

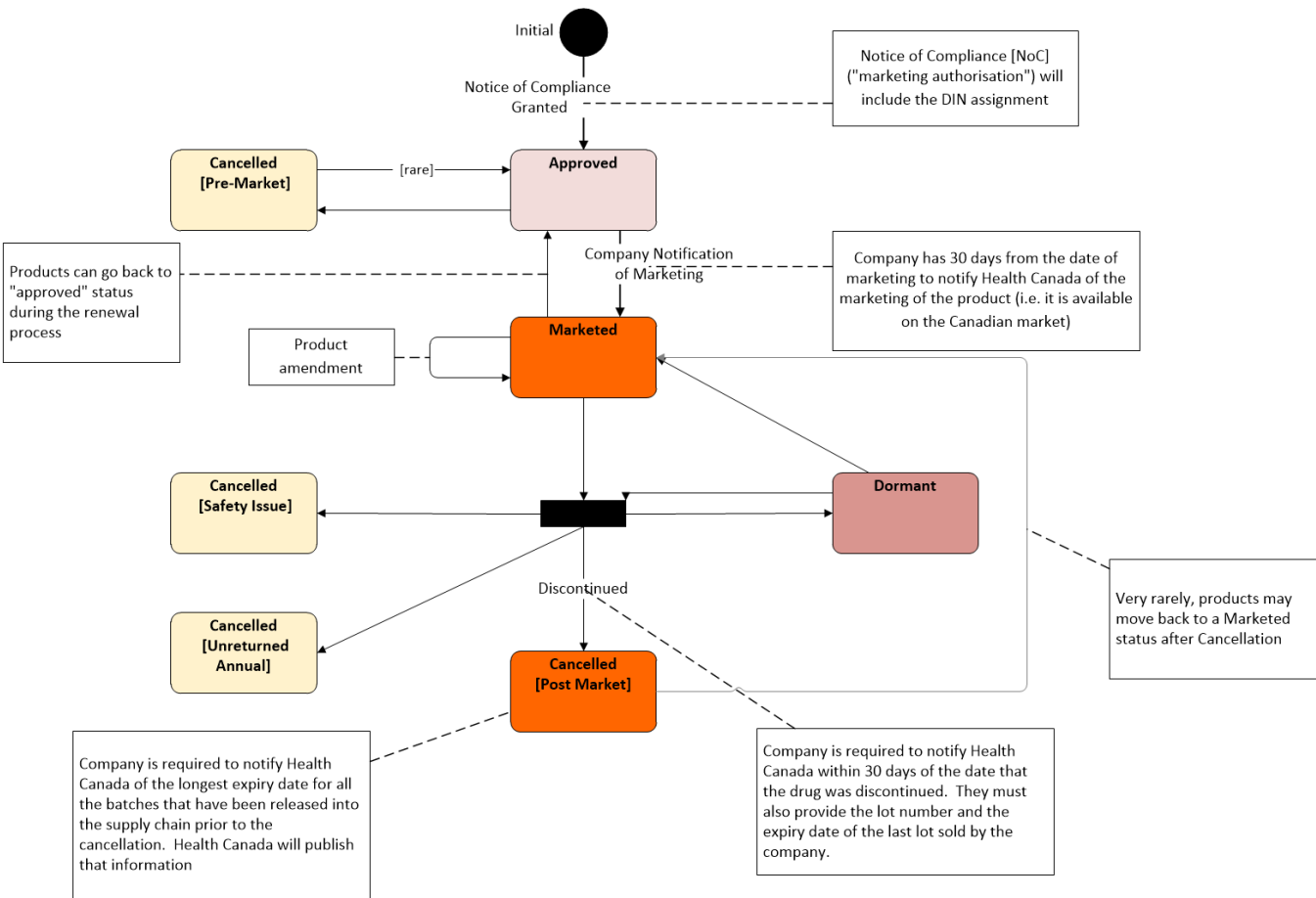
Status

Status

The Non-Proprietary Therapeutic Product (NTP), Therapeutic Moiety (TM) and the Manufactured Product (MP) have a status attribute. The status attribute reflects the lifecycle of availability of the medicinal product concept 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 but it is derived from the information available in the DPD.

(Note: NoC stands for Notice of Compliance)

Figure 1: The Status Lifecycle for Products in the DPD



The allowable status strings for all concept classes in the Canadian Clinical Drug Data Set will be "Active", "Inactive" and "Deprec" 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 marketed; it was "Active" but is no longer so. It should not be prescribed as it would not be possible to find the product to dispense to patients
- "Deprec": the concept is Deprecated. Concepts with this status indicate a concept that was created in error or is now an orphan concept (no longer linked to any MP due to a change in formal name) and should not be used in systems; it is an exceptional status. This status type applies to all of the file types with a status attribute EXCEPT the Special Groupings file.

Manufactured Product Status

The MP will not appear in the Canadian Clinical Drug Data Set until its status in the DPD has been set to "marketed" (from "approved"), at which point it will have an "Active" status in CCDD. The accompanying status date will usually be the first marketing date in the DPD.

The MP status will be set to "Inactive" when the product status in the DPD has been set to either:

- "cancelled-post market" and the expiry date of the last batch released into the supply chain has been reached as shown below in figure 2; the status date corresponds to the last batch expiry date

- "cancelled-post market" with no last batch expiry date; the status date corresponds to the date of that change in the DPD
- or "dormant"; the status date corresponds to the date of that change in the DPD.

Conversely, an MP (and possibly therefore the associated NTP and TM) status may revert from "Inactive" back to "Active", if the relevant product(s) is/are returned to the market unchanged, for example if a "dormant" product returns to "marketed". MPs may have the exceptional status of "Deprec" (deprecated) if they are found to have been created in error; no product that corresponds to that concept has existed; the status date corresponds to the date of the deprecation. The figure below shows how statuses for the Manufactured Product will be represented.

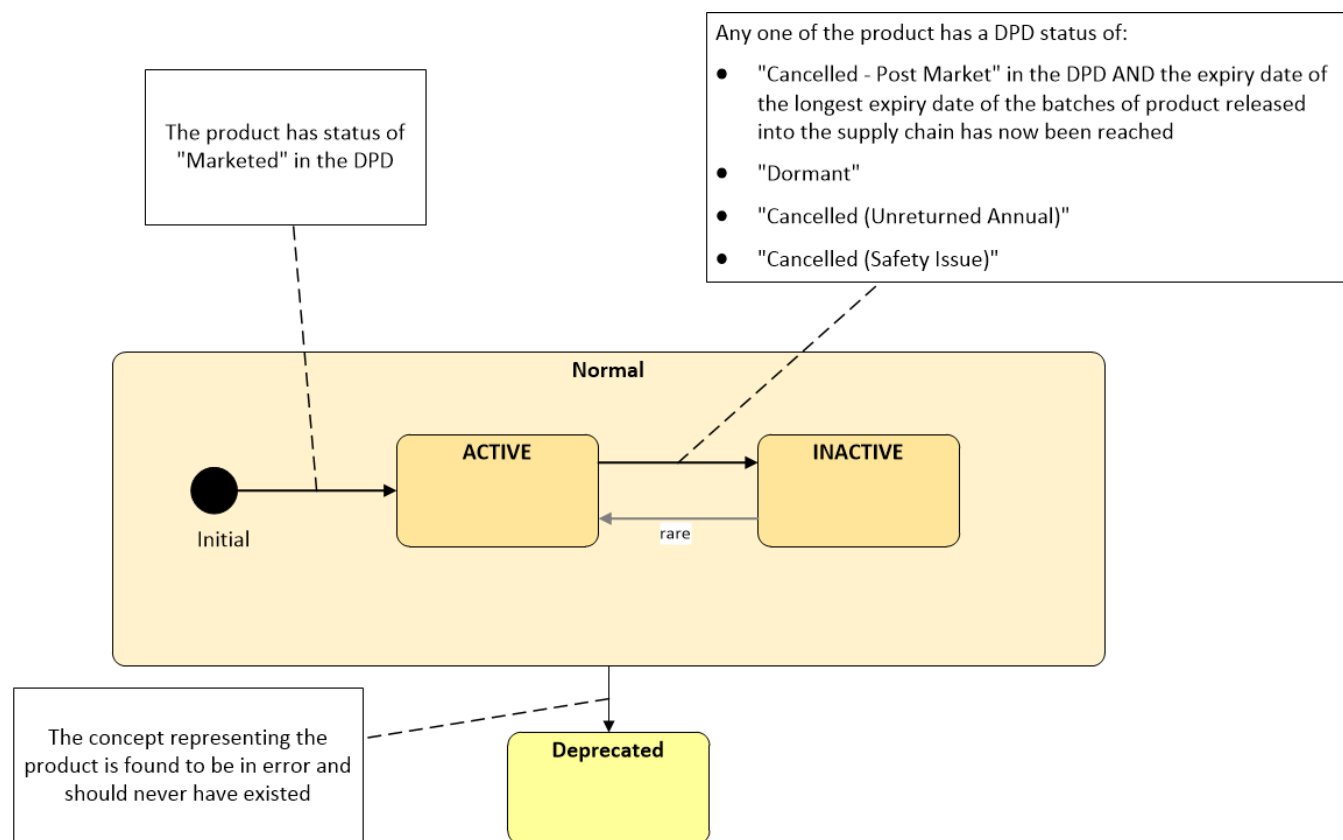


Figure 2: Manufactured Product Status Lifecycle in the Canadian Clinical Drug Data Set

Non-Proprietary Therapeutic Product and Therapeutic Moiety Product Status

An NTP and TM do not appear in the Canadian Clinical Drug Data Set until one or more of their related MPs have a status of "marketed" in the Health Canada DPD. The product 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. An NTP and TM status may also revert from "Inactive" back to "Active" if one or more of their associated MP(s) is/are returned to the market unchanged. NTPs and TMs may have the exceptional status of "Deprec" (deprecated) if they are found to have been created in error (no product that corresponds to that concept representation has existed) or if it is now an orphan concept (no longer associated with any MP due to a change in DPD). In either case, the status date corresponds to the date of the deprecation. The figure below shows how statuses for the NTP and TM will be represented.

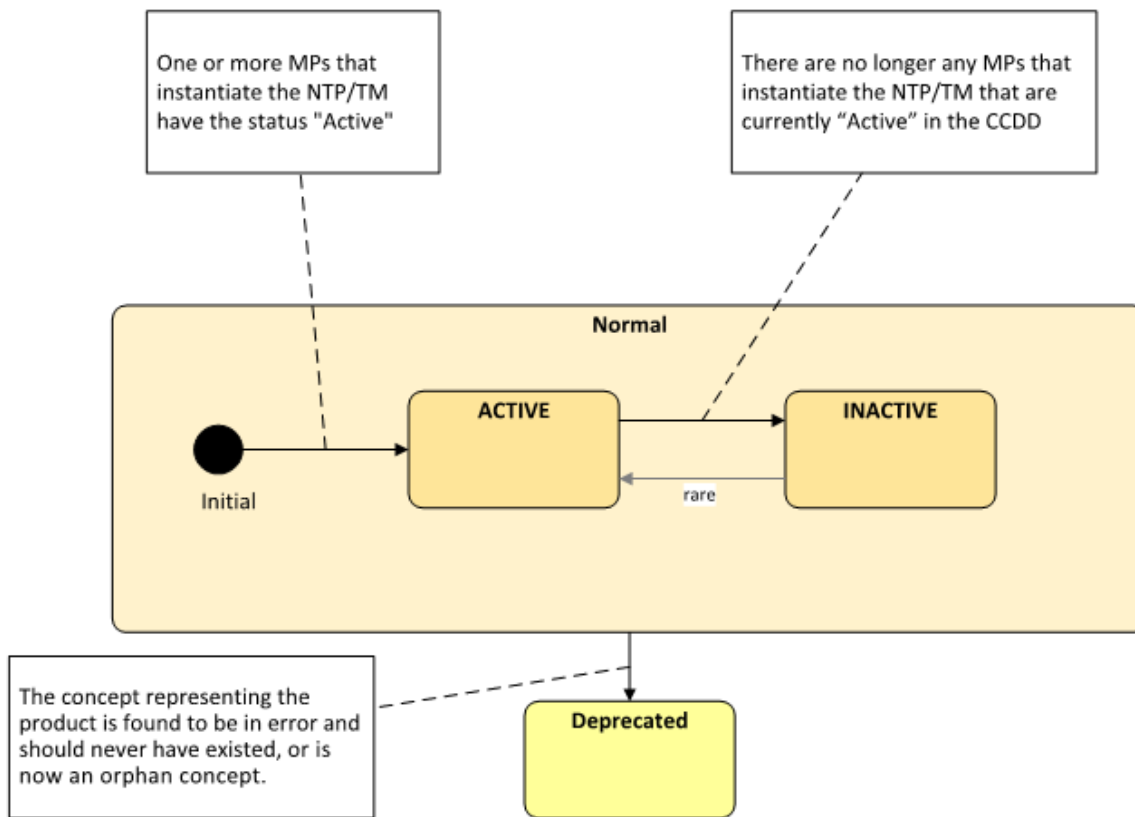


Figure 3: NTP (and TM) Product Status Lifecycle in the Canadian Clinical Drug Data Set