**Issue Number: 014**

Supporting Identification of Controlled Substances in the Canadian Clinical Drug Data Set

### The Issue

There is a new emerging requirement in Canada for a nationally consistent way to identify opioid products to enable digital health solutions and medication processes in the implementation of appropriate (additional) actions in the medication process to assist in the opioid crisis.  
This paper will discuss a proposed change to the Canadian Clinical Drug Data Set (CCDD) to identify opioid products. The solution adopted should, if at all possible, be extensible to support identification and management of products containing any controlled substances, as future requirements may need.

1. Background Information

Canada faces a serious and growing opioid crisis. This is a complex health and social issue with devastating consequences for individuals, families, and communities. Many agencies, including Canada Health Infoway and Health Canada have committed to supporting an opioid management initiative in Canadian healthcare to improve prevention, treatment and harm reduction associated with problematic opioid use through timely, concrete actions that deliver clear results and we commit to reporting on our progress in delivering those results. The CCDD, as a national medicinal product terminology, can play a supporting role in this by providing a data structure and data to implement federal, provincial and territorial opioid management initiatives.

The requirement to provide additional supporting information is well known in medicinal product terminology. As well as providing unique and unambiguous machine readable codes and human readable descriptions for medicinal products to be used in the medication process (e-prescribing, dispensing etc.) and EHRs (including the Medication Profile) and supporting processes such as medication reconciliation, a medicinal product terminology can provide additional reference information that accompanies these product representations to support specific use cases of importance to that jurisdiction. For example, in many countries with a national health system, the national medicinal product terminology can additionally provide official reimbursement information) including (as attributes) the official reimbursement codes (e.g. UK, Australia and Ireland).

The current requirement in Canada is to provide information to identify opioid products and their regulations, so that any medication process can then implement appropriate (additional) actions in the medication process. For example, a prescriber selecting an opioid product for a patient who has not previously had an opioid prescription might be alerted and offered other non-opioid alternatives to prescribe.

In the future, information for products containing other controlled substances may be added, based on need.

Currently, the scope of this information is constrained to the scope of the CCDD, which is medicinal products authorized for supply in Canada. As such, any information about unlicensed substances and the recording of any substance used “recreationally” is out of scope. Compounded products containing an opioid active ingredient substance are also currently out of scope.

### *Proposed actions and Options for resolution*

#### Identification of opioid products

Health Canada is working to produce a list of therapeutic moieties (both singly and in multi-ingredient products) that will be identified in this way based on the recent regulations posted here - <http://www.gazette.gc.ca/rp-pr/p1/2017/2017-06-17/html/reg8-eng.php>.

#### Considerations for the CCDD Model

### *Possible implementation pattern 1: Using the TM class and an attribute*

1. Will all NTPs and TMs associated with a TM be implicated?
   1. Would products with a very low strength (e.g. OTC codeine) be exempt?

**Possibly/probably**

* 1. Would products with a particular dose form be exempt or more closely monitored (e.g. injectable fentanyl products)

**Possibly/probably**

1. Combination products do not have a TM; if any combination products have an opioid component, these will not be identifiable if the information is held at TM level and propagated



The opioid indicator information would “propagate down” to all NTPs and MPs related to that TM. If an attribute is used, there should be some sort of “null” value offered (although currently that is not provided for the NTP type attribute; this should be considered in the future).

Possible implementation pattern 1 is not recommended, as it does not give enough flexibility to deal with the requirement to identify different types of opioids at different levels, nor is it easily extensible to support identification of groupings of products containing other substances requiring additional monitoring and/or control.

### *Possible implementation pattern 2: Could a separate class hold the information and be associated to the affected concepts?*

This alternative pattern holds the opioid management information in a separate class and uses a relationship table to associate it to any/all appropriate concepts in the CCDD. In the drawing below, a relationship is shown to each class; it could be that only the NTP relationship is used, or the TM and the NTP or all three relationships are used.



This approach has the advantage of being very flexible, allowing each concept, of whatever class within the CCDD, to be associated to its correct information directly; there is no absolute requirement to propagate information through the CCDD class relationships. Also, this is an “extension” to the existing model, thereby keeping the core CCDD model intact. It has the (possible) disadvantage of being quite “conceptual”; it is likely that within an actual implementation, database designers would denormalize this information to each coded concept (as indeed they would if the information was held as an attribute at TM and required propagation).

### *Describing the Controlled Substance Management information*

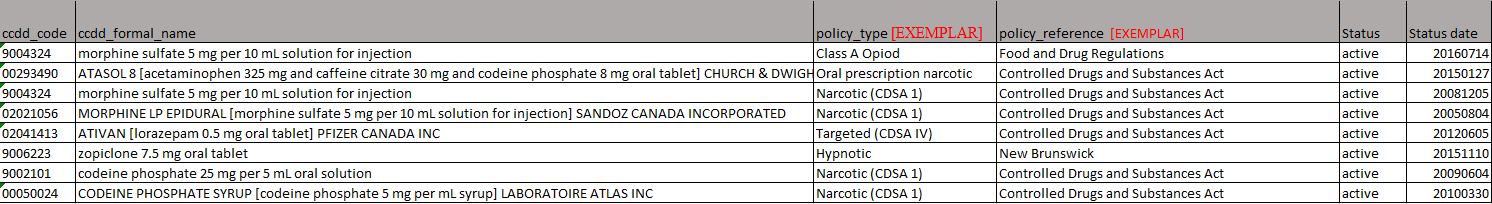
The controlled substance management information is described using two attributes to specify firstly the policy type and secondly a reference to the policy itself (which may be a url).



The status of the association of between the product and the information is also provided, and means that historic association information can be maintained.

The delivery of the controlled substance management information is provided in a separate table, as shown below. The first two columns provide the relevant CCDD concept, the second two columns provides the policy information, which may be national or provincial, and the final two columns provide the status and date of the association between the product and the policy.

The deliverable would therefore be a dataset of information in the following format:



A sample file has been provided here <https://infocentral.infoway-inforoute.ca/en/resources/docs/med-mgmt/canadian-clinical-drug-data-set/ccdd-discussion-papers/2172-issue-14-sample-file-ccdd-controlled-substances-final>

### *Recommendation*

Recommend Pattern 2 as above.

### *Discussion and Comments*

Suggestions received to include all controlled substances to support drug monitoring programs as opposed to only opioids.

* Based on this suggestion, we have broadened the scope to include all controlled substances that require monitoring or control. The initial focus will be on opioids.

There was also a request to include substances not licensed for human use such as carfentanil which has played a significant role in the current opioid crisis.

* At this time, unlicensed substances are not in scope. However, the format for the file will be such that this content can be considered in the future.

### *Decision*

To use pattern 2 and the format as described above.

### *Document History*

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| --- | --- | --- |
|  | Date | Comments |
| Issue raised | 10 April 2017 |  |
| Issue documented | 7 June 2017 |  |
| Issue document posted/circulated | June 13th |  |
| Issue discussed | June 20th and 4 July 2017 |  |
| Issue resolved | 4 July 2017 |  |