



CALYX™

Best Practice: Emergency Use Applications

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)
N/A	11-Oct-2021	New Best Practice

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3 Document Purpose

The purpose of this document is to provide a Best Practice guide for the management of the Emergency Use Applications in Calyx RIM Registrations Component.

3.1 Scope

This document only defines the set up and management of the Emergency Use Applications in Calyx RIM Registrations Component.

An **Emergency Use Authorisation** (EUA) allows for the temporary use of a medicine under specific conditions as long as emergency circumstances apply. The medicine however remains unlicensed and **cannot be put on the market**, contrary to a (conditional) marketing authorisation.

Whilst Emergency Use Authorisations are allowed under the EU pharmaceutical legislation, the use of a vaccine for which a Member State has issued such an authorisation is restricted to the authorising Member State only under its responsibility.

4 Data Administration Activities

4.1 Application Category

An Application Category = “Emergency Use” 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.

Application Type = Emergency Use

Name = Emergency Use

Display Name = Emergency Use

Entity XML Type Name = Default Application Type

Application Category = Emergency Use

Countries = All applicable countries

4.3 Legal Basis

For European Union markets there are new legal basis assigned for Emergency Use:

Legal Basis Name: Article 5(1) of Directive 2001/83/EC

Legal Basis Code: 12

Legal Basis Name: Article 5(2) of Directive 2001/83/EC

Legal Basis Code: 13

Legal Basis Name: Article 83(2) of Regulation (EC) No 726/2004

Legal Basis Code: 16

4.4 Event Types and Secondary Event Types

Create as appropriate as per organisational needs.

5 Best Practice

1. Create an Emergency Use Application for the country or region that will be applying to their Health Authority for approval for Emergency Use.
 - a. Reviewing Country: Select Country
 - b. Application Name: Follow organisation naming conventions (e.g. <Product Name + Dose Form(s)> <CC> Emergency Use)
 - c. Application Type: Emergency Use
 - d. Legal Basis: As Applicable
 - e. Procedure Type: National or EU CP as applicable
 - f. Product: Select Product
 - g. Complete other fields as required by your organisation
2. Create an Event
 - a. Event Name: Follow organisation naming convention (e.g. Emergency Use Application for <Product Name>)
 - b. Associate the Product
 - c. Complete other fields as required by your organisation
 - d. Associate the Product PDS
3. Create a Sequence entity as required by your organisation to capture the submission of the application package for the emergency use programme. Create an Assembly as required by your organisation.
4. Update Event-Country Status as required by your organisation.
5. 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.
6. 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 Emergency Use product).
7. If required, the Marketing status of the Emergency Use Package Set(s) can also be captured on a per country basis.