

Creation of Selling Units

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Introduction

With the latest changes introduced in the product architecture, SANITY functionality has been enhanced to reflect complex products with different Dosage Forms and complex pack configurations. This will also help us to calculate proper counting/ extended units, which will give us the basis to calculate API quantity properly. Further, it enables SANITY to have a cleaner data structure for better reporting & analytics.

Creation process of Primary Pack(s) and Selling Unit(s) has been changed a little and the same has been described below. Some terminologies have been described below:

Primary Pack -

- Primary Pack contains the pharmaceutical product itself. Typical types of Primary Pack are blisters, bottles, syringes, vials etc.
- The formulation of a product defines the type of closure and packaging required to ensure the product is protected properly, therefore, Primary Pack must be considered at the initial phase of product formulation

Selling unit -

- Selling Unit contains the Primary Pack(s) and is normally the form in which the pharmaceutical products are sold in the sales channels. It does not have direct contact with the product
- Typical types of Selling Unit include carton boxes (incl. printing/labelling) that often contain several Primary Packs units as well the leaflet.
- In exceptional cases, the Final Selling Unit contains multiple Selling Units (bundle), which are not sold individually (e.g., 2 inhalers each packed in carton box are combined in an outer carton box or foil wrapping)

So that users can choose correct options in SANITY, some more terminologies have been described below:

- **Regular Primary Pack** –the primary pack contains same kind of units (e.g., a blister containing same 15 mg tablets)
- **Complex Primary Pack** – the primary pack contains different kind of units (e.g., a blister containing tablets of different strength like oral contraceptives).

Below an example: Natazia(Estradiol valerate + Dienogest)

But what might this do for me?

Days 1-2

Help your body build up the lining of the uterus with a 3-mg dose of estradiol valerate

Days 3-7

Slow the lining growth with dienogest, while reducing estradiol valerate

Days 8-24

Stabilize the lining of the uterus by raising the dienogest level

Days 25-28

Promote a controlled period by ending with a short interval of further reduced estradiol valerate, followed by 2 days of no hormones

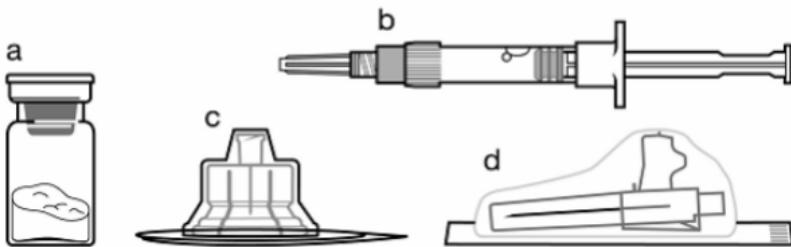


Source: [Natazia: Official patient website](#)

Regular Selling Unit – the selling unit contains same primary packs (e.g., a carton box containing 2 same vials or 3 same blisters).

Complex Selling Unit – the selling unit contains different kind of primary packs. Below an example: Sandostatin (Octreotide acetate)

Included in the injection kit:



- a. One vial containing Sandostatin LAR powder,
- b. One prefilled syringe containing the vehicle solution for reconstitution,
- c. One vial adapter for drug product reconstitution,
- d. One safety injection needle.

Source: - [Novartis official website](#)

Product Selling Units creation

You can create Selling Unit(s) on Product Target to reflect the Selling Unit(s) from the originator, and those Selling Unit(s) can later be added (if needed) to respective Portfolio Project(s).

In this section, Regular Primary Pack and Regular Selling Unit creation will be explained. Later, the creation of Complex Primary Pack & Complex Selling Unit will be explained.

To do that, go to the corresponding Product target.

The screenshot shows the Product Targets page for the Janumet product. The 'Manage Packs and Units' button is highlighted with a red box. The page displays various product details and navigation tabs like New, Assessment, Polymorph Screening, Pre-Dev, Selection, and Decision.

Click on “Manage Packs and Units” button.

The screenshot shows the 'Strength Selection' dialog box. The 'Strength Selection' tab is highlighted with a red box. It lists product strengths and dosage forms, with checkboxes for 100 mg + 1000 mg and 20 mg + 300 mg. A 'Next' button is at the bottom right.

Select the Strength & Dosage Form(s), which you want to create the Selling Unit(s) for. You can add multiple Strength & Dosage Form(s) as well if you intend to create Primary Pack(s) and Selling Unit(s) containing multiple Strength & Dosage Form(s).

Click on “Next” button to proceed further.

Click on “Add Regular Primary Pack”

Select the correct strength from the Product Strength dropdown, that you will be creating the Primary Pack(s) for.

Choose the correct “Primary Pack Type” and “Primary Pack Unit”.

Provide the correct “Count”. For example, if a Blister contains 10 tablets, the Count is 10 and Primary Pack Unit is pcs (pieces). If a Vial contains 5 ml liquid, the Count is 5 and Primary Pack Unit is ml.

Once you are done with creating all the Primary Pack(s), click on “Save and continue with Selling Units”.

Click on “Add regular selling unit” button.

Choose the “Primary Pack” you want to include in your Selling Unit from the Primary Pack dropdown. Also fill the “Primary Pack Count” field up. For example, if there are 3 Blisters in a Selling Unit (box), “Primary Pack Count” is 3, if there are 2 vials in a Selling unit (box), “Primary Pack Count” is 2. Click on “Add regular selling unit” button and repeat the process for all the Selling Unit(s) creation. Once you are done with all the Selling Unit(s) creation, click on “Create Selling Unit” button.

You can see all the Product Selling Unit(s) created in the “Packs & Units” tab in respective Product Target record.

Project Selling Unit creation

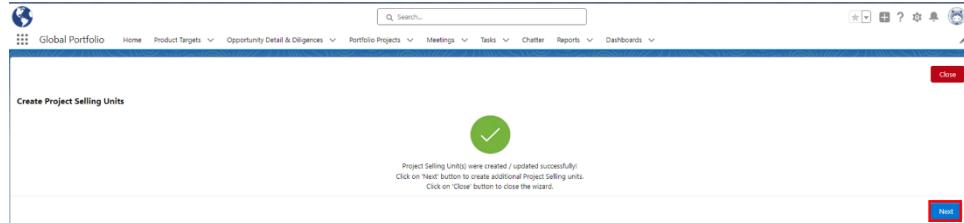
If the parent Product Target already has Selling Unit(s), these Selling Unit(s) can be added (if needed) to Portfolio Project. Also, new Selling Unit(s) can be created from the Portfolio Project.

Navigate to the Portfolio Project, which you want to create selling unit(s) for. Click on “Create Project Selling Units” button.

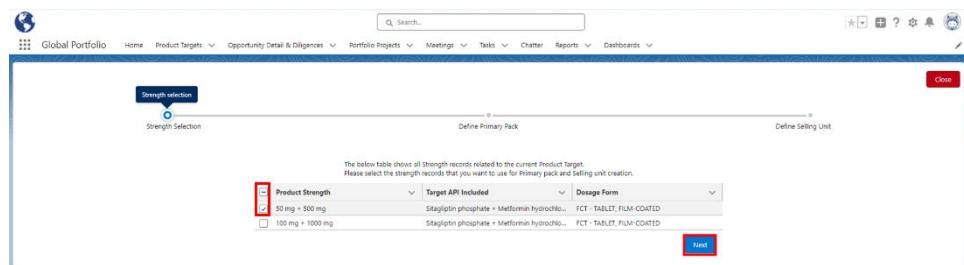
In this section, you will be given an option to import Selling Unit(s), which are in the parent Product Target, but not in current Portfolio Project. You will see nothing in this screen, if no Selling Unit(s) are fulfilling these criteria.

Choose the Product Selling Unit(s) you want to import in this Portfolio Project. If you don't want to import any Product Selling Unit(s) in this Portfolio Project, do not select anything.

Click on "Next" button.

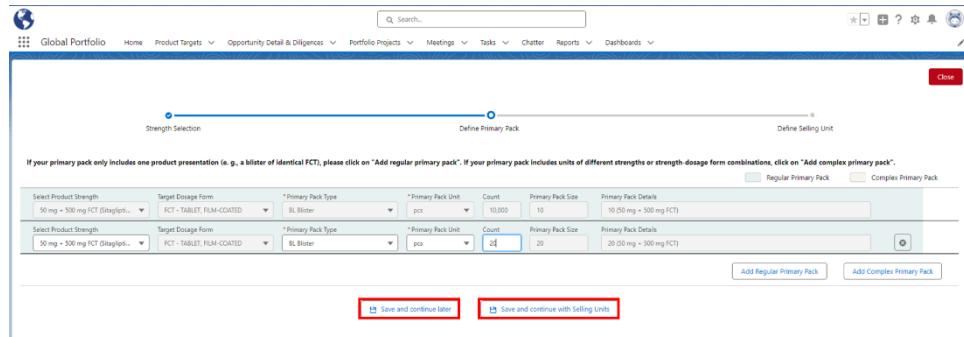


Click on "Next" button to create additional Project Selling Unit(s). If no additional Project Selling Unit(s) are needed, select the "Close" button at the right top corner of the screen.



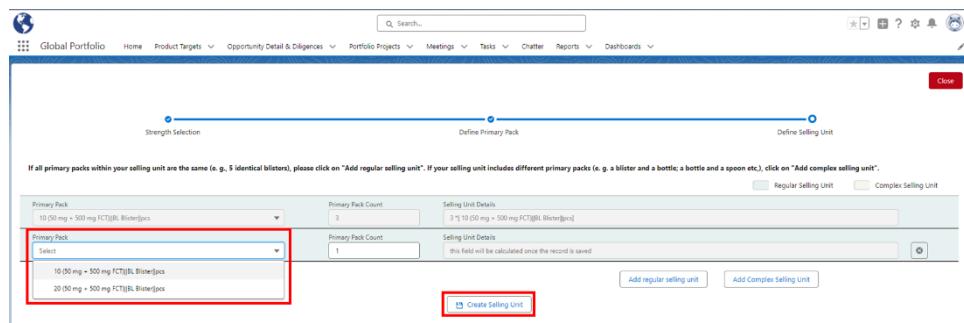
Select the correct strength(s), that you will be creating the Primary Pack(s) for. You can add multiple Strength & Dosage Form(s) as well, if you intend to create Primary Pack(s) and Selling Unit(s) containing multiple Strength & Dosage Form(s).

Click on "Next" button.



Choose the correct "Primary Pack Unit" and "Primary Pack Unit".

Provide the correct "Count". For example – if a Blister contains 20 tablets, the Count will be 20 and Primary Pack Unit will be pcs. If a Vial contains 5 ml liquid, the Count should be 5 and Primary Pack Unit will be ml. Once you are done with creating all the Primary Pack(s), click on "Save and continue with Selling Units".



Click on "Add regular selling unit" button.

Choose the "Primary Pack" you want to include in your Selling Unit.

Also fill the “Primary Pack Count” field up. For example – if there are 1 blister in a Selling unit (box/ carton), “Primary Pack Count” will be 1, if there are 2 vials in a Selling unit (box/ carton), “Primary Pack Count” will be 2.

Click on “Add regular selling unit” button and repeat the process for all the Selling Unit(s) creation. Once you are done with all the Selling Unit(s) creation, click on “Create Selling Unit” button.

You can see all the Project Selling Unit(s) created in the “Str & Packs” tab in respective Portfolio Project record.

Complex Primary pack creation

In this section, the creation of complex Primary Pack is illustrated based on an example – Natazia (Estradiol valerate + Dienogest)

In this product, a blister contains tablets of different strengths.

But what might this do for me?

Days 1-2

Help your body build up the lining of the uterus with a 3-mg dose of estradiol valerate

Days 3-7

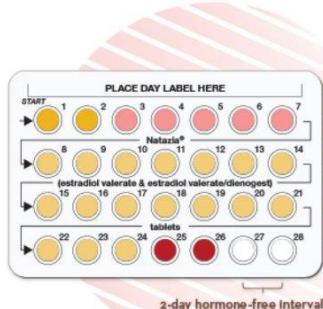
Slow the lining growth with dienogest, while reducing estradiol valerate

Days 8-24

Stabilize the lining of the uterus by raising the dienogest level

Days 25-28

Promote a controlled period by ending with a short interval of further reduced estradiol valerate, followed by 2 days of no hormones



Source: [Natazia: Official patient website](#)

Pre-requisite: Product Strength(s) has already been set up in SANITY.

Go to the corresponding Product target.

Click on “Manage Packs and Units” button.

The below table shows all Strength records related to the current Product Target.
Please select the strength records that you want to use for Primary pack and Selling unit creation.

Product Strength	Target API Included	Dosage Form
0	Insert	TAB - TABLET
1 mg	Estradiol valerate	TAB - TABLET
2 mg + 2 mg	Estradiol valerate + Dienogest	TAB - TABLET
2 mg + 3 mg	Estradiol valerate + Dienogest	TAB - TABLET
3 mg	Estradiol valerate	TAB - TABLET

Send

Select the Strength & Dosage Form, which are needed to create Primary Pack(s) for. As Primary Pack contains multiple strengths, those should be added one by one into complex Primary Pack.
Click on “Next” button to proceed further.

If your primary pack only includes one product presentation (e.g., a blister of identical FCT), please click on "Add regular primary pack". If your primary pack includes units of different strengths or strength-dosage form combinations, click on "Add complex primary pack".

Add Regular Primary Pack Add Complex Primary Pack

Save and continue later Save and continue with Selling Units

Click on “Add Complex Primary Pack”

If your primary pack only includes one product presentation (e.g., a blister of identical FCT), please click on "Add regular primary pack". If your primary pack includes units of different strengths or strength-dosage form combinations, click on "Add complex primary pack".

Select Product Strength	Target Dosage Form	*Primary Pack Type	*Primary Pack Unit	Count	Primary Pack Size	Primary Pack Details	Additional Strengths
0 TAB (empty)	Select	Select	Select	1,000	1	Value will be calculated upon change	>
1 mg TAB (estradiol valerate)	Select	Select	Select	1,000	1	Value will be calculated upon change	>
2 mg + 2 mg TAB (estradiol valerate)	Select	Select	Select	1,000	1	Value will be calculated upon change	>
2 mg + 3 mg TAB (estradiol valerate)	Select	Select	Select	1,000	1	Value will be calculated upon change	>
3 mg TAB (estradiol valerate)	Select	Select	Select	1,000	1	Value will be calculated upon change	>

Save and continue later

Select the correct strength from the Product Strength dropdown, that you will be creating the Primary Pack(s) for.

Choose the correct “Primary Pack Type” and “Primary Pack Unit”.

Provide the correct “Count” for that particular strength. In this example, the blister contains 2 pcs of 3 mg Estradiol Valerate tablets, the Count is 2 and Primary Pack Unit is pcs.

If your primary pack only includes one product presentation (e.g., a blister of identical FCT), please click on "Add regular primary pack". If your primary pack includes units of different strengths or strength-dosage form combinations, click on "Add complex primary pack".

Select Product Strength	Target Dosage Form	*Primary Pack Type	*Primary Pack Unit	Count	Primary Pack Size	Primary Pack Details	Additional Strengths
3 mg TAB (estradiol valerate)	TAB - TABLET	BL Blister	pcs	2	2	2 (3 mg TAB)+ 3 (2 mg + 2 mg TAB)	>

Save and continue later Save and continue with Selling Units

Click on “Additional Strengths” button and repeat the process for all the tablets of different strengths inside that blister.

If your primary pack only includes one product presentation (e.g., a blister of identical FCT), please click on "Add regular primary pack". If your primary pack includes units of different strengths or strength-dosage form combinations, click on "Add complex primary pack".

Select Product Strength	Target Dosage Form	*Primary Pack Type	*Primary Pack Unit	Count	Primary Pack Size	Primary Pack Details	Additional Strengths
3 mg TAB (estradiol valerate)	TAB - TABLET	BL Blister	pcs	2	2	2 (3 mg TAB)+ 3 (2 mg + 2 mg TAB)	>
2 mg + 2 mg TAB (estradiol valerate)	TAB - TABLET	BL Blister	pcs	2	2	2 (3 mg TAB)+ 3 (2 mg + 2 mg TAB)	>

Save and continue later Save and continue with Selling Units

You can see the details of your Complex Primary Pack in the “Primary Pack Details” field as you advance through the process.

If you want to create more Regular/ Complex Primary Pack(s), select accordingly (Add Regular Primary pack/ Add Complex Primary pack) and repeat the process.

Once you are done with creating the whole Primary Pack(s), click on “Save and continue with Selling Units”.

For the given example, click on “Add regular selling unit” button.

Choose the “Primary Pack” you want to include in your Selling Unit from the “Primary Pack” dropdown. Also fill the “Primary Pack Count” field up. For example – if there is 1 blister in a Selling unit (box/ carton), “Primary Pack Count” will be 1, if there are 3 blisters in a Selling unit (box/ carton), “Primary Pack Count” will be 3.

Please click on “Add regular selling unit” button and repeat the process as needed.

Click on “Add regular selling unit” button and repeat the process for all the Selling Unit(s) creation if you want to create additional Selling Unit(s).

Once you are done with all the Selling Unit(s) creation, click on “Create Selling Unit” button.

You can see the created Primary Pack(s) and Selling Unit(s) in the “Packs & Units” tab in the corresponding Product Target.

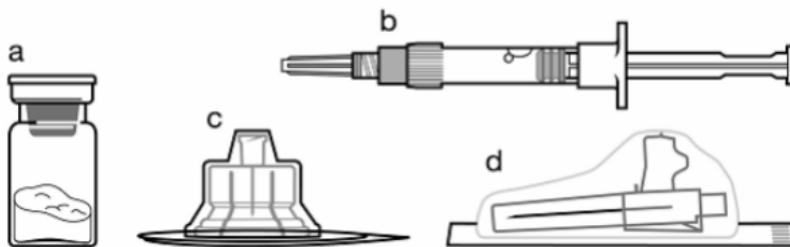
You can also create Project Selling Units in the exact same way from the corresponding Portfolio Project. (refer to Project Selling Unit creation section)

Complex Selling Unit creation

For Complex Selling Unit Creation an example of Octreotide acetate [Sandostatin LAR] will be given.

Description - Unit packs containing one 6 mL glass vial (a) with rubber stopper (bromobutyl rubber), sealed with an aluminium flip-off seal, containing 10 mg powder for suspension for injection and one 3 mL colourless pre-filled glass syringe (b) with front and plunger stopper (chlorobutyl rubber) with 2 mL solvent, co-packaged in a sealed blister tray with one vial adapter (c) and one safety injection needle (d).

Included in the injection kit:



- One vial containing Sandostatin LAR powder,
- One prefilled syringe containing the vehicle solution for reconstitution,
- One vial adapter for drug product reconstitution,
- One safety injection needle.

Source: - Novartis official website

Strength Link	Dosage + Strength	API Combination	Innovative	GMD Status
1 PSCU - 10 mg	10 mg PSCU	Octreotide acetate	<input checked="" type="checkbox"/>	Draft
2 Inert	(0 / 3 ml USV	inert	<input checked="" type="checkbox"/>	Draft
3 Inert	0 DEV	inert	<input checked="" type="checkbox"/>	Draft

Pre-requisite – Product Strength(s) has already been properly set up in SANITY.

Go to the corresponding Product target.
Click on “Manage Packs and Units” button.

Select the Strength & Dosage Form(s), which you want to create the Selling Unit(s) for. Click on “Next” button to proceed further.

Click on “Add Regular Primary Pack”

Select the correct strength from the Product Strength dropdown, that you will be creating the Primary Pack(s) for.

Choose the correct “Primary Pack Type” and “Primary Pack Unit”.

Provide the correct “Count”. For example – if a vial contains 10 mg powder, the Count will be 10 and Primary Pack Unit will be mg. If a syringe contains 3 ml liquid, the Count should be 3 and Primary Pack Unit will be ml.

Once you are done with creating all the Primary Pack(s), click on “Save and continue with Selling Units”.

Click on “Add Complex Selling Unit” button.

Choose the “Primary Pack” you want to include in your Selling Unit from the Primary Pack dropdown. Also fill the “Primary Pack Count” field up. For example – if there is 1 vial in a Selling unit (box/ carton), “Primary Pack Count” will be 1.

Click on “Add Primary Pack” button and add all the Primary Pack(s) in the Selling Unit.

If all primary packs within your selling unit are the same (e.g., 5 identical blisters), please click on "Add regular selling unit". If your selling unit includes different primary packs (e.g., a blister and a bottle; a bottle and a spoon etc.), click on "Add complex selling unit".

Primary Pack: 10 (10 mg PSU)(Vi Vial)
Select Primary Pack: 3 (0.3 ml USV)(Sy Syringe)
Select Primary Pack: 1 (0 DEV)(BL Blister)

Primary Pack Count: 1
Primary Pack Details: 1 * 10 (10 mg PSU)(Vi Vial) + 1 * 3 (0.3 ml USV)(Sy Syringe) = 1 * 1 (0 DEV)(BL Blister)

Additional Primary Pack:

Regular Selling Unit: Complex Selling Unit:

Add regular selling unit Add Complex Selling Unit

Once you are done with all the Selling Unit(s) creation, click on “Create Selling Unit” button.

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Product Target: Octreotide acetate DEV|USV|PSOU

Packs & Units Forecasts BD & Scouting Quip

Primary Packs (3)

Primary Pack	Pack Type	Complex Prim. ...	# of Strs	Primary Pack Name
1 10 (10 mg PSU)	Vi Vial		1	PP-000721
2 3 (0.3 ml USV)	Sy Syringe		1	PP-000722
3 1 (0 DEV)	BL Blister		1	PP-000723

Selling Units (1)

Selling Unit Name	Dosage	Total Pack	# Prim. Pac...	Complex U...	Selling Unit Details (extended)
1 * 10 (10 mg PSU) * 1 * 3 (0.3 ml USV) * 1 (0 DEV)	PSOU USV DEV	3,000	3		1 * Primary Pack 1 * Primary Pack 2 * Primary Pack 3 Primary Pack

Product Target APIs (2)

PTAU-0000000118	PTAU-0000000119
Target API Name: Octreotide acetate	Target API Name: Insert
Insert	Insert
API Sequence: 2	API Sequence: 2

Files (0)

Upload Files Or drop files

Pre-Launch Forecast Review Potential Allocation In-Market

All Sandoz Pre-Launch Forecasts w or w/o Product Rights (no unsigned BD)

We can't draw this chart because there is no data.

Related List Quick Links:

- Product Target APIs (2)
- Portfolio Projects (Product Targets) (0)
- Opportunity Detail & Diligences (0)
- Business Development Deal (0)
- Product Lists (0)
- Forecasts and Actuals (0)
- Forecast (0)
- Actual (0)
- Forecasted (0)

- Forecasts and Actuals (0)
- Meeting Agenda Items (0)
- BEAT Countries (0)
- Sandoz SKU (0)
- Product Details (0)
- Product Targets (0)

Show All (20)

You can see all the Product Selling Unit(s) created in the “Packs & Units” tab in respective Product Target record.

You can also create Project Selling Unit(s) in the exact same way from the corresponding Portfolio Project. (Refer to Project Selling Unit creation section)