

DEVICE JURISDICTION

A.

1(a) **Device with primary purpose of delivering or aiding in the delivery of a drug that is distributed without a drug (i.e. unfilled)**

Example :

- device that calculate drug dosages
- drug delivery pump and/or catheter infusion pump for implantation
- iontophoreses device
- medical or surgical kit (e.g. tray) with reference in instructions for use with specific drug (e.g. local anaesthetic)
- nebulizer
- small particle aerosol generator (SPAG) for administering drug to ventilated patient
- splitter block for mixing nitrous oxide and oxygen
- syringe, jet injector, storage and dispensing equipment

Status : Device and drug, as separate entities.

1(b) **Device with primary purpose of delivering or aiding in the delivery of a drug and distributed containing a drug (i.e. 'prefilled delivery system')**

Example :

- nebulizer
- oxygen tank for therapy and OTC emergency use
- prefilled syringe
- transdermal patch

Status : Combination product.

2. **Device incorporating a drug component with the combination product having the primary intended purpose of fulfilling a drug function**

Example :

- bone cement containing antimicrobial agent
- cardiac pacemaker lead with steroidcoated tip
- condom, diaphragm, or cervical cap with contraceptive or antimicrobial agent (including virucidal agent)
- dental device with fluoride
- dental wood wedge with hemostatic agent

- percutaneous cuff (e.g. for catheter or orthopedic pin) coated / impregnated with antimicrobial agent
- skin closure or bandage with antimicrobial agent
- surgical or barrier drape with antimicrobial agent
- tissue graft with antimicrobial or other drug agent
- urinary and vascular catheter coated / impregnated with antimicrobial agent
- wound dressing with antimicrobial agent

Status : Combination product.

3. **Drug incorporating a device component with the combination product having the primary intended purpose of fulfilling a drug function**

Example :

- skin prep pads with antimicrobial agent
- surgical scrub brush with antimicrobial agent

Status : Combination product. (Lead agency : drug authority)

4(a) **Device used in the production of a drug either to deliver directly to a patient or for use in the producing medical facility (excluding use in a registered drug manufacturing facility)**

Example :

- oxygen concentrators (home or hospital)
- oxygen generator (chemical)
- ozone generator

Status : Device. (Both agencies)

4(b) **Drug/device combination product intended to process a drug into a finished package from**

Example :

- device that uses drug concentrates to prepare large volume parenterals
- oxygen concentrators (hospital) output used to fill oxygen tanks for use within that medical facility

Status : Combination product (Both authorities).

B.1 Device used concomitantly with a drug to directly activate or to augment drug effectiveness

Examples :

- biliary lithotripter used in conjunction with dissolution agent
- cancer hyperthermia used in conjunction with chemotherapy
- current generator used in conjunction with an implanted silver electrode (drug) that produces silver ions for an antimicrobial purpose
- materials for blocking blood flow temporarily to restrict chemotherapy drug to the intended site of action
- UV and/or laser activation of oxsoresalen for psoriasis or cutaneous Tcell lymphoma

Status : Device and drug, as separate entities.

2. Device kits labeled for use with drugs that includes both device(s) and drug(s) as separate entities in one package with the overall primary intended purpose of the kit fulfilling a device function

Example :

- medical or surgical kit (e.g. tray) with drug component

Status : Combination product (device lead).

C. Liquids, gases, or solids intended for use as devices (e.g. implanted, or components, parts, or accessories to devices)

Example :

- dye for tissues used in conjunction with laser surgery, to enhance absorption of laser light in target tissue
- gas mixtures for pulmonary function testing devices
- gases used to provide 'physical effects'
- hemodialysis fluids
- hemostatic devices and dressings
- injectable silicone, collagen, and teflon
- liquids functioning through physical action applied to the body to cool or freeze tissues for therapeutic purposes
- liquids intended to inflate, flush, or moisten (lubricate) indwelling device (in or on the body)
- lubricants and lubricating jellies
- ophthalmic solutions for contact lenses
- organ/tissue transport and/or perfusion fluid with antimicrobial or other drug agent, i.e. preservation solutions

- powders for lubricating surgical gloves
- sodium hyaluronate or hyaluronic acid for use as a surgical aid
- solution for use with dental 'chemical drill'
- spray on dressings not containing a drug component

Status : Device.

D. **Products regulated as drugs**

Example :

- irrigation solutions
- purified water or saline in a prefilled nebulisers for use in inhalation therapy
- skin protectants (intended for use on intact skin)
- sun screens
- topical/internal analgesic/antipyretic

Status : Drug.

E. **Ad hoc jurisdictional decisions**

Example :

- motility marker constructed of radiopaque plastic (device)
- brachytherapy capsules, needles, etc., that are radioactive and may be removed from the body after radiation therapy has been administered (device)
- skin markers (device)

Status : Device or drug.

General criteria affecting drug/device determination :

a). **Device criteria**

- i. A liquid, powder, or other similar formulation intended only to serve as a component, part, or accessory to a device with a primary mode of action that is physical in nature.
- ii. A product that has the physical attributes (e.g. instrument, apparatus) and does not achieve its primary intended purpose through chemical action within or on the body, or by being metabolized.

- iii. The phrase 'within or on the body' does not include extra corporeal systems or the solutions used in conjunction with such equipment. Such equipment and solutions will be regulated as devices.
- iv. An implant, including an injectable material, placed in the body for primarily a structural purpose even though such as implant maybe absorbed or metabolised by the body after it has achieved its primary purpose.
- v. A device containing a drug substance as a component with the primary purpose of the combination being to fulfill a device function is a combination product and will be regulated as a device.
- vi. A device (e.g. machine or equipment) marketed to the user, pharmacy, or licensed practitioner that produces a drug will be regulated as a device or combination product by drug authority. This does not include equipment marketed to a licensed drug manufacturer.
- vii. A device whose labeling or promotional materials make reference to a specific drug or generic class of drug unless it is prefilled with a drug ordinarily remains a device. It may however be subject to the combination product regulation.

b). **Drug criteria**

- i. A liquid, powder, tablet, or other similar formulation that achieves its primary intended purpose through chemical action within or on the body, or by being metabolized, unless it meets one of the specified device criteria.
- ii. A device that serves as containers for a drug or a device that is a drug delivery system attached to the drug container where the drug is present in the container is a combination product and will be regulated by the drug authority.
- iii. A device containing a drug substance as a component with the primary purpose of the combination product being to fulfill a drug purpose is a combination product and will be regulated by the drug authority.
- iv. A drug whose labeling or promotional materials makes reference to a specific device or generic class of device ordinarily remains as a drug will be regulated by the drug authority. However, it may also be subject to the combination product regulation.