Unit of Presentation

Unit of Presentation for the NTP

The unit of presentation is one of the definitional components of an NTP, although it is not mandatory for all types of concepts (see below). It is a qualitative component of the concept that describes how the NTP is "presented" by the manufacturer, in units that can be counted into a package (although note that CCDD does not represent pack sizes for medicinal products). The unit of presentation also supports expression of strength; it provides the denominator for the strength ratio for the majority of products (the quantity of active substance per unit of presentation).

As stated in the Substance Strength Set Section, the expression of strength in the Canadian Clinical Drug Data Set (CCDD) is primarily presentation strength.

1) For the majority of products, particularly used in primary care, the unit of presentation is in effect the basic discrete solid dose form - "tablet", "suppository", and the expression of strength does not require the unit of presentation to be explicitly stated (e.g., "amoxicillin 250 mg *per capsule* oral capsule" - the "per capsule" does not need to be described in the NTP or MP formal name and French description.

2) For some products, the unit of presentation needs to be stated explicitly. These include:

- products whose dose form is powder or granules which may (or may not) be dissolved or suspended before administration and where the unit of presentation holds (or "bounds") the amount of dosage form. In this case the expression of strength requires the unit of presentation to be explicitly stated in the strength description:
    - cefotaxime sodium 2 g *per **vial*** powder for solution for injection
    - colestipol hydrochloride 5g *per **sachet*** granules for oral suspension
- products "presented" by the manufacturer with a metered dosing valve, such that the strength is the amount of active ingredient substance "per actuation", where the actuation is the unit of presentation and is stated in the strength description:
    - beclomethasone dipropionate 50 mcg per actuation pressurized inhalation
    - testosterone 12.5 mg per actuation cutaneous gel
- products that have a “continuous phase” dosage form (liquids and semi-solids) where the unit of presentation is an intimate container that holds (or "bounds") the dosage form. The presentation strength is the amount present in the unit of presentation, expressed as a ratio of quantity of active ingredient substance in the volume held in the unit of presentation, which is stated explicitly at the end of the NTP description.
        - metoclopramide hydrochloride 10 mg per 2 mL solution for injection ***ampoule***
    - where two or more products with the same presentation strength have different units of presentation (usually syringes, ampoules and vials) it is important to describe these in the formal name to allow prescribers to select the correct presentation and to allow systems to track individual products correctly. For example, the NTPs for LIDOCAINE HYDROCHLORIDE INJECTION 100 mg per 5 mL products separate (as shown below in bold):
        - lidocaine hydrochloride 100 mg per 5 mL solution for injection **ampoule**
        - lidocaine hydrochloride 100 mg per 5 mL solution for injection **syringe**
        - lidocaine hydrochloride 100 mg per 5 mL solution for injection **vial**
    - when the product strength is exceptionally expressed as concentration strength (see Substance Strength Set for exceptions), the amount held (bound) in the unit of presentation (the denominator when expressed as presentation strength) is entered at the end of the NTP description with the unit of presentation:
        - insulin glargine 100 unit per mL solution for injection **3 mL cartridge**
        - insulin glargine 100 unit per mL solution for injection **3 mL pen**
        - insulin glargine 100 unit per mL solution for injection **10 mL vial**

Some products do not have a unit of presentation; there is no intimate container or metered dosing valve. These products are supplied directly in a package (which is not described in CCDD), for example cutaneous semi-solids administered as "some" and liquids administered as "drops". Therefore, strength must be expressed as a concentration, for example:

- hydrocortisone 1% cutaneous cream
- timolol hydrochloride 0.5% ophthalmic drops