

Here are my concerns across the 3 areas identified in your email:

1. *Number of concepts that would be affected by these proposed changes is minimal.*

Yes, with respect to the amount of content in the hierarchy, the number of concepts to which these attributes can be added seems trivial. Therefore, I don't think this will offer much assistance in a hierarchy clean-up. In the meantime, the risk is that it creates a false sense for users that these attributes will support analytics or querying for "this kind of thing" in SNOMED. In my opinion, attributes of this type (very low use and difficult to apply) basically can't be relied on for anything.

2. *Amount of effort required to determine where these new attributes would be applied*

This is also a significant issue. The set of concepts that might be containers that could be used for a sample/specimen is very ill-defined and will make it difficult to apply these attributes consistently. Additionally, I find guidance on use of these attributes confusing. However, the greatest hurdle is that devices in SNOMED are generic representations of proprietary devices and finding consistent/reliable information about these containers/collection devices is very challenging.

I had some involvement in the Medical Device Project which involved the incorporation of a significant part of the GMDN database (over 10,000 new concepts, 20,000 new descriptions, and 20,000 new relationships) into SNOMED International in a tight timeframe in 2014-2015. For the January 2015 Release, I participated in a limited clean-up effort related to the added GMDN content. My recollection is that, based only on the device names, there were significant challenges in determining exactly what a device does, is, contains, etc.

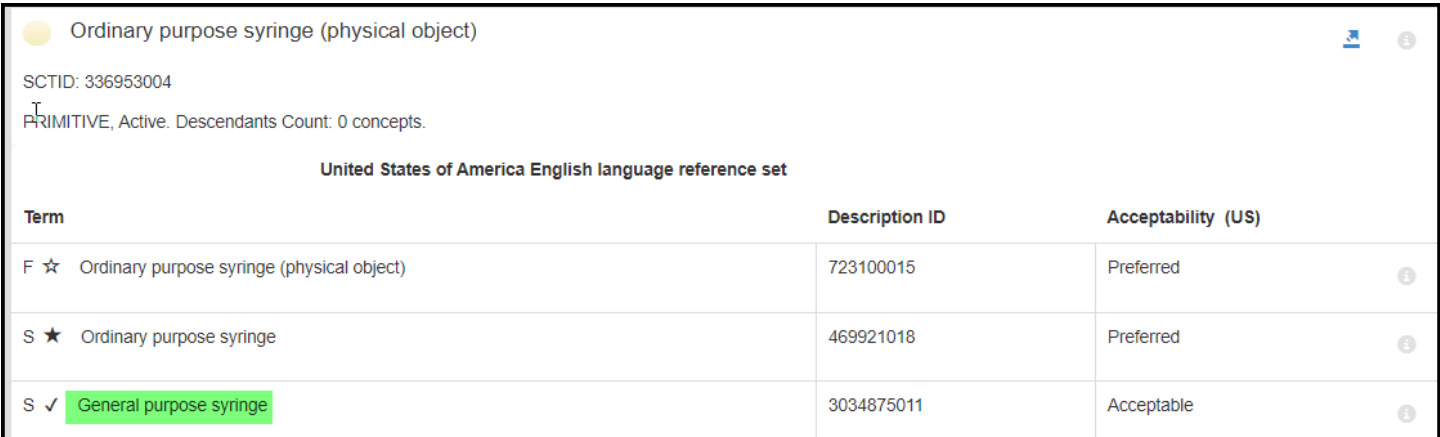
Also, there were significant challenges related to merging "duplicates". Some SNOMED Fully Specified Names "corresponded" to GMDN Preferred Terms but did not fully capture the GMDN definitions for those GMDN Preferred Terms (which often exceed 255 characters). Additionally, the degree of research to get information about these devices and what they definitely or possibly may contain will be extensive and definitive resources may be difficult to identify. For these reasons, I think it is safer to assert less and allow some ambiguity around these concepts than to make potentially incorrect assertions.

Below is an example of the challenge of these devices in SNOMED that was revealed by the GMDN incorporation:

EXAMPLE: 336953004 | Ordinary purpose syringe (physical object) |

SNOMED had 336953004 | Ordinary purpose syringe (physical object) | since 2002.

In 2015-01-31, the new description "General purpose syringe" was added as the result of trying to merge existing SNOMED content with the new GMDN content (which contained GMDN code 47017 General purpose syringe):




The screenshot shows a SNOMED concept page for 'Ordinary purpose syringe (physical object)'. It includes the SCTID: 336953004 and a table of descriptions. The table has three columns: Term, Description ID, and Acceptability (US). The 'General purpose syringe' row is highlighted in green.

Term	Description ID	Acceptability (US)
F ☆ Ordinary purpose syringe (physical object)	723100015	Preferred
S ★ Ordinary purpose syringe	469921018	Preferred
S ✓ General purpose syringe	3034875011	Acceptable

The [WHO document](#) below provides the GMDN definition for “47017 General-purpose syringe”. Per GMDN, this device is typically made of silicone and may have plunger anti-sticking properties (internal coating).

13	4	GMDN name	General-purpose syringe
14	5	GMDN code	47017
15	6	GMDN category	10 single-use devices
16	7	UMDNS name	Syringes
17	8	UMDNS code	13929
18	9	UNSPS code (optional)	41105104
19	10	Alternative name/s (optional)	Injection syringes, single-use Sterile injection syringe, general use Syringe, piston Sharp injury protection(SIP)
20	11	Alternative code/s (optional)	S 36278, 04 19 09; S 34578, 100206021; MS 32171, FMF
21	12	Keywords (optional)	Injection Devices, Infection Control, Drug Administration
22	13	GMDN/UMDNS definition (optional)	A sterile device that consists of a calibrated hollow barrel (cylinder) and a moveable plunger intended to be used to inject fluids (e.g. medication) into, and/or withdraw fluids/gas from, the body or a medical device for various medical applications. At the distal end of the barrel is a male connector (typically a Luer lock type) for the attachment of the female connector (hub) of a hypodermic needle or an administration set. It is typically made of plastic and silicone materials and may have plunger anti-sticking properties (internally precoated with compatible substances) allowing smooth plunger movement, either manually or by a syringe pump. This is a single-use device.

All kinds of devices get “mapped” to these codes. For example [197128 Disposable Medical Supplies Pty Ltd - Syringe, general-purpose](#) is mapped to “47017 General-purpose syringe”.



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 197128 Disposable Medical Supplies Pty Ltd - Syringe, general-purpose

ARTG entry for Medical Device Included Class Is

Sponsor Disposable Medical Supplies Pty Ltd

Postal Address PO Box 8617, PERTH BC, WA, 6849
Australia

ARTG Start Date 3/05/2012

Product Category Medical Device Class Is

Status Active

Approval Area Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
 - Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Shanghai Channelmed Import & Export Co Ltd Channelmed Group	Room 1402 No 707 Zhangyang Road Shanghai, , 200120 China

Products


1 . Syringe, general-purpose

Product Type	Effective Date
Single Device Product	3/05/2012

GMDN 47017 Syringe, general-purpose

Intended Purpose For general medical purposes used to inject fluids (e.g., medication) into, or withdraw fluids/gas from, the body, or a medical device.

Below is another [syringe](#) that is assigned GMDN code “47017: General purpose syringes”. This product definitely has a lubricant (anti-sticking material) whereas the GMDN code 47017 (linked to 336953004 | Ordinary purpose syringe (physical object)) may have an anti-sticking material. Without proprietary product names for our devices, I am not sure how we will know for certain what an item contains or is made of. The only certainty will be the few FSNs that have this information. The vast majority of the time, this information (coating, intent, container substance, container separator, etc) will not be included in an FSN.

TECHNICAL DATA SHEET
BD Discardit™ II Syringe without needle Sterile, Single use, Latex Free
1. General Information
<i>1.1 General</i>
The BD Discardit™ II syringe is a medical single use product for injection and/or aspiration of medical fluids, including both, corporal fluids (blood, etc) and drugs. The lubricant included in the barrel material allows for a smooth advancement of the plunger without the need of a rubber ring.


- The effort will be undertaken outside of the internal content team, so the folks that are interested in any potential benefits would be the ones doing the work.*

Allowing an external content team to undertake a task that is challenging for experienced internal content modelers may decrease the likelihood of achieving the intended outcome.