

Briefing Note: Substance and Medicinal Product role groupers

November 2023

Consultation on inactivation of role groupers in Substance and Medicinal Product hierarchies

Purpose

The purpose of this note is to solicit feedback on the proposal to inactivate role groupers in the Substance hierarchy and the Medicinal Product hierarchy.

Feedback is sought from the Editorial Advisory group (EAG), Member Forum (MF), Content Managers Advisory Group (CMAG), Drug Extension User Group (DEUSG) and the Clinical Leads Group as to where these role groupers are currently in use.

Background

High-level role groupers in the Substance hierarchy have been intended to support the organization of the hierarchy based on roles. An example of such a role grouper is 373265006 |Analgesic (substance)|.

Substance role groupers have been an issue in SNOMED CT for many years. Role based groupers are associated with a particular purpose or outcome. A role does not belong to a substance *per se* but instead is associated with a manufactured product and its usage. Roles are a function of the way a product is formulated or presented.

In 2018 a solution was proposed to move the role groupers from the Substances hierarchy to the Products hierarchy--and specifically the “therapeutic roles” to the Medicinal Product hierarchy. While a small percentage (20%) of the role groupers have been created in the Medicinal product hierarchy, e.g. 53009005 |Medicinal product acting as analgesic agent (product)|, the majority of the role groupers remain in the Substances hierarchy at this time.

Issues

The following issues apply to role groupers in the Substance hierarchy and the Medicinal Product hierarchy and for which we invite feedback:

- Roles are not “always and necessarily true” for a given substance or product, and are subject to change.
- The therapeutic role groupers that have been created in the Medicinal Products hierarchy as the result of proposed resolution in 2018:
 - are incomplete, and were never intended to group the whole Medicinal Products hierarchy by ‘role’ but were created only to replace those Substance hierarchy roles used in SNOMED CT disorders/procedures. Many have no (or few) subtypes assigned at present.
 - use an additional axiom methodology that is not part of the drug concept model (non-defining) to group different levels of the Medicinal Product hierarchy.
- Roles must be assigned at varying levels in the Medicinal Product hierarchy, with each concept needing to be addressed individually and manually (e.g. based on dosage, strength and method of administration etc.).
- Deciding *which* medicinal product roles to create is subjective (*not conformant with being Understandable, Reproducible and Useful*) and idiosyncratic based on the particular formulation of a medicinal product within a jurisdiction.
- New and different roles can be given to existing clinical drugs as research is published based on clinical trials and adopted by authoritative bodies in a specific country as roles can vary by jurisdiction.
- Off-label use cannot be comprehensively addressed.
- Other licensed proprietary therapeutic role classification systems exist that may be more comprehensive, internationally applicable, up-to-date and accessible.
- Multiple roles may be unaccounted for (e.g. a single substance or product with local and systemic applications and different formulations, including multiple ingredient products, may have many and varied roles).
- Incorrect roles or misinterpreted clinical roles may lead to patient harm.

The Proposal

Based on these observations/issues, the following proposal has been developed by an internal working group for consultation and feedback by members, stakeholders, and terminology experts:

1. Inactivate role groupers in the Substance hierarchy and inactivate therapeutic role groupers created to date in the Medicinal Product hierarchy.
2. Concepts in hierarchies such as clinical findings and procedures that use Substance role groupers in their definition are proposed to be retained as primitive. The attribute value pairs for these types of concepts will be removed; therefore, there is no expectation that they will subsume any subtype concepts in the international release. If any National

Extension wishes to retain these groupers, they can choose to use these groupers as intermediate primitive groupers and assign appropriate subtypes at their own discretion.

3. Following the removal of role groupers from the Substance hierarchy in the International Edition, member countries can, if required, reactivate groupers in National Extensions.

Here is a summary of the proposed content changes:

- 270 Substance role groupers to be inactivated.
- ~ 3000 concepts are defined by these substance role groupers as attribute values. The attribute value pairs pointing to these Substance role groupers will be removed from the definition of these concepts. As a result the definition status for these concepts may change from fully defined to primitive.
 - For example, 399097000 |Administration of anesthesia (procedure)| is a member of SNOMED CT to MedDRA simple map and Global Patient Set. It is also used to define 21 concepts in the disorder hierarchy. This concept will continue to remain in the SNOMED International release. However its status will change to primitive as a result of inactivation of substance role grouper 373266007 |Anesthetic (substance)| and removal of “Direct substance” attribute value.
 - While the number of the concepts that are defined by substance role groupers seems high, an internal analysis shows that only slightly over 200 of these concepts are in active use (e.g. Refset).
- 178 Medicinal Product role groupers to be inactivated. None of these concepts are used to define additional concepts in SNOMED International edition

A list of affected Substance role groupers to be inactivated (as well as the concepts defined by them) can be provided upon request.

Member/user requirements

Because of the issues identified above and in order to have a clear path forward, Members, vendors, and other stakeholder groups are asked to provide focused feedback as follows regarding the role groupers:

1. Who is using the SNOMED CT Substance role groupers?
2. Is anyone using existing Medicinal Product therapeutic role groupers?
3. How do Members and others users currently use the SNOMED CT Substance role groupers?
4. If you do not use SNOMED CT Substance role groupers what solution do you use for grouping the roles? i.e. are any existing classifications for medicinal product therapeutic role groupers already in use in your country?
5. If the changes in the proposed solution are implemented how will this impact your current or planned use of SNOMED CT?

Where use cases exist, please provide examples. If another mechanism or classification is employed to determine roles for products or substances, please provide that information.

Next Steps

Please provide feedback on the points above. **Send comments to (info@snomed.org) by December 15th, 2023 with the heading attention of Nicki Ingram and Farzaneh Ashrafi.**

Based on member and stakeholder feedback a further briefing note will be issued outlining the way forward.

Approvals	Date	Name
Chief Terminologist	October 31st, 2023	James T. Case
Director of Content and Mapping	October 31st, 2023	Monica Harry
CSRM	November 2nd, 2023	Jane Millar

Nicki Ingram and Farzaneh Ashrafi, November 2023