**Issue Number: 012**

DIN Granularity in the Canadian Clinical Drug Data Set

### The Issue

Some authorizations granted by Health Canada and assigned a DIN cover what should be, according to the Canadian Clinical Drug Data Set (CCDD) Editorial Guidelines, more than one Manufactured Product (MP) and associated Non-proprietary Therapeutic Product (NTP). The CCDD granularity reflects how the products are usually described in formularies and in the product files of the knowledgebase vendors, and therefore is needed to facilitate accurate mapping of the Canadian Clinical Drug Data Set to these.

The products involved are those that primarily differentiated by using presentation strength (as a proxy for unit of presentation) whereas the authorization is made at “concentration strength”.

1. Background Information

The activities in the medication process (particularly prescribing and dispensing) need to identify which presentation is appropriate (for example so that the patient can use “the contents of one UDV” without having to do any math and measurement to get their correct dose quantity). The CCDD therefore needs to create representations for each of these presentations at the MP level, which in turn will create NTP representations as appropriate.

For example:

The authorized DIN [02097176] for RATIO-IPRATROPIUM UDV manufactured by TEVA CANADA LIMITED covers two presentations of “ipratropium bromide 125 mcg per mL inhalation solution”[[1]](#footnote-1):

* 125 mcg per 1 mL UDV
* 250 mcg per 2 mL UDV

Each of these should be represented as separate MPs:

* RATIO-IPRATROPIUM UDV (ipratropium bromide 125 mcg per 1 mL) TEVA CANADA LIMITED
* RATIO-IPRATROPIUM UDV (ipratropium bromide 250 mcg per 2 mL) TEVA CANADA LIMITED

and their associated NTPs:

* ipratropium bromide 125 mcg per 1 mL
* ipratropium bromide 250 mcg per 2 mL

There are other similar products described in the Health Canada Drug Product Database (DPD) that look as if they are affected by the same issue, but do have separate DINs for the different presentations. It can be difficult to work out which DIN relates to which presentation when looking at the DPD browser. When using the DPD Extract database, it is possible to query from the DIN into other parts of the database and to confirm the presentation size (in the Packaging table) for each of these DINs.

For example:

PMS-IPRATROPIUM from PHARMASCIENCE INC has DINs:

* 02231136 which is the 250 mcg per 1 mL 20 mL bottle
* 02231244 which is the 250 mcg per 1 mL UDV
* 02231245 which is the 500 mcg per 2 mL UDV

In this case, there is no requirement to create new DINs, just to be sure which is which and describe the product (and particularly its strength) appropriately.

The current understanding is that the data in the Packaging table in the DPD Extract database is not consistently maintained and that some of the data in that table is in text strings rather than in machine processable structures (for example, for clindamycin injection the Packaging table has one entry of “2/6/60ML”). However, to support the creation of the correct concepts in the CCDD, this unit of presentation information will be verified through appropriate sources.

### *Proposed actions and Options for resolution*

#### Process

The diagram below provides an overview of the proposed steps to resolve the issue.



The proposed detailed action includes:

1. Identify the products in the Drug Product Database (DPD) that require intervention; these are likely to be products with dose forms of nebuliser solution, solution/suspension/emulsion for injection and possibly some semi-solid preparations (e.g. the testosterone gel product)
2. Author the granular MP concepts that with the correct description (according to the Editorial Guidelines), particularly with the correct presentation strength
3. Assign new MP codes to the new MP concepts. The new codes would not be available from the DPD extract but only in the CCDD. The two possible options:
   1. Option 1: Append a suffix to the existing DIN e.g.
      1. 0209717601 for RATIO-IPRATROPIUM UDV 250 mcg per 1 mL
      2. 0209717602 for RATIO-IPRATROPIUM UDV 500 mcg per 2 mL

The concerns with the above approach are as follows:

In principle: the use of identifiers with meaning is not advised in good terminology practice (ref: the Cimino desiderata). In practice: the possibility of making mistakes in generation of meaningful identifiers, such that errors occur in parsing them, is such that it is likely that provision of a relationship table (such as described below) would be necessary. Secondly, it will mean that MP identifiers will have variable length(s) and implementers may ascribe meaning to the length (which would be unwise)

* 1. Option 2: Create completely “new” MPs for the products and provide an additional mapping table as part of the CCDD deliverable as in the drawing below:



The mapping file would have content such as this:

|  |  |  |  |
| --- | --- | --- | --- |
| **DPD DIN** | **DPD Product Description** | **CCDD MP** | **CCDD MP Formal Name** |
| 02097176 | RATIO-IPRATROPIUM 125 mcg per mL UDV | 87453721 | RATIO-IPRATROPIUM 125 mcg UDV (ipratropium bromide 125 mcg per 1 mL nebuliser solution) RATIO PHARMACEUTICALS |
| 02097176 | RATIO-IPRATROPIUM 125 mcg per mL UDV | 87453844 | RATIO-IPRATROPIUM 250 mcg UDV (ipratropium bromide 250 mcg per 2 mL nebuliser solution) RATIO PHARMACEUTICALS |

*Note: in neither of the two options above would the existing DIN (in this example 02097176) with its product name of “RATIO-IPRATROPIUM 125 mcg per mL UDV” be present in the MP file within the CCDD.*

1. Having created the new MP concepts, new NTP concepts and relationships will be generated.

#### Current and future policy

Health Canada policy for some products affected by this unit of presentation issue, notably the unit dose pre-filled syringes, has changed and is now to issue separate DINs for the different presentations, even though they have the same concentration strength (see 10-112936-541, 10 June 2010). This notification states that the scope of this policy change may be extended for all unit dose injectables (and possibly other products) in the future.

#### 2.3 ISO Identification of Medicinal Products (IDMP)

IDMP holds both concentration strength, presentation strength, unit of presentation and unit of presentation size for an IDMP MPID (medicinal product ID) and then the number of those items present in the package for the PCID (packaged product ID). The “definitional attributes” for IDMP MPID include unit of presentation, and where appropriate, its size (e.g. 2 mL unit dose vial). The CCDD MP at the level of granularity proposed corresponds closely to the IDMP MPID and the creation of the concepts to achieve this therefore brings the granularity of information close to the IDMP structure.

### *Recommendation*

That the above process be adopted, using Option 2.

The format for the file be used as found here - <https://infocentral.infoway-inforoute.ca/en/resources/docs/med-mgmt/canadian-clinical-drug-data-set/ccdd-discussion-papers/2170-issue-12-sample-file-format-mp-to-din-mapping>

### *Discussion and Comments*

Selecting Option 2 above should also support resolution of a known DIN issue, that of the existing Health Canada policy allowing a DIN to change when product company name changes. The DPD could continue its practice (for the interim, since there is policy change anticipated in the near future) to allow the DIN for the product to be retained and transferred when the company name changes, but in the CCDD the product will have a new MP assigned. The new MP code would then be associated back to the original DIN through the mapping table.

### *Decision*

There was agreement to proceed with the recommendation as described above and with the sample file format provided.

### *Document History*

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|  | Date | Comments |
| Issue raised | 10 April 2017 |  |
| Issue documented | 31 May 2017 |  |
| Issue document posted/circulated | June 13th |  |
| Issue discussed | June 20th and July 4 |  |
| Issue resolved | July 4th |  |

1. Note that there is also DIN [02097168] for a 250 mcg per mL inhalation solution of RATIO-IPRATROPIUM which is a 20 mL bulk bottle [↑](#footnote-ref-1)