



## Drug and Medical Device Combination Product Decisions

The following types of combination products were classified by the Therapeutic Products Classification Committee in accordance with the *Policy on Drug/Medical Device Combination Products*, October 20, 1998. This list also included products which are not combination products but where the classification of either drug or device was difficult to determine.

It is the policy of the Programme that:

1. A combination product will be subject to either the *Medical Devices Regulations* or the *Food and Drug Regulations* according to the principal mechanism of action by which the claimed effect or purpose is achieved.
2. Where the principal mechanism of action by which the claimed effect or purpose is achieved by pharmacological, immunological, or metabolic means, the combination product will be subject to the *Food and Drug Regulations*, unless that action occurs *in vitro*, without reintroducing a modified cellular substance to the patient, in which case the product will be subject to the *Medical Devices Regulations*.
3. Where the principal mechanism of action by which the claimed effect or purpose is **not** achieved by pharmacological, immunological, or metabolic means, but may be assisted in that effect or purpose by pharmacological, immunological, or metabolic means, the combination product will be subject to the *Medical Devices Regulations*.

This listing is not all-encompassing, due in part to the complexity and uniqueness of combination products. It should be used only as a guide in determining the status of combination products. This listing will be updated periodically.

### A) **Combination products that have been classified as drugs:**

- prefilled syringes
- patches for transdermal drug delivery
- implants whose primary purpose is to release a drug
- wound dressings whose primary purpose is to deliver a drug
- dental products impregnated with a drug whose primary purpose is to deliver a drug
- red blood cell processing solutions
- contrast media
- peritoneal dialysis solutions
- alcohol swabs

**B) Combination products that have been classified as devices:**

- drug coated devices such as catheters, shunt sensors, or pacemaker leads
- drug impregnated devices
- wound dressings and surgical barriers containing an antimicrobial agent
- wound dressings whose primary purpose is to act as a barrier to pathogens
- blood bags containing anticoagulant or preservation solutions
- bone cement containing antibiotic
- novel bone void fillers, e.g. collagen matrix with bone morphogenic protein
- injectable collagen
- sodium hyaluronate nasal solution
- urea breath test (accessory to device)
- device for ex vivo photodynamic cell processing

**C) Combinations of drugs and devices to which this policy does not apply and which must comply with both the *Food and Drug Regulations* and the *Medical Devices Regulations***

- kits (e.g. epidural tray containing drugs and devices; first aid kit containing a drugs and devices)

**D) Products for which neither set of regulations apply**

- minimally manipulated tissue

**List Updated: July 21, 2014**