

# Qinecsa **HaloPV Products Module**

For HaloPV 6.0 and above

Guiding Slides on **HaloPV** Products  
Module

# Introduction to HaloPV



- › **Access to HaloPV**
- › **General Overview**
  - › Main Menu
  - › Home Page
- › **Products Module Overview**
  - › Overview
  - › Workflows
  - › Functionality menu
- › **Product Forms**
  - › Product Forms

# General Overview: List of HaloPV Modules



**Products**



**Clinical Trials**



**Organizational  
Entities**



**Case Intake and  
Processing**



**Defective  
Medicines**



**Device Vigilance**



**Literature**



**Signals**



**Risks**



**Dictionaries**



**Aggregate Reporting**



**Term Collections**



**PSMF**



**Regulatory Intelligence**



**Data Collection Programs**



**Quality**



**Agreements**




**Submissions**



**Data Mart**

# Accessing HaloPV using credentials or SSO

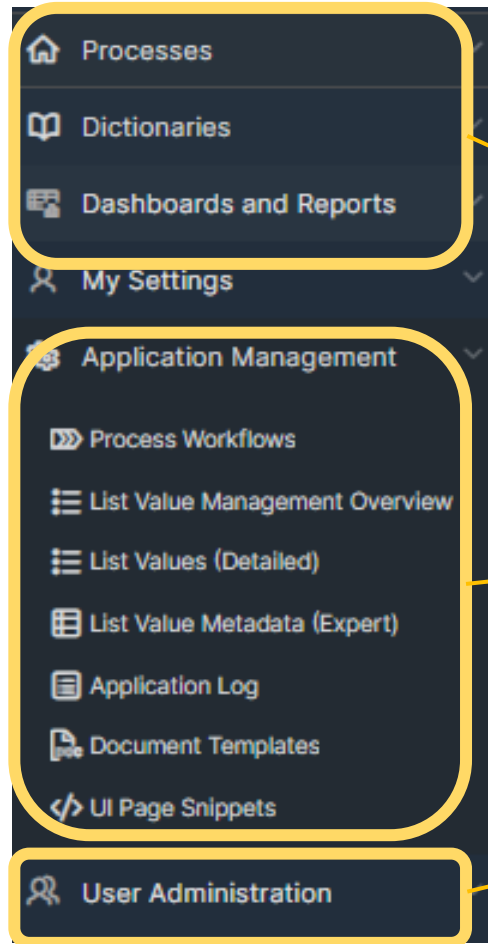
The image shows a login interface for 'HALO DEV'. At the top, the text 'HALO DEV' is displayed in a grey header. Below this is a decorative graphic with orange and dark blue abstract shapes. Underneath the graphic are two input fields: the first is labeled 'username' with a person icon, and the second is labeled 'password' with a key icon. At the bottom of the form are two green buttons: 'Single-sign-on with Azure AD' with a circular arrow icon, and 'Log In'.

Use login details below to access HaloPV.

## [Login Page](#)

- As a HaloPV normal user, please access the application by either using your user credentials or by clicking the **Single sign-on with Azure AD** button.
- If you have access but not an Azure account, enter your username and password and click the **Log In** button.

# General Overview – Main Menu



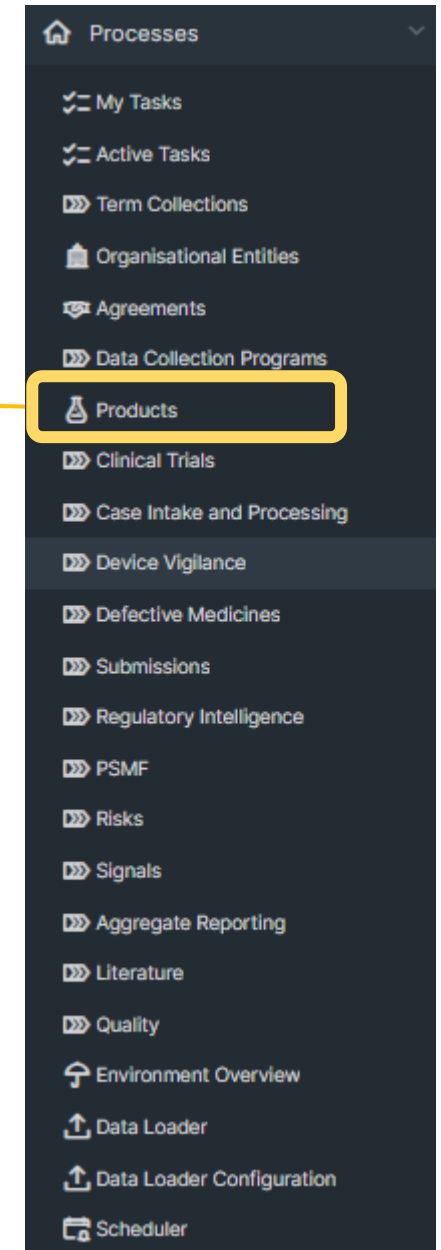
In the left pane, you will find the section **Processes** (This section lists all **Modules** available to a HaloPV user), **Dictionaries** (contains standard and custom dictionaries) and **Dashboards and Reports** (gives access to HaloPV dashboards and application reports).

**Products** is one of the modules of HaloPV.

**Note:** depending on user role, other links may be available

The **Application management** role gives access to the **Application management process**. In this section the user can update workflow configuration, list of values, document templates – including access to the general application log.

The **User Admin** role gives access to the **User administration process**. In this section users can be created/updated, and roles updated.



**Note:** For details on HaloPV common features available for each workflow, records and worklist please refer to “**User Guide - Introduction and Main Features HaloPV**”.

# General Overview - Home Page

The screenshot displays the HaloPV Home Page interface. On the left is a dark sidebar with a navigation menu including: Processes, My Tasks, Active Tasks, Term Collections, Entities, Agreements, Data Collection Programs, Products, Clinical Trials, Case Intake and Processing, Device Incidents Processing, Submissions, Requirements Intelligence, PSMF, Signals, Aggregate Reporting, Environment Overview, Data Loader, Data Loader Configuration, Scheduler, Dictionaries, Dashboards and Reports, My Settings, Application Management, and User Administration. The main content area features several widgets: a top header with the HaloPV logo, system time (19-FEB-2025 05:27:14 GMT (+00:00)), and environment (HALO); a 'Welcome back' message; a 'My organization' widget showing 'Insile Test Root'; an 'Entity information' widget with fields for Entity ID (2) and Entity Name (Insile Test Root), and a 'Switch Entity' button; a 'Quick Search' bar; a 'User menu' with options like 'My tasks', 'Help Center', and 'Log out'; an 'Individual task ribbon' showing task counts (e.g., 'My open assigned tasks: 11'); a 'Quick Links' section with links like 'Need support for HALO PV?', 'Training', and 'ICSR Handling and submission tracking'; and an 'Open Record' section with a 'Master ID' field (123456). Callouts with yellow boxes and arrows point to these specific features, providing additional context.

**Callouts:**

- HaloPV version System time and Environment**: Points to the top header area.
- Quick Search**: Points to the search bar.
- Your username**: Points to the user profile in the top right.
- User menu**: Points to the dropdown menu in the top right.
- Entity information**: Points to the widget showing Entity ID and Name.
- My organization**: Points to the widget showing the current organization.
- Individual task ribbon**: Points to the section showing task counts.
- Quick Links**: Points to the section with various utility links.
- Processing compliance widget**: Points to the 'Open Record' section.
- Record Id Search**: Points to the 'Master ID' field.
- Add more Widgets on home screen**: Points to the 'Add another widget' button.

**Note:** For details on HaloPV common features available for each workflow, records and worklist please refer to “User Guide - Introduction and Main Features HaloPV”.

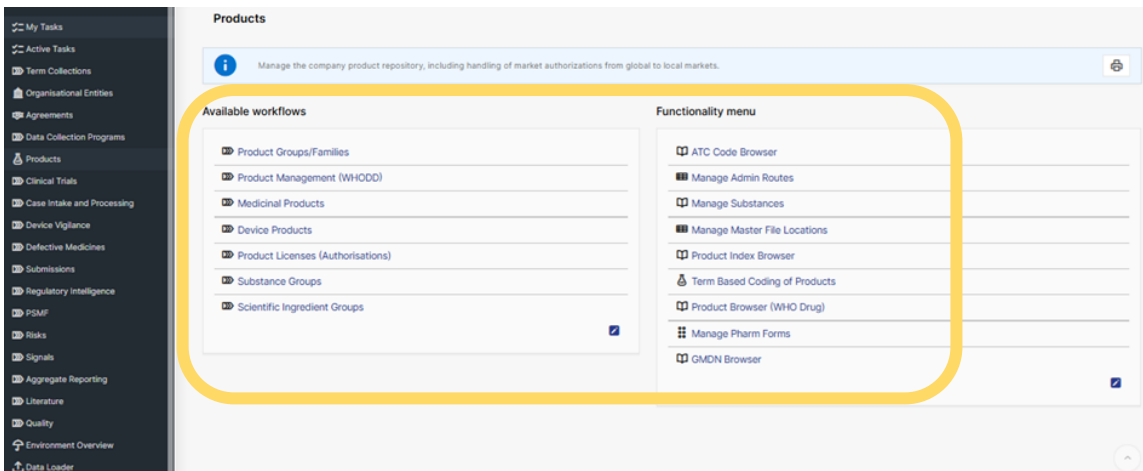
# Abbreviations

Abbreviation	Definition/Expansion
<b>Admin Route (ADM) / Route of Administration (RoA)</b>	How a medicine is administered to the body. e.g., Orally, Rectally.
<b>Anatomical Therapeutic Classification (ATC)</b>	A taxonomy of expert codes used to describe the system/area in the body which a medicine targets.
<b>Coding</b>	The process of matching a reported term (Product / Substance / Device) to a known item in the dictionary.
<b>Devices</b>	A Medical Device which often has a medicinal counterpart. e.g., An inhaler, a syringe.
<b>DEVIDs</b>	Device IDs
<b>Formulation</b>	A combination of Ingredients.
<b>IBD</b>	International Birth Date (IBD) refers to the date when a pharmaceutical company first receives marketing authorization for a medicinal product in any country worldwide.
<b>IDMP</b>	Identification of Medicinal Products: A set of international standards developed to uniquely identify medicinal products across different regulatory agencies. It ensures consistency in drug information, helping with pharmacovigilance and global drug safety.
<b>Ingredient (ING)</b>	A Substance when it is referenced by a Product.
<b>License</b>	Authority given to sell a medicinal product in a given jurisdiction and is usually granted by the NCA.
<b>Marketing Authorisation Holder (MAH)</b>	The company or organisation which holds the license.
<b>Medicinal Product (MP)</b>	A drug as packaged, with branding. It may contain multiple Pharmaceutical Products.
<b>Medicinal Product Dictionary (MPD)</b>	The whole dictionary of Medicinal Products, containing details of the pharmaceutical products and substances which comprise each medicinal product. It includes all related master data sets such as ADMs, PHF, ATCs, MFLs, Sources, etc.
<b>Medicinal Product Group / Family</b>	A user-defined Group or Family of Products, with a custom name. e.g., Lemsip, which may comprise of 30 different Medicinal Products, having different ingredients/strengths/flavours, etc., but typically belong to one brand and/or company or have a common active ingredient (e.g. Paracetamol).

Abbreviation	Definition/Expansion
<b>MFL</b>	Master Facility Lists: Comprehensive databases listing healthcare facilities, aiding in health management and planning.
<b>Misspelling</b>	A Misspelling is an unofficial name of a Product or Substance. Used to handle commonly misreported terms avoiding manual intervention.
<b>NDA</b>	New Drug Application: This is the formal request submitted to regulatory agencies (like the FDA in the U.S.) to approve a new pharmaceutical drug for sale and marketing. It includes data on the drug's safety, efficacy, and manufacturing process.
<b>Non-Proprietary Combination Generic (NPCG).</b>	An MHRA-specific term for a Scientific Ingredient Group.
<b>Pharmaceutical Form (PHF) / Dosage Form</b>	This is the format of the medicine as it is packaged. E.g. a Capsule, a Tablet, a Suppository, etc.
<b>Pharmaceutical Product (PP)</b>	A Pharmaceutical Product is a distinct drug packaged inside a Medicinal Product. It comprises a formulation (set of ingredients) and a Pharmaceutical Form.
<b>Preferred Name (PN)</b>	The Preferred Name of a Substance or Product is the primary name declared in its definition. Preferred Names should be unique across the Product Dictionary.
<b>Product Brand Group (PBG)</b>	An MHRA-specific term for a Medicinal Product Group / Family
<b>Product Index (PI)</b>	The Product Index is a table of distinct terms derived from or like the name of the medicinal product which is built in advance, so that reported drug names can be matched against it. A single record in the Product Index can represent multiple Medicinal Products, Pharmaceutical Products, Scientific Products or Devices.
<b>Scientific Ingredient Group (SIG)</b>	A user-defined formulation, or set of ingredients, with a custom name. e.g., Cocodamol represents Paracetamol, and Codeine in combination.
<b>Scientific Product (SP)</b>	A Scientific Product (SP) represents a distinct formulation (combination of substances), each with a defined quantity (strength). The SP also has a single Pharmaceutical Form.



# HaloPV - Products Module



The **HaloPV Products module** facilitates efficient management of products based on families, individual items, and licenses. It enables capturing detailed information related to pharmaceutical products and devices, such as substances, NDA codes, and IBD. Products can be entered using the IDMP structure, including Medicinal Product, Pharmaceutical Product, Device, Ingredients, and Substances. Additionally, it can create a Product Index and synonym mapping for coding and linking reported names to actual products.

Key features:

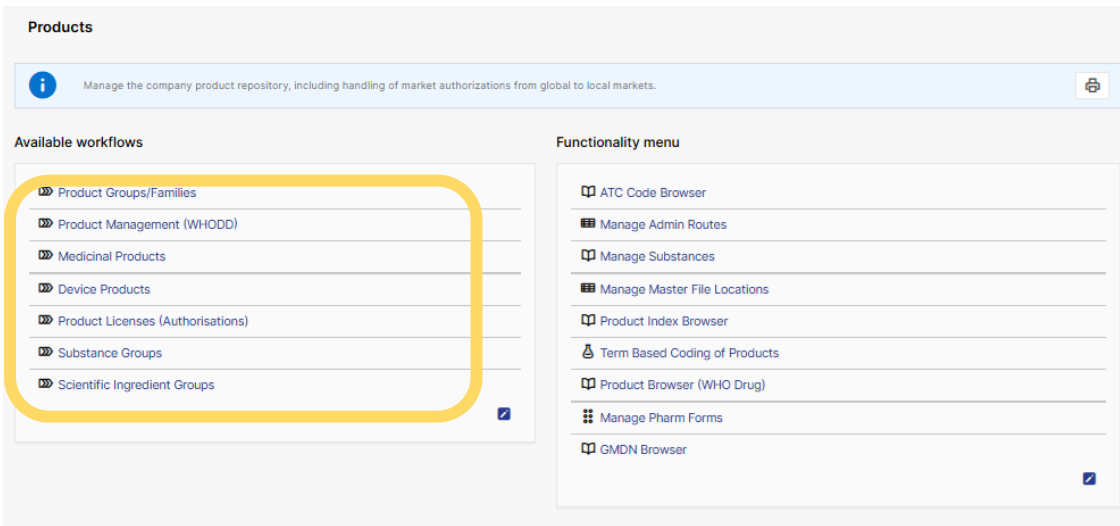
- › Standalone functionality or integration with systems like RIMS (Regulatory Information Management System) or safety databases.
- › Links seamlessly with other modules for comprehensive product information and populates Annex H in the PSMF module.
- › Advanced APIs allow rich import/export capabilities, along with compatibility for xEVMPD/EU Article 57 standards.
- › Ensures compliance with GxP validation requirements and offers cloud readiness.

Integrated resources include EDQM and reference dictionaries for Substances, Admin Routes, Pharmaceutical Forms, Sources/References, and ATC Codes. The module supports real-time index generation and event-driven coding updates for dynamic functionality.

HaloPV is a one stop application that truly assists PV science professionals with aspects of PV data management.

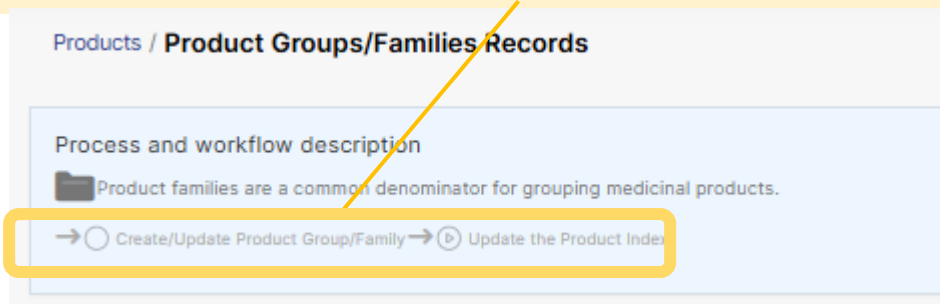


# HaloPV - Products Module - Workflows



The workflows typically comes with steps for record creation with manual entry of required data and an automated step to update the product index (names may vary).

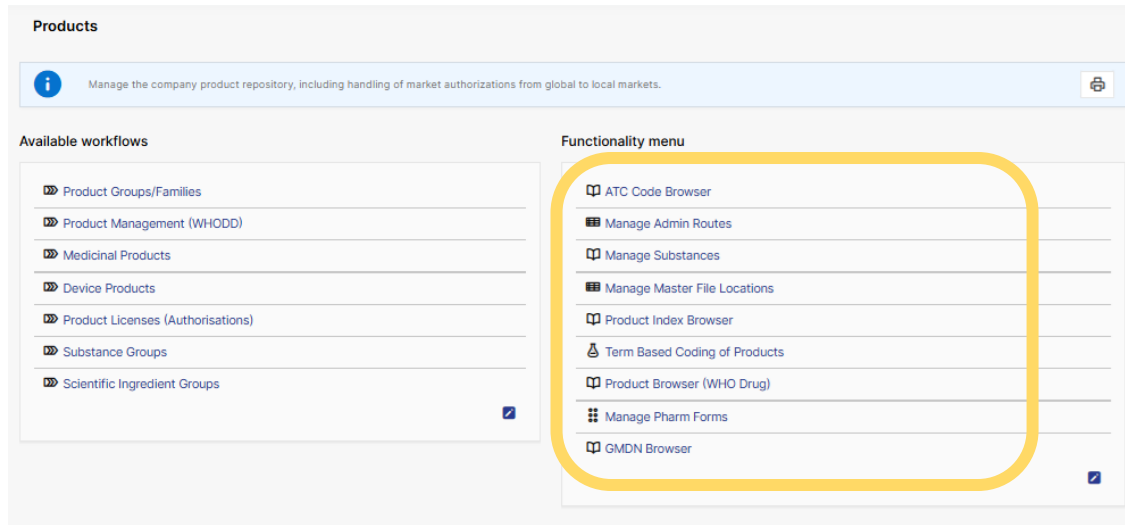
If required, the new workflow steps can be configured to configure specific processes also each step can be configured to be accessed by a different user role.



- > **Product Groups/Families** - Product families are a common denominator for grouping medicinal products.
- > **Products Management (WHODrug)** - WHO Drug products (access might be restricted to HaloPV). The complete dictionary of Medicinal Products, comprising of Pharmaceutical Products, Ingredients (which reference Substances), includes all related entities such as Admin Routes, Pharm Forms, ATCs, MFLs, Sources, etc.
- > **Medicinal Products** – Allows entry and maintenance of product details at a Medicinal Product level.
- > **Device Products** - Allows entry and maintenance of device details.
- > **Product License (Authorisations)** - Allows entry and maintenance of product details at the product license level.
- > **Substance Groups** – Allows grouping of substances.
- > **Scientific Ingredient Groups** - Scientific Ingredient Groups are collections of ingredients in one or more medicinal products.

The Product Index is a catalog of all possible name variations for Medicinal Products and Devices whose data structures are based on ISO IDMP. Use of PI will be covered in the following slides.

# HaloPV - Products Module – functionality menu



HaloPV Products module functionality menu includes links to various browsers.

- **ATC code browser** – Allows users to search in the classification system 'Anatomical Therapeutic Chemical (ATC)' entries updated in your HaloPV - WHO Drug Dictionary
- **Manage Admin Routes** – Manage or add new entries to your HaloPV list of routes of administration, e.g., EDQMs and local codes.
- **Manage Substances** – Allows users to search the HaloPV Substance Browser using the substance name, type, preferred name, language code, variation type, etc.
- **Manage Master File Locations** – Allows user to manage/configure locations for the MFL (Maser File Location)
- **Product Index Browser** – Product Index is a catalog of all possible name variations. A Medicinal Product has many possible reportable names. A name variation can apply to many Medicinal Products.
- **Term based coding of products** – Allows users to review the cording of the reported drugs, e.g., reported product terms, reported substance terms, reported device terms, products or substances misspellings, and MedDRA synonyms.
- **Product Browser (WHO Drug)** – Allows user to browse WHO Drug Dictionary.
- **Manage Pharm Forms** – Manage/edit the HaloPV list of Pharmaceutical Dosage forms.
- **GMDN Browser** – Browse international naming and grouping conventions for medical devices.

# Record Worklist –

## Common Feature

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

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

Show Last  
Last 90 Days

Records (Products families)

Go Rows 50 Actions

☒ Product Groups = ANR

Record ID	Product Groups	Assigned to	Overall due date	Last updated	Priority	Keywords	Current Task	Assignment Date
M-34834488	ANR	-		08-APR-2025 10:27AM	4	-	Create/Update Product Group/Family	-

### Actions available for all workflow worklists

- **Batch** allows the user to batch update multiple records. It is possible to perform batch actions, such as re-assignment of the records, changing record priority, changing workflow status (routing), and addition/ removal of tags from records.
- **Auto-assign** can be triggered either on a record level (assigning individual records) or on a workflow level (running on all records in the workflow) – this requires the Workflow Manager role. If no limit is provided, the system limits to 50 cases per user.
- **Create from Wizard** can be used to create a new record in a workflow.
- **Refresh and Print**

The records list is an **Interactive Record list**. As with all Interactive Reports in HaloPV, several actions can be performed. For e.g.

- Add or remove columns from the list
- Apply filters
- Go to a record directly by clicking on Record ID/Title

**Note:** For details on HaloPV common features available for each workflow, records and worklist please refer to “User Guide - Introduction and Main Features HaloPV”.

# Products Records page –

## View/ Edit record

The screenshot displays the 'View/edit record' interface for a Medicinal Product. The top navigation bar includes a breadcrumb trail: 'Create/Update Medicinal Product' → 'Update Product index for Medicinal Products'. Below this, a 'Complete task' button is visible. The main content area is divided into several sections:

- Task instructions:** Enter relevant information pertaining to the product attributes.
- About:** Fields for Record ID (34834489), Organization (Insife Test Root), Priority (Set priority), Role to process task (Product Module), Task due (Add date), Workflow due (Add date), and Tags.
- Task activities (red status means mandatory):** A table showing the current task 'Medicinal Product Details' with a green status icon.
- Data forms:** A section for entering product details, including Description, Notes and linking, Reason for Nullification, and URL.
- Links / other activities:** A list of actions: 'Create new Product License', 'Associate Product Family', and 'Product Index for Medicinal Product'.
- Related Records:** A table at the bottom showing a list of related records.

The 'Related Records' table is an interactive report with the following data:

Title	Type	Workflow	Organization	Status	Territory	Reporting destination	Link Type	Reason	Created By	Related Record Created	Assigned To
Product Licenses (Authorisations) - Medicinal Products - ANR (34834491)	Spontaneous - Drug	Product Licenses (Authorisations)	Insife Test Root	COMPLETED	United States of America (the) (US)		ICSR parent-child case		AKULA.NAGARAN@INSIFE.COM	31-DEC-2024 07:12AM	
ANR - (Parent) (34834488)		Product Groups/Families	Insife Test Root	Create/Update Product Group/Family			Linked record		ALOK.KUSHWAH@INSIFE.COM	08-APR-2025 07:11AM	

### Actions available for all records -

- Open in new Window – can be used to open records in a new browser window
- Refresh
- Print
- Copy Record ID to Paste Buffer
- Notification(s)
- Attachment(s)
- Save Record
- Return – To return to view edit record page.
- Close Record
- More Menu

**Data Forms** displays links to the available Data Forms for the current workflow step.

- Click on the link to open the respective form where data can be entered, edited or reviewed.

**Links/other** activities allows the user to perform other actions relevant to the record depending on the workflow and workflow step the record is currently in.

The **Related Records** list is an **Interactive Report**. It displays the list of related records linked to the record currently being viewed, their workflow and Link Type along with other details.

**Note:** For details on HaloPV common features available at HaloPV for each workflow, records and worklist please refer to “User Guide - Introduction and Main Features HaloPV”.

# HaloPV – Product Management

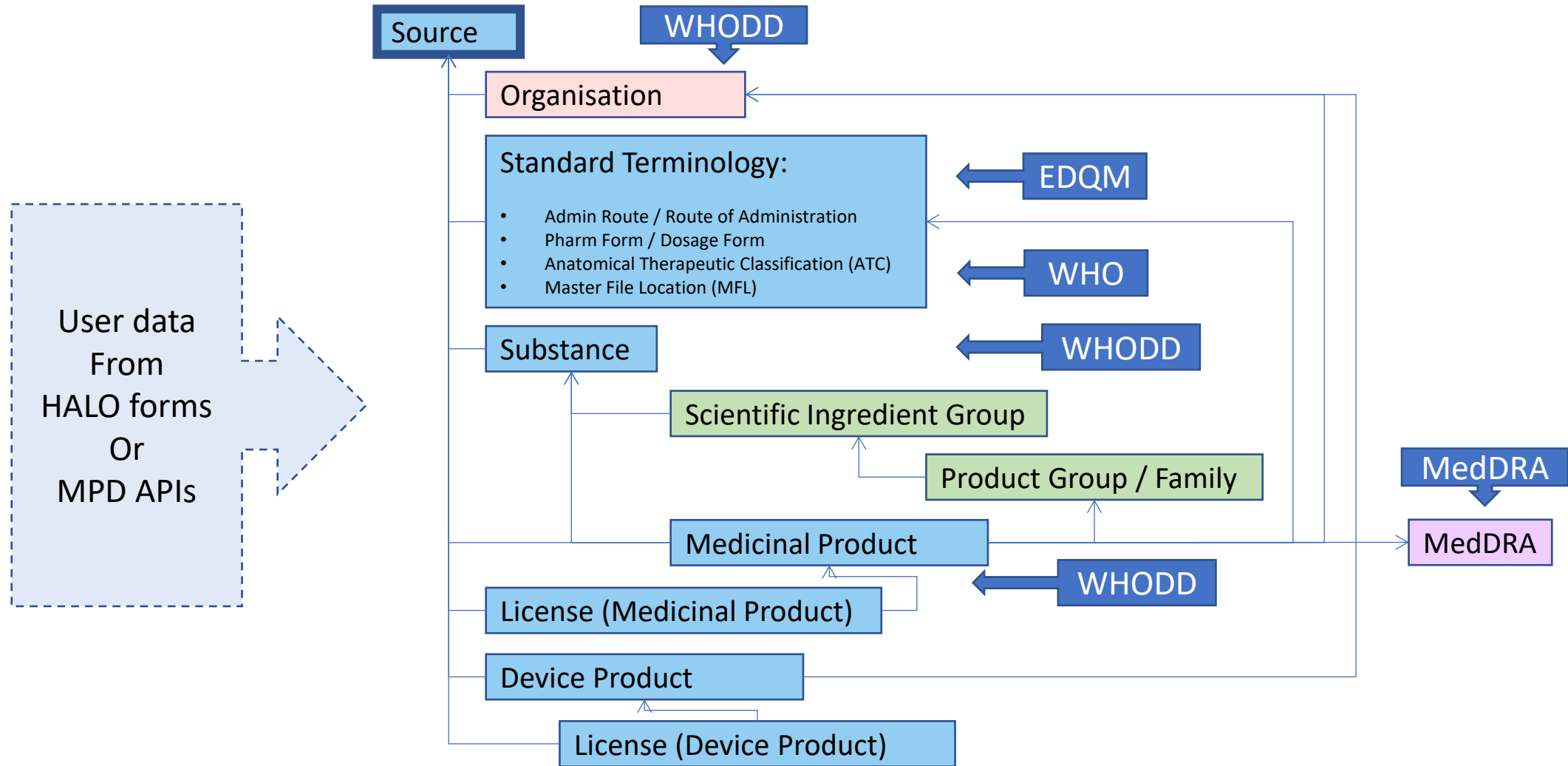
## Glossary

- **Sources** - A source represents an informational authority, such as a pharmacopeia. HaloPV comes with a pre-defined list of sources imported from the WHO Drug Dictionary. When integrating with multiple satellite systems, source is an essential attribute to distinguish two records from different systems whose IDs coincide. Hence, 'Source' pairs well with the SENDER\_LOCAL\_CODE attribute in HaloPV – indeed, both fields should always be used together for any integration development.
- **Organizations** – Organizations are Entities; for example, a Marketing Authorisation Holder (MAH) or National Competent Authority (NCA). The list of Organisations available for selection can be added and managed in the **Entities Module**.
- **Routes of Administration / Admin Routes** - Admin Routes represent the different ways a Medicinal Product may be administered (e.g., Oral, subcutaneously). The Admin Routes available in HaloPV come from EDQM. However, Investigational Medicinal Products may refer to developmental or proposed Admin Routes which have not yet been adopted into the standard EDQM list.
- **Pharmaceutical Forms / Dosage Forms** – Pharmaceutical Forms represent the different formats a Medicinal Product may be packaged as or administered as (e.g., Tablet, Solution for Injection). The Admin Routes available in HaloPV come from EDQM. However, Investigational Medicinal Products may refer to developmental or proposed Pharmaceutical Forms which have not yet been adopted into the standard EDQM list.
- **Anatomical Therapeutic Classifications (ATCs)** - ATCs are a coding system used to classify the therapeutic areas a Medicinal Product may target (e.g., Endocrine). The ATC code list available in HaloPV is the standard list of ATCs provided by the WHO/ UMC.
- **Substances** - Substances list is used to define a product's ingredients. Substance variants are an optional subtype of Substances, typically related to another substance by virtue of active moiety or an added salt. A substance and its variants typically belong to the same Substance Group. For example, "Ibuprofen" and "Ibuprofen Sodium" are independent substances in the same Substance Group. The substance list available in HaloPV comes from the WHO DD which is updated annually.
- **Product Index** is a catalogue of all possible name variations for Medicinal Products and Devices whose data structures are based on ISO IDMP.

**Note:** For details on HaloPV Dictionary management and Drug/Product Coding, please refer to respective guides (on demand)

# HaloPV – Product Management

## Dependency Map

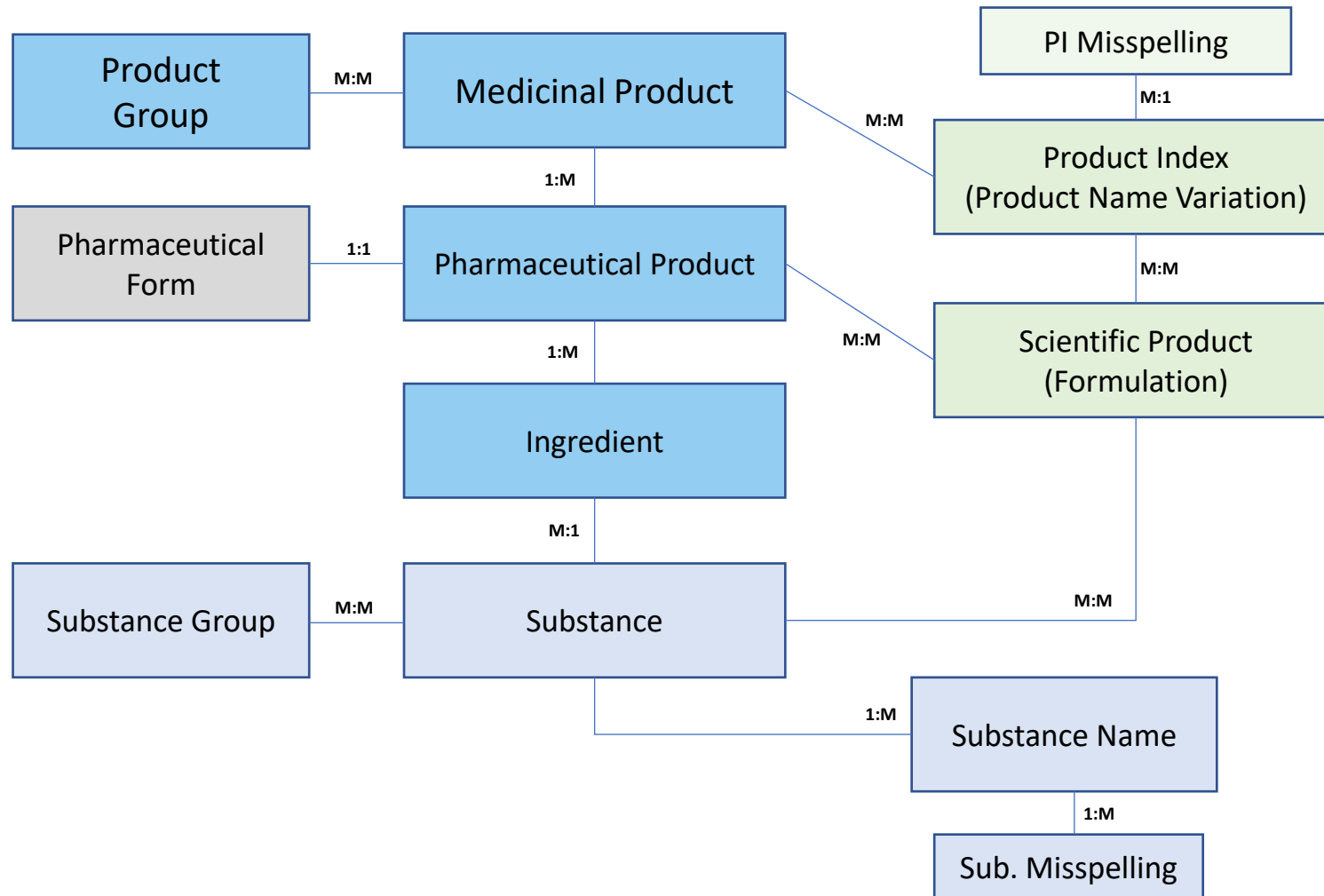


**Note:** For details on HaloPV Dictionary management and Drug/ Product Coding, please refer to respective guides (on demand)

RESTRICTED

# HaloPV – Product Management

## Halo MPD Logical Data Model



- Core Medicinal Product & Device data structures are based on ISO IDMP.
- The **Product Index** is a catalogue of all possible name variations
- A Medicinal Product has many possible reportable names.
- A name variation can apply to many Medicinal Products
- The **Scientific Product** is a logical entity representing a scientifically distinct product. I.E. A set of ingredients, strength & pharmaceutical form.
- A Pharmaceutical Product has exactly 4 Scientific Products.
- A Scientific Product can apply to many Medicinal Products.
- Each SP has its name on the PI.
- 1:M – represents – One to many relationship and vice versa.
- M:M represents many to many relationship.

**Note:** For details on HaloPV Dictionary management and Drug/ Product Coding, please refer to respective guides (on demand)

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# Products Forms –

## Product Groups/Families

Medicinal Product Groups/Families can refer to a parent Scientific Ingredient Group (Mostly for manual organizational use only).

Product families are a common denominator for grouping medicinal products. A user-defined Group or Family of Products with a custom name. e.g., Lemsip, which may comprise 30 different Medicinal Products, having different ingredients/strengths/flavors, etc., but typically belong to one brand and/or company.

Actions available for all records data forms -

- **Save**
- **Return** – To return to view edit record page.

The screenshot shows a web application interface for managing product groups. The top section, titled 'Product Group details', contains a form for editing a record. The form includes fields for 'Group/Family Name' (set to 'ANR'), 'Halo Code' (set to 'PGR34834488'), 'Description', 'Product Type' (set to 'Medicinal Product / Drug'), 'Name Variation Type' (set to 'Product Group / Family (PGR) 1:1'), 'Source', and 'Source system local code'. There is a 'Comments' section and a 'Rebuild PI' button. A yellow box highlights a 'Return' button with a green checkmark icon. Below the form is a table listing medicinal products. The table has columns for 'Medicinal Product Title', 'Strength Part', 'Product Company Name', 'Country Iso2 Code', 'Sender Local Code', and 'Halo Code'. The first row shows 'Medicinal Products - ANR' with a strength part of 'US' and a halo code of 'PGR34834488'. A yellow box highlights the table area.

Product Group details

ANR -

Group/Family Name: ANR Halo Code: PGR34834488

Description:

Product Type: Medicinal Product / Drug Name Variation Type: Product Group / Family (PGR) 1:1

Source: Source system local code

Comments:

Rebuild PI

Button for manual PI refresh

Medicinal Product Title	Strength Part	Product Company Name	Country Iso2 Code	Sender Local Code	Halo Code
Medicinal Products - ANR	US				PGR34834488

Form to insert Product Group/ families details, This form allows users to add relevant information to the Product Family, e.g. Product Type.

Users can include optional fields such as 'Name variation type', 'Source,' 'Source system local code', and 'Comments'.

Section listing Medical products in the current product group/ family

# Products Forms –

## Product Management (WHODD)

HaloPV Product Dictionary and WHODrug dictionary connect in this Process workflow. The complete dictionary of Medicinal Products comprises of Pharmaceutical Products and Ingredients that reference Substances, including master data entities such as Admin Routes, Pharm Forms, ATCs, MFLs, Sources, etc.

The workflow Product (External, WHODrug) allows users to review the data form, Medicinal Product details. Additional tasks might be available in the step. The workflow has the same configuration as detailed in section **Medicinal Products**.

The workflow, in most cases, is only available to the HaloPV Product Development team. But, in case your company manage this workflow. Remember, as with any other task in the application, you must have the corresponding role assigned to process the record.

For detailed information regarding specifications and integrations, please refer to the –

- HaloPV ICSR Coding System Specification
- HALO Medicinal Product Dictionary Export API
- HALO ICSR Coding System Specification -SS-608

# Products Forms – Medicinal Products

A Medicinal Product (MP) is the final packaged product ready to be sold or used in a clinical trial. It may contain multiple Pharmaceutical Products (e.g., cream and a capsule or powder and solvent) which are scientifically different, but not packaged separately.

The screenshot shows the 'Medicinal Product Details' form. At the top, a navigation bar includes tabs for 'Product Details', 'Package(s)', 'Pharmaceutical Product(s)', 'Product Names', 'Public Identifiers (MPIDs)', and 'Product Index'. The 'Product Details' tab is active. The form is divided into several sections: 'Medicinal Product Details' (with fields for Full Presentation Name, Main Code, Medicinal Product Description, Product Short Name, Product Generic Name, Other Descriptive Name, Product Type, Master File Location, and checkboxes for Special Measures, Pediatric Use, Additional Monitoring, and Suppression Coding), 'Organization information' (with fields for Product Company Name, Marketing Authorization Holder, Dates, and Identifiers), 'Orphan status' (with checkboxes for Orphan Designation and fields for Orphan Indication Type, Orphan Procedure Number, Orphan Authorization Date, and Orphan Designation Number), and 'Information parts (DMP)' (a grid of fields for Invented Name Part, Strength Part, Formulation Part, Target Pop Part, Device Part, Time Period Part, Flavour Part, Scientific Name Part, Pharm Form Part, Intended Use Part, Container Pack Part, and Trademark Name Part). At the bottom, there is an 'ATC(s) List' section with a table for selecting ATC codes. Annotations with yellow boxes and lines point to the navigation tabs, the 'Return' button, the 'ATC(s) List' section, and the 'Data grid need to be saved separately' text.

Medicinal Product Details

Medicinal Products - ANR - Medicinal Product

Product Details | Package(s) | Pharmaceutical Product(s) | Product Names | Public Identifiers (MPIDs) | Product Index

Medicinal Product Details

Full Presentation Name: Medicinal Products - ANR Main Code: PPD34834489

Medicinal Product Description

Product Short Name: Product Generic Name:

Other Descriptive Name:

Product Type: Medicinal Product / Drug

Master File Location:

☐ Special Measures? ☐ Pediatric Use? ☐ Additional Monitoring? ☐ Suppression Coding

Country: United States of America (the) (US) Language Code:

Justification:

Comments:

Organization information

Product Company Name (free text):

Marketing Authorization Holder (selected): Intra Test Root

Dates

Date of most recent update to Summary: Characteristics (DMP)

Effective Date:

Withdrawal Date:

Identifiers

Main Code: PPD34834489

Product Code (if available):

Source of Information:

Source system local code:

Orphan status

☐ Orphan Designation

Orphan Indication Type:

Orphan Procedure Number:

Orphan Authorization Date:

Orphan Designation Number:

Information parts (DMP)

Invented Name Part: Scientific Name Part:

Strength Part: Pharm Form Part:

Formulation Part: Intended Use Part:

Target Pop Part: Container Pack Part:

Device Part: Trademark Name Part:

Time Period Part:

Flavour Part:

ATC(s) List

Selected ATC:

ATC Code:

No data found

Actions available for all records data forms -

- **Save**
- **Return** – To return to record overview page.

Form allows the user to enter or edit MP information such as product type, MAH, country, language, additional monitoring, orphan status, ATC(s), information about the package (batch, serial number, package ID), active ingredient(s), strength, pharmaceutical form, route of administration, etc.

**Additional tabs on this form:**

- **Package(s)**: contains details such as package description and identifiers (package ID, batch ID, and serial number)
- **Pharmaceutical Product(s)**: This section allows users to add the pharmaceutical form, the Ingredient(s) List (including strength), and Routes of Administration
- **Product Names**: Allows users to add the Source, name variation, and Language code.
- **Public Identifiers (MPIDs)**: Allows users to add Source and Medicinal Product Identifier (MPID)
- **Product Index** : Displays autogenerated product index for the product.

Data grid need to be saved separately

List of ATC's the Product belongs to.

# Products Forms – Device Products

A Device Product is a Medical Device that may or may not have a medicinal counterpart (E.g., Thermometer or Inhaler). In the HaloPV Product Dictionary, such medicinal device combination products would need to be represented in two places – as a Medicinal Product and as a Device (though they may be associated within HaloPV). The sub-sections of a Device are manufacturing Batches and Device IDs (DEVIDs). Since Devices do not contain substances, no Scientific Product is derived, and only the Product Index is updated to include names for coding purposes against incidents or adverse events.

Device Product details

Demo Device -

Device product details

Device Title / Full Presentation Name  
Demo Device

Info Code  
DEV34844095

Device Description

Product Type  
Devices

Authorization / Validity Type  
Authorized

Trademark / Brand Name

Model Number

Quantity Per Package

Listing / Catalogue Number

☐ Sterility Product?

☐ Sterilization Required?

Sterilization Method

Device Usage (Count)

A usage count of 1 implies a Single-Use device.

☐ Active Device?

☐ Measuring Device?

☐ Custom Made Device?

☐ Implantable Device?

Device Type Identifier

Device Type Code

Device Type Description

Device Sub Type Identifier

Device Sub Type Code

Device Sub Type Description

Registration Status

Date Returned To Manufacturer

Comments

Refresh PI

The following product index records are associated with this Device Product:

Product Index

Organization

Manufacturer (selected)

Public Identifiers (DevIDs)

Source

Source system local code

Info Code  
DEV34844095

Identifier (short description)

Identifying text

Unique Device Identifier (UDI)

Unique Device Identifier

Search: All Text Columns

Go

Edit

Save

Add Row

Source (optional)

Nomenclature Code System

Nomenclature Value

No data found

Registered batches for the device

Go

Actions

Actions available for all records data forms -

- **Save**
- **Return** – To return to view record overview page.

Data grid need to be saved separately

Allows the user to add device product details, such as product type, manufacturer, Public Identifiers, registered batches, registration, classification, etc.

Section listing Medical products in the current product group/ family.

Allows users to access the Product Index (WHODD) of the existing Device Product. This functionality is only available if the service has been agreed upon for your HaloPV system.

Note: Additional configuration may be required e.g., dictionaries.

# Products Forms –

## Product Licenses (Authorisations)

Medicinal Product License

Demo Product License - Licenses from WhoDD (external)

Medicinal Product License Details

License details

License Title  
**Demo Product License**

License Description

Product Type  
**Medicinal Product / Drug**

Trade name

Legal basis

Authorization Procedure details

Authorization Procedure (selected)

Application Type

Application Number

Authorization Status

Authorization Number

Authorization Country

Authorization Jurisdiction

Marketing Status

Risk Of Supply Shortage?

Risk Of Supply Shortage Comments

Source

Source System Local Code

Comments

☐ Suppress Coding Flag

Organization information

Marketing Authorisation Holder

Dates

International birth date

Application Date

Auth Procedure Start Date

Auth Procedure End Date

Validity period start date

Validity period end date

Exclusivity start date

Exclusivity end date

Authorization Date

First Authorised Date

Marketing Start Date

Marketing Stop Date

Withdrawal Date

Identifiers

WHODrug MPID

This is used to populate WHODrug IDs automatically (i.e. in Drug and Past Drug history pages)

A Product License represents a Marketing Authorisation to sell a Product in a territory. In HaloPV, the License exists as a separate entity that can apply and be reused across multiple products. This contrasts with many other systems whereby the License attributes, such as the Authorisation Number, are merely facets of the Product. The License entity is the same, regardless of whether it relates to Medicinal Products or Device Products, though the relevant attributes populated are different.

This form allows the user to enter and edit product license information. Each product license should be linked with one medicinal product. A medicinal product can have many licenses linked to it.

### Actions available for all records data forms

- 
- Save
- Return – To return to view record overview page.

Form to insert Product License details, allows the user to add product license details, such as product type, MAH, country, authorization country WHODrug, details of the authorization, dates, etc.

This section is used to populate WHODrug IDs automatically (i.e. in Drug and Past Drug history pages)

# Products Forms – Substance Groups

A Product Substance Groups represents list of Active Ingredients used to define products as an attribute.  
The list of active ingredients is hence available to be selected when creating a product.

## Actions available for all records data forms

- 
- Save
- Return – To return to view record overview page.

Substance group form allows users to create or update Substance Group Details .

This section allows users to search, select and add selected substances to the group -

- Users can search for a substance from the left grid using the search filter.
- Then select the required Substance and click on “Add selected substances to group” button.
- The selected substances will appear in right hand side grid where users can –
  - Select the primary substance.
  - Delete an existing substance.

Substance Group details

**Demo Substance Group -**

Substance Group details

Substance Group Name  
**Demo Substance Group**

Halo Code  
**SGR34843951**

Description

Substance Group Type  
**Auto from AI**

Source  Source system local code

Comments

☐ Suppress Coding  
Exclude this Substance Group from coding.

**Rebuild PI**

**Button to manual build PI**

Substances available **Add selected substances to group →**

Search: All Text Columns **Go** **Actions** **Reset**

☒ ☒ Substance Preferred Name contains 4-Amino

<input type="checkbox"/>	<input type="checkbox"/>	Substance Preferred Name ↑	Halo Code	Source Name	Source Halo Code
<input type="checkbox"/>	<input type="checkbox"/>	4-amino-3-hydroxybutyric acid	SUB212193		
<input type="checkbox"/>	<input type="checkbox"/>	4-aminobenzoic acid calcium salt	SUB218352		

1 - 2

Substances in group

Primary substance

Primary substance in group

Other substances in the group will be considered variants of the primary substance

Search: All Text Columns **Go** **Actions** **Reset**

Delete	Substance Name ↑	Halo Code	Source Name	Source Halo Code
<b>Delete</b>	4-Amino-3-phenylbutyric acid hydrochloride	SUB223712		

1 - 1

# Products Forms –

## Scientific Ingredient Groups

A Scientific Ingredient Group comprises two or more Substances. They may be grouped by various definitions, such as a Non-Proprietary Combination Generic (e.g., Co-codamol). This allows for the creation of a manual Scientific Product with a custom name (e.g., “Co-codamol” rather than the default “Codeine Paracetamol”).

Scientific Ingredient Group details

### COCODAMOL -

Return

Scientific Ingredient Group Name  
**COCODAMOL**

Halo Code  
**SIG34175527**

Description

Product Type  
**Medicinal Product / Drug**

Source

Sender local code

Scientific Code  
**AI=SUB230675;AI=SUB232911**

Calculated automatically

Comments  
**test**

☐ Suppress Coding  
Exclude this Scientific Ingredient Group from coding.

**Button to manual build PI**

Available Substances **Add selected Substances to the group →**

This panel shows the dictionary of all available substances, minus those which have already been chosen.

Search: All Text Columns Go Actions

Search for '4-amino'

	Halo Code	Sender Local Code	Substance Name ↑	Source Name	Type	Deprecated Flag
<input type="checkbox"/>	SUB212193	1732	4-amino-3-hydroxybut...		Substance...	N
<input type="checkbox"/>	SUB223712	34566	4-Amino-3-phenylbut...		Substance...	N
<input type="checkbox"/>	SUB218352	27303	4-aminobenzoic acid c...		Substance...	N

1 - 3

← Remove selected ingredients from group Substances included in Scientific Ingredient Group

Search: All Text Columns Go Actions

Substance replaced

Substance nullified

	Substance Name ↑	Halo Code	Type
<input type="checkbox"/>	Codeine	SUB230675	Substance 1:1
<input type="checkbox"/>	Paracetamol	SUB232911	Substance 1:1

1 - 2

### Actions available for all records data forms

- Save
- Return – To return to view record overview page.

Scientific Ingredient Group form allows users to create or update Scientific Ingredient Group details and select ingredients for grouping.

Note: The group can be saved once the group has at least 2 Substances assigned to it.

This section allows user to search, select and add selected substances to a group -

- Users can search for substance from the left hand side grid using the search filter.
- Then select the required substance and click on “Add selected substances to group” button.
- The selected substances will appear in right hand side grid where users can remove a substance using “Remove selected substances from group” button.



**Qinecsa**

Thank you

