



BEST PRACTICE: SUNSET CLAUSE REPORTING

1 Revision History

When Ennov releases a new version of Ennov InSight, they issue Release Notes which explain the new features and updates. The Ennov Business Consulting Team reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release notes-documented upgrade changes this Best Practice
- No Impact = Release notes-documented upgrade changes do not affect this Best Practice

When Release Notes impact Best Practice documentation, Ennov recommends that clients review the entire Release Notes for a full understanding of all changes associated with this Best Practice documentation.

Software Version	Release/Revision Date	Summary of Change(s) (Refer to Release Notes for Full Description)
v7.3.1	28-Jun-2024	Update Best Practice for Ennov rebranding & for v7.3.1 – No Impact. Correction made to section Questions Answered by the Sunset Clause Marketing Query.
v7.3	01-Mar-2024	Update Best Practice for v7.3 – No Impact (minor reformatting only)
v7.2	04-Apr-2023	Update Best Practice for v7.2 – No Impact
v7.1	13-Jan-2022	Update Best Practice for v7.1 – No Impact
v7.0	30-Apr-2021	Update Best Practice for v7.0 – No Impact
N/A	13-Apr-2021	Update Best Practice for Calyx Rebranding – No Impact
v6.2 CHF6	21-Oct-2020	Update Best Practice for v6.2 CHF6 – No Impact
v6.2 CHF5	03-Aug-2020	Update Best Practice for v6.2 CHF5 – No Impact
v6.2 CHF4	28-Feb-2020	Update Best Practice for v6.2 CHF4 – No Impact
v6.2 CHF3	27-Jun-2019	Update Best Practice for v6.2 CHF3 – No Impact
v6.2 CHF2	15-Feb-2019	Update Best Practice for v6.2 CHF2 – No Impact

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3 Document Purpose

The purpose of this document is to provide Best Practice guidance for managing and reporting on Sunset Clause data, which tracks package set marketing data within a specified Product Family and time frame.

The Sunset Clause is a European initiative that invalidates a Marketing Authorization if:

- The medicinal product is not placed on the market within 3 years of the authorization being granted or,
- Where a medicinal product previously placed on the market is no longer actually present on the market for three consecutive years

Ennov recommends maintaining specific package set data on Registration and Product Detail Set screens to support the Sunset Clause Marketing Status query of the Product Detail Management module.

4 Scope

This document covers the following:

- Maintaining Package Set fields on Registration screens
- Running the Sunset Clause Marketing query
- Questions answered by the Sunset Clause Marketing query

5 Maintaining Package Set Data for Sunset Clause Tracking

In addition to Product and Application data, data for the following screens and fields should be maintained for Package Set tracking on the Sunset Clause Marketing Status query:

- Registration Attributes:
 - Package Set
 - MAH/Organization
- Package Set-Country Attributes:
 - Country
 - Currently marketed in this country?
 - Marketed Date
 - Marketing Cessation Date (as needed)
 - Temporary Cessation Date (as needed)
- Product Detail Set Attributes:
 - Exemption Date

6 Running the Sunset Clause Marketing Status Query

Use the Sunset Clause Marketing Status query to assess the marketing status of (a) given Package Set(s).

1. Navigate to the Product Detail Management tab and select the Sunset Clause Marketing Status Query.
2. In the query filter screen, complete required and desired fields.
3. All fields tracked by the query will display in the query results set if they have been populated.

You may refine your view of the results set by deselecting fields from the results set view.

7 Questions Answered by the Sunset Clause Marketing Query

Clients typically run the Sunset Clause Marketing query to answer specific questions which may include:

What Products are likely to be in danger of hitting the 3-year mark?

Answering this question requires some analysis by the query requester/recipient.

- If a Product has only one Package Set, and that Package Set has not been marketed for 3 years (or will not be), then the Product license will be invalid at the 3-year mark.
- If a Product has more than one Package Set, and any one of the Package Sets is currently marketed or has been within the past 3 years, then the Product will not be invalidated.

To perform an analysis on multi-Package Set Products, users must review the **Marketing Cessation Date** or **Temporary Cessation Date** field for all Package Sets associated with the Product.

- If at least one Package Set is actively on the market within the past 3 years, then the Product registration remains valid.
- If none of the Package Sets is actively on the market – or will not be at the 3-year mark – the Registration can be invalidated.

When Product X was last marketed?

- The **Marketed Date** field located on the Package-Set Country Attributes screen should respond to this question if selected in the query results set. This date proves the Package Set was marketed at some point, so the field should populate regardless of whether the Product is currently marketed.
- To find out if the Product is currently marketed, users should check the **Currently marketed in this country?** field. If the Not Marketed, Suspended or Temporarily unavailable values display, it should be accompanied by a date in either the Marketing Cessation Date or Temporary Cessation Date field.