# Status

## Introduction

The Non-Proprietary Therapeutic Product (NTP), Therapeutic Moiety (TM) and the Manufactured Product (MP) have a status attribute that needs to be populated. This status reflects is the availability of the product that concept represents in the supply chain and therefore by implication its availability for use in e-prescribing and dispensing to patients. The concepts in the Canadian Clinical Drug Data Set have a different status lifecycle from the products in the DPD both to avoid confusion and to reflect the use cases for the Canadian Clinical Drug Data Set terminology. The derivation of the Canadian Clinical Drug Data Set statuses is described below, and is based on the information available in the DPD. For a storyboard example, please see [Appendix B, Status Example](file:///C:\Users\Julie\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\XACIHUGU\Editorial%20Guidelines%20July%20Replan.docx#_Appendix_B,_Product).

The allowable status for all concept classes in the Canadian Clinical Drug Data Set will be “Active” and “Inactive” and the format for the status (change) date will be YYYYMMDD.

* “Active”: the product that the concept describes is available on the Canadian market
* “Inactive”: the product that the concept describes is no longer available on the Canadian market; it was “Active” but is no longer so. It should not be prescribed as it would not be possible to find the product for it to be dispensed to patients

Note: the status of concepts in the CCDD is not a “terminology metadata status” as is present in some terminologies (e.g. where a concept may have a status of “retired” because it has been found to be inaccurate or replaced with an alternative concept).

## DPD DIN Status

The state diagram below shows the DIN status for product that are present in the DPD and the events that act as a trigger to move a product to a different status. The definitions of each status are given after the diagram.



Figure 4: The Status Lifecycle of the DIN (Drug Identification Number) for Products in the DPD

* **Approved** refers to a product with an active DIN that has been reviewed and authorized for sale in Canada but has not yet been marketed in Canada
* **Cancelled (Pre-Market)** refers to a DIN that is cancelled before it was ever marketed in Canada
* **Marketed** refers to a product with an active DIN that is currently being sold in Canada
* **Dormant** refers to a product with an active DIN that was previously marketed in Canada but for which the manufacturer has suspended sale for period of at least 12 months
* **Cancelled (Unreturned Annual)** refers to a product with a DIN that is cancelled due to failure to provide the Annual Notification pursuant to Section C.01.014.6 (2) (a) of the Regulations
* **Cancelled (Safety Issue)** refers to a product with a DIN that is cancelled following the suspension of a Notice of Compliance pursuant to Section C.01.014.6 (1) (b) of the Regulations or to Section C.01.014.6 (2) (b) of the Regulations due to failure to provide evidence regarding the safety and effectiveness of a drug, pursuant to Section C.01.013 of the Regulations
* **Cancelled (Post-Market)** refers to a product with a DIN that is cancelled further to the discontinuation of the sale by the manufacturer pursuant to Section C.01.014.6 (1) (a) of the Regulations  
  When a manufacturer notifies Health Canada of discontinuation of sales, they will also provide, within 30 days, the lot number and expiry date for the last lot (therefore with the longest expiry date) sold into the supply chain. This information will be present in the DPD Status/History table for the Cancelled-Post Market product.

## Manufactured Product Status

An MP will not appear in the Canadian Clinical Drug Data Set until its status in the DPD has been set to “Marketed”, at which point it will have an “Active” status in the Canadian Clinical Drug Data Set. The MP status date for the active status will be the date the product is marketed.



Figure 5: Manufactured Product Status Lifecycle in the Canadian Clinical Drug Data Set

The MP status will be set to “inactive” in the CCDD when one of the following occurs to the product’s DIN status in the DPD:

* “Cancelled – Post market” **AND** the expiry date of the last lot released into the supply chain has been reached; effective at the end of the month of the expiration date
* “Cancelled [Safety issue]”; effective at the end of the month that the cancellation occurs
* “Cancelled (Unreturned annual)”; effective at the end of the month that the cancellation occurs
* “Dormant”; effective at the end of the month that the change to dormant occurs in

## Non-Proprietary Therapeutic Product and Therapeutic Moiety Product Status

An NTP and TM do not appear in the Canadian Clinical Drug Data Set until there are one or more active MPs to support them. The NTP status date for “Active” will be the earliest date the NTP was instantiated by an active Manufactured Product, and the status date for “Inactive” will be the date that the last related Manufactured Product was set to inactive. The figure below shows how statuses for the NTP and TM will be represented.



Figure 6: NTP and TM Product Status Lifecycle in the Canadian Clinical Drug Data Set

Although it occurs infrequently, an MP and possibly an NTP and TM may have their status changed back from “Inactive” to “Active”, if the relevant product(s) is/are returned to the market unchanged.