums (as adhesives or lubricants) including Polyhydroxy compounds and Cellulose derivatives

Product category: Medical Device

Rationale: Adhesives and lubricants primarily act by physical means and are regulated as medical devices.

Dusting powders, therapeutic uses

Product category: Medicine

Rationale: Principal intended action is primarily achieved through pharmacological or metabolic means. Absorption of fluids by physical means is ancillary action.

Dextranomer dressing

Product category: Medical Device

Rationale: Act by physical means to absorb wound exudate, wound debris, and micro-organisms.

Riboflavin eye drops intended for the treatment of keratoconus activated via illumination with Ultraviolet A (UVA) light

Product category: Medicine

Rationale: UVA photoactivation of riboflavin eye drops increases collagen cross-linking in the cornea to strengthen the cornea which is achieved by pharmacological or metabolic means.

Urea, salicylic acid and other chemical preparations used to remove corn/callus

Product category: Medicine

Rationale: Principal intended action is primarily achieved by metabolic means.

Substance that changes or buffers Potential of hydrogen (pH) in a lumen or cavity of the body

Product category: Medicine

Rationale: Principal intended action is primarily achieved by metabolic means.

Radioactive sources and implants

Product category: Medical Device

Rationale: Use energy to operate which is considered as physical means.

Footnotes

1. Based on EU borderline and classification guidance. MDCG 2022-5 - https://health.ec.europa.eu/system/files/2023-06/mdcg_2022-5_en.pdf
2. Ancillary – an accessory, subsidiary or helping thing – Macquarie Dictionary

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Topics: Legislation Therapeutic goods regulation

Page history

3 May 2024

Updated section 'Examples of boundary and combination products and their product category'.

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1 December 2023

Updated guidance content.

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1 November 2005

Updated to reflect alcohol swabs with no claims regulated as medica devices, alcohol swabs with antiseptic claims regulated as medicines