Health Canada Santé Canada

GUIDANCE DOCUMENT

Cancellation of a Drug Identification Number (DIN) and Notification of the Discontinuation of Sales

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Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related products and food by: • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

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FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

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1. INTRODUCTION

A Drug Identification Number (DIN) serves as an identifier of a drug and its associated characteristics. The assignment of a DIN indicates that a drug has undergone a successful Health Canada review process and is currently authorized for sale in Canada. The issuance of a Notice of Compliance (NOC) following a successful review is also required for the sale of drugs that are regulated under Part C, Division 8 of the *Food and Drug Regulations* (the Regulations). All authorized DIN products are listed on the Drug Product Database (DPD) online, as either approved, marketed, dormant or cancelled (refer to Appendix C for a list of all available online statuses). As the information contained on the DPD online is accessed by different parties such as patients, healthcare professionals, pharmaceutical companies, and provincial and territorial governments, it is crucial for the health and safety of all Canadians that this information be accurate and up to date.

2. PURPOSE

The purpose of this guidance document is to provide assistance in interpreting sections C.01.014.6 and C.01.014.7 of the Regulations for the cancellation of a DIN and the notification to health Canada of the discontinuation of the sale of a drug. This guideline is designed to facilitate proper compliance by the manufacturers and to enhance consistency in the application of these regulatory requirements.

3. SCOPE

This guidance document applies to all drugs which have been issued a DIN pursuant to section C.01.014.2 (1) of the Regulations. This includes all prescription and non-prescription drugs for human and veterinary use as well as disinfectants.

Note: This guidance document covers the mandatory reporting of a discontinuation of the sale of a product that has a DIN assigned by Health Canada, pursuant to section C.01.014.7 of the Regulations. Authorization Holders must also comply with the requirements of sections C.01.014.8 to C.01.014.12 of the Regulations to report drug shortages and discontinuations of the sale of drugs included in Schedules I, II, III, IV or V to the *Controlled Drugs and Substances Act*, prescription drugs, drugs listed in Schedules D and C to the Act and drugs that may be sold without a prescription, but are administered only under a practitioner's supervision on the reporting website, and to notify Health Canada of the interruption of sales of a drug (12 months without sale). Refer to the document *Guide to Reporting Drug Shortages and Discontinuations* for more information.

4. POLICY OBJECTIVES

The policy objectives that guide the regulatory authority for DIN cancellation and the requirement for reporting drug discontinuation to Health Canada are as follows:

- to provide the public with timely, reliable and accurate information on the availability of drugs in Canada; and
- to help protect the health and safety of Canadians from the sale of unsafe drugs

These objectives should be considered when complying with the Regulations including when interpreting the regulatory requirements for specific situations.

5. DEFINITIONS

Authorization Holder or **Drug Authorization Holder** means, in respect of a drug,
(i) the person to whom a document was issued under subsection C.01.014.2 (1) that sets out the drug identification number assigned for the drug; and
(ii) in the case of a drug that is listed in Schedule C to the Act, the manufacturer to whom a notice of compliance in respect of the drug was issued under section C.08.004 or C.08.004.01.

Discontinue (as per section C.01.001 (1) of the Regulations), means, in respect of the sale of a drug by the authorization holder of the drug, to permanently cease the sale of the drug.

Discontinuation date
- If a manufacturer is selling a drug and decides to discontinue its sale, the date of the discontinuation is the date of the last sale by the manufacturer.
- If a manufacturer has temporarily stopped selling a drug and then decides to discontinue its sale later, the discontinuation date is the date on which the decision to discontinue the sale was made.

Drug Identification Number (DIN) is a computer-generated eight digit number assigned by Health Canada to a drug prior to being marketed in Canada. It identifies all drugs under the Regulations sold in a dosage form in Canada and is located on the label of prescription and non-prescription drugs that have been evaluated and authorized for sale in Canada. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; route of administration.

Expiration date (as per section C.01.001 (1) of the Regulations), means
(a) in the case of a drug in dosage form, the earlier of the following dates, expressed at minimum as a year and month:

(i) the date up to and including which the drug maintains its labelled potency, purity and physical characteristics, and
(ii) the date after which the manufacturer recommends that the drug not be used; and

(b) in the case of an active ingredient, whichever of the following dates is applicable, expressed at minimum as a year and month:
(i) the retest date, or
(ii) the date after which the manufacturer recommends that the active ingredient not be used.

Lot number (as per section A.01.010 of the Regulations), means any combination of letters, figures, or both, by which any food or drug can be traced in manufacture and identified in distribution.

Manufacturer or Distributor (as per section A.01.010 of the Regulations), means a person, including an association or partnership, who under their own name, or under a trade, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug.

6. GUIDANCE FOR IMPLEMENTATION

The next part of this document provides:

- the exact text of the relevant sections of Part C, Division 1 of the Regulations (presented in italics),
- Health Canada's interpretation of these sections,
- information on their operational implementation, and
- guidance on how companies can comply with the requirements.

6.1 Section C.01.014.6 Cancellation of a Drug Identification Number (DIN)

Section C.01.014.6 outlines the circumstances under which Health Canada has the authority to cancel a DIN.

C.01.014.6
(1) The Director shall cancel the assignment of a drug identification number for a drug where
(a) the person to whom a *document was issued under subsection C.01.014.2(1) that sets out the drug identification number assigned for the drug advises under section C.01.014.7 that they have discontinued the sale of the drug;*
(b) the drug is a new drug in respect of which the notice of compliance has been suspended pursuant to section C.08.006; or
(c) it has been determined that the product in respect of which the number was assigned is not a drug.
(2) The Director may cancel the assignment of a drug identification number for a drug where
(a) the manufacturer of the drug has failed to comply with section C.01.014.5; or

(b) the manufacturer to whom the number was assigned has been notified pursuant to section C.01.013 that the evidence he submitted in respect of the drug is insufficient.

6.1.1 Section C.01.014.6 (1) (a): Cancellation Due to Discontinuation of Sale

The Director shall cancel the assignment of a drug identification number for a drug where the person to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number assigned for the drug advises under section C.01.014.7 that they have discontinued the sale of the drug;

The cancellation of the DIN is initiated by the Director further to the receipt of a sale discontinuation notification from a manufacturer or a designated representative pursuant to section C.01.014.7 of the Regulations.

Once received, the DIN cancellation date will be added to the DPD online database generally within a week of receipt. If the product has never been marketed the status of the drug will be updated on the DPD online to "Cancelled (Pre-Market)". If the product was marketed the status of the drug on the DPD online will be updated to "Cancelled (Post-Market)". The Office of Submissions and Intellectual Property (OSIP) will send confirmation to the manufacturer or the designated representative that the DIN cancellation has been processed.

For products that were marketed before the cancellation of the DIN, the expiry date of the last lot distributed in Canada, the lot number, and the DIN cancellation date will be posted on the DPD online. For further information on the consequences of a DIN Cancellation, please refer to section 7.

6.1.2 Section C.01.014.6 (1) (b): Cancellation following the suspension of a Notice of Compliance (NOC)

The Director shall cancel the assignment of a drug identification number for a drug where the drug is a new drug in respect of which the notice of compliance has been suspended pursuant to section C.08.006.

As outlined by section C.08.002 (1) (c) of the Regulations no person can sell a drug with a suspended NOC. This prohibition on sale applies to the manufacturers and to all other parties such as wholesalers, retailers, pharmacists and medical practitioners and is effective on the date the NOC is suspended.

Following the suspension of the NOC, a written notice will be provided to the manufacturer to inform them that their DIN will be cancelled in accordance with section C.01.014.6 (1) (b) of the Regulations.

Health Canada will subsequently update the status of the drug on the DPD and a confirmation of the cancellation of the DIN will be sent to the manufacturer. The new status of the DIN "Cancelled (Safety Issue)" will be reflected on the DPD online the day following notification that the DIN has been cancelled.

6.1.3 Section C.01.014.6 (1) (c): Cancellation as Product is Not a Drug

The Director shall cancel the assignment of a drug identification number for a drug where it has been determined that the product in respect of which the number was assigned is not a drug.

The cancellation of the DIN is initiated by the Director when it is determined that the corresponding product is not a drug under the Regulations. In this scenario, Health Canada will explain to the manufacturer in writing that the product is being reclassified and will no longer be regulated as a drug under the Regulations. The manufacturer will be provided further information regarding the date on which the product's status will be changed and the DIN(s) cancelled. If applicable, information on which set of Regulations the product will be subject to in order for the product to be marketed on the Canadian market will be provided.

Following the reclassification of the product, Health Canada will cancel the DIN and remove the product from the DPD online. A confirmation of the cancellation of the DIN will be sent to the manufacturer.

6.1.4 Section C.01.014.6 (2) (a): Cancellation Due to Failure to Provide Annual Notification

The Director may cancel the assignment of a drug identification number for a drug where the manufacturer of the drug has failed to comply with section C.01.014.5.

Every year manufacturers must provide a signed copy of the Annual Drug Notification Form (ADNF) to Health Canada. The ADNF serves as an attestation that all the information previously provided by the manufacturer with respect to the drug is correct, and to provide any related updates to Health Canada.

Before the first day of October the OSIP will contact the manufacturers that have failed to return a signed copy of the ADNF to remind them of their regulatory obligations.

If by the first of October the ADNF has not been received by Health Canada, as per section C.01.014.5 of the Regulations, the Director may initiate the cancellation of the DIN(s). A written final notice will be provided to the manufacturer to inform them that their DIN(s) will be cancelled in accordance with section C.01.014.6 (2) (a) of the

Regulations and that they can no longer sell the drug as per C.01.014 (1) of the Regulations.

Health Canada will subsequently update the status of the drug on the DPD online to "Cancelled (Unreturned Annual)" and a confirmation of the cancellation of the DIN will be sent to the manufacturer.

6.1.5 Section C.01.014.6 (2) (b): Cancellation due to Concerns Regarding Safety and Efficacy

The Director may cancel the assignment of a drug identification number for a drug where the manufacturer to whom the number was assigned has been notified pursuant to section C.01.013 that the evidence he submitted in respect of the drug is insufficient.

The cancellation of the DIN may be initiated by the Director when a manufacturer fails to provide Health Canada with sufficient evidence regarding the safety and effectiveness of the drug for its recommended use.

Prior to the cancellation of the DIN, in accordance with Section C.01.013(1) of the Regulations, the manufacturer will be requested in writing by the Director to submit evidence by a specified date. Pursuant to section C.01.013(2), if the evidence submitted is not sufficient, the Director will notify the manufacturer in writing and the Director may determine that a DIN cancellation is warranted.

Following the determination that a DIN cancellation is warranted, a written notice will be provided to the manufacturer to inform them that their DIN is being cancelled in accordance with section C.01.014.6.2 (b) of the *Regulations* and that they can no longer sell the drug as per C.01.014(1) of the *Regulations*. For further information on the consequences of a DIN Cancellation, please refer to section 7.

Health Canada will subsequently update the status of the drug on the DPD and a confirmation of the cancellation of the DIN will be sent to the manufacturer. The new status of the DIN "Cancelled (Safety Issue)" will be reflected on the DPD online the following day.

6.2 Section C.01.014.7 Discontinuation Notification

The person to whom a document was issued under C.01.014.2(1) that sets out the drug identification number assigned for a drug shall, within 30 days after the day on which they discontinue sale of the drug in Canada, submit the following information to the Minister:

(a) the drug identification number assigned for the drug under that subsection;

(b) the date on which the holder discontinued sale of the drug; and

(c) the latest expiration date of the drug that the holder sold and the lot number of that drug.

This section of the Regulations allows the Department to ensure that the drug information provided on the Department's website is accurate and up to date, while maintaining regulatory oversight of drugs available on the Canadian market until their expiry dates.

As noted earlier in the Definition section, discontinue (as per section C.01.001 (1) of the Regulations), means, in respect of the sale of a drug by the manufacturer of the drug, to permanently cease the sale of the drug.

The manufacturer[1] must notify Health Canada within 30 calendar days of the date the sale of the drug was discontinued.

The sale discontinuation notification from the manufacturer should be in writing on company letterhead and signed by an authorized official. It must have the following information:

- The DIN number of the discontinued product.
- The discontinuation date of the product.
- The lot number and expiry date of the last lot sold by the manufacturer.

The sale discontinuation notification should be sent electronically.

1- Documents for submissions in "non-eCTD electronic-only" format must be sent by one of the following ways:

- by email to SIPD-DINREQUEST@HC-SC.GC.CA,

[1] Manufacturers may have a third party, such as an importer, act on their behalf and submit the notification

- on electronic media to :

  Office of Submissions and Intellectual Property (OSIP)
  Finance Building
  101 Tunney's Pasture Driveway
  Address Locator: 0201A1
  Ottawa, Ontario
  K1A 0K9

2- Documents for submissions in eCTD format must be sent via the Common Electronic Submissions Gateway (CESG).

For more information on how to submit transactions to Health Canada, please refer to section "Transmission of Electronic Data" in the guidance documents:

- *Preparation of Drug Regulatory Activities in Electronic Common Technical Document Format,* for regulatory activities in eCTD format; and

- *Preparation of Drug Regulatory Activities in the "Non-eCTD Electronic-Only" Format,* for regulatory activities in "non-eCTD electronic-only" format.

When Health Canada receives the notification of discontinuations, the Department will proceed to cancel the DIN as described in Section 6.1.1 of this document.

6.3 Section C.01.014.12 Twelve months without sale

This section of the guidance document only applies to the following drugs for human use:

- drugs included in Schedules I, II, III, IV or V to the *Controlled Drugs and Substances Act* (http://laws-lois.justice.gc.ca/eng/acts/C-38.8/);
- prescription drugs (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_list_fin_ord-eng.php);
- drugs listed in Schedules D and C to the Act (http://laws.justice.gc.ca/eng/acts/F-27/);
- drugs that may be sold without a prescription, but are administered only under a practitioner's supervision (e.g. hemodialysis solutions, pre-filled syringes with epinephrine for severe allergic reactions, magnetic resonance imaging (MRI) contrast agents).

C.01.014.12

(1) If a period of 12 months has elapsed since an authorization holder for a drug last sold the drug, they shall notify the Minister of that fact within 30 days after the day on which that period ends.

(2) The authorization holder shall, within 30 days after the day on which they resume the sale of the drug, notify the Minister of that fact.

Manufacturers[2] are required to submit a notification to Health Canada within 30 calendar days after a period of twelve consecutive months that a product has not been sold on the Canadian market. Manufacturers are also required to submit a notification to Health Canada once they decide to resume selling on the Canadian market. This section allows the Department to ensure that the drug information provided in the DPD online is accurate and up to date. It also assists in maintaining regulatory oversight of drugs that are available on the Canadian market and in responding to drug shortages.

6.3.1 Reporting 12 months without sale

The manufacturer must notify Health Canada within 30 calendar days after the product has not been sold on the Canadian Market for a period for 12 continuous months.

The 12 months without sale notification from the manufacturer should be in writing on company letterhead and signed by an authorized official.

The 12 months without sale notification should be sent electronically. For instructions on how to submit transactions to Health Canada, please refer to the instructions in section 6.2 of this guidance.

Once the notification is received by Health Canada the status of the drug will be updated on the DPD online to “Dormant”.

If subsequent to notifying Health Canada of the period without sale, the manufacturer determines that they will not resume sale of the product on the Canadian market they must submit a sale discontinuation notification as outlined in Section 6.2 of this guidance document.

If subsequent to notifying Health Canada of the period without sale, the manufacturer determines that they will resume sale of the product on the Canadian market they must

[2] Manufacturers may have a third party, such as an importer, act on their behalf and submit the notification

submit, within 30 days after commencing sale of the drug, a signed and dated Drug Notification Form (DNF) in accordance with section C.01.014.12.2 of the Regulations.

7. CONSEQUENCES OF THE DRUG IDENTIFICATION NUMBER (DIN) CANCELLATION

When the DIN of a drug is cancelled pursuant to section C.01.014.6 of the Regulations, no further sales may be made by the manufacturer since C.01.014 (1) of the Regulations prohibits manufacturers from selling drugs without a DIN.

So as not to create undue burden on industry, Health Canada may allow other parties in the downstream chain of distribution such as wholesalers, retailers, pharmacists and medical practitioners to continue to sell or distribute the remaining drug products after the DIN is cancelled, if the expiry date of the drug product lot is not passed and so long as the cancellation of the DIN was not due to health or safety reasons. Products without a valid DIN/NOC cannot be imported.

The manufacturer remains subject to post-market obligations for its own drug that is distributed prior to the cancellation of the DIN until the expiration of the last lot distributed or the longest time period referred to in the Regulations.

For example, requirements for manufacturers to report adverse drug reactions as per section C.01.017 of the Regulations, and for wholesalers and distributors to keep records as per section C.02.022 of the Regulations are still applicable after the DIN is cancelled.

To illustrate possible consequences of DIN cancellation after the sale of the drug has been discontinued and no safety issue is associated with the cancellation of the DIN[3]:

A manufacturer discontinues the sale of a drug on February 28th and informs Health Canada on the same day. Health Canada cancels the DIN. However, the drug is currently on the market and the expiry date of the last lot is December 30th. The manufacturer is responsible for all the serious adverse drug reactions reporting requirements of section C.01.017 for the drug.

Wholesalers, retailers, pharmacists and medical practitioners may continue to sell or distribute the drug until December 30th, if there were lots of the drug which were already in their possession before the DIN was cancelled. However an importer cannot continue to import the drugs without an active DIN.

[3] Please note that this scenario is illustrative only. Authorization holders should consult the Regulations for the obligations which apply to their particular circumstances.

The wholesalers, distributors and importers are still responsible for all the record keeping requirements of section C.02.022 of the Regulations for all the lots of the drug that existed on the market, including the ones after the DIN was cancelled (i.e. between September 30th and December 30th). Pursuant to section C.02.022 of the Regulations, records shall be retained for one year after the expiration date of the last lot unless the establishment license specifies some other period.

The manufacturer can continue to file the appropriate submission[4] whenever significant updating of the product monograph is required in order to incorporate additions or other changes related to safety (particularly with respect to warnings and precautions, adverse reactions, and route of administration) that may be necessary as a result of newly available information, up until all the lots of the drug that existed on the market have expired.

If Health Canada becomes aware of any risk or non-compliance with respect to a drug with a cancelled DIN, Health Canada will take appropriate actions to mitigate the risk in accordance with the *Compliance and Enforcement Policy* (POL-0001).

8. COMMERCIAL EXPORTATION

When a manufacturer, holding a DIN for a drug, discontinues the sale of that drug for consumption in Canada but continues to export the drug, the type of exportation will determine whether the sale of the drug is considered to be discontinued in Canada.

- To export a drug in compliance with the Act and the Regulations without invoking section 37 of the Act, manufacturers require, among other things, an authorization to sell the drug (DIN and/or NOC) since these types of commercial exportations are usually considered sales in Canada. In this case, the exported drug is not considered to be discontinued and manufacturers are not required to send a sale discontinuation notification to Health Canada. The product will continue to appear in the DPD online with the status "Marketed" and the manufacturer remains subject to post-market obligations.

- If a drug which was destined for consumption in Canada is discontinued, but continues to be exported pursuant to section 37 of the Act, the drug is considered discontinued in Canada. Manufacturers are exempted from the application of the Act[5] when a drug is exported by invoking section 37 of the Act and the conditions set out in that section have been met. In

[4] Supplement to a New Drug Submission (SNDS), Supplement to an Abbreviated New Drug Submission (SANDS)

[5] Please note that according to s.37(1.1)(b) of the Act, despite section 37(1) of the Act, section 8, subsection 9(1) and section 11 of the Act apply to a drug that is not a natural health product.

this case, manufacturers will be required to send a sale discontinuation notification to Health Canada for the drug that has been discontinued. The DIN will be cancelled and the status of the product in the DPD online will be changed to “Cancelled (Post-Market)”.

For more information on section 37 of the Act, see Intention to Invoke Section 37 of the Canada Food and Drugs Act for Products Being Exported (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/frm_0038_tc-tm-eng.php).

APPENDICES

APPENDIX A: GLOSSARY

Act (the): *Food and Drugs Act*

ADNF: Annual Drug Notification Form

DIN: Drug Identification Number

DPD: Drug Product Database

NOC: Notice of Compliance

OSIP: Office of Submissions and Intellectual Property

Regulations (the): *Food and Drug Regulations*

APPENDIX B: REFERENCES

- *Compliance and Enforcement Policy* (POL-0001) (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm-eng.php)
- *Drug Identification Number (DIN) Enforcement Policy* (POL-0040) (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0040_tc-tm-eng.php)
- *Food and Drugs Act* (http://laws-lois.justice.gc.ca/eng/acts/f-27/)
- *Food and Drug Regulations* (http://laws-lois.justice.gc.ca/eng/Regulations/c.r.c.,_c._870/index.html)
- *Guidance Document: Preparation of Drug Regulatory Activities in Electronic Common Technical Document Format* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ctd/gd_prep_non_ectd_ld-eng.php)
- *Guidance Document: Preparation of Drug Regulatory Activities in the "Non-eCTD Electronic-Only" Format* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ctd/gd_prep_non_ectd_ld-eng.php)
- *Guidance Document: Guide to Reporting Drug Shortages and discontinuations*

- Health Canada's Drug Product Database (www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php)

- Intention to Invoke Section 37 of the Canada Food and Drugs Act for Products Being Exported (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/frm_0038_tc-tm-eng.php)

APPENDIX C: LIST OF ONLINE STATUSES

- **Approved** refers to an active DIN that has been reviewed and authorized for sale in Canada but has not yet been marketed in Canada.

- **Marketed** refers to an active DIN that is currently being sold in Canada.

- **Dormant** refers to 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 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 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 (Pre-Market)** refers to a DIN that is cancelled before it was ever marketed in Canada.

- **Cancelled (Post-Market)** refers to 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.