MP Formal Name Pattern

Manufactured Product (MP)

This section describes the rules that govern the description of a unique Manufactured Product and the naming pattern used for Manufactured Products.

Describing MPs

A CCDD Manufactured Product concept is a brand specific medicinal product that is, or within the lifetime of the CCDD has been, available for prescribing and dispensing in Canada. Most have been or are currently licensed for use in Canada. Some authorizations granted by Health Canada and assigned a DIN cover what should be, according to the Canadian Clinical Drug Data Set (CCDD) Model and Editorial Guidelines, more than one Manufactured Product (MP) and associated Non-proprietary Therapeutic Product (NTP). The products involved are those that are primarily differentiated by using presentation strength (and/or proxy for unit of presentation) whereas the authorization is made at “concentration strength”.

For example:

The authorized DIN ((Drug Identification Number) [02300435] for MYLAN-IPRATROPIUM SOLUTION manufactured by MYLAN PHARMACEUTICALS ULC covers three presentations of “ipratropium bromide 250 mcg per mL inhalation solution:

- 250 mcg per 1 mL unit dose vial
- 500 mcg per 2 mL unit dose vial
- 250 mcg per mL bulk bottle

The CCDD creates three separate MPs:

MP Code	MP Formal Name	MP French Description
77700360	MYLAN-IPRATROPIUM SOLUTION (ipratropium bromide 250 mcg per 1 mL nebulizer solution unit dose vial) MYLAN PHARMACEUTICALS ULC	MYLAN-IPRATROPIUM SOLUTION (bromure d’ipratropium 250 mcg par 1 mL solution pour inhalation par nébuliseur fiole unidose) MYLAN PHARMACEUTICALS ULC
77700362	MYLAN-IPRATROPIUM SOLUTION (ipratropium bromide 500 mcg per 2 mL nebulizer solution unit dose vial) MYLAN PHARMACEUTICALS ULC	MYLAN-IPRATROPIUM SOLUTION (bromure d’ipratropium 500 mcg par 2 mL solution pour inhalation par nébuliseur fiole unidose) MYLAN PHARMACEUTICALS ULC
77700361	MYLAN-IPRATROPIUM SOLUTION (ipratropium bromide 250 mcg per mL nebulizer solution 20 mL bottle) MYLAN PHARMACEUTICALS ULC	MYLAN-IPRATROPIUM SOLUTION (bromure d’ipratropium 250 mcg par mL solution pour inhalation par nébuliseur 20 mL bouteille) MYLAN PHARMACEUTICALS ULC

and their associated NTPs:

- ipratropium bromide 250 mcg per 1 mL nebulizer solution unit dose vial
- ipratropium bromide 500 mcg per 2 mL nebulizer solution unit dose vial
- ipratropium bromide 250 mcg per mL nebulizer inhalation solution 20 mL bottle

In the MP_file, the single Health Canada DIN for the more granular MPs is also provided; please refer to the Technical Specification for more information.

Waters of Hydration

See also Appendix C, Hydration and Solvation

Water of hydration information is present for the precise ingredient substance in a small number of Manufactured Products. The Canadian Clinical Drug Data Set describes the rules for how waters of hydration will be represented (see Appendix C). In MP concepts, in order to correctly identify (for mapping purposes) those Manufactured Products where waters of hydration are included in the precise active ingredient substance, this information will be included in the MP formal name pattern.

The following table provides examples of how waters of hydration will be applied to the MP:

NTP_code	NTP formal name	MP_code	MP formal name	DPD precise active ingredient
9002921	esomeprazole (esomeprazole magnesium) 20 mg gastro-resistant tablet	02339099	APO-ESOMEPRAZOLE (esomeprazole (esomeprazole magnesium) 20 mg gastro-resistant tablet) APOTEX INC	esomeprazole magnesium
		02423855	ACT ESOMEPRAZOLE (esomeprazole (esomeprazole magnesium **dihydrate**) 20 mg gastro-resistant tablet) ACTAVIS PHARMA COMPANY	esomeprazole magnesium **dihydrate**

MP Naming Pattern

A correct and unambiguous formal name for the MP will enable vendor mapping to their local content.

MP names use the DPD Product Name and the DPD Company Name, with the associated NTP name placed in brackets between these two, with the addition of any solvate/hydrate description included for the substance(s) in the NTP part of the name. In the small number of cases where this produces duplicate MP names, the DPD Descriptor (if one exists) is added after the DPD Product Name.

The DPD Company name, as used in the Health Canada DPD, indicates the organization (company) that holds the authorization to place the product on the market in Canada, i.e., the market authorization holder. This may not be the company that has manufactured the product, but it is the company that holds the legal responsibility for the use of the product in Canada and should be the same as the company named on the product label/packaging.

The DPD Product Name, DPD Descriptor and DPD Company Name will use the letter case as it is in the DPD, which is usually upper case, whereas the NTP name in brackets will be all lower case.

This can be summarized as:

> <<DPD PRODUCT NAME>> <<(ntp name)>> <<DPD COMPANY NAME>>

when de-duplicating MPs names, this pattern will be:

> <<DPD PRODUCT NAME>> <<DPD DESCRIPTOR>> <<(ntp name)>> << COMPANY NAME>>

and occasionally, when solvation is present in a precise ingredient substance:

> <<DPD PRODUCT NAME>> <<(ntp name including waters of hydration)>> << COMPANY NAME>>

The next sections describe how the components will be used in the MP pattern.

MP Formal Name and French Description for Single Ingredient

For single ingredient products, the pattern will be as follows:

<<Product name>> <<(ntp name)>> << Company Name>>

Examples:

MP Code	MP Formal Name	MP French Description
00878928	NORVASC (amlodipine (amlodipine besylate) 5 mg oral tablet) PFIZER CANADA INC	NORVASC (amlodipine (bésylate d'amlodipine) 5 mg comprimé oral) PFIZER CANADA INC
02297485	ACT AMLODIPINE (amlodipine (amlodipine besylate) 5 mg oral tablet) ACTAVIS PHARMA COMPANY	ACT AMLODIPINE (amlodipine (bésylate d'amlodipine) 5 mg comprimé oral) ACTAVIS PHARMA COMPANY

MP Formal Name and French Description for Multiple Ingredient

For multiple ingredient products, the pattern will be as follows:

<<Product name>> << (ntp name)>> << Company Name>>

Examples:

MP Code	MP Formal Name	MP French Description
02382822	CLINDOXYL ADV GEL (benzoyl peroxide 3 % and clindamycin (clindamycin phosphate) 1 % cutaneous gel) GLAXOSMITHKLINE INC.	CLINDOXYL ADV GEL (peroxyde de benzoyle 3 % et clindamycine (phosphate de clindamycine) 1 % gel cutané) GLAXOSMITHKLINE INC
02411318	APO-AMLODIPINE-ATORVASTATIN (amlodipine (amlodipine besylate) 10 mg and atorvastatin (atorvastatin calcium propylene glycol solvate) 10 mg oral tablet) APOTEX INC	APO-AMLODIPINE-ATORVASTATIN (amlodipine (bésylate d'amlodipine) 10 mg et atorvastatine (solvate de propylène glycol d'atorvastatine calcique) 10 mg comprimé oral) APOTEX INC

MP Considerations and Exceptions

Duplicate information in MP formal name and French description pattern

When a DPD Product Name includes information that is also part of the naming pattern there will be duplicate information in the MP formal name. The current Health Canada practice with confirming product names is to exclude this information but it is present in the older products, although when these go through their periodic review, it is usually being removed. The following are examples of Product Names that include strength, dose form and/or other information.

MP Examples that include duplicate information:

MP Code	Existing DPD Product Name	Example MP Formal Name	Example MP French Description
02243826	PRAVASTATIN-40	PRAVASTATIN-40 (pravastatin sodium 40 mg oral tablet) PRO DOC LIMITEE	PRAVASTATIN-40 (pravastatine sodique 40 mg comprimé oral) PRO DOC LIMITEE
02167786	APO-METFORMIN - TAB 500MG	APO-METFORMIN - TAB 500MG (metformin hydrochloride 500 mg oral tablet) APOTEX INC	APO-METFORMIN - TAB 500MG (chlorhydrate de metformine 500 mg comprimé oral) APOTEX INC

Where multiple MPs have different MP codes (and different DINs) but a non-unique MP Formal Name:

For MP concepts where the basic naming pattern (<<DPD PRODUCT NAME>> <<(ntp name)>> <<DPD COMPANY NAME>>) produces a formal name description that is **not unique**, the DPD descriptor (or a portion thereof) is added to the MP pattern following the DPD Product Name, giving the pattern <<DPD PRODUCT NAME>> <<DPD DESCRIPTOR>> <<(ntp name)>> << COMPANY NAME>>.

Table of Examples of MP concepts with a modified MP formal name pattern where the DPD descriptor is added:

DIN	DPD Product name	DPD Descriptor	Modified MP Formal Name	Modified MP French Description
01934163	NOVAMOXIN	SUGAR REDUCED	NOVAMOXIN SUGAR REDUCED (amoxicillin (amoxicillin trihydrate) 250 mg per 5 mL oral suspension) TEVA CANADA LIMITED	NOVAMOXIN SUGAR REDUCED (amoxicilline (trihydrate d'amoxicilline) 250 mg par 5 mL suspension orale) TEVA CANADA LIMITED
00452130	NOVAMOXIN		NOVAMOXIN (amoxicillin (amoxicillin trihydrate) 250 mg per 5 mL oral suspension) TEVA CANADA LIMITED	NOVAMOXIN (amoxicilline (trihydrate d'amoxicilline) 250 mg par 5 mL suspension orale) TEVA CANADA LIMITED
02352761	AMOXICILLIN	SUGAR-REDUCED	AMOXICILLIN SUGAR-REDUCED (amoxicillin (amoxicillin trihydrate) 125 mg per 5 mL oral suspension) SANIS HEALTH INC	AMOXICILLIN SUGAR-REDUCED (amoxicilline (trihydrate d'amoxicilline) 125 mg par 5 mL suspension orale) SANIS HEALTH INC
02352745	AMOXICILLIN		AMOXICILLIN (amoxicillin (amoxicillin trihydrate) 125 mg per 5 mL oral suspension) SANIS HEALTH INC	AMOXICILLIN (amoxicilline (trihydrate d'amoxicilline) 125 mg par 5 mL suspension orale) SANIS HEALTH INC
02243861	FUCITHALMIC	WITHOUT PRESERVATIVE	FUCITHALMIC WITHOUT PRESERVATIVE (fusidic acid 1 % ophthalmic drops) AMDIPHARM LIMITED	FUCITHALMIC WITHOUT PRESERVATIVE (acide fusidique 1 % gouttes ophtalmiques) AMDIPHARM LIMITED
02243862	FUCITHALMIC	WITH PRESERVATIVE	FUCITHALMIC WITH PRESERVATIVE (fusidic acid 1 % ophthalmic drops) AMDIPHARM LIMITED	FUCITHALMIC WITH PRESERVATIVE (acide fusidique 1 % gouttes ophtalmiques) AMDIPHARM LIMITED

In rare cases, the DPD descriptor will be too long or not suitable for use as a modifier of the DPD Product Name. In such cases, only a portion of the DPD descriptor will be used. In the ADYNOVATE example below, the reconstituted strength, as seen in the DPD descriptor, is excluded from the modified MP formal name to reduce the risk that it be confused with the product strength.

Table of Examples of MP concepts with a modified MP formal name pattern where only a portion of the DPD descriptor is added:

DIN	DPD Product name	DPD Descriptor	Modified MP Formal Name	Modified MP French Description

02498588	ADYNOVATE	**500 UNITS/ML** (2 ML DILUENT) - SINGLE USE VIAL	ADYNOVATE (2 ML DILUENT) - SINGLE USE VIAL (rurioctocog alfa pegol **1000 unit per vial** powder for solution for injection with diluent solution) TAKEDA CANADA INC	ADYNOVATE (2 ML DILUENT) - SINGLE USE VIAL (rurioctocog alfa pégol **1000 unité par fiole** poudre pour solution injectable avec solution diluante) TAKEDA CANADA INC
02459051	ADYNOVATE	**200 UNITS/ML** (5 ML DILUENT) - SINGLE-USE VIAL	ADYNOVATE (5 ML DILUENT) - SINGLE-USE VIAL (rurioctocog alfa pegol **1000 unit per vial** powder for solution for injection with diluent solution) TAKEDA CANADA INC	ADYNOVATE (5 ML DILUENT) - SINGLE-USE VIAL (rurioctocog alfa pégol **1000 unité par fiole** poudre pour solution injectable avec solution diluante) TAKEDA CANADA INC
02498545	ADYNOVATE	**250 UNITS/ML** (2 ML DILUENT) - SINGLE USE VIAL	ADYNOVATE (2 ML DILUENT) - SINGLE USE VIAL (rurioctocog alfa pegol **500 unit per vial** powder for solution for injection with diluent solution) TAKEDA CANADA INC	ADYNOVATE (2 ML DILUENT) - SINGLE USE VIAL (rurioctocog alfa pégol **500 unité par fiole** poudre pour solution injectable avec solution diluante) TAKEDA CANADA INC
02459043	ADYNOVATE	**100 UNITS/ML** (5 ML DILUENT) - SINGLE-USE VIAL	ADYNOVATE (5 ML DILUENT) - SINGLE-USE VIAL (rurioctocog alfa pegol **500 unit per vial** powder for solution for injection with diluent solution) TAKEDA CANADA INC	ADYNOVATE (5 ML DILUENT) - SINGLE-USE VIAL (rurioctocog alfa pégol **500 unité par fiole** poudre pour solution injectable avec solution diluante) TAKEDA CANADA INC
02498537	ADYNOVATE	**125 UNITS/ML** (2 ML DILUENT) - SINGLE USE VIAL	ADYNOVATE (2 ML DILUENT) - SINGLE USE VIAL (rurioctocog alfa pegol **250 unit per vial** powder for solution for injection with diluent solution) TAKEDA CANADA INC	ADYNOVATE (2 ML DILUENT) - SINGLE USE VIAL (rurioctocog alfa pégol **250 unité par fiole** poudre pour solution injectable avec solution diluante) TAKEDA CANADA INC
02459035	ADYNOVATE	**50 UNITS/ML** (5 ML DILUENT) - SINGLE-USE VIAL	ADYNOVATE (5 ML DILUENT) - SINGLE-USE VIAL (rurioctocog alfa pegol **250 unit per vial** powder for solution for injection with diluent solution) TAKEDA CANADA INC	ADYNOVATE (5 ML DILUENT) - SINGLE-USE VIAL (rurioctocog alfa pégol **250 unité par fiole** poudre pour solution injectable avec solution diluante) TAKEDA CANADA INC

Note that there are some products that even with this additional rule, still generate non-unique MP Formal Names; however, this is acceptable if only one of the products has a status of Active. In the event the DPD descriptor does not provide useful differentiating information, the DPD PRODUCT NAME in the CCDD will be modified to create a meaningful distinction between the products.

Manufactured Product Name Changes

Current Health Canada policy allows pharmaceutical companies to transfer ownership of a product while retaining the same DIN. This means that the Company Name component of a CCDD Manufactured Product may change although the mp_code remains the same. Similarly, product names may undergo minor changes, usually to remove strength or dose form information, but also to remove a prefix from a generic manufactured product name.

Examples of MP name changes:

CCDD Release	DIN	MP Formal Name	MP French Description	Comment
February 2018	02225964	APO-TEMAZEPAM (temazepam 15 mg oral capsule) APOTEX INC	APO-TEMAZEPAM (témazépam 15 mg capsule orale) APOTEX INC	Company change and Name change – prefix removed
March 2018	02225964	TEMAZEPAM (temazepam 15 mg oral capsule) AA PHARMA INC	TEMAZEPAM (témazépam 15 mg capsule orale) AA PHARMA INC	
February 2018	02302063	RASILEZ (aliskiren (aliskiren fumarate) 150 mg oral tablet) NOVARTIS PHARMACEUTICALS CANADA INC	RASILEZ (aliskirène (fumarate d'aliskirène) 150 mg comprimé oral) NOVARTIS PHARMACEUTICALS CANADA INC	Company change
March 2018	02302063	RASILEZ (aliskiren (aliskiren fumarate) 150 mg oral tablet) NODEN PHARMA DAC	RASILEZ (aliskirène (fumarate d'aliskirène) 150 mg comprimé oral) NODEN PHARMA DAC	
March 2019	02243961	DITROPAN XL -(10MG) (oxybutynin chloride 10 mg prolonged-release oral tablet) JANSSEN INC	DITROPAN XL -(10MG) (chlorure d'oxybutynine 10 mg comprimé oral à libération prolongée) JANSSEN INC	Strength removed from brand name
April 2019		DITROPAN XL (oxybutynin chloride 10 mg prolonged-release oral tablet) JANSSEN INC	DITROPAN XL (chlorure d'oxybutynine 10 mg comprimé oral à libération prolongée) JANSSEN INC	

For a medicinal product terminology such as CCDD, this level of change in the formal name of a concept is not ideal. The situation is under active review.