Creation of Selling Units

Contents

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)
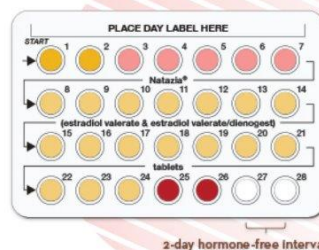
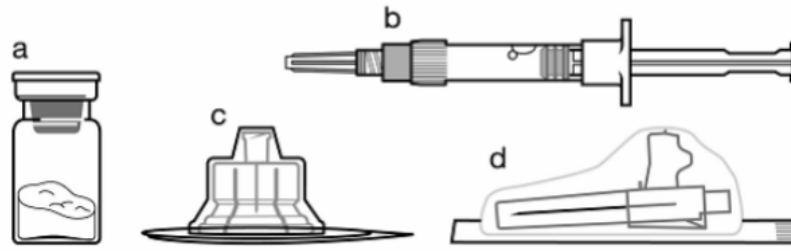Source: Natazia: Official patient website

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.

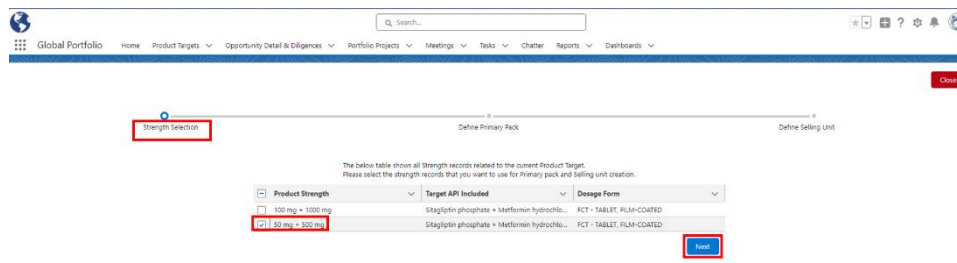Source: - <u>Novartis official website</u>

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.
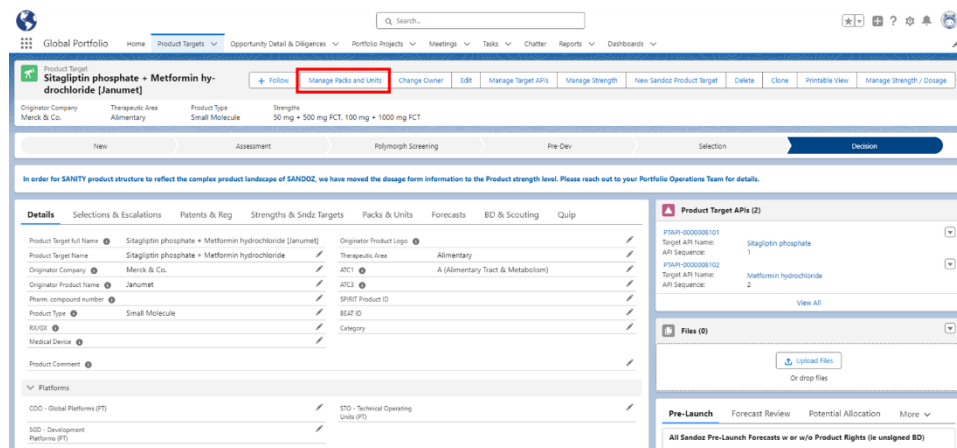
Click on "Manage Packs and Units" button.

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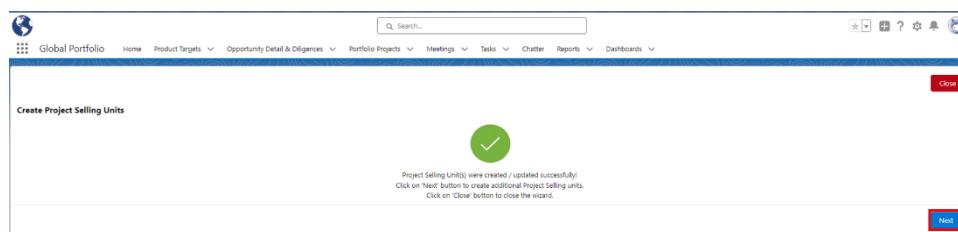
Click on "Next" button to create additional Project Selling Unit(s). If no additional Project Selling Unit(s) are needed, select the "Close" button at the right top corner of the screen.
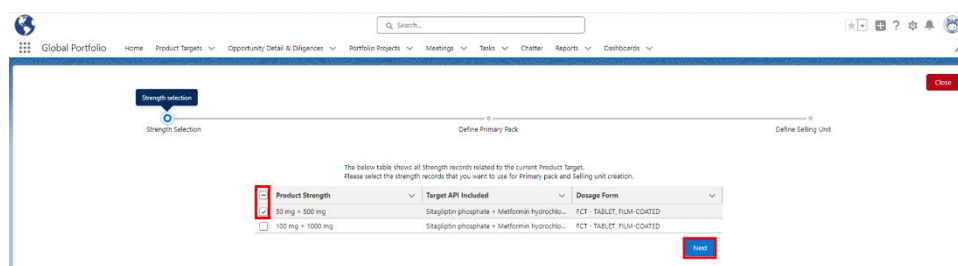

Select the correct strength(s), that you will be creating the Primary Pack(s) for. You can add multiple Strength & Dosage Form(s) as well, if you intend to create Primary Pack(s) and Selling Unit(s) containing multiple Strength & Dosage Form(s).

Click on "Next" button.
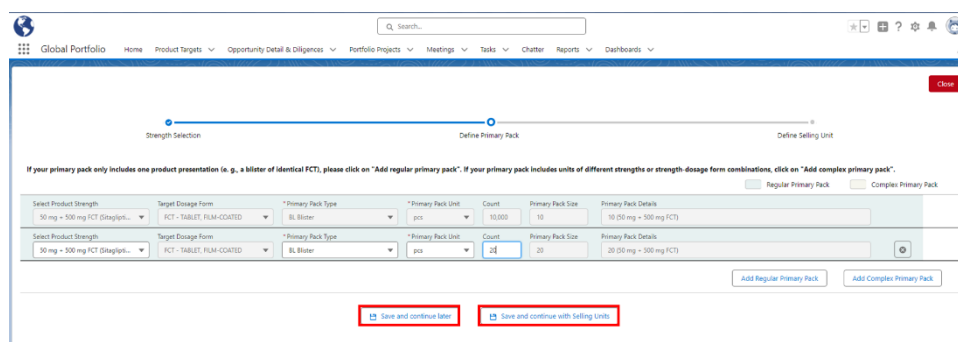
Choose the correct "Primary Pack Unit" and "Primary Pack Unit".

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".
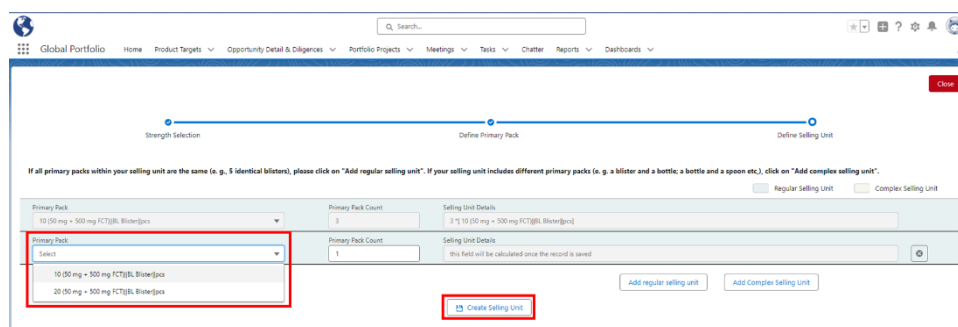
Click on "Add regular selling unit" button.

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.
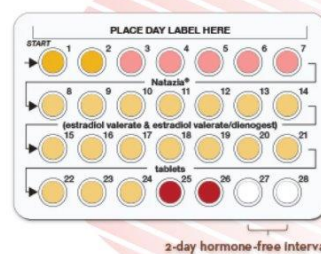
Source: Natazia: Official patient website

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.

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.

Click on "Add Complex 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 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.

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

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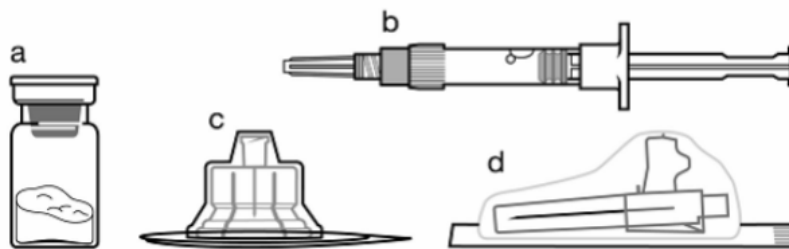You can also create Project Selling Units in the exact same way from the corresponding Portfolio Project.
(refer to Project Selling Unit creation section)

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:

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**

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.

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.
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)