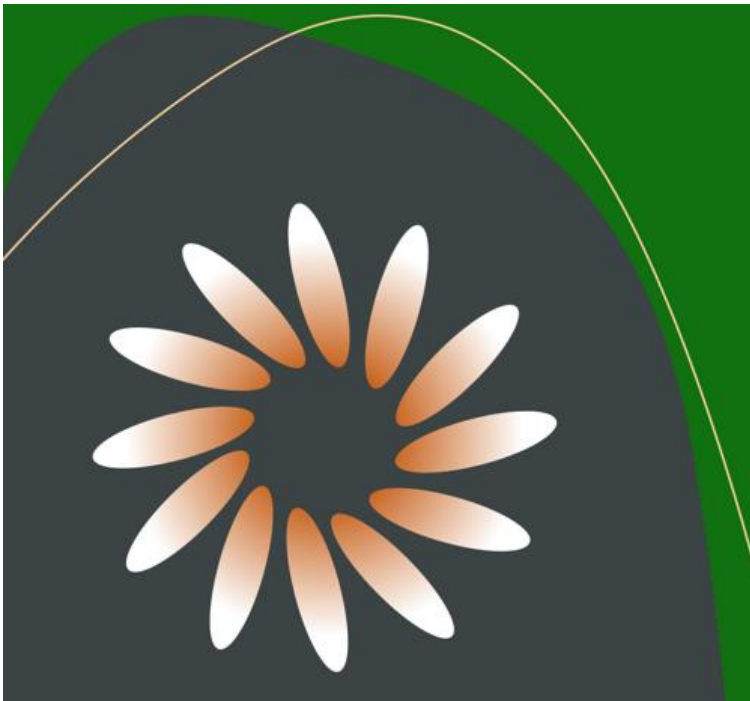# Products Module

HALOPV /PROHALO 4.X USER MANUAL

This is an end-user guide for the **Products Module** of the drug safety solution **HALOPV/PROHALO.**

Contents

1. HALOPV Products Module User Manual

User Manual - Release 4.X (4.2 first released March 2023)

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The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

2. Preface

The information in this user manual is based on the standard package of the Products Module and functionalities, which are subject to change. The latest product information, including release notes for HALOPV and multi-tenant HALOPV, is available at:

https://www.halopv.com or

https://insife.com/halopv

2.1 Insife Support

The Insife Support team can be reached at support@insife.com 24/7, depending on the agreed terms. Furthermore, the Insife Support team handles upgrades related to modules requiring MedDRA codes, EDQM codes, WHO Drug dictionary, and more.

3. Introduction

3.1 Purpose of this document

This User Manual describes the Products Module features of HALOPV. It is intended as a module guide, which should be considered one of the general manuals. You will find a manual for each Module separately at https://insife.com/halopv-user-guides-tutorials.

The overall guide for using general features is available online on General features (insife.com)

3.2 Modules of HALOPV

At the time of writing this manual, HALOPV modules comprise:

- Aggregate Reporting Module
- Agreements Module
- Clinical Trials Module
- Complaints Module
- Data Collection Programs Module
- Device Incidents Processing Module
- Entities Module
- ICSRs (Medicine and Vaccine Incidents) Module
- Literature Monitoring Module
- Labelling Module
- Medical Information and Communications Module
- Pharmacovigilance System Master File (PSMF) Module
- Products Module
- Quality Module
- Requirements Intelligence Module
- Risks Module
- Signals Module
- Submissions Module

Besides the modules, you will also find a separate manual for application administration and user administration in Admin Guide (insife.com).

3.3 About HALOPV (incl. PROHALO)

HALOPV is a cloud-based system. Internet connectivity is required. You can use your computer, tablet, or smartphone to access the system. Your organization should have provided you with the correct link to access your instance of HALOPV/PROHALO.

4. Navigating the Products Module

Once you log into HALOPV with your user credentials, on the left Menu, you will find the list of Modules to which your user has access. To review HALOPV access and general features, please refer to our **General Features User Manual** and **User Guide Introduction and Main Features**.

The **Products Module** will show if your user has the role to access the Module. The list of process workflows can be configured to add a second level of restriction. So, when implementing your HALOPV system, ensure roles are assigned to a process workflow level.

In the **Product Module,** users can manage the company product repository, including handling market authorizations from global to local markets.
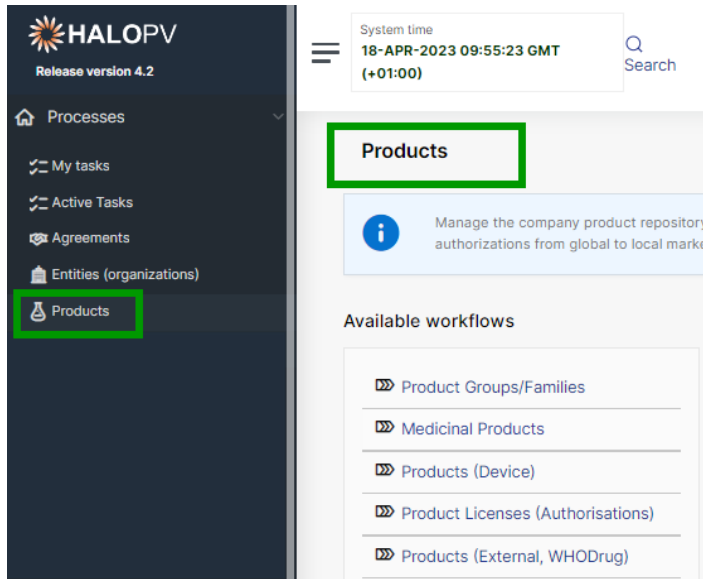
Figure 1 - The left Menu displays the Products Module available for users with the appropriate access role

4.1   Module Main Screen

The Main screen displays the list of process workflows available in the Module Products – including the Functionality Menu.

It is important to note that the workflows may be configured to local requirements in your HALOPV setup. Hence the workflows may look different from the standards, and some workflows and menus might not be available to the user view.
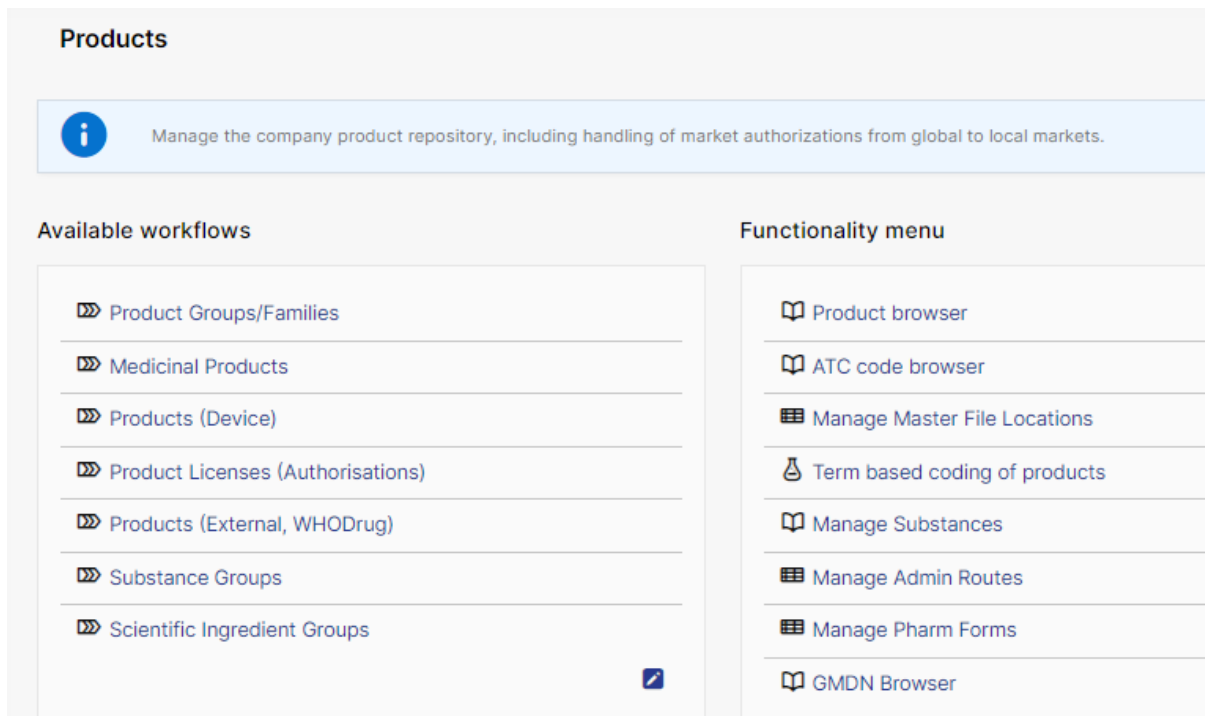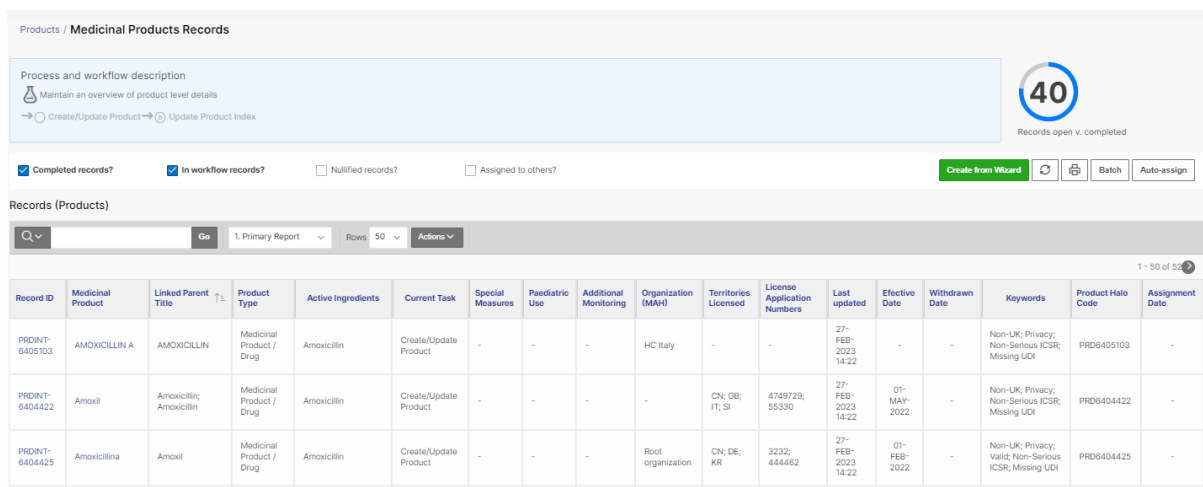

Figure 2 - The standard list of Workflows and Functionality Menu items for the Products Module

4.2   Standard Workflows

Users can access the record worklist by clicking on one of the available workflows. **E.g., Product Groups/Families**. The view will display the Record (s) created in the process workflow.

The Records worklist may have different columns, depending on the selected workflow. However, the principle is the same for all workflows. The standard list displays the ***Record ID, Title of the Record, the Type, Current task, Overall Due date*** *(the date the task is due to comply with set timelines),* etc.

> It is important to note that the workflows may be configured to local requirements in your HALOPV setup. Hence the workflows may look different from the Standard.

Figure 3 - When clicking on a process workflow, the following screen displays the Process workflow description, current tasks, and a worklist of records (configured per process workflow, e.g., Family, Product, Licenses), where the Record ID or Title/Identifier can be clicked to access the individual Record.

The columns' names may vary depending on your system configuration.

End users can update reports using the **Actions** button**.** Please consult the **User Guide - Interactive Reports**.

Please note that access to Records is restricted to the user role assigned to you, e.g., if ***you have read-only access to the current workflow***, the user cannot create or nullify records. Still, it might have the roles to access and execute the task(s) assigned within the Record.

Figure 4 - The screen displays the user's restriction to create new records.

Figure 5 - The screen displays a worklist without restriction to the user to create new records (Create from Wizard button is available).

Figure 6 - The screen displays an example of a record where the user has 'Read-only' access. The Record is locked, and the 'Complete Workflow' button is missing.
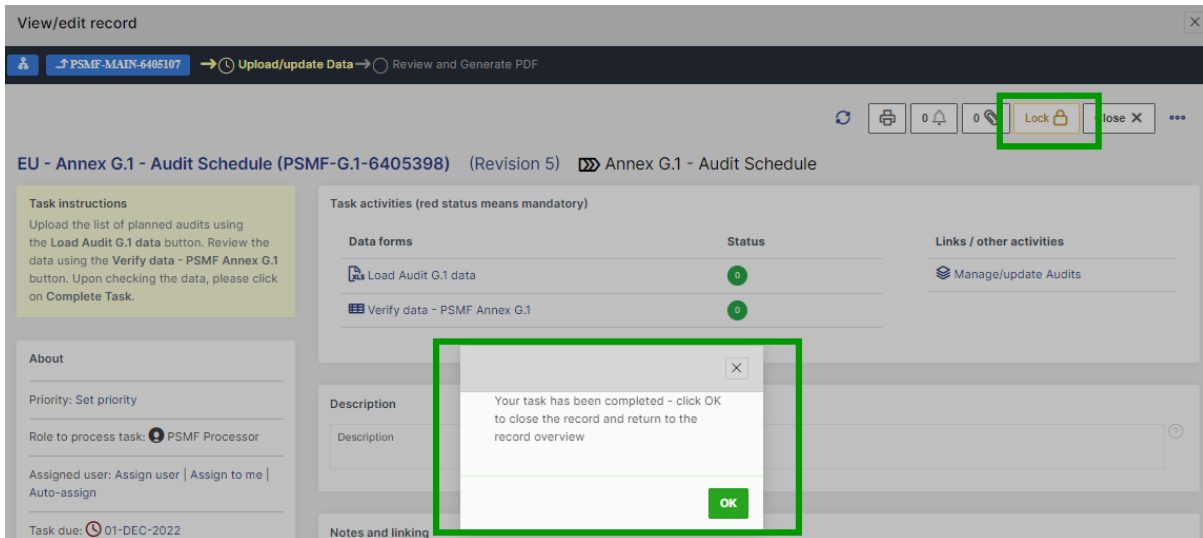
Figure 7 - The screen displays an example of a user missing the role to access the workflow's step. In this example, the role to access the step is 'PSMF Processor'

4.3   Workflows Structure

Clicking on the **"Record ID"** or **"Title/Identifier"** takes you to the individual Record, as shown below.

Figure 8 - The screen displays an example of a user with the role to access the first step, including 'Related Records' .

A Workflow is a graphical representation of an active and inactive step, your role, the tasks assigned to that role, and the due date.

The **Task instructions** are shown in the application on the left side of the screen, highlighted in yellow. Follow the task instruction for further information about the step.

The **About** section shows the role requires to access the step, the due task date, and the overall due date of the workflow.

The record view also displays the current user in the step. As long as a user has a record opened, no other user can perform any task in the Record. To release the lock, click the '**Close X**' button; otherwise, the Record will be locked with your user for 30 mins after no activity is registered.

The **Task activities** and **Link/other activities** sections contain all required tasks buttons to execute in the step.

The current process step is highlighted in yellow.

The top part of the view shows a link to the parent record. The Products Module uses a different type of parent-child relationship, as a single record might have different 'parents' records. See the example in the section **Related Records.**

A workflow step may have task actions. The status is marked with colors:

- **Green mark:** the task is not mandatory.
- **Red mark:** the task action is mandatory and cannot be completed before some actions are taken.
- **Pending actions:** the task has activated validation rule(s). This is usually linked to a mandatory task (red mark) that requires your attention.

If an existing record should be moved to a further step, **e.g.,** from **Step 1** to **Step 4**, or a different workflow, the user can use the *change workflow* functionality located on the left corner of the record view. This applies to workflows that have more than two steps.
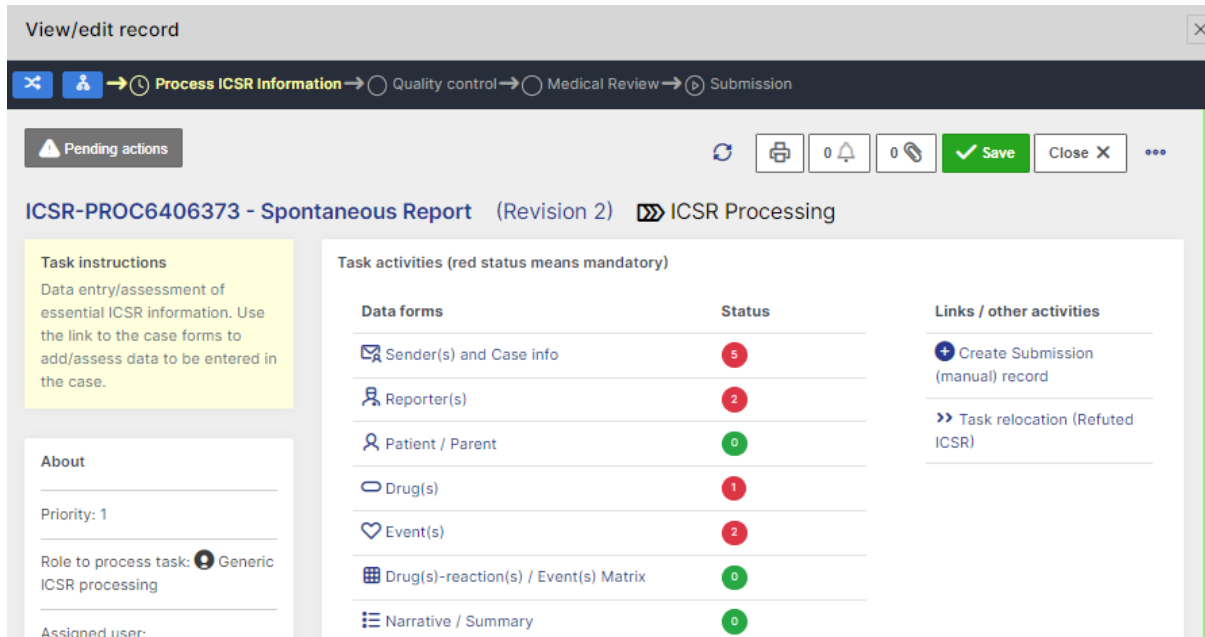
Figure 9 - Example of a record with four steps with validation rules and pending actions

4.3.1 Workflows Available in the Products Module

The workflow structure of the Products depends on the business processes. Therefore your HALOPV system configuration might vary regarding the number of steps, titles, descriptions, and task actions. Below is an example of the HALOPV/PROHALO standard package for the Products Module.

- o **Product Groups/Families** - Product families are a common denominator for grouping medicinal products.
- o **Medicinal Products** – Help users maintain an overview at a product level details. For instance, a drug packaged with branding.
- o **Product License (Authorisations)** - Help users maintain an overview of product license level details.
- o **Products (Device)** – Help users maintain an overview at a device level details.
- o **Products (External, WHODrug)** – WHO Drug products (access might be restricted to Insife). The complete dictionary of Medicinal Products, comprising Pharmaceutical Products, Ingredients (which reference Substances), includes all related entities such as Admin Routes, Pharm Forms, ATCs, MFLs, Sources, etc.
- o **Substance Groups** - Active Ingredients are used to define products as an attribute. The list of active ingredients is hence available when creating a product.
- o **Scientific Ingredient Groups** - Scientific Ingredient Groups are collections of ingredients in one or more medicinal products.
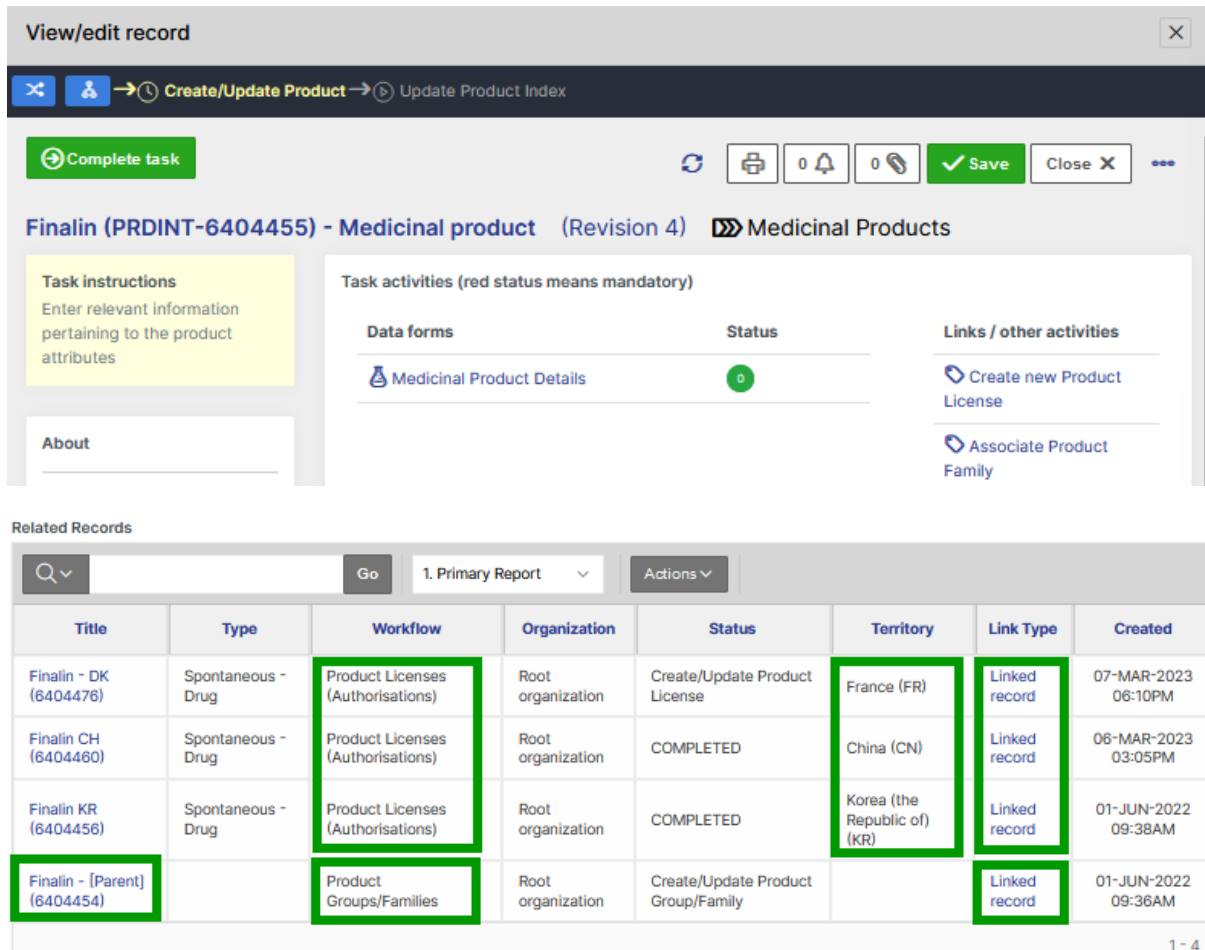
Depending on your system configuration, the **Functionality Menu** can include the following:

- **The Product Index** – 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.
- **ATC code browser** – Allows users to search in the classification system 'Anatomical Therapeutic Chemical (ATC)' entries updated in your HALOPV - WHO Drug Dictionary

- **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.
- **Manage Substances** – Allows users to search in **HALOPV Substance Browser**; the substance name, type, preferred name, language code, variation type, etc.
- **Manage Admin Routes** – Manage or add new entries to your HALOPV list of routes of administration, e.g., EDQMs and local codes.
- **Manage Pharm Forms** – Manage/edit the HALOPV list of Pharmaceutical Dosage forms.
- **GMDN Browser** - Browse international naming and grouping conventions for medical devices.

4.4   Workflow Steps Overview

A record workflow usually consists of a **create/update** step, a **review** step, and an **approval step**. It might be that your local business requirement only requires two steps, '**Update/Upload**' or '**Review/Approve**' or an automatic step, as shown in the example below.

Figure 10 - Example of a workflow with two steps and related records.

When creating new products, such as a **Medicinal Product**, assign a parent record using the **Associate Product Family** data form. Otherwise, no dependencies will be created between parent and child records. See the example in Figure 10.

The following sections will further explain some of the Products' workflows. The workflows below represent unique functionalities that can be used across workflows. Thus, in this Manual, we will list only the relevant workflows that cover most of the functionalities across HALOPV related to the Products Module.

- Product Groups/Family
- Medicinal Products
- Products (Device)
- Product Licenses (Authorization)
- Products (External, WHODrug)
- Substance Groups
- Scientific Ingredient Groups

4.4.1   User Roles Relevant to the Products Module

Users must be assigned roles to access the relevant modules. Furthermore, user roles can allow access or editing rights for a record in a specific workflow task step. Please consult the table below for standard user roles provided by the system. Your administrator may have configured other user roles. For a description of how to administer users and user roles, please refer to the [Admin Guide (insife.com)](insife.com)

Defined Usergroup name (Role)	Description
Generic product management	Required for accessing the Products Module (Main Menu)
Product processor	Users with this role can process the information/data in the workflow step.
Products Module	Workflow owner. The role can create records and assign a due date.
Automation	The role can only be assigned as read-only

4.5   Workflow: 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.

In HALOPV/PROHALO, the workflow structure in Family, Medicinal Products, Devices, Medicinal Products (Internal), and Medicinal Licenses have a similar configuration. The workflow is composed of two steps. Users must update the data forms, and by completing the steps, Automator will update the Product Index in the second step.

The Product Groups/Families workflow comprises two steps, as shown below.

4.5.1 Create/Update Product Group/Family (Step 1)

The first step allows users to update the data form, **Product Family details.** Additional tasks might be available in the step.

As with any other task in the application, you must have the corresponding role assigned to process the Record in the task step.

Figure 11 - Product Groups/Families, step 1

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: Product processor

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

The task step contains the following task activities:

Data form action	Description
Product Family 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'.
Create New Product	This task action helps users create new products as child records in the Product Family workflow.

*Figure 12 - Example of the **Product Family details** form*

*Figure 13 - Example of the **Create new Product** form*

Once you click **'Create and return'**, your new product will be available in the section **'Related Records'** as a 'Linked record' section. You can click on the Record to update information in the Medicinal Product details form.

Figure 14 - Example of the new Medicinal Product record

4.5.2   Notify the PI of Product Group/Family Created (Step 2)

The second step is automatic. The automator will update the Product Index.

Figure 15 - Example of a completed record

Once the second step is completed, please click '**Close X**' to close the record session. Otherwise, your user will lock the Record, and other users will be unable to perform any task.

4.6 Workflow: Medicinal Products

A Medicinal Product (MP) is the authorized packed drug with branding as sold. It may contain multiple Pharmaceutical Products (e.g., Lemsip day vs. night) which are scientifically different, but not sold separately.

In HALOPV/PROHALO, the workflow structure in Family, Medicinal Products, Devices, Medicinal Products (Internal), and Medicinal Licenses have a similar configuration. The workflow is composed of two steps. Users must update the data forms, and by completing the steps, Automator will update the Product Index in the second step.

The Medicinal Products workflow comprises two steps, as shown below.

4.6.1 Create/Update Product (Step 1)

The first step allows users to update the data form, **Medicinal Product details.** Additional tasks might be available in the step.

As with any other task in the application, you must have the corresponding role assigned to process the Record in the task step.
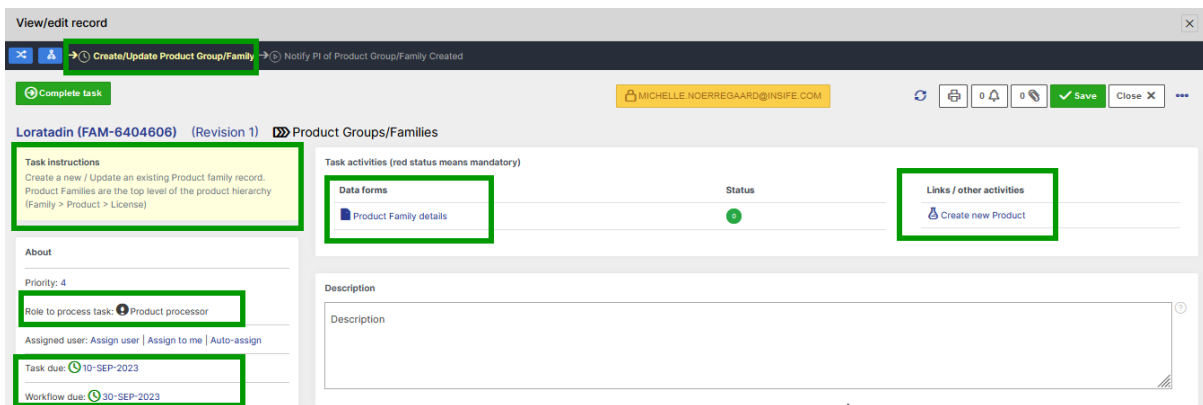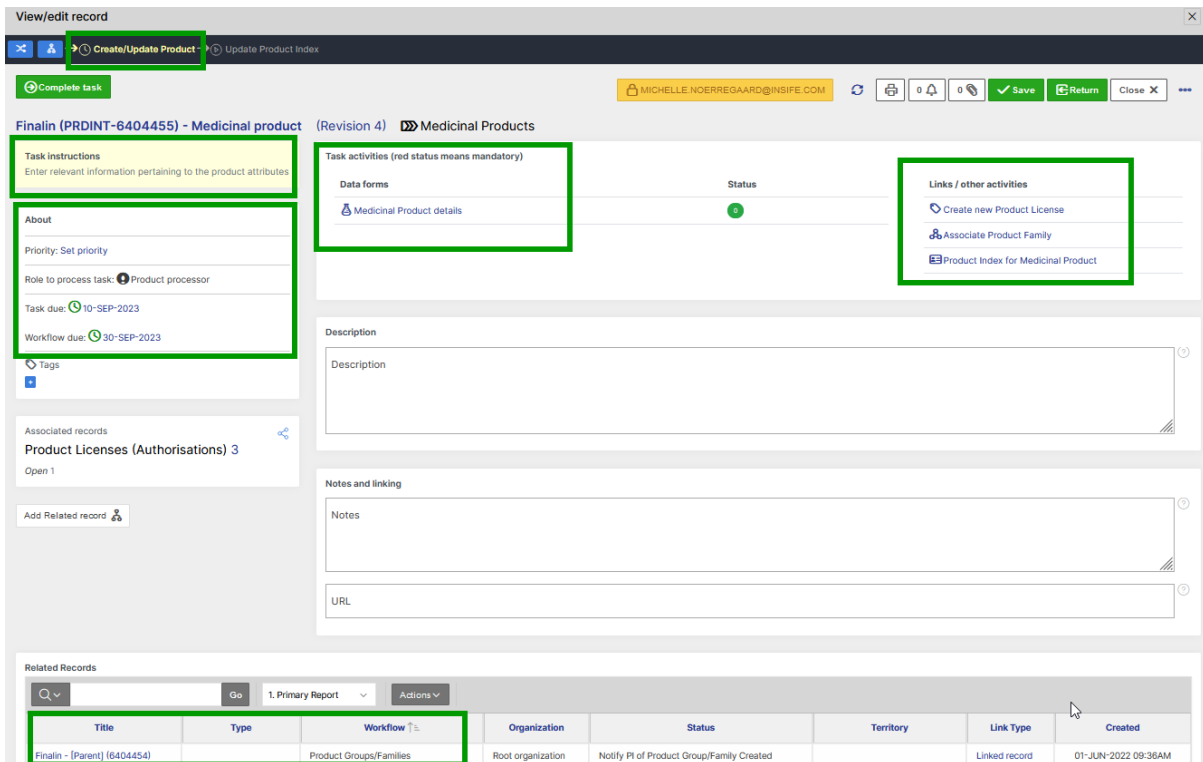

Figure 16 – Medicinal Product workflow, step 1

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: Product processor

Task instructions (as shown in the application): Enter relevant information pertaining to the product attributes.

The task step contains the following task activities:

Data form action	Description
Medicinal Product details	This task action allows the user to add product details, 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.
Create New Product License	This task action helps users create new product licenses as child records in the Medicinal Product workflow.
Associate Product Family	This task action allows users to link an existing Medicinal Product to an existing Family Product.
Product Index for Medicinal Product	Access the Product Index (WHODD) of the existing Medicinal Product. This functionality is only available if the service has been agreed upon for your HALOPV system. Note: Additional configuration regarding internal products and licenses is required. E.g., dictionaries.
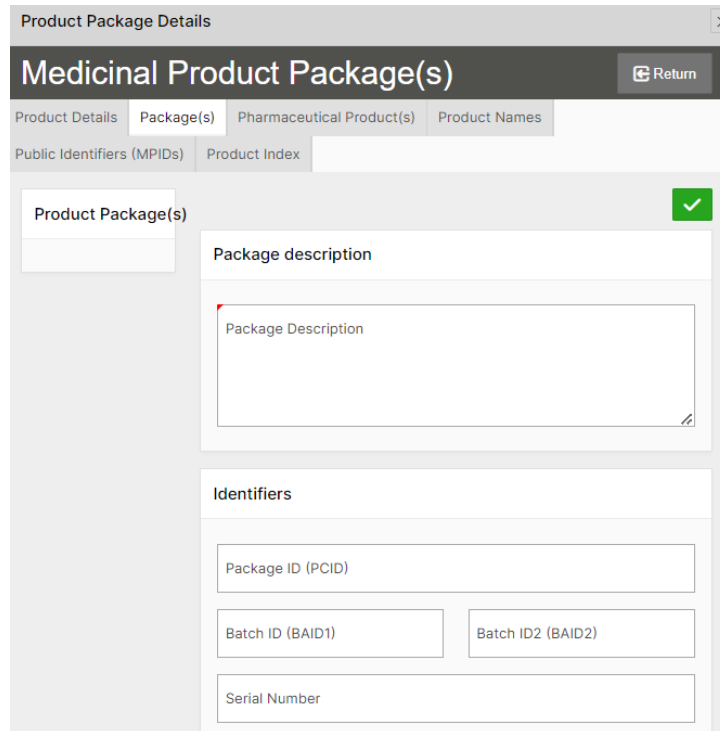
*Figure 17 - Example of the **Medicinal Product details** form, first tab*

Organizations can request Insife validation rules for specific fields, e.g., Records cannot be completed until the 'Product Type' and 'Investigational or Authorized' fields are selected.

Additional tabs:
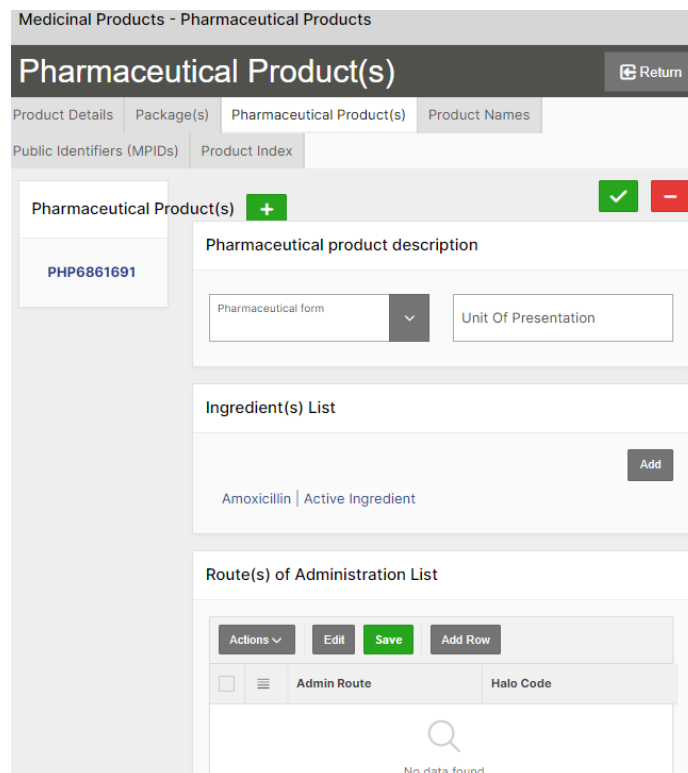
- **Package(s):** In this section, users can add Package Description and Identifiers (Package ID, Batch ID, and Serial Number)

Figure 17a – Package(s) tab in Medicinal Product Details form

- **Pharmaceutical Product(s):** This section allows users to add the pharmaceutical form, the Ingredient(s) List (including strength), and Routes of Administration
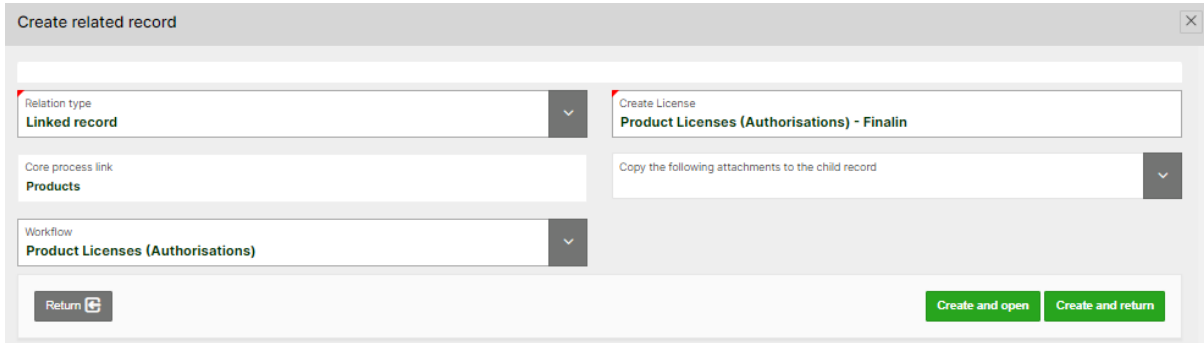
Figure 17b – Pharmaceutical Product(s) tab in Medicinal Product Details form

- **Product Names:** Allows users to add the Source, name variation, and Language code *(This tab is mainly used for the workflow: Product (External, WHODrug))*

- **Public Identifiers (MPIDs):** Allows users to add Source and Medicinal Product Identifier (MPID) *(This tab is mainly used for the workflow: Product (External, WHODrug))*
- **Product Index:** Details on this tab are covered in the section **Products (External, WHODrug)**

*Figure 18 - Example of the **Create new Product License** form*

Once you click **'Create and return'**, your new product license will be available in the **'Related Records'** section as **'Linked record'**. You can click on the Record to update information in the Product License details form.

Figure 19 - Example of the new Medicinal License Product in the Related Records section

4.6.2 Update Product Index (Step 2)

The second step is automatic. The automator will update the Product Index.

Please ensure to complete License records before completing the second step.

Figure 20 - Example of a completed record

Once the second step is completed, please click '**Close X**' to close the record session. Otherwise, your user will lock the Record, and other users will be unable to perform any task.

4.7   Workflow: Products (Device)

A Device Product is a Medical Device that may or may not have a medicinal counterpart. E.g., Thermometer vs. 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 are also not associated with Substances, no Scientific Product is derived, and only the Product Index is updated to include names for coding purposes against incidents.

In HALOPV/PROHALO, the workflow structure in Family, Medicinal Products, Devices, Medicinal Products (Internal), and Medicinal Licenses have a similar configuration. The workflow is composed of two steps. Users must update the data forms, and by completing the steps, Automator will update the Product Index in the second step.

The Products (Device) workflow comprises two steps, as shown below.

| Create/Update Device Product | Notify PI of Device Created |

4.7.1 Create/Update Device Product (Step 1)

The first step allows users to update the data form, **Device Product details.** Additional tasks might be available in the step.

As with any other task in the application, you must have the corresponding role assigned to process the Record in the task step.
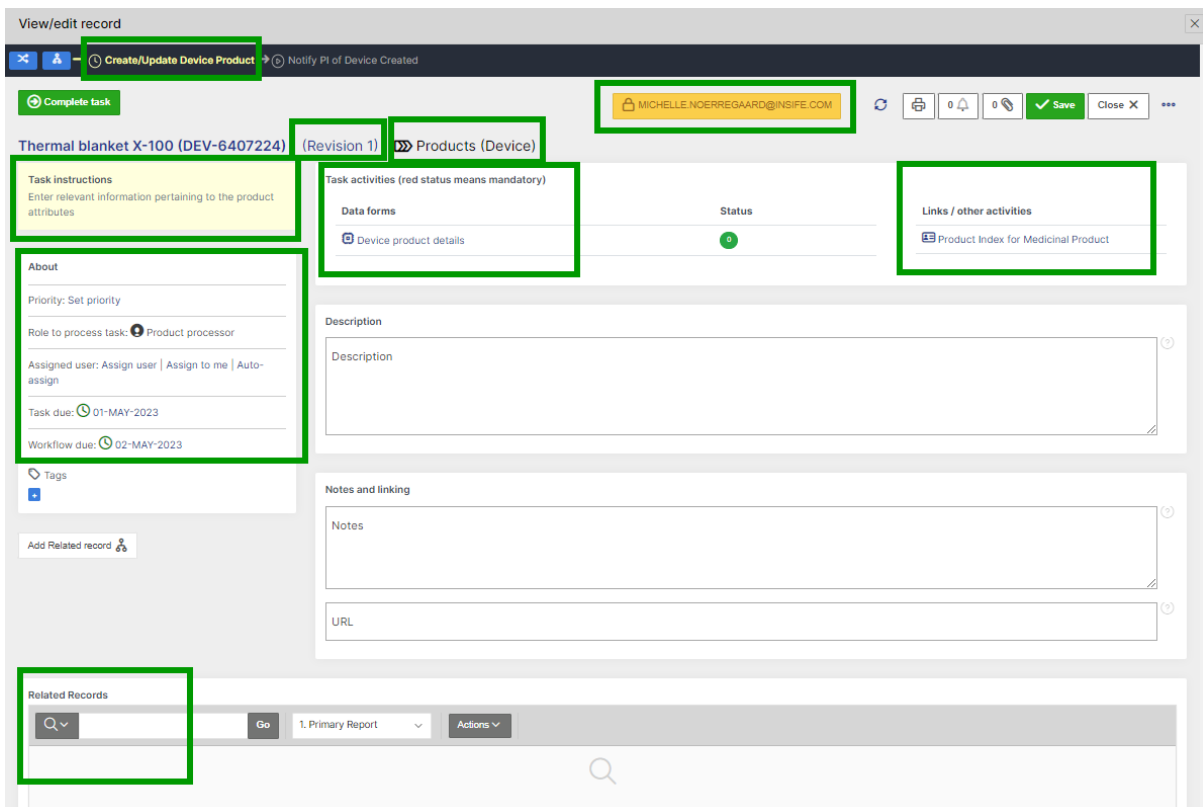
Figure 21 – Example of a Products (Device) workflow, step 1

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Related record section may include linked records to licenses.

Role to process task: Product processor

Task instructions (as shown in the application): Enter relevant information pertaining to the product attributes.

The task step contains the following task activities:

Data form action	Description
Device Product details	This task action allows the user to add device product details, such as product type, manufacturer, Public Identifiers, registered batches, registration, classification, etc.
Product Index for Medicinal Product	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.
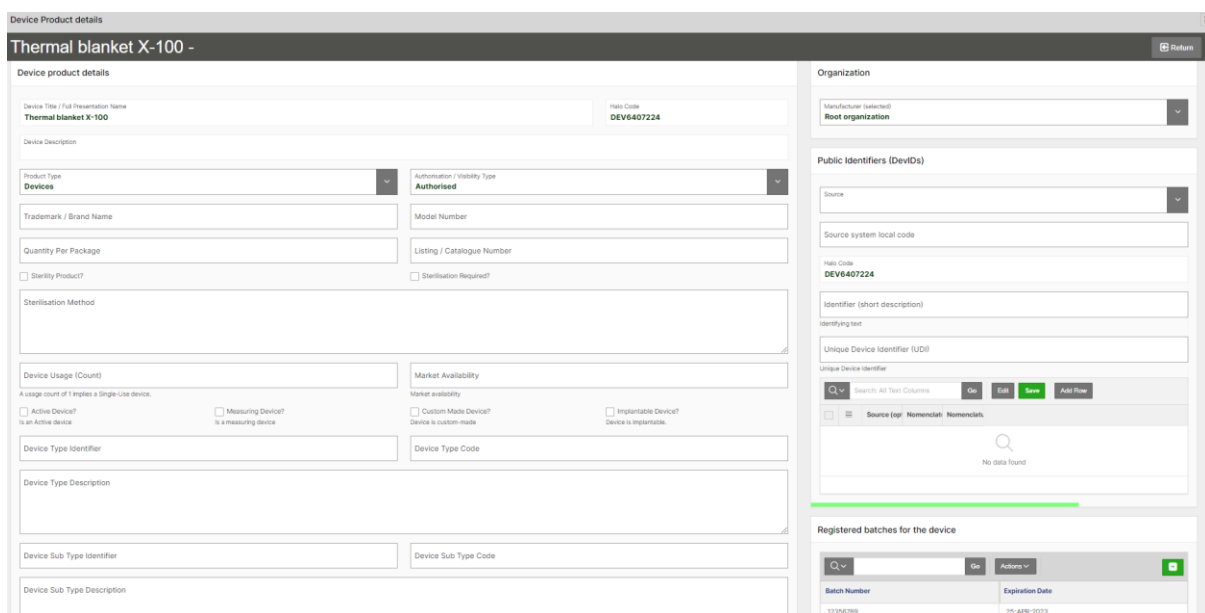
*Figure 22 - Example of the **Device Product details** form*

Organizations can request Insife validation rules for specific fields, e.g., Records cannot be completed until the 'Product Type' and 'Authorization' fields are selected.

4.7.2   Notify the PI of Device Created (Step 2)

The second step is automatic. The automator will update the Product Index.

Once the second step is completed, please click **'Close X'** to close the record session. Otherwise, your user will lock the Record, and other users will be unable to perform any task.
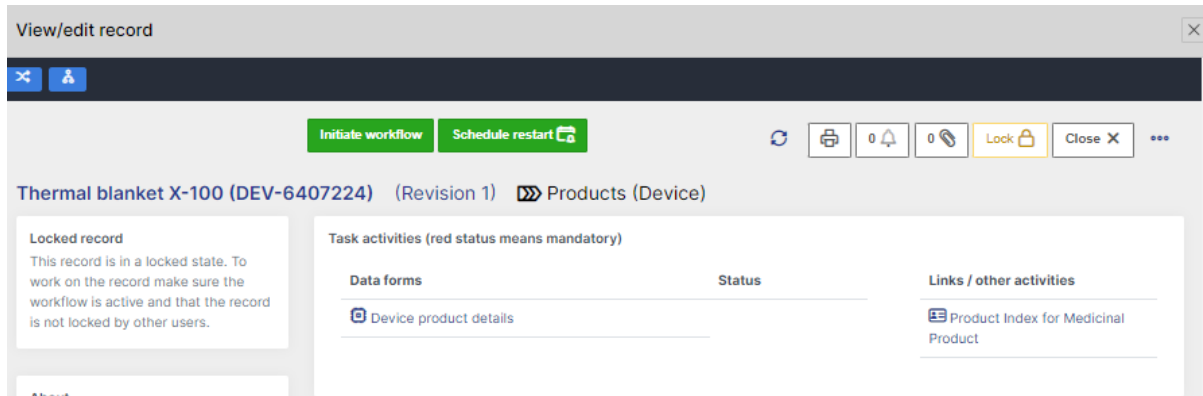
Figure 23 - Example of a completed record

4.8   Workflow: Product Licenses (Authorizations)

A 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.

In HALOPV/PROHALO, the workflow structure in Family, Medicinal Products, Devices, Medicinal Products (Internal), and Medicinal Licenses have a similar configuration. The workflow is composed of two steps. Users must update the data forms, and by completing the steps, Automator will update the Product Index in the second step.

The Product License (Device) workflow comprises two steps, as shown below.

4.8.1   Create/Update Product License (Step 1)

The first step allows users to update the data form, **Medicinal Product License details.** Additional tasks might be available in the step.

As with any other task in the application, you must have the corresponding role assigned to process the Record in the task step.
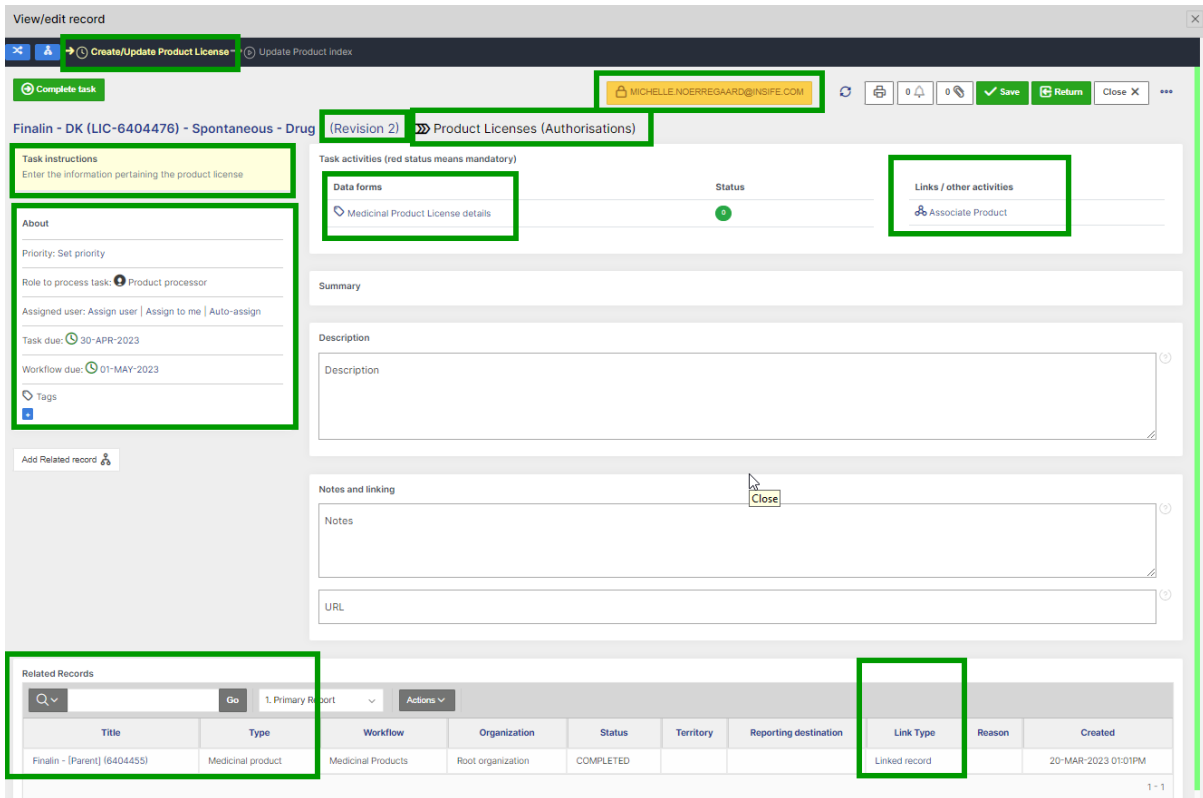
Figure 24 – Medicinal Product License workflow, step 1

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: Product processor

Task instructions (as shown in the application): Enter relevant information pertaining to the product license.

The task step contains the following task activities:

Data form action	Description
Medicinal Product License details	This task action allows the user to add product license details, such as product type, MAH, country, authorization country WHODrug, details of the authorization, dates, etc.
Associate Product	This task action allows users to link an existing Product License to an existing Medicinal Product.

*Figure 25 - Example of the **Medicinal Product License** form*

*Figure 26 - Example of the **Create new Product License** form*

Organizations can request Insife validation rules for specific fields, e.g., Records cannot be completed until the 'Product Type' and 'Investigational or Authorized' fields are selected.
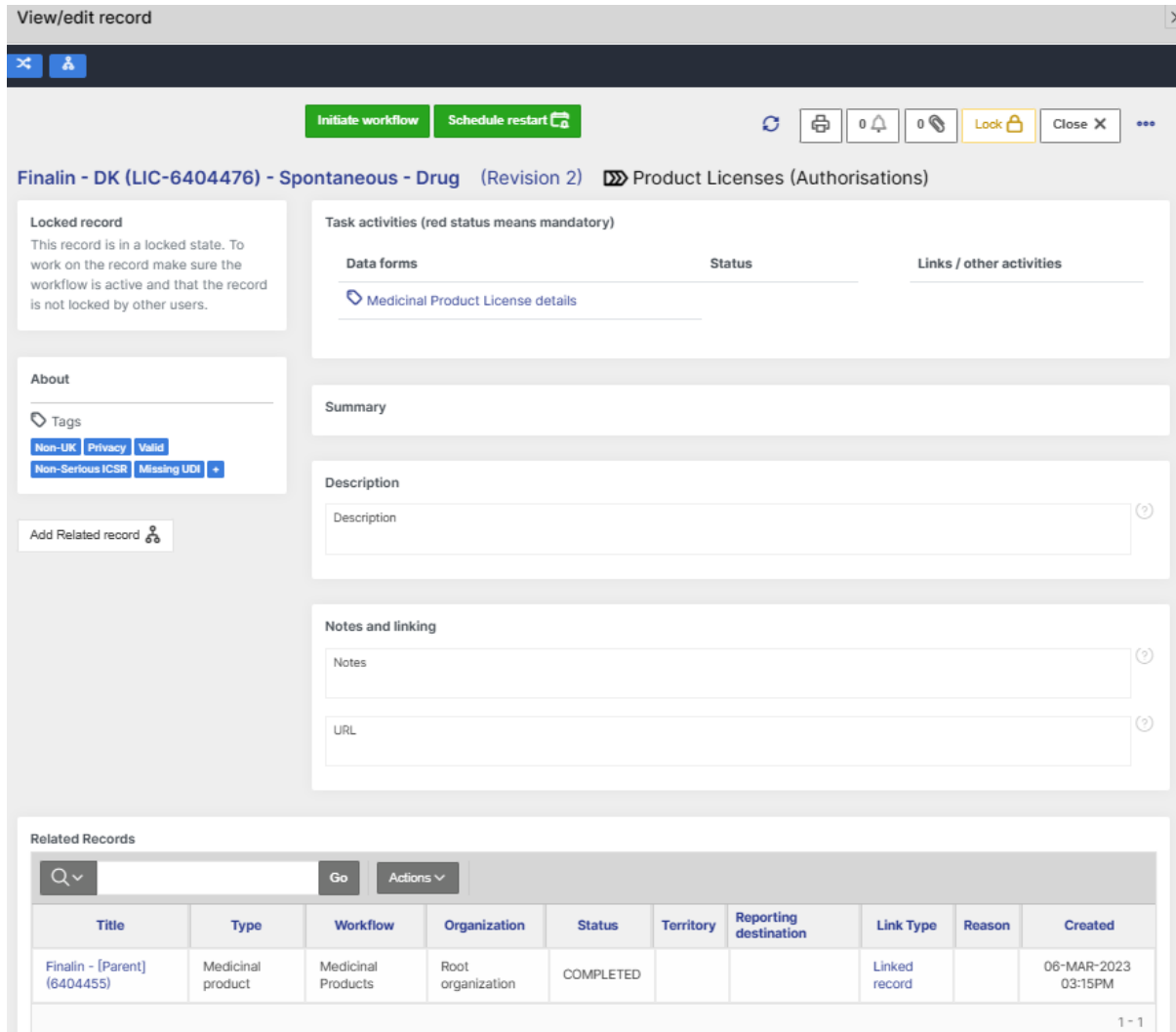
Once you click **'Create and return'**, your new product will be available in the **'Related Records'** section as **'Linked record'**. You can click on the Record to update information in the Medicinal Product details form.

Figure 27 - Example of the link records in the Related Records section

4.8.2   Update Product Index (Step 2)

The second step is automatic. The automator will update the Product Index.

Once the second step is completed, please click '**Close X**' to close the record session. Otherwise, your user will lock the Record, and other users will be unable to perform any task.

Figure 28 - Example of a completed record

4.9   Workflow: Products (External, WHODrug)

HALO Product Dictionary and **WHODDrug dictionary** connect in this Process workflow.

The complete dictionary of Medicinal Products comprises 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 Insife 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.

.

> **Note:** Please ensure your WHODrug dictionary, EDQM codes list, etc., are updated to the latest version. Otherwise contact support@insife.com

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Create/Update Product (External, WHODrug)

In the following subsections, we will briefly review terminologies and dependencies in HALOPV required when coding products for ICSRs:

- HALO Product Dictionary and WHO Drug, and
- HALO Product Information in ICSR

For detailed information regarding specifications and integrations, please refer to the **HALOPV ICSR Coding System Specification, HALO Medicinal Product Dictionary Export API,** and **HALO ICSR Coding System Specification -SS-608**

4.9.1   HALO Product Dictionary and WHO Drug

Sources

A source represents an informational authority, such as a pharmacopeia. HALOPV comes with a set of Sources imported from the WHO Drug Dictionary. Considering integration 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

Entities can refer to an Organization; for example, Medicinal Products have a Marketing Authorisation Holder (MAH). The list of MAH will be available on your HALOPV application in the **Entities Module.**

Routes of Administration / Admin Routes

As part of the Standard Terminology, Admin Routes represent the different ways a Medicinal Product may be taken (e.g., Oral); thus, these are referred to by Products. HALOPV comes with Admin Routes from EDQM. However, Investigational Medicinal Products may refer to development or proposed Admin Routes which have not yet been adopted into the standard EDQM list.

Pharmaceutical Forms / Dosage Forms

As part of the Standard Terminology, Dosage Forms represent the different formats a Medicinal Product may be produced in (e.g., Tablet, Capsule), and thus these are referred to by Products. HALOPV comes with Dosage Forms from EDQM. However, Investigational Medicinal Products may refer to development or proposed Pharm Forms which have not yet been adopted into the standard EDQM list.

Anatomical Therapeutic Classifications (ATCs)

As part of the Standard Terminology, ATCs represent therapeutic areas a Medicinal Product may target (e.g., Endocrine); thus, these are referred to by Products. HALOPV comes with the standard list of ATCs provided annually by the WHO. However, Investigational Medicinal Products may refer to the development or proposed ATCs that have not yet been adopted into the standard WHO list.

N.B. HALO_CODEs for ATCs = The ATC Code itself.

Master File Locations (MFLs)
MFLs are the legal address where documentation for a Medicinal Product is held by the company.

MedDRA
MedDRA is not part of the MPD, but MedDRA (usually LLT or PT) codes may be referenced in Medicinal Products as indications (soft binding).

Substances
Substances form the basis of 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. HALOPV comes with Substances from the WHO DD.

In summary, the **Product Index** is a catalog of all possible name variations for Medicinal Products and Devices whose data structures are based on ISO IDMP.

A Medicinal Product has many possible reportable names. A name variation can apply to many Medicinal Products. All of these Name Variations can be system-generated automatically on an event-driven basis whenever a Product is registered or updated in the Product Dictionary. The combinations & concatenations are derived from the populated fields in the definition of the Medicinal Product (MP), in conjunction with the Pharmaceutical Form from each Pharmaceutical Product (PP). In principle, the combinations could be user configurable. Below is the HALO Product Dictionary logical data model.

HALO Product Dictionary

Logical Data Model
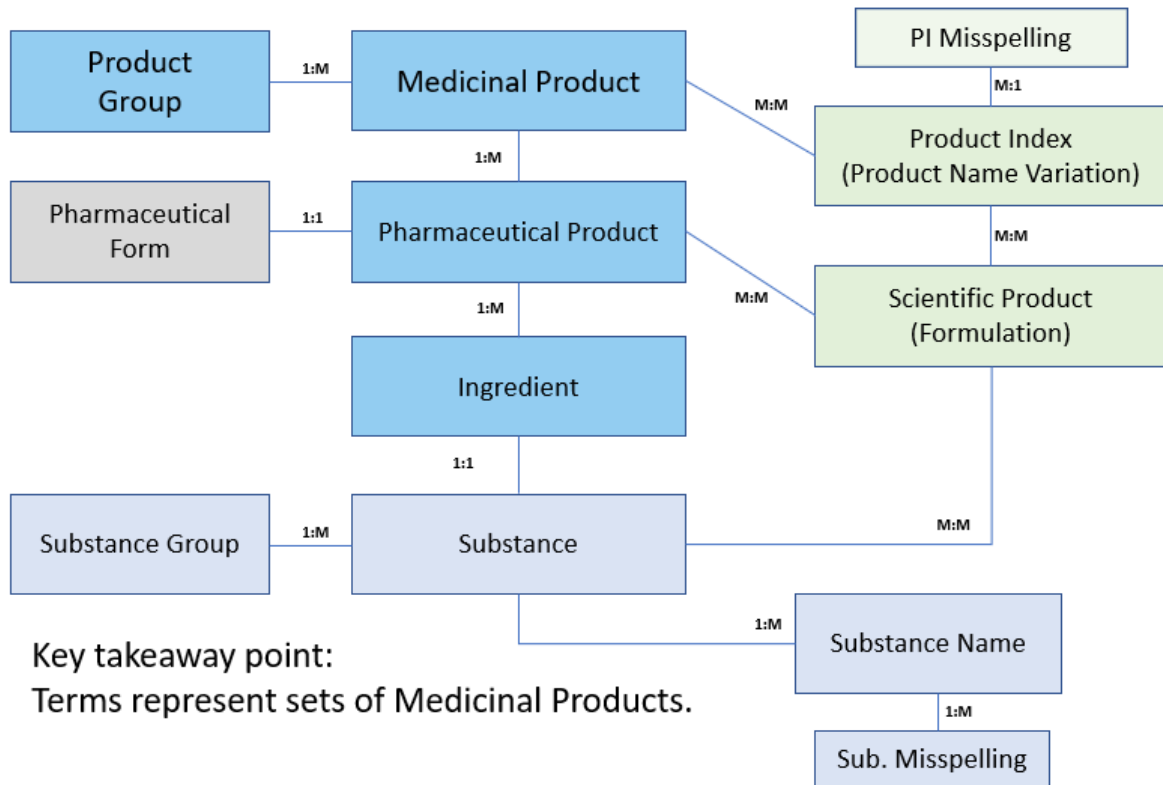
Figure 29 – HALO Product Dictionary data model

4.9.2   HALO Product(s) Information in ICSRs

The purpose of coding Drugs and Substances reported in Individual Case Safety Reports (ICSRs) to the Medicinal Product Dictionary (MPD) in HALOPV is to take the structured information received in the ICSR and identify the real Medicinal Products in question. The ICSR comprises three Drug sections:

- G.k. Drug,
- D.8.r. Patient Past Drug history
- D.10.8.r. Parent Past Drug history (in case of child/foetus patient) Each Drug in each ICSR can be coded to the most specific term possible, without adding information that was not given.

The coding of Drugs and Substances in the ICSR, links the ICSR to a set of possible associated products. Even given an Authorisation Number – this is not one unique Medicinal Product but a set.

When the user wants to code an ICSR to a specific Drug, a specific Medicinal Product, or a very specific Pharmaceutical Product, the user sets the respective override fields in the ICSR. The coding engine then 'sees' these values instead of the original verbatim ones from the report. Drugs in G.k.2.2 are always coded to the Product Index. Via a misspelling, if necessary. Drugs in G.k.2.2 can be coded to any level in the Product Index (see illustration below).

The coding engine is deterministic by necessity. This means that the same inputs always yield the same output. This is a requirement to avoid continuously fluctuating results downstream. Rules are added to make a consistent selection in case of multiple matches.

Coding terms from ICSRs

Coding engine inputs/outputs – overriding the reported information to force user coding
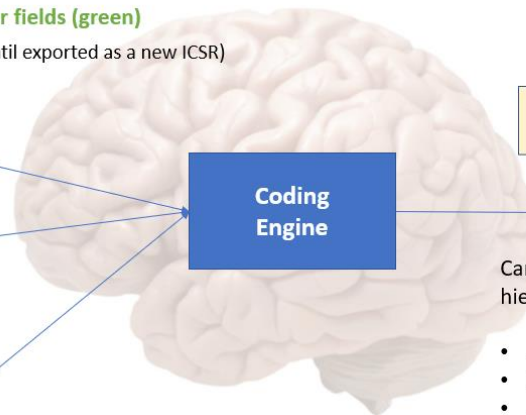
Figure 30 – The illustration shows how drugs are coded to the Product Index in HALOPV.

Using HALOPV Product Index provides benefits to organization performance when processing ICSRs, such as:

- Automatic generation of the *Product Index* facilitates both coding (case intake) and provides a structure for signal detection.
- When a Medicinal Product is registered in the MPD (e.g. "Lemsip Max"), unique combinations and concatenations of Product Name Variations are identified automatically, by scanning all attributes, such as brand name, company name, product full name, short name, etc. For example:

  Reckitt Benckiser Lemsip Max Cold & Flu lemon
  Reckitt Benckiser Lemsip Max Cold & Flu lemon 1000mg
  Reckitt Benckiser Lemsip Max Cold & Flu lemon powder
  Reckitt Benckiser Lemsip Max Cold & Flu lemon 1000mg powder

  These names provide additional automatic coding targets for ICSRs. In the case, reported drugs (G.k.2.2) were expressed this way.

- Users do not have to manually maintain these names, nor the relationships between Products and Group/Family names.

- Since Medicinal Products with the same name variations are grouped, this provides another way of aggregating ICSRs/reactions for signal detection analysis. For example, all Lemsip Max variants, regardless of the flavor version.

- The automatically generated lesser forms (fewer concatenations) serve as another level of aggregating ICSRs/reactions for signal detection analysis by various portions of the name.

- It facilities signal detection analysis by product brand name.

The process for coding Substances and Drugs is detailed below. Each process is a cascading sequence of steps. Typically, once a match is found, processing stops for that Substance/Drug. Generally, the early steps are optimistic and try to get a specific match. Subsequent steps become less specific and more generic in an effort to match something at least.

Drug coding process for cases

Drug coding Overview


```
                    ┌──────────────────────────────┐
                    │        ICSR Received         │
                    └──────────────────────────────┘
                                  │
                                  ▼
                    ┌──────────────────────────────┐
                    │ Stage 1: Match reported PhPID │
                    │ / MPID to the PI             │
                    └──────────────────────────────┘
                              Not found
                    ┌──────────────────────────────┐
                    │ Stage 2: Match reported Drug  │
                    │ Name to the PI               │
                    └──────────────────────────────┘
                              Not found
                    ┌──────────────────────────────┐
                    │ Stage 3: Match reported Auth. │
                    │ Number + Country to the PI   │
                    └──────────────────────────────┘
                              Not found
                    ┌──────────────────────────────┐
                    │ Stage 4.1: Identify the       │
                    │ Scientific Product           │
                    └──────────────────────────────┘
                              Not found
                    ┌──────────────────────────────┐
                    │ Stage 4.2: Match the Scientific│
                    │ Product to the SP dictionary │
                    └──────────────────────────────┘
                                  │
                               Manual
```
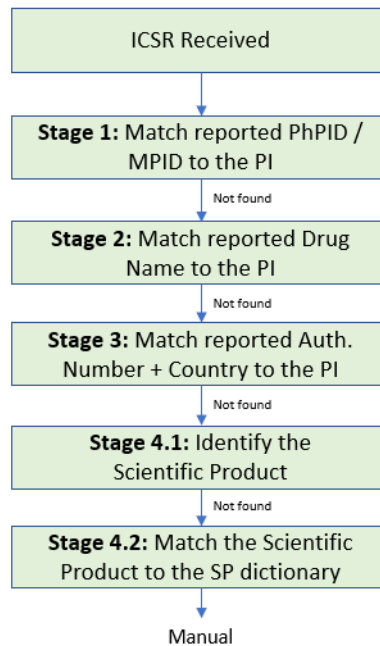
Figure 31 – Codifying process – Drug coding overview for ICSRs

- Receipt of an ICSR triggers event-driven codifying

- **Stage 1:** Match the reported PhPID / MPID to the 1:1 record in the Product Index

  - **Stage 1.1:** If a PhPID is specified in G.k.2.1.2, link to specific PI record. Stop.

  - **Stage 1.2:** If an MPID is specified in G.k.2.1.1, link to specific PI record. Stop.

  - **Stage 2:** Match the reported Drug name to the Product Index

  - **Stage 2.1:** If a Drug name is given in G.k.2.2, link it to the PI record. Stop.

  - **Stage 2.2:** If a Drug name is given in G.k.2.2, link it to the PI record *via a Misspelling*. Stop.

The target of the Misspelling must be non-nullified.

  - **Stage 3:** Match the reported Authorisation Number (G.k.3.1) + Country (G.k.3.2) to the PI.

  - Match the reported Auth' Number + Country combination to the Medicinal Product, and to the PI via the most specific Full Presentation Name. Stop.

- **Stage 4.1:** If all Substances are coded, identify the Scientific Product from the complete set, in conjunction with strengths reported (G.k.2.3.r.3, G.k.2.3.r.4) if present. Also include the Pharmaceutical form (G.k.4.r.9.2b / G.k.4.3.9.1) if present. Continue.

- **Stage 4.2:** Match the identified Scientific Product to a known Scientific Product in the dictionary. Find the most-specific corresponding Product Index record.

Note that the coded Substances are assembled into a Scientific Product, which is a set of Ingredients with Strength and Pharm Form information, if present. The Scientific Product is used only at a late stage of coding the Drug, and only if the Drug could not be coded based on its reported name.

- Receipt of an ICSR triggers event-driven coding

- **Stage 1:** Match the reported Substance ID (G.k.2.3.r.2b) to the specific Substance. Uses SubIDs held against Substances in the MPD.

- **Stage 2:** Match the reported Substance name (G.k.2.3.r) to a Substance Preferred Name. Substance Preferred Names are unique.

- **Stage 3:** Match the reported Substance name (G.k.2.3.r) to a Substance Alias or Translation. Multiple matches can occur. An order of precedence applies.
  - Prefer most specific Substance Name Type.
  - Prefer non-deprecated Substance.
  - Prefer older Substances (*deterministic* rule).

- **Stage 4:** Match the reported Substance name (G.k.2.3.r) to a Substance *via a Misspelling*.
  - Misspelling must be non-nullified.
  - Target of Misspelling must also be non-nullified.

Figure 32 – Codifying process – Coding of Substances

Note: For additional information regarding the coding of products in ICSRs, please refer to **HALO ICSR Coding System Specification -SS-608**

4.10 Substance Groups

Active Ingredients are used to define products as an attribute. The list of active ingredients is hence available when creating a product.

The Subtance Group workflow comprises two steps, as shown below.

4.10.1 Create/Update Substance Group (Step 1)

The first step allows users to update the data form, **Substance Group details.** Additional tasks might be available in the step.

As with any other task in the application, you must have the corresponding role assigned to process the Record in the task step.

Figure 33 - Substance Groups, step 1

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: Generic product management
Task instructions (as shown in the application): Create or update Substance Group Details

The task step contains the following task activities:

Data form action	Description
Substance Group details	This form allows users to create or update Substance Group Details
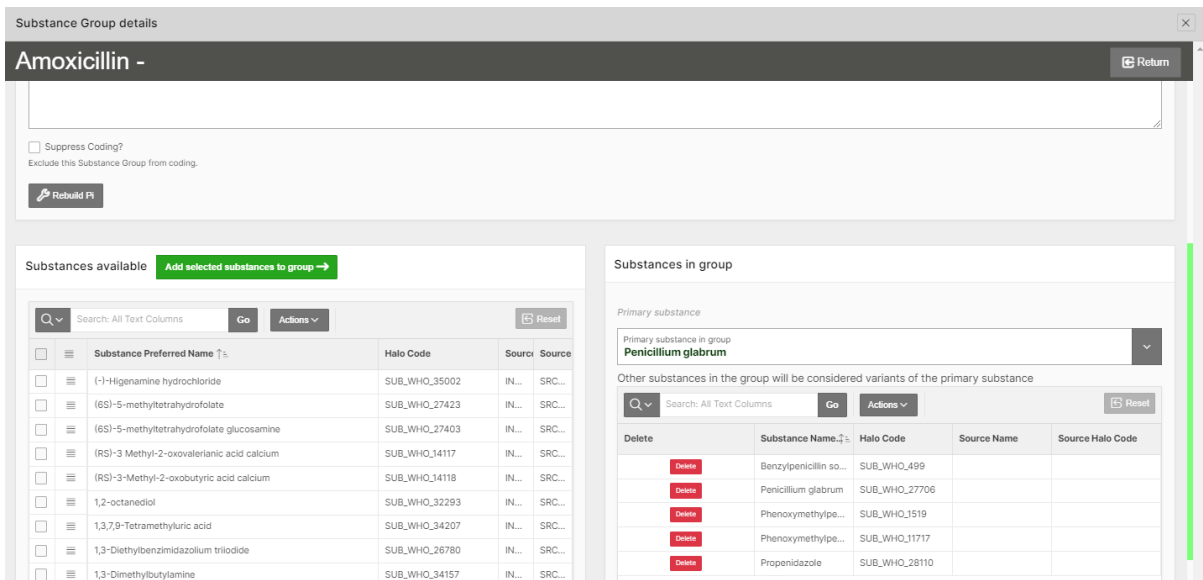
Figure 34 – Example of the Substance Group details form

4.10.2 Notify the PI of Substance Group Created (Step 2)

The second step is automatic. The automator will update the Product Index.

Once the second step is completed, please click '**Close X**' to close the record session. Otherwise, your user will lock the Record, and other users will be unable to perform any task.

Figure 35 - Example of a completed record

4.11 Scientific Ingredient Groups

Scientific Ingredient Groups are collections of ingredients in one or more medicinal products. A Scientific Ingredient Group comprises two or more Substances, which can be defined and grouped by users. 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"), so it helps add additional names which can be used for coding at a high level.

A Scientific Ingredient Group is typically created after Substances as it refers to them.

The Scientific Ingredient Group workflow comprises two steps, as shown below.

4.11.1 Create/Update Scientific Ingredient Group (Step 1)

The first step allows users to update the data form, **Scientific Ingredient Group details.** Additional tasks might be available in the step.

As with any other task in the application, you must have the corresponding role assigned to process the Record in the task step.
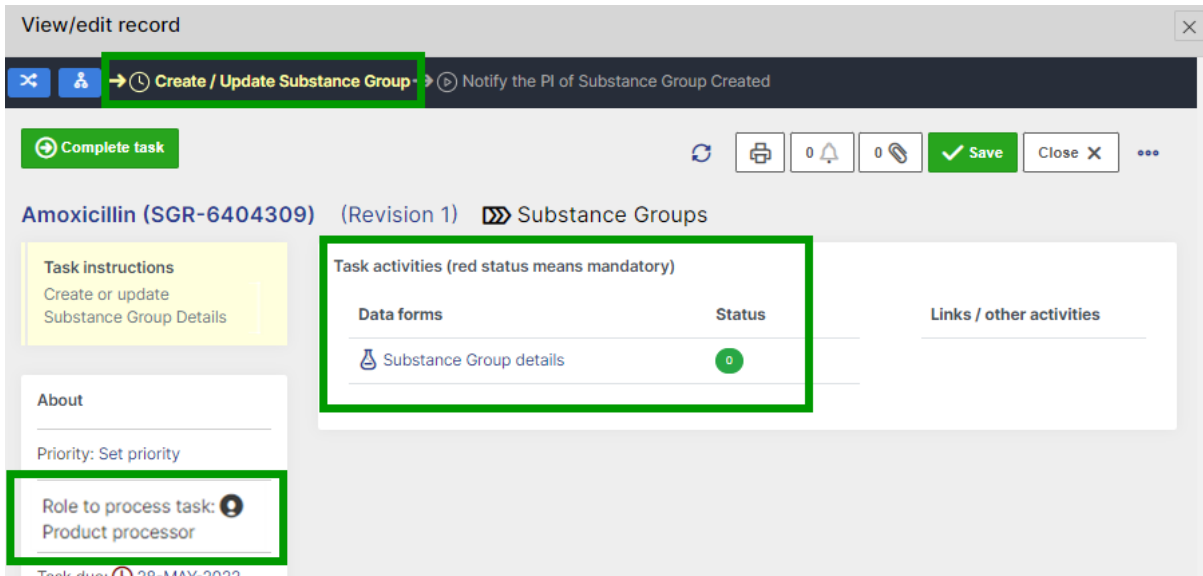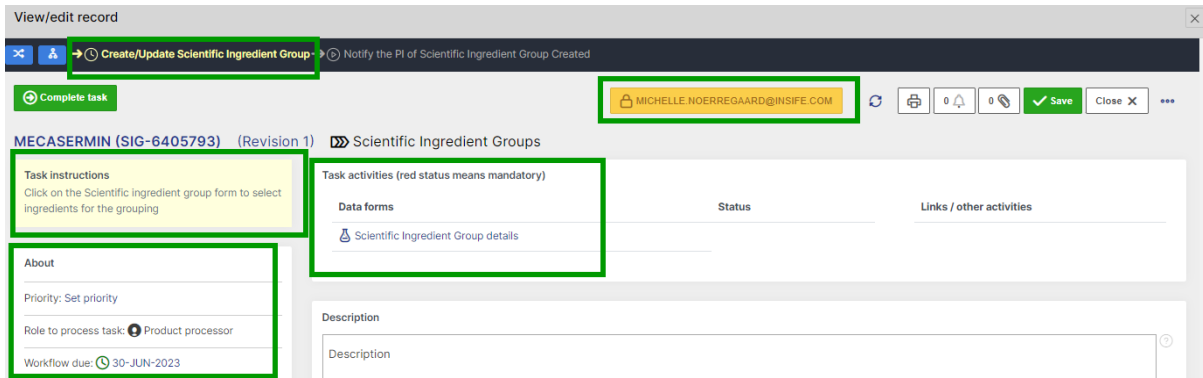
Figure 36 – Scientific Ingredient Groups, step 1

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: Product processor

Task instructions (as shown in the application): Click on the Scientific ingredient group form to select ingredients for the grouping

The task step contains the following task activities:

Data form action	Description
Scientific Ingredient Group details	This form allows users to create or update Scientific Ingredient Group Details and select ingredients for the grouping. Note: Once the group has at least 2 Substances, it can be saved.
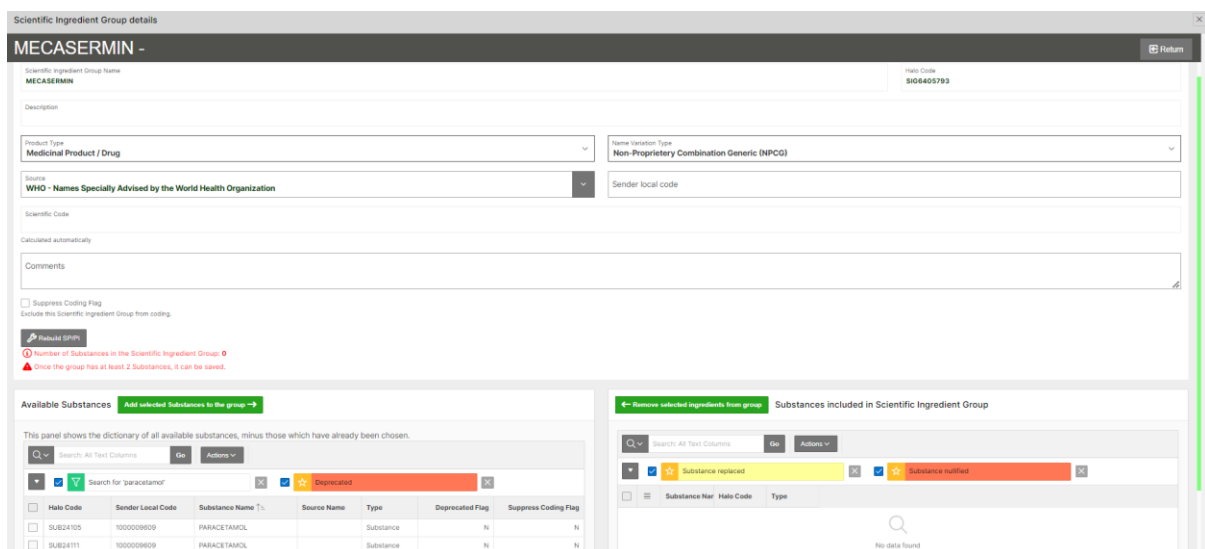
Figure 37 – Example of the Scientific Ingredient Group details form

4.11.2 Notify the PI of Scientific Ingredient Group Created (Step 2)

The second step is automatic. The automator will update the Product Index.

Once the second step is completed, please click **'Close X'** to close the record session. Otherwise, your user will lock the Record, and other users will be unable to perform any task.
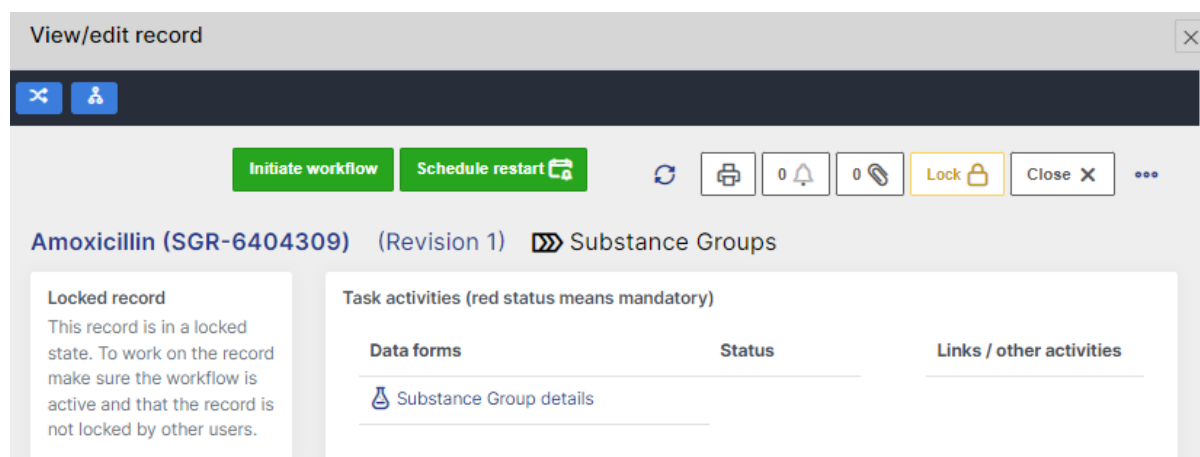

Figure 38 - Example of a completed record

To review additional HALOPV **User Guides** and **User Manuals** please visit our website https://insife.com/halopv-user-guides-tutorials or contact your system administrator.

4.12 Abbreviations

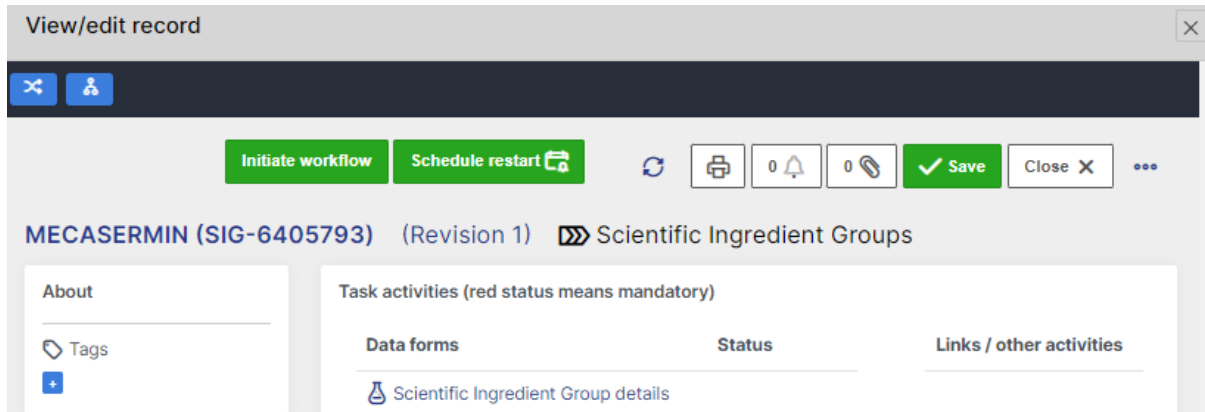| Abbreviation	Definition/Expansion
Admin Route (ADM) / Route of Administration (RoA)	How a medicine is administered to the body. e.g., Orally, Rectally.
Anatomical Therapeutic Classification (ATC)	A taxonomy of expert codes used to describe the system/area in the body which a medicine targets.
Coding	The process of matching a reported term (Product / Substance / Device) to a known item in the dictionary.
Devices	A Medical Device which often has a medicinal counterpart. e.g., An inhaler, a syringe.
DEVIDs	Device IDs
Formulation	A combination of Ingredients.
Ingredient (ING)	A Substance when it is referenced by a Product.
Individual Case Safety Reports (ICSRs)	A format of Safety Report message used for storage and transmission of Drug safety incidents.
License	Authority given to sell medicine in a given jurisdiction and is usually granted by the NCA.
Marketing Authorisation Holder (MAH)	Marketing Authorisation Holder
Medicinal Product (MP)	A drug as packaged, with branding. It may contain multiple Pharmaceutical Products.
Medicinal Product Dictionary (MPD)	The whole dictionary of Medicinal Products, comprising Pharmaceutical Product, comprising Ingredients which reference Substances. Includes all additional related master data entities such as Admin Routes, Pharm Forms, ATCs, MFLs, Sources, etc.
Medicinal Product Group / Family	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.
Master File Locations (MFLs)	Master File Locations
Misspelling	A Misspelling is an unofficial name of a Product or Substance. Used to handle commonly misreported terms avoiding manual intervention.

Abbreviation	Definition/Expansion
Non-Proprietary Combination Generic (NPCG).	An MHRA-specific term for a *Scientific Ingredient Group.*
Pharmaceutical Form (PHF) / Dosage Form	This is the format of the medicine as it is packaged. E.g. a Capsule, a Tablet, a Suppository, etc.
Pharmaceutical Product (PP)	A Pharmaceutical Product is a distinct drug packaged inside a Medicinal Product. It comprises a formulation (set of ingredients) and a Pharmaceutical Form.
Preferred Name (PN)	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.
Product Brand Group (PBG)	An MHRA-specific term for a Medicinal Product Group / Family
Product Index (PI)	The Product Index is a table of distinct reportable terms, build in advance, so that reported Drugs can be matched against it. A single record in the Product Index can represent multiple Medicinal Products, Pharmaceutical Products, Scientific Products or Devices.
Scientific Ingredient Group (SIG)	A user-defined Formulation, or set of Ingredients, with a custom Name. e.g., Co-codamol represents Paracetamol, Codeine.
Scientific Product (SP)	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.

4.13 List of References

References
[1] HALOPV ICSR Coding System Specification
[2] HALO Medicinal Product Dictionary Export API
[3] HALO ICSR Coding System Specification -SS-608