Best Practice: Named Patient Programme/ Import License

CALYX.AI

1 Best Practice 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-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, 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)
v7.0	30-Apr-2021	Update Best Practice for 7.0 - No Impact
N/A	18-Mar-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

2 Contents

3 Document Purpose

The purpose of this document is to provide a Best Practice guide for the management of the Named Patient Programme/Import License in Calyx RIM® Registrations Component.

3.1 Scope

This document only defines the set up and management of the following activity in Calyx RIM® Registrations Component.

1. Named Patient Programme
2. Import License

4 Data Administration Activities

4.1 Application Category

An Application Category = “Import License” must be created/available.

4.2 Application Type

Appropriate Application Type must be created/available that is aligned with the name of the activity for a country/region.

Example 1. Named Patient

Application Type = Named Patient
Name = Named Patient
Display Name = Named Patient
Entity XML Type Name = Default Application Type
Application Category = Import License
Countries = All applicable countries

Example 2. Import Application

Application Type = Import Application
Name = Import Application
Display Name = Import Application

Entity XML Type Name = Default Application Type

Application Category = Import License

Countries = All applicable countries

4.3 Legal Basis

For European Union markets there are new legal basis that may need to be assigned for Parallel Import:

Legal Basis Name: Parallel importation notified in accordance with Article 76(3) of Directive 2001/83/EC

Legal Basis Code: 14

Legal Basis Name: Parallel importation notified in accordance with Article 76(4) of Directive 2001/83/EC

Legal Basis Code: 15

4.4 Event Types and Secondary Event Types

Create as appropriate as per organisational needs.

5 General Considerations

Allows pharmaceutical companies to provide their “post approval/authorised” medicinal products to patients around the world where Medicinal Products are:

i. *Approved in one country but NOT approved in the patients’ home country*
ii. *Discontinued in the patients’ home country but still commercially available in another county*
iii. *In short supply in the patients’ home country but still readily available in another country.*

A prerequisite for the management of Named Patient information in Calyx RIM® Registrations Component is that the product of interest, MUST have an approved License in at least one country.

6 Best Practice

1. Create a Named Patient Application or Import Application for the country that will be applying to their HA to import product for medicinal needs on a Named Patient programme/Import License.
    a. Application Name: Follow organisation naming conventions (e.g. <Product Family Name> <CC> Named Patient).
    b. Application Type: Named Patient or Import Application
    c. Procedure Type: National.
    d. Reviewing Country: Select Country.
    e. Legal Basis: as applicable
    f. Product: Select Product
    g. Complete other fields as required by your organisation.

2. OPTIONAL: Create a Reference on the Named Patient Application or Import Application to link to the reference Approved Application that is associated with the Product for distribution.

3. Create an Event
    a. Event Name: Follow organisation naming convention (e.g. Application for License to import <IMP Name> on as Named Basis).
    b. Associate the Product
    c. Complete other fields as required by your organisation.
    d. Associate the Product PDS

4. Create a Sequence entity as required by your organisation to capture the submission of the application package for the import license on Named Patient programme. Create an Assembly as required by your organisation.

5. Update Event-Country Status as required by your organisation.

6. Upon receipt from the respective HA that the application has been approved/accepted:
    a. Create a Reference on the Event for the approval letter or equivalent as required by your organisation.
    b. Approve and Close the Event as required by your organisation.

7. OPTIONAL: Create a Registration record as required by your organisation. (Note: this is not a conventional authorisation, but the entity can be used to capture the additional HA details that are applicable to the Named Patient product).

8. If required, the Marketing status of the Named Patient Use Package Set can also be captured.