Briefing Note (BN): Patches and change to strength policy
October 2024
Informational BN for patches in medicinal products

Purpose

The purpose of this briefing note is to inform the SNOMED International Community of Practice and select Advisory Groups and Project Groups of changes addressing some identified rounding issues in medicinal products by changing the /1 hour normalization of patch products to usual manufacturer's stated strength /24 hours (or /1 hour or /16 hours or /72 hours may be appropriate) see below.

Note: An earlier meeting with the Drug Extension User Group discussed a proposed change to rounding guidance in medicinal products from rounding to 3 decimal places to rounding to 3 significant figures. Although this guidance could be limited to only those cases where SNOMED International staff performed a normalization calculation, feedback received from DEUSG group members indicated wider issues across the international edition of SNOMED, for example, the change from milligram to microgram following normalization calculations, and the effect of any change on extensions when reconstituting back to the real clinical drug from the normalized /1 strength. At this time this change will be placed on hold awaiting further expert input.

Background

The rounding issue was originally revealed during discussions by the Drug Extension User Group meeting in February 2021, as part of a list comprising the DEUSG Issues Register of user issues identified by the Community of Practice.

In certain scenarios a calculation and rounding to 3 decimal places are performed by SNOMED International terminologists for normalization purposes as required by the international drug model therefore:

- 2mg / 3 mL as a concentration strength will be 666.667 microgram/ 1 mL

A challenge is that following the Editorial Guidelines means that the concentration strength used for SNOMED CT international concepts differs from the authorized literature for the product. This also means that the implementer and/or user do not get exactly the concepts they expect, because they are unlikely to be totally familiar with the Editorial Guidelines. National extensions may find it hard to match and classify their Real Clinical Drugs with the international core model.

Issue for patches

Manufacturers produce patches with a certain total amount of drug, which is slowly released over a specified time (commonly 24 hours).

- Example 1: Glyceryl trinitrate 10 mg/24 h transdermal patch

https://www.medicines.org.uk/emc/product/9213/smpc#gref One patch contains glyceryl trinitrate 37.4 mg. The average amount of glyceryl trinitrate absorbed from each patch in 24 hours is 10 mg.

Current SNOMED CT international edition:

769527001 |Product containing precisely glyceryl trinitrate 416.667 microgram/1 hour prolonged-release transdermal patch (clinical drug) |

- Example 2: Rotigotine 4mg per 24 hour patches

https://www.medicines.org.uk/emc/product/1996/smpc current SNOMED CT:
769520004 |Product containing precisely rotigotine 166.667 microgram/1 hour prolonged-release transdermal patch (clinical drug)|

Solution

Patch strengths are to be changed to the timing as stated in the SPC. Currently patch strengths are normalized to per 1 hour. In rare cases (e.g. fentanyl) per 1 hour is the correct non-normalized strength. There is a clinical difference between a per 16-hour patch and a per 24-hour patch, which we are not capturing by having an hourly rate.

Next steps

- Review strengths of existing patches and change to /24 hours (or /16h, /72 hours or per 1/h) including undertaking research (SPC and other authorized sources).
- Update Editorial Guidelines.

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