



BEST PRACTICE: NAMED PATIENT PROGRAM/IMPORT LICENSE

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
v7.3	01-Mar-2024	Update Best Practice for v7.3 – No Impact
v7.2	04-Apr-2023	Update Best Practice for v7.2 – No Impact
v7.1	13-Jan-2022	Update Best Practice for 7.1 - No Impact
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

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3 Document Purpose

The purpose of this document is to provide a Best Practice guide for the management of the Named Patient Program/Import License in Ennov InSight®.

4 Scope

This document only defines the set up and management of the following activity in Ennov InSight.

1. Named Patient Program
2. Import License

5 Data Administration Activities

5.1 Application Category

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

5.2 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

5.3 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

5.4 Event Types and Secondary Event Types

Create as appropriate as per organizational needs.

6 General Considerations

Named patient programs and import licenses allow pharmaceutical companies to provide their “post approval/authorized” medicinal products to patients around the world where Medicinal Products are:

- Approved in one country but NOT approved in the patients’ home country
- Discontinued in the patients’ home country but still commercially available in another country
- 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 Ennov InSight Registrations is that the product of interest must have an approved License in at least one country.

7 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 program/Import License.
 - a. **Application Name:** Follow organization 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:** <as appropriate>
 - e. **Legal Basis:** <as appropriate>
 - f. **Product:** <as appropriate>
 - g. Complete other fields as required by your organization.
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 organization 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 organization.
 - d. Associate the Product PDS.
4. Create a Sequence entity as required by your organization to capture the submission of the application package for the import license on Named Patient program. Create an Assembly as required by your organization.
5. Update Event-Country Status as required by your organization.
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 organization.
 - b. Approve and Close the Event as required by your organization.
2. OPTIONAL: Create a Registration record as required by your organization. (Note: this is not a conventional authorization, but the entity can be used to capture the additional HA details that are applicable to the Named Patient product).
3. If required, the Marketing status of the Named Patient Use Package Set can also be captured