

Insife

How to configure a product

Version 1.0, For HALOPV 5.0



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About Medicinal Products

- Medicinal products are substances that are used to treat diseases, to relieve complaints, or to prevent such diseases or complaints in the first place.
- In addition to their benefits, medicinal products may also have side effects, some of which may be undesirable and / or unexpected. Hence, activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem are crucial.
- All medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorized for use.

Prerequisite

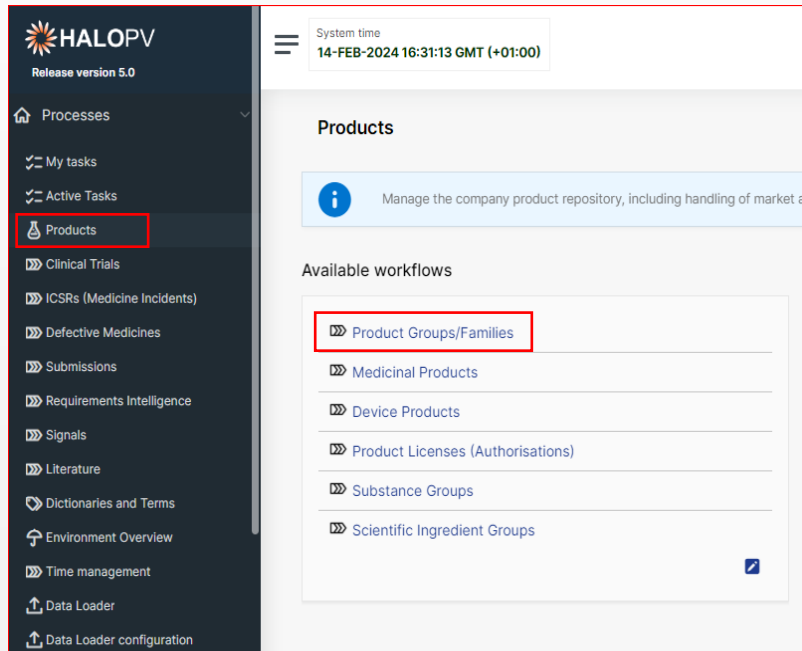
To be able to configure a product in HALOPV, you need to have access to:

- Product Module
- Product processor role
 - Please reach to HALOPV Support to configure this form at your instance.

Setting up Product Group/Families

On the left navigation pane 'Processes', Products:

- Select Product Groups/Families
- Click on 'Create from Wizard'. Enter the details for the record and click on Create.



Product Group/ Families - Grid

User can review an existing product family/group by selecting/ clicking on the 'Product Groups/Families Records' workflow.

- The top section of the page reflects the selected workflow and process and Workflow description.
- The next section provides checkboxes to filter records on the worklist:
 - Completed records?: list the records that are in completed state (all steps of the workflow have been completed)
 - In workflow records?: lists records that are in progress or at some workflow state within a defined workflow
 - Nullified records?: lists records that are nullified
 - Assigned to others?: lists records assigned to other users

Products / Product Groups/Families Records

Process and workflow description
Product families are a common denominator for grouping medicinal products.
→ Create/Update Product Group/Family → Update the Product Index

30
Records open v. completed

Completed records? In workflow records? Nullified records? Assigned to others?

Create from Wizard Batch Auto-assign

Records (Products families)

Go Rows 50 Actions

Row text contains 'family'

1 - 3 of 3

Record ID	Product Groups	Assigned to	Overall due date	Last updated	Priority	Keywords	Current Task	Assignment Date
FAM-32492755	Test Product Family 01	-		-	4	-	Create/Update Product Group/Family	-
FAM-32492770	Product Family A	-		-	4	-	Create/Update Product Group/Family	-
FAM-6406308	HALO Product Family Test	-		18-DEC-2023 07:00AM	4	-	-	-

Product Group/ Families - Details

Once the product family is created, the system navigates to the view/edit record page.

- Click on 'Product Family details' form to select the Product Type, Name Variation type and the source for the family
- Click on save to save the form.
- Click on Return to return to the view/edit record page
- User can change the family/product group name by clicking on the title. It opens a basic information page, the user can edit the name and save.
- Click on 'Create new Product' under Links/other activities
- On the create related record page, select Relation type and Workflow. Click on 'Create and open'.
- Click on Return to return to the view/edit record page.

View/edit record

Create/Update Product Group/Family → Update the Product Index

Pending actions

Product Family 01 (FAM-32492773) (Revision 1) Product Groups/Families

Task instructions
Create a new / Update an existing Product family record. Product Families are the top level of the product hierarchy (Family > Product > License)

Task activities (red status means mandatory)

Data forms	Status	Links / other activities
Product Family details	1	Create new Product

Links / other activities
Create new Product

About

Priority: Set priority

Role to process task: Generic product management

Assigned user: Assign user | Assign to me | Auto-assign

Tags

Description

Description

Medicinal product - Details

On the view/edit record page for Product Family:

- User can change the family/product group name by clicking on the title. It opens a basic information page, the user can edit the name and save.
- Click on 'Medicinal Product Details' to add information for the product.

View/edit record

→ Create/Update Product → Update Product Index for Medicinal Products

Pending actions

Medicinal Products - Test Product Family 01 (PRDINT-32492777) - [Select type] (Revision 1) Medicinal Products

Task instructions
Enter relevant information pertaining to the product attributes

About
Priority: Set priority
Role to process task: Generic product management
Tags

Add Related record

Task activities (red status means mandatory)

Data forms	Status	Links / other activities
Medicinal Product Details	!	Create new Product License Associate Product Family Product Index for Medicinal Product

Description

Description

Medicinal product – Product Details

On the medicinal product details form, user shall be able to enter the following information:

- Product Short Name
- Product Generic Name
- Other Descriptive Name
- Select Product Type
- Select Master Location File
- Select Country
- Select Language Code
- Jurisdiction
- Comments
- Select Special Measures, Pediatric Use, Additional Monitoring, Suppress Coding
- IDMP Information
- ATC Codes
- Organization Information

Note : The name of the Medicinal Product has to be unique. For e.g. you can name a product “Aspirin - 500 mg - Tablet” and another one “Aspirin - 250 mg – Capsule.

The screenshot displays a web application window titled "Medicinal Product Details" for "Test Product Family 01". The interface includes a navigation bar with tabs for "Product Details", "Package(s)", "Pharmaceutical Product(s)", "Product Names", "Public Identifiers (MPIDs)", and "Product Index". The main content area is divided into several sections:

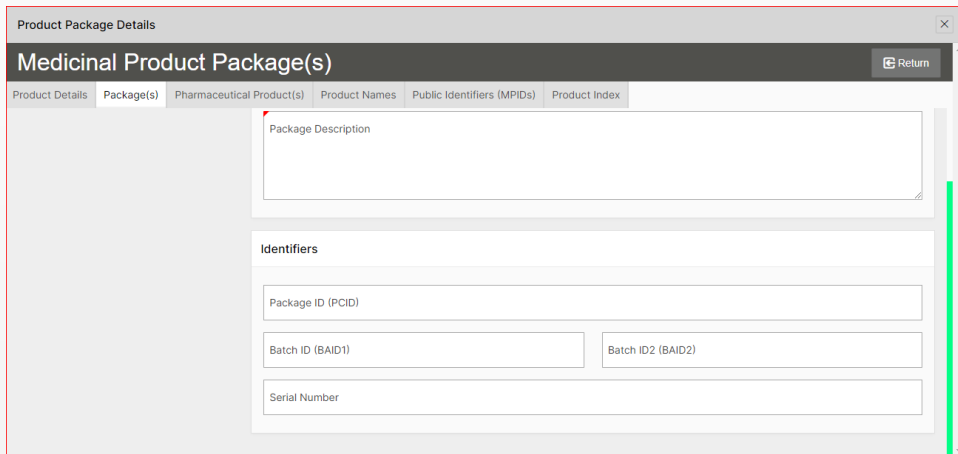
- Medicinal Product Details:** Contains fields for "Full Presentation Name" (filled with "Medicinal Products - Test Product Family 01"), "Halo Code", "Medicinal Product Description", "Product Short Name" (filled with "Azax"), "Product Generic Name" (filled with "AZ"), "Other Descriptive Name" (filled with "Azax-T"), "Product Type" (dropdown menu set to "Medicinal Product / Drug"), and "Master File Location".
- Organization information:** Contains fields for "Product Company Name (freetext)" (filled with "ABC Company"), "Marketing Authorization Holder (selected)" (dropdown menu set to "ABC Pharma Norway"), "Date of most recent update to Summary Product Characteristics" (calendar icon), and "Effective Date" (calendar icon).

A green checkmark icon is visible in the top right corner of the form area, indicating successful data entry or validation.

Setting up Medicinal product – Package(s)

On the medicinal product details form, user shall be able to enter the following information:

- Package Description
- Identifier Information (Package ID, Batch ID etc)



The screenshot displays a web application window titled "Product Package Details" with a sub-header "Medicinal Product Package(s)". The interface includes a navigation menu with tabs for "Product Details", "Package(s)", "Pharmaceutical Product(s)", "Product Names", "Public Identifiers (MPIDs)", and "Product Index". The main content area is divided into two sections: "Package Description" with a large text input field, and "Identifiers" with four input fields: "Package ID (PCID)", "Batch ID (BAID1)", "Batch ID2 (BAID2)", and "Serial Number". A "Return" button is located in the top right corner of the form area.

Setting up Medicinal product – Pharmaceutical Product(s)

On the medicinal product details form, user shall be able to enter the following information:

- Pharmaceutical Product Description
- Ingredients
- Route of Administration

The screenshot displays a web application interface for managing pharmaceutical products. The main title is "Pharmaceutical Product(s)" with a "Return" button. Below the title are tabs for "Product Details", "Package(s)", "Pharmaceutical Product(s)", "Product Names", "Public Identifiers (MPIDs)", and "Product Index". The "Pharmaceutical Product(s)" tab is active, showing a list of products with a "+" icon and a green checkmark. The product ID "PHP23428211" is visible. The main form area contains three sections: "Pharmaceutical product description" with a dropdown for "Pharmaceutical form" and a text field for "Unit Of Presentation"; "Ingredient(s) List" with an "Add" button; and "Route(s) of Administration List". At the bottom, there are buttons for "Actions", "Edit", "Save", and "Add Row".

Setting up Medicinal product – Product Names

On the medicinal product details form, user shall be able to enter the following information:

- Source and Name Variation for Products

Source	Name Variation	Language Code
A Comprehensive Chinese-Latin-English Dictionary of the Nam...	Paracetamol	EN
AEMPS - Agencia Espanola de Medicamentos y Productos Sanil...	Crocin	EN

Setting up Medicinal product – Public Identifiers (MPIDs)

On the medicinal product details form, user shall be able to enter the following information:

- Source and MPIDs for Products

<input checked="" type="checkbox"/>	Source	Medicinal Product Identifier (MPID)
<input checked="" type="checkbox"/>	AGES - Oesterreichische Agentur für Gesundheit und Ernährungssicherheit GmbH	12345

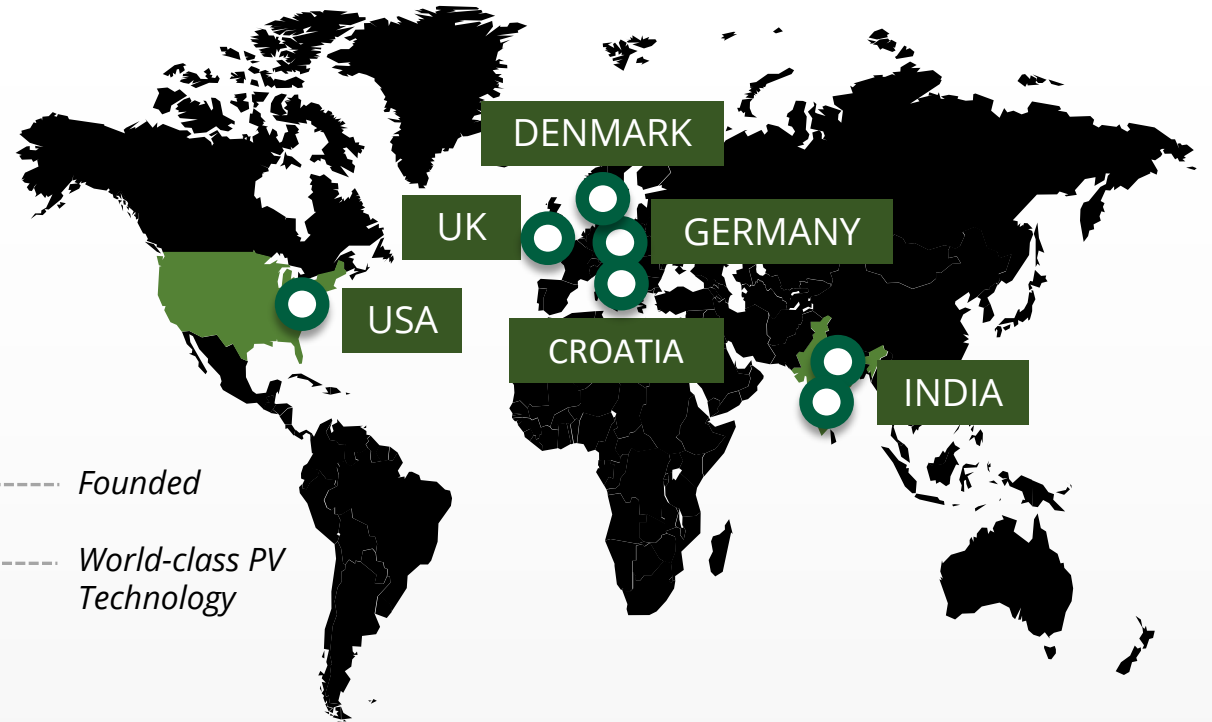
About Insife

Game-changing drug safety **technology** and consulting

Insife are supporting our clients with best-in-class technology and domain expertise from our global footprint

Insife consists of approx. 100 PV FTEs across the world, making us the biggest Europe-based company of its kind

We are ISO 9001, ISO 27001, ISO 14001 and GDPR certified



2017 ----- *Founded*

2023 ----- *World-class PV Technology*

Who are using our technologies?

5

Tier-1 Pharma companies

2

Tier-1 Regulatory Agencies

20+

SME pharma /biotechs

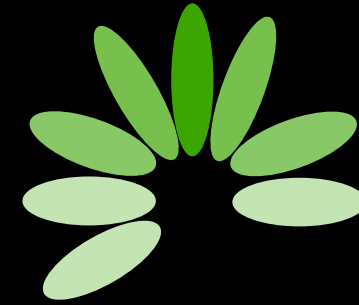


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Contact us at hello@insife.com