



CALYX™

CALYX™
Best Practice:
Managing
Package Set
Marketing
Information

CALYX.AI

1 Revision History

When Calyx releases a new version of Calyx RIM, they issue Release Notes which explain the new features and updates. Calyx reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release notes change this Best Practice
- No Impact = Release notes do not change this Best Practice

When Release Notes impact Best Practice documentation, Calyx 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)
v7.0	30-Apr-2021	Update Best Practice for v7.0 – Impact
N/A	09-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 a Best Practice guide for the management of Package Set Marketing Information in Calyx RIM for Registrations.

4 Scope

This document covers the Best Practice for managing the Marketing information tracked in the Registration Package Set-Country entity in Calyx RIM for Registrations.

The following activities are considered.

1. Initial Launch/Marketing
2. Temporary cessation and restart of Marketing
3. Permanent cessation of the Marketing
4. MAH Transfer
5. License Withdrawal
6. Withdrawal of Package Set from the License
7. Package Set Recall

5 Data Administration Activities

The Data Administration activities in Calyx RIM for Registrations.

1. Locate the Registration Status Values under the Registration Maintenance section in Data Administration and ensure all the required “Registration Status” values are available.
2. Locate the Legal Status Values under the Application Maintenance section in Data Administration and ensure all the required “Legal Status of Supply” values are available.

6 General Considerations

Definition of a Package Set

In Calyx RIM for Registrations, the Package Set defines how the product is presented to the end user (pharmacist, medical practitioner, patient etc.) – other possible names are Presentations and Pack size, SKU. Examples include:

1. Blister pack containing 10 Film coated Tablets
2. 1mL Prefilled Syringe
3. Bottle containing 100 capsules

License and Package Sets

Irrespective of the registration, e.g. one license number per Package Set, one license number for all Package Sets for a product or one license number for all Package Sets for all Products, the marketing information in Calyx RIM for Registrations is always captured at the Package Set level (in Calyx RIM for Registrations, the Registration Package Set Country entity).

Reasons for capturing Marketing information

Calyx RIM for Registrations provides the capability to track the Marketing status to:

1. Help in the prioritisation of regulatory effort and resource where activity for registration maintenance will be focused on those products where at least one of the Package Sets is marketed.
2. Support Health Authority requirements in countries that require this information.
3. Support the “Sunset” clause compliance, as required for EU registered products
4. Support mandatory regulatory reporting requirements, e.g. Annex H of the PSMF.

Marketing of Package Sets

The Marketing information captured in the Registration Package Set Country entity pertains to whether the Package Set is “actively” being released or has “ceased” to be released into the distribution chain by the MAH. The term “Marketed” or “Marketing” is used interchangeably in this document and refers to the release of the package set into the distribution chain.

The Marketing information **does not** relate to whether the Package Set is actually “On the Market”/“On the Shelf”.

Attribute definitions within the Registration Package Set Country entity

Registration Package Set-Country Entity Attributes

Attribute	Definition
Country	The country associated to the Marketing information on the specified Package Set.
Currently marketed in this country?	<p>Flag to indicate whether or not the Package Set is being released into the distribution chain by the MAH for this country.</p> <p>If checked, then this indicates that the Package Set is being Marketed.</p> <p>The checkbox will be unchecked by default</p>
Additional License Number	License/Registration number for the individual country. The purpose of this field is to track the country specific license information for Centralised Procedure registrations.
Legal Status of Supply	The legal status of supply of the Medicinal Product as classified by the Regulatory Medicines Agency shall be specified (e.g. subject to medical prescription or not). The legal status of supply should be described using an appropriate controlled vocabulary.
Marketed Date	The Date the specified Package Set is released into the distribution chain by the MAH stated on the Registration entity.
Marketing Cessation Date	The Date the Package Set is "permanently" ceased/discontinued to be released into the distribution chain by the MAH OR the Date of the transfer of the License.
Temporary Cessation Date	The Date the Package Set is "temporarily" ceased/discontinued to be released into the distribution chain by the MAH
Reason for Temporary Cessation	The reason for temporary cessation of the marketing of the Package Set
Estimated Return to Market Date	The date when the Package Set is planned to be re-released back into the distribution chain by the MAH
Restart Marketed Date	The date the Package Set was re-released into the distribution chain by the MAH after a temporary cessation of the marketing.
Registration-Package Set Country Keywords	Free format text box where users can enter text for searching purposes
Registration-Package Set Country Description	Free format text box for entering descriptive information
Registration-Package Set Country Comments	Free format text box where users can enter information that will be stamped with the Date/time/userid of the person entering the information.

7 Package Set Marketing Information

Pre-requisite: License is created for the Package Set(s)

7.1 Initial Launch/Marketing of the Package Set

The date the specified Package Set is **first** released into the distribution chain by the MAH is the “Marketed Date”. This is equivalent to the “Launch Date” and therefore, this date will not change.

The “Launch Date/Commercial Launch Date, is the first day the product is available and can be sold to the wholesalers, distributor(s), and pharmacies, i.e. product launch signifies the point at which consumers first have access to a new product.

Once the Launch Date is known – complete the Registration Package Set-Country entity as follows:

1. Check the “**Currently marketed in this country?**”.
2. If applicable enter the Additional License Number (CP only) into the “**Additional License Number**” field.
3. Enter the Legal Status of Supply for the specific Package Set for the specific country.
4. Enter the “Launch date” into the “**Marketed Date**” field.

Modify Package Set Country Association	
Application Name:	Top Product - MAA - MR - AT
Application Code:	AT/H/000111
License Code:	BE123000
Product Detail Set Name:	TOPAMAX topiramate 25 mg Film-coated tablet
Package Set Name:	25 mg Film-coated tablet 60 count x 1 vial
Country:	Belgium
Currently marketed in this country?:	<input checked="" type="checkbox"/>
Additional License Number:	<input type="text"/>
Legal Status of Supply:	Prescription-Only <input type="button" value="v"/>
Marketed Date:	01-Mar-2017 <input type="button" value="c"/>
Marketing Cessation Date:	<input type="text"/> <input type="button" value="c"/>
Temporary Cessation Date:	<input type="text"/> <input type="button" value="c"/>
Reason for Temporary Cessation:	<input type="text"/>
Estimated Return to Market Date:	<input type="text"/> <input type="button" value="c"/>
Restart Marketed Date:	<input type="text"/> <input type="button" value="c"/>
Registration-Package Set Country Keywords:	<input type="text"/>
Registration-Package Set Country Description:	<input type="text"/>
Registration-Package Set Country Comments:	<input type="text"/>

Interpretation of the Package Set information above.

The Package Set was launched (first released into the distribution chain by the MAH) on the 01-Mar-2017 as a Prescription Only pharmaceutical product and is currently still being marketed.

At some point after the Launch date the MAH may decide not to continue with the marketing of the Package Set. Effectively, this means the MAH will no longer release the Package Set into the distribution chain. This could be either “Temporary” or “Permanent”.

(note: This is NOT the withdrawal of the Package Set from the Market – it is the cessation of the Marketing of the Package Set into the distribution chain).

7.2 Temporary Cessation of the Marketing of the Package Set.

When the date of the temporary cessation of the marketing of the Package Set is known, complete the Registration Package Set-Country entity as follows:

1. Uncheck the “**Currently marketed in this country?**” check box (to indicate the Package Set is no longer being released into the distribution chain).
2. Enter the date when the Package Set ceased to be released into the distribution chain by the MAH by completing the “**Temporary Cessation Date**” field.
3. Enter the reason (if known) for the Temporary cessation in the free text “**Reason for Temporary Cessation**” field. *(Note: Some Health Authorities require the reason for the cessation of the marketing of a Package Set)*
4. If known, enter the date when the Package Set is planned to be re-released back into the distribution chain by the MAH, in the “**Estimated Return to Market Date**” field.
- 5.

Modify Package Set Country Association	
Application Name:	Top Product - MAA - MR - AT
Application Code:	AT/H/000111
License Code:	BE123000
Product Detail Set Name:	TOPAMAX topiramate 25 mg Film-coated tablet
Package Set Name:	25 mg Film-coated tablet 60 count x 1 vial
Country:	Belgium
Currently marketed in this country?:	<input type="checkbox"/>
Additional License Number:	<input type="text"/>
Legal Status of Supply:	Prescription-Only <input type="button" value="v"/>
Marketed Date:	01-Mar-2017 <input type="button" value="c"/>
Marketing Cessation Date:	<input type="text"/> <input type="button" value="c"/>
Temporary Cessation Date:	09-Oct-2017 <input type="button" value="c"/>
Reason for Temporary Cessation:	Supply Chain Issue <input type="text"/>
Estimated Return to Market Date:	01-Jan-2018 <input type="button" value="c"/>
Restart Marketed Date:	<input type="text"/> <input type="button" value="c"/>
Registration-Package Set Country Keywords:	<input type="text"/>
Registration-Package Set Country Description:	<input type="text"/>
Registration-Package Set Country Comments:	<input type="text"/>

Interpretation of the Package Set information above.

The Package Set was launched (first released into the distribution chain by the MAH) on the 01-Mar-2017 as a Prescription Only pharmaceutical product. On the 09-Oct-2017 the Package Set “Temporarily” ceased to be marketed due to Supply Chain Issues. The estimated date for the Package Set to be re-released to the distribution chain is the 01-Jan-2018.

7.3 Restart of the Marketing of the Package Set.

When the date of the restart of the marketing of the Package Set is known, complete the Registration Package Set-Country entity as follows:

1. Check the “**Currently marketed in this country?**” check box (to indicate the Package Set is being released into the distribution chain).
2. Enter the date the Package Set was re-released into the distribution chain by the MAH, into the “**Restart Marketed Date**” field.

Modify Package Set Country Association	
Application Name:	Top Product - MAA - MR - AT
Application Code:	AT/H/000111
License Code:	BE123000
Product Detail Set Name:	TOPAMAX topiramate 25 mg Film-coated tablet
Package Set Name:	25 mg Film-coated tablet 60 count x 1 vial
Country:	Belgium
Currently marketed in this country?:	<input checked="" type="checkbox"/>
Additional License Number:	<input type="text"/>
Legal Status of Supply:	Prescription-Only
Marketed Date:	01-Mar-2017
Marketing Cessation Date:	<input type="text"/>
Temporary Cessation Date:	09-Oct-2017
Reason for Temporary Cessation:	Supply Chain Issue
Estimated Return to Market Date:	01-Jan-2018
Restart Marketed Date:	15-Jan-2018
Registration-Package Set Country Keywords:	<input type="text"/>
Registration-Package Set Country Description:	<input type="text"/>
Registration-Package Set Country Comments:	<input type="text"/>

Interpretation of the Package Set information above.

The Package Set was launched (first released into the distribution chain by the MAH) on the 01-Mar-2017 as a Prescription Only pharmaceutical product. On the 09-Oct-2017 the Package Set “Temporarily” ceased to be marketed due to Supply Chain Issues. The estimated date for the Package Set to be re-released to the distribution chain was the 01-Jan-2018 but was actually re-released on the 15-Jan-2018.

7.4 Subsequent Temporary Cessation of the Marketing of the Package Set

If the Package Set, once again is temporarily ceased from being released into the distribution chain and the date of the temporary cessation is known, complete the Registration Package Set-Country entity as follows:

1. Uncheck the “**Currently marketed in this country?**” check box (to indicate the Package Set is no longer being released into the distribution chain).
2. Enter the date when the Package Set ceased to be released into the distribution chain by the MAH by completing the “**Temporary Cessation Date**” field. *(note: This will overwrite the previous temporary cessation date).*
3. Enter the reason (if known) for the Temporary cessation in the free text “**Reason for Temporary Cessation**” field. *(note: This will overwrite the previous reason for the temporary cessation of the marketing).*
4. If known, enter the date when the Package Set is planned to be re-released back into the distribution chain by the MAH, in the “**Estimated Return to Market Date**” field. *(note: This will overwrite the previous planned return to market date).*
5. Reset the “**Restart Marketed Date**” field to null (no date). *(note: This will overwrite the previous restart marketed date).*

Modify Package Set Country Association	
Application Name:	Top Product - MAA - MR - AT
Application Code:	AT/H/000111
License Code:	BE123000
Product Detail Set Name:	TOPAMAX topiramate 25 mg Film-coated tablet
Package Set Name:	25 mg Film-coated tablet 60 count x 1 vial
Country:	Belgium
Currently marketed in this country?:	<input type="checkbox"/>
Additional License Number:	
Legal Status of Supply:	Prescription-Only
Marketed Date:	01-Mar-2017
Marketing Cessation Date:	
Temporary Cessation Date:	27-Mar-2018
Reason for Temporary Cessation:	Manufacturer Site delays
Estimated Return to Market Date:	04-Jul-2018
Restart Marketed Date:	
Registration-Package Set Country Keywords:	
Registration-Package Set Country Description:	
Registration-Package Set Country Comments:	

NOTE: The historical marketing information pertaining to the temporary cessation will be available via the audit trail (or captured and preserved in reports), current information will be displayed that will enable regulatory decisions to be made.

Interpretation of the Package Set information above.

The Package Set was launched (first released into the distribution chain by the MAH) on the 01-Mar-2017 as a Prescription Only pharmaceutical product. On the 27-Mar-2018 the Package Set “Temporarily” ceased to be marketed

due to Manufacturer Site Delays. The estimated date for the Package Set to be re-released to the distribution chain is the 04-Jul-2018.

Capture the restart of the marketing information as described in section 5.3 above.

7.5 Permanent Cessation of the Marketing of the Package Set (post temporary cessation).

If after the last temporary cessation and re-marketing of the Package Set, the company then decides to permanently cease to market the Package Set, complete the Registration Package Set-Country entity as follows:

1. Uncheck the “**Currently marketed in this country?**” check box (to indicate the Package Set is no longer being released into the distribution chain).
2. Enter the date when the Package Set permanently ceased to be released into the distribution chain by the MAH by completing the “**Marketing Cessation Date**” field.

Modify Package Set Country Association	
Application Name:	Top Product - MAA - MR - AT
Application Code:	AT/H/000111
License Code:	BE123000
Product Detail Set Name:	TOPAMAX topiramate 25 mg Film-coated tablet
Package Set Name:	25 mg Film-coated tablet 60 count x 1 vial
Country:	Belgium
Currently marketed in this country?:	<input type="checkbox"/>
Additional License Number:	<input type="text"/>
Legal Status of Supply:	Prescription-Only
Marketed Date:	01-Mar-2017
Marketing Cessation Date:	13-Nov-2018
Temporary Cessation Date:	27-Mar-2018
Reason for Temporary Cessation:	Manufacturer Site delays
Estimated Return to Market Date:	04-Jul-2018
Restart Marketed Date:	09-Jul-2018
Registration-Package Set Country Keywords:	<input type="text"/>
Registration-Package Set Country Description:	<input type="text"/>
Registration-Package Set Country Comments:	<input type="text"/>

Interpretation of the Package Set information above.

The Package Set was launched (first released into the distribution chain by the MAH) on the 01-Mar-2017 as a Prescription Only pharmaceutical product. On the 27-Mar-2018 the Package Set “Temporarily” ceased to be marketed due to Manufacturer Site delays. The estimated date for the Package Set to be re-released to the distribution chain was the 04-Jul-2018 but was actually re-released on the 09-Jul-2018. On the 13-Nov-2018 the Package Set permanently ceased to be marketed (released into the distribution chain).

7.6 Permanent Cessation of the Marketing of the Package Set (no prior temporary cessation of marketing)

If sometime after the initial launch, the company decides to no longer market the Package Set, complete the Registration Package Set-Country entity as follows:

1. Uncheck the “**Currently marketed in this country?**” check box (to indicate the Package Set is no longer being released into the distribution chain).

2. Enter the date when the Package Set permanently ceased to be released into the distribution chain by the MAH by completing the “**Marketing Cessation Date**” field.

Modify Package Set Country Association	
Application Name:	Top Product - MAA - MR - AT
Application Code:	AT/H/000111
License Code:	BE123000
Product Detail Set Name:	TOPAMAX topiramate 25 mg Film-coated tablet
Package Set Name:	25 mg Film-coated tablet 60 count x 1 vial
Country:	Belgium
Currently marketed in this country?:	<input type="checkbox"/>
Additional License Number:	<input type="text"/>
Legal Status of Supply:	Prescription-Only <input type="button" value="v"/>
Marketed Date:	01-Mar-2017 <input type="button" value="Add"/>
Marketing Cessation Date:	13-Nov-2018 <input type="button" value="Add"/>
Temporary Cessation Date:	<input type="text"/> <input type="button" value="Add"/>
Reason for Temporary Cessation:	<input type="text"/>
Estimated Return to Market Date:	<input type="text"/> <input type="button" value="Add"/>
Restart Marketed Date:	<input type="text"/> <input type="button" value="Add"/>
Registration-Package Set Country Keywords:	<input type="text"/>
Registration-Package Set Country Description:	<input type="text"/>
Registration-Package Set Country Comments:	<input type="text"/>

Interpretation of the Package Set information above.

The Package Set was launched (first released into the distribution chain by the MAH) on the 01-Mar-2017 as a Prescription Only pharmaceutical product. On the 13-Nov-2018 the Package Set “Permanently” ceased to be marketed.

7.7 Other Scenarios to Consider

7.7.1 MAH Transfer

After the initial launch and marketing of the Package Set, the company may decide to transfer the license to a third party. This is known as an MAH Transfer.

On the date the license gets transferred (note: the MAH on the Package Set registration entity does not change), complete the Registration Package Set-Country entity as follows:

1. Uncheck the “**Currently marketed in this country?**” check box (to indicate the Package Set is no longer being released into the distribution chain by the MAH that is on the Package Set Registration entity).
2. Enter the date when the Package Set permanently ceased to be released into the distribution chain by the MAH by completing the “**Marketing Cessation Date**” field. This is the date in which the license was transferred to the third party.

Modify Package Set Country Association	
Application Name:	Top Product - MAA - MR - AT
Application Code:	AT/H/000111
License Code:	BE123000
Product Detail Set Name:	TOPAMAX topiramate 25 mg Film-coated tablet
Package Set Name:	25 mg Film-coated tablet 60 count x 1 vial
Country:	Belgium
Currently marketed in this country?:	<input type="checkbox"/>
Additional License Number:	<input type="text"/>
Legal Status of Supply:	Prescription-Only <input type="button" value="v"/>
Marketed Date:	01-Mar-2017 <input type="button" value="c"/>
Marketing Cessation Date:	13-Nov-2018 <input type="button" value="c"/>
Temporary Cessation Date:	<input type="text"/>
Reason for Temporary Cessation:	<input type="text"/>
Estimated Return to Market Date:	<input type="text"/>
Restart Marketed Date:	<input type="text"/>
Registration-Package Set Country Keywords:	<input type="text"/>
Registration-Package Set Country Description:	<input type="text"/>
Registration-Package Set Country Comments:	<input type="text"/>

Interpretation of the Package Set information above.

The Package Set was launched (first released into the distribution chain by the MAH) on the 01-Mar-2017 as a Prescription Only pharmaceutical product. On the 13-Nov-2018 the Package Set “Permanently” ceased to be marketed by the MAH captured on the Package Set Registration entity due to the license being transferred to a third party.

7.7.2 License Withdrawal

Prior to the license associated with the Package Set being withdrawn, the marketing cessation date will be captured as outlined above (sections 5.5 or 5.6).

7.7.3 Withdrawal of Package Set from the License

Prior to the withdrawal of the Package Set from the license, where applicable, the marketing cessation date will be captured as outlined above (sections 5.5 or 5.6).

7.7.4 Package Set Recall

A Package Set “Recall”, implies that a Package Set is “physically” withdrawn from the market, i.e. removed from the shelf/pharmacies/ etc. As mentioned above, the Registration Package Set-Country entity in Calyx RIM for Registrations does not relate to whether the Package Set is “On the Market”/“On the Shelf”. It pertains to whether the Package Set is “actively” being released or not being released into the distribution chain by the MAH.

Therefore, in this situation, in parallel to the product recall, the Package Set will cease to be released into the distribution chain and this temporary/permanent cessation of the marketing of the Package Set can be captured in the Registration Package Set-Country entity as detailed in sections 5.2 to 5.6.