

User Guide PEI-C Rebuild

Version 1-0



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1. Introduction

The use of PEI-C Rebuild provides the pharmaceutical industry with a tool for electronic submissions of batch release applications.

Please take your time to read this manual, since we have tried our best to describe all essential functions of the application in detail. If you have any questions after reading the manual, please feel free to contact our helpdesk on cr_support@pei.de. To help our support team, please quote the version number and your log-in data. You will find this information on the left-hand side of your screen below the navigation menu (Figure 2, box (3)).



Important!

We have marked all the information which we consider as especially important with the symbol shown here in the left margin.

2. Login

After your application for the access data at DIMDI, you will receive your user ID and password in two separate letters. That way, you will have access to the various different professional applications. In your quality as marketing authorisation holder, you will be able to assign and administrate additional access authorisations.



You will only be entitled to receive an authorisation for access from DIMDI if you are a marketing authorisation holder.

If you are an authorised company, you will receive the access data from the marketing authorisation holder who authorised you to submit the application.

You will find the PEI-C Rebuild application in the navigation menu to the left on the PharmNet.Bund welcome page www.pharmnet.bund.de.



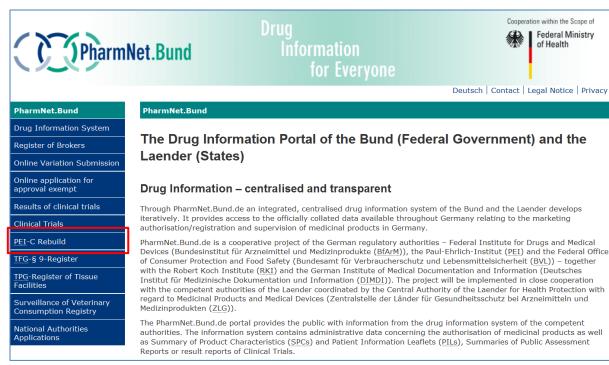


Fig. 1: entry zone PharmNet.Bund



3. General operating functions

The application provides a number of icons which are used in various places. These are listed below:

a) Carbage can



Clicking on this icon will remove the previously inserted data again. The carbage can will typically be found in places where data can be entered manually, e.g. in places where documents can be uploaded or with hierarchical structures, which users compiled themselves, such as the component tree.

b) Pen



The pen represents the *edit* function. Clicking on *edit* will unlock data currently only displayed so that they can be edited. The pen can for instance be found with reports.

c) Printer



The printer represents the *print* function. It can typically be found on each page in the top right-hand corner. You can click on this icon to print the current page.

d) Page up



You will find this icon at the bottom of each page on the right. It makes navigating to the beginning of the page easier for you.

e) Information



You will find this icon in various places. Move the mouse cursor over it, and you will receive some information on the appropriate field.

Required fields are marked with a dot. You will receive an error message if you have forgotten to complete one or more required fields.

The *continue* and *back* buttons are available on almost all screens. These are used to scroll forward or back one page. Many pages also provide you with the option of saving your current entries into a template using the *save as draft* function.



4. Making an application for a batch release

4.1.General information

After successful registration, you will see the start screen of the application. On this screen, you can select the type of application. If you do not automatically start on this screen or have moved to a different section of the application, click *new application* in the *navigation menu* (1) to return to the start screen.

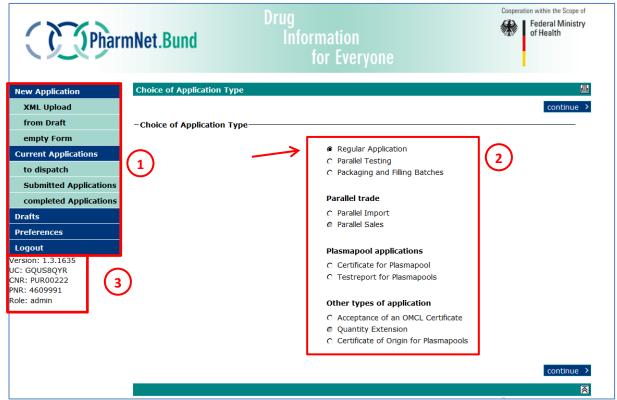


Fig. 2: start screen - choice of application type

In the navigation menu (box 1), you can select whether you wish to start with the empty template, upload a batch release application in XML format or use your own template for an application. In addition, the navigation menu offers you the choice to display or manage current applications or saved templates, change settings, or exit the application.

Box (2) shows the application types available to you for the application for a new batch release. These are described in the sections below. Regular applications are described in detail. For all other application types, the differences between these application types and the regular application will be described.



The application types of *parallel sales* and *quantity extension* do not have a function on the start page. Parallel sales have not yet been implemented in this version of the application. Quantity extensions can solely be made as a follow-up application.

You will find your administrative data (box 3) in the section below the navigation menu of each page. Please provide these data, if you have a question for the helpdesk.



The chart below is designed to provide a map for you, which you can use to obtain an overview of the sequence of the screens.

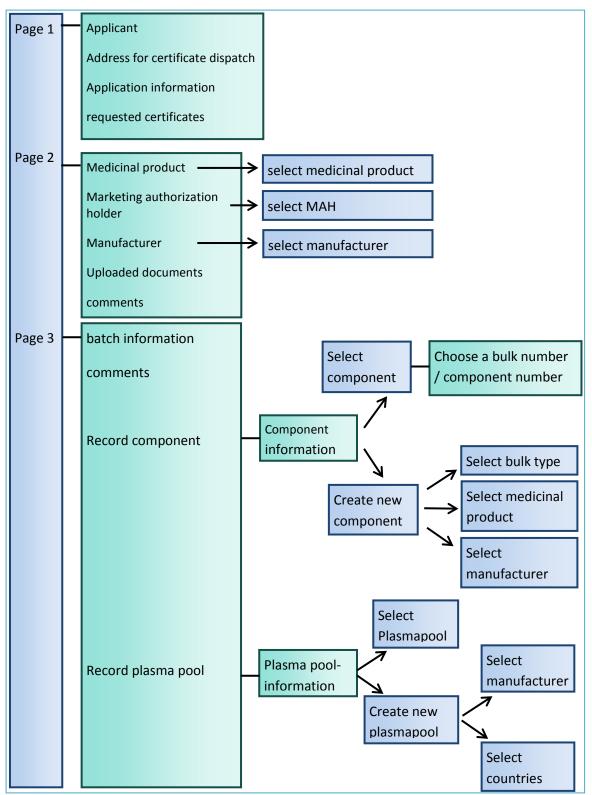


Fig. 3: overview of the sequence of the screens for a Regular Application



4.2. Major types of administration

4.2.1. Regular application

The option "Regular application" has been selected on the start screen (Figure 2) by clicking the check box.

Click the *continue* button on the right of the screen to start creating a new batch release application.

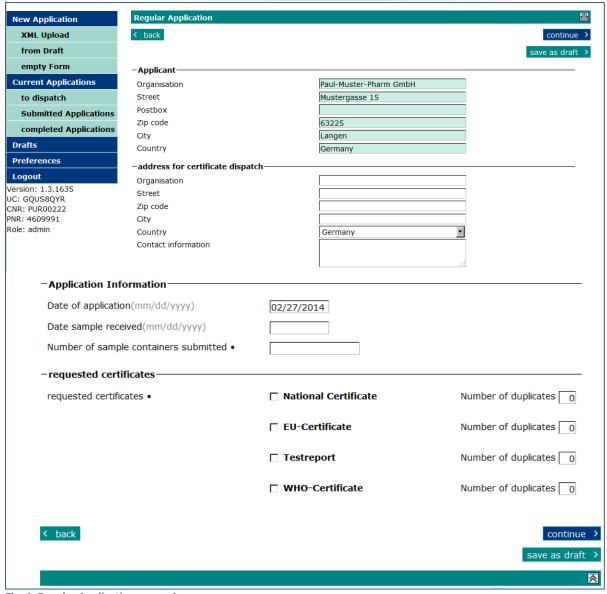


Fig. 4: Regular Application - page 1

The marketing authorisation holder will automatically be retrieved as **Applicant**.

- The **address for certificate dispatch** can be entered as free text; if no text is entered, the certificate will be sent to the applicant.
- The default value for the **date of application** is always the date of today, however, a different date can be entered. Dates in the future can also be entered, if the application is only in preparation, and the user has planned not to send it yet.



- In the **number of sample containers submitted** field, please enter the number of containers which you will transmit to the PEI for testing or as deferred sample.
- In the section **requested certificates** check the releases required; also enter the number of additional copies if necessary. (if the check box for type of release is checked and a "1" is indicated for the number of copies, you will receive one original and one copy.)
- Select *continue* to go to the second screen of the regular application.

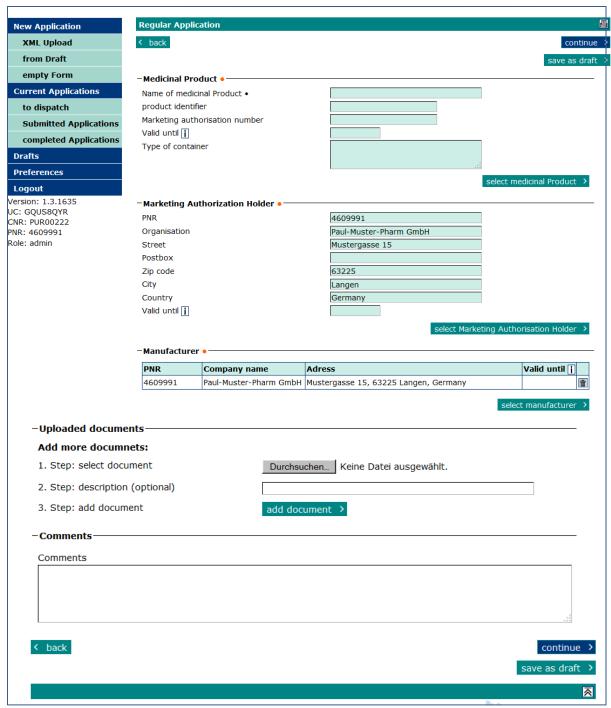


Fig. 5: Regular Application - page 2

This screen consists of several sections which will be explained in detail below.

- Medicinal product
- Marketing authorisation holder



- manufacturer
- uploaded documents
- comments

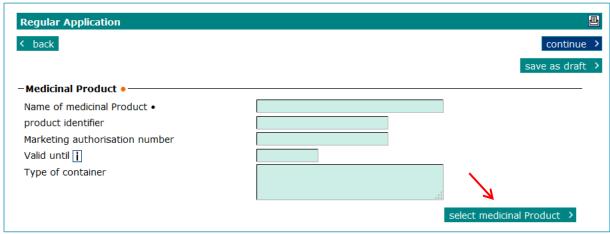


Fig. 6: Regular Application - page 2 - select medicinal product

In this section, *select medicinal product* for which you wish to make the application.

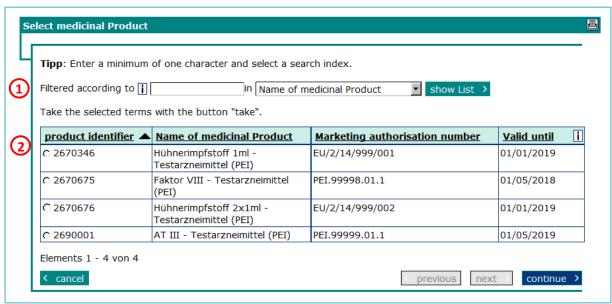


Fig. 7: Regular Application - select medicinal product

The following options are available for selecting the product:

- 1. The product can be selected by means of the **search function** (1) by entering the name of the medicinal product, the ENR or the marketing authorisation number.
- You can select your product from the product list (2). As a matter of course, a user can only select from his own products. The list can be sorted by headings (by means of a click on the appropriate heading), and you can scroll back and forwards in the list by clicking on the previous and next buttons.



To display the current product list, enter "*" in the search field, then click on the **show list** button.



Click continue to accept the product selected. You will return to the current main screen.



Fig. 8: Regular Application - page 2 - medicinal product selected

After selecting the product, another button is available: **select additional medicinal products**. Here, you can apply for the release of a batch with a multi-ZNR range if you have selected a product, the package size of which is not part of the German batch release. For further information, please refer to Section 4.3.

In the next step, you can *select Marketing Authorisation Holder* if required.

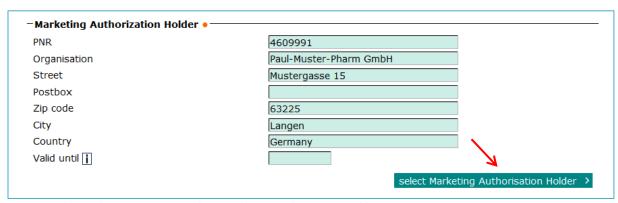


Fig. 9: Regular Application - page 2 - select Marketing Authorisation Holder

This slightly confusing option is available for the following reason: If the address information of a marketing authorisation holder changes, while this marketing authorisation holder is still the same legal entity, it is still possible to market batches with the old address information for a limited defined period of time. This menu option enables you to select the old address information.

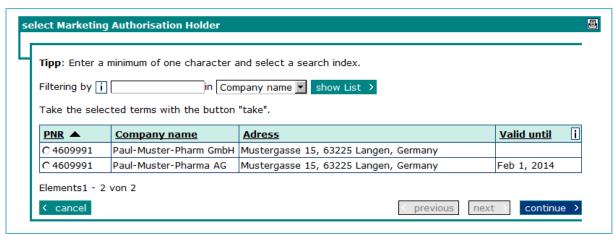


Fig. 10: Regular Application - select Marketing Authorisation Holder



In the next section, you can *select manufacturer*. The manufacturers stored in the database of the federal authorities of the above selected medicinal product are automatically shown in a list.

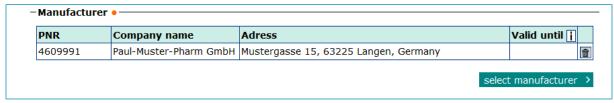


Fig. 11: Regular Application - page 2 - select manufacturer

If more than one manufacturer exists, or a manufacturer has changed, you can adapt the selection manually using the **select manufacturer** button. The carbage can icon at the end of the line can be used to delete an out-of-date manufacturer.

Caution!



The selection of other /more recent manufacturers in this section will never replace the appropriate notification of variation to be submitted to the federal authorities.



Fig. 12: Regular Application - select manufacturer

The following options are available for selecting the manufacturer:

- 1. Selection by means of the **search function** (1) by entering company name, PNR, zip code, city, or country.
- 2. Selection by means of the **manufacturer list** (2). The list can be filtered by headings by clicking on the list, and you can scroll in the list using the "next" and "previous" buttons.

Click *continue* to accept the manufacturer selected. You will return to the current main screen.



Add more documnets:	
1. Step: select document	Durchsuchen Keine Datei ausgewählt.
2. Step: description (optional)	
3. Step: add document	add document >

Fig. 13: Regular Application - page 2 - uploaded documents

The section **uploaded documents** is used to attach additional documents. Formats supported include .rtf, .jpg, .doc, .xls and .pdf . You can use the **Durchsuchen (search)** button to select the document on your computer. You also have the option to give a document an additional descriptive name.

Use the *add document* button to attach the document to your current application. Proceed in the same way to attach additional documents.

Attached documents are displayed as follows

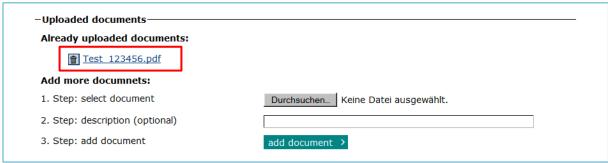


Fig. 14: Regular Application - page 2 - with document uploaded

You can make **comments** at the bottom of page 2 of the regular application. Thus, you can transmit valuable information and notes to a contact person who will process the documents.



Fig. 15: Regular Application - page 2 - comments

On the third page of the regular application, enter the information on the batch for which you wish to apply for a release. This page consists of three sections:

- Batch information
- comments
- Component information



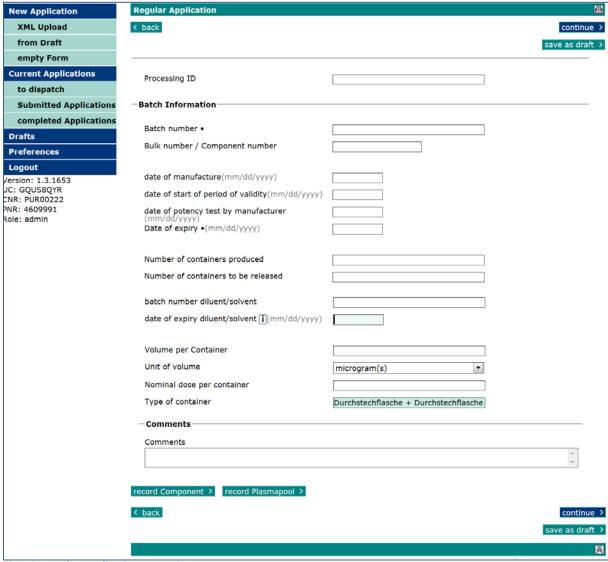


Fig. 16: Regular Application - page 3

Fill in the appropriate fields with the information on the batch for which the application is made. The **processing ID** will be assigned automatically. Please quote this ID in all further correspondence with the PEI.

The **type of container** is accepted automatically by the system from the PEI database. If more than one type of container is listed in the database for one application, you can select the type of container for which you make the application.

The following section shows how you can build up your batch with *Components* and / or *Plasmapools* contained in the batch. Thus, you will save time, since components / plasmapools once created are stored in the application, and can be used again if you wish to make further applications with the same components / plasmapools.





Fig. 17: Regular Application - page 3 - record component / Plasmapool

Components can be inserted in any depth. Likewise, you can indicate one or more plasmapools which have contributed to a batch or one of the components.

Click **record Component** and you will see this screen:

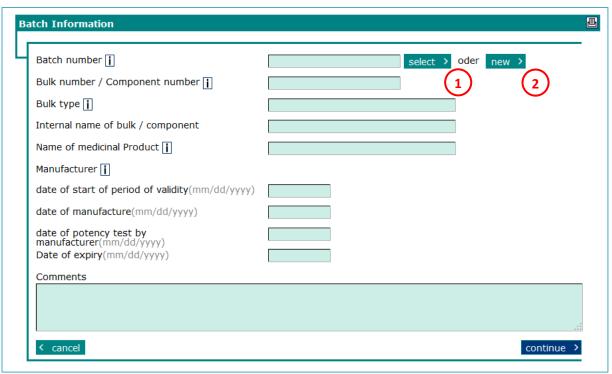


Fig. 18: Regular Application - component information

Here, you can add the batch name of the component from the list of the batch names already stored in the system. Choose **select** (1) or **new** (2).

If you choose *select* in a component from the list (1), you will obtain this screen:



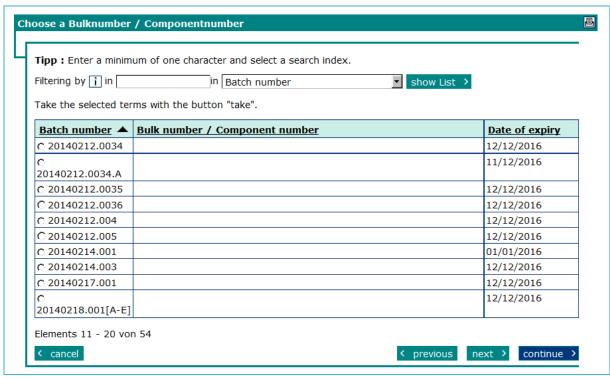


Fig. 19: Regular Application - select component

Use the search function and click **show list**, then select a batch as component as the batch for which an application is made.

To select the component, you will have the following options:

- The selection can be made using the **Search function** by entering the batch name or bulk number / component number.
- 2. The **list presentation** displays all the batches already saved by you for selection. The list can be sorted by headings (by means of a click on the appropriate heading), and you can scroll up and down in the list by clicking on the **previous** and **next** buttons.

Click *continue* to accept the batch selected as component. You will return to the current main screen of the component.

Click **new** (2) on the page of the component information (Figure 18) for creating a component. You will see this screen:



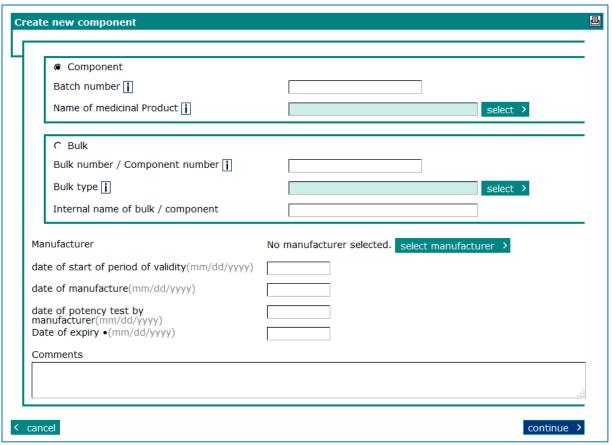


Fig. 20: Regular Application - create new component

In this screen, you can indicate a batch name or a bulk / component number. Depending on whether the component is an authorised medicinal product or a product type, you can select the name of the product or the bulk type and the bulk name. Click the appropriate *select* button to proceed to the following screens on which you will find the search function, and the list presentation can be used in the same way as already described above.

From the product name list, select a product if this is part of a component of the batch for which an application is to be made.



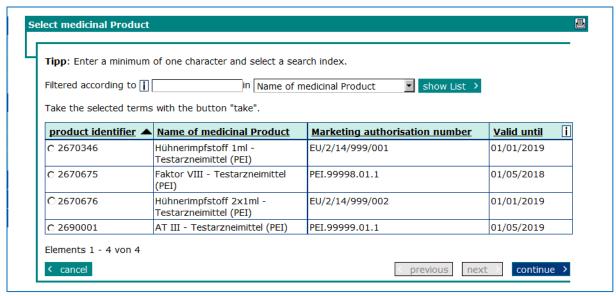


Fig. 21: Regular Application - select medicinal product as component

Select *continue* to return to the screen for creating a new component (Figure 20).

If a product type is part of a component in your batch, select your product type from the list of bulk types.

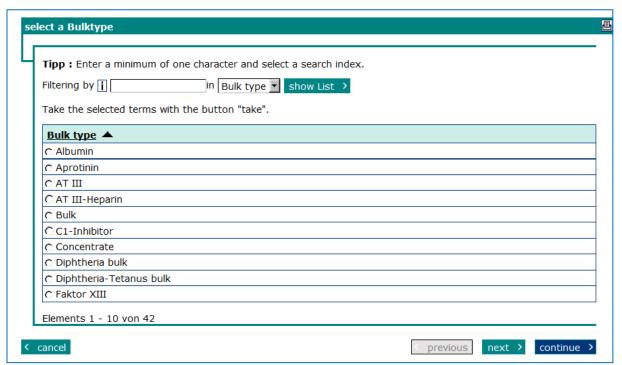


Fig. 22: Regular Application - select bulk type as component

Click continue to return to the screen for creating a new component (Figure 20).

Then select the manufacturer of the component.



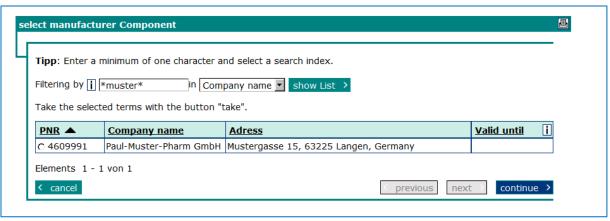


Fig. 23: Regular Application - select manufacturer component

After you have entered the other details required on the component in the appropriate fields and typed your notes as desired, click *continue* to accept the completed component in your application.

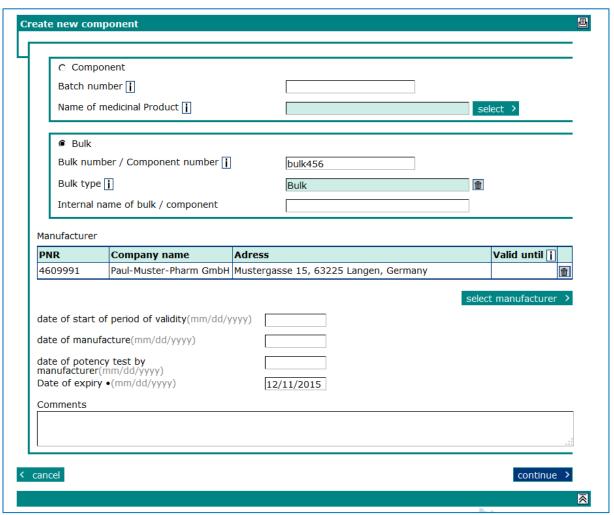


Fig. 24: Regular Application - accept new created component



egular Application	
back	save as d
Processing ID	
Batch Information	
Batch number •	A222333
Bulk number / Component number	
date of manufacture(mm/dd/yyyy)	
date of start of period of validity(mm/dd/yyyy)	
date of potency test by manufacturer(mm/dd/yyyy) Date of expiry •(mm/dd/yyyy)	12/12/2016
Number of containers produced	
Number of containers to be released	
batch number diluent/solvent	
date of expiry diluent/solvent [](mm/dd/yyyy)	
Volume per Container	
Unit of volume	microgram(s)
Nominal dose per container	
Type of container	Durchstechflasche + Durchstechflasche
-Comments	
Comments	
Included Components	(1) (2) (3) (4)
L⊞ bn: bulk456	
record Component > record Plasmapool >	
< back 5 6	7 continue
	save as draft

Fig. 25: Regular Application - page 3 - with component

After accepting a component, several options are available to continue (marked with the appropriate number in the screen shot):

- 1. Add an own component to the component in the corresponding line
- 2. Add an own plasmapool to the component in the corresponding line
- 3. Edit the component information in the corresponding line
- 4. Delete the component in the corresponding line
- 5. Add another component to the batch for which the application is to be made (at the same level



- 6. Add a plasmapool to the batch for which the application I to be made (at the same level)
- 7. Continue your batch release application without adding another component / plasmapool

Record plasmapool is available only if you have selected a blood product on page 2 of the regular application.

After clicking *record plasmapool* you will see this screen on which you can enter information on the plasmapool.

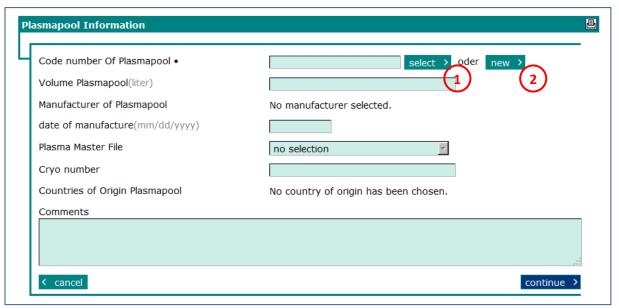


Fig. 26: Regular Application - Plasmapool Information

Here, too, you will have the option to select a plasmapool already created (1) or create a new plasmapool (2).

If you wish to **select** a plasmapool, you will obtain this page by clicking the appropriate button:



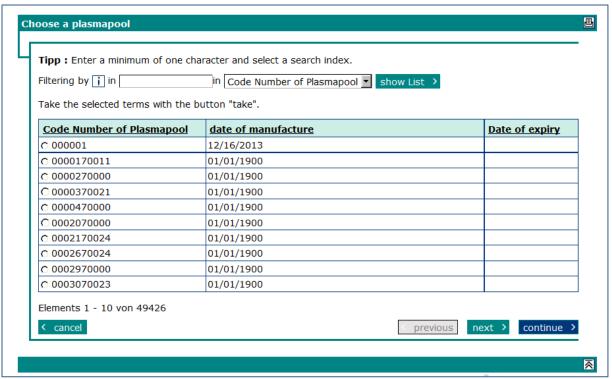


Fig. 27: Regular Application - select Plasmapool

On this screen, as explained for comparable screens, you will again have the option to select a plasmapool using the search field or the list selection. Click *continue* to accept the plasmapool selected in the main template. Here, all the necessary data of the plasmapool from the database will automatically be accepted.

If you wish to create a new plasmapool (*create new*), click on the appropriate button and fill in at least the compulsory fields on the screen below:

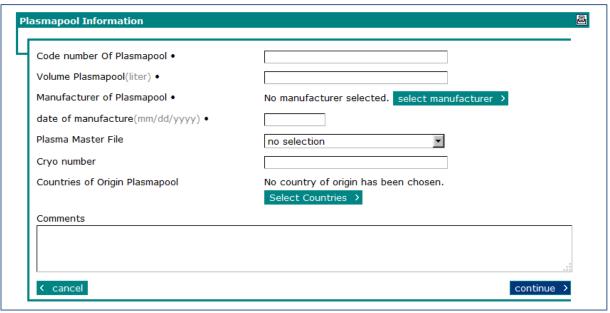


Fig. 28: Regular Application - create new Plasmapool



Click **select manufacturer** and you will see the screen on which you will find some search and list functions already known to you. Click **continue** to accept the manufacturers selected in the plasmapool information.

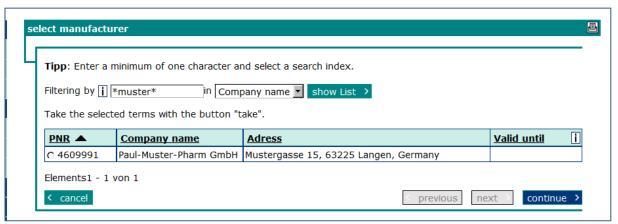


Fig. 29: Regular Application - select manufacturer Plasmapool

Click *select countries* to obtain the screen below on which you can select one or more than one countries of origin.

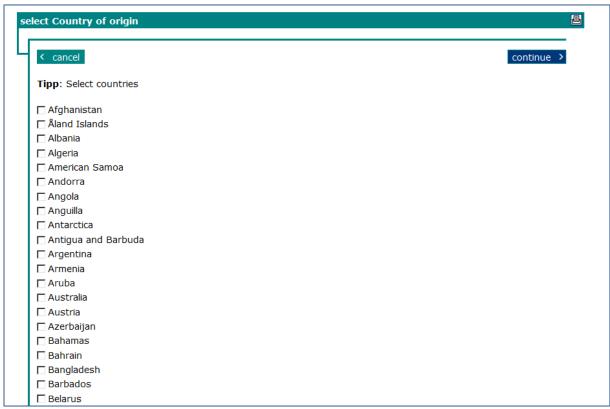


Fig. 30: Regular Application select countries

After completing the other fields on the plasmapool information screen, confirm this information by clicking *continue* to accept this plasmapool in your application.



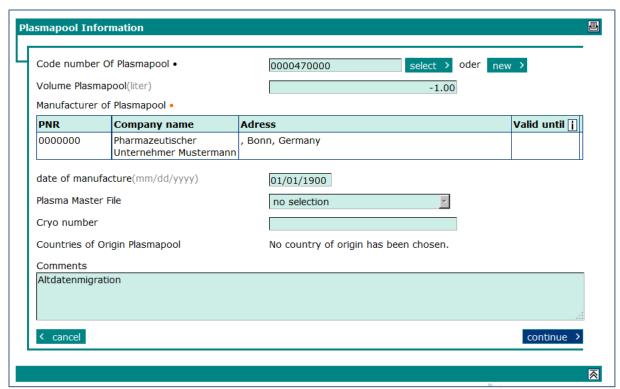


Fig. 31: Regular Application - record Plasmapool

An application with a component tree inserted, consisting of batches and plasmapools could then look like this:



New Application	Regular Application	
XML Upload	< back	continue >
from Draft		save as draft >
empty Form		
Current Applications	Processing ID	
to dispatch		
Submitted Applications	-Batch Information-	
completed Applications	Batch number •	A222333
Drafts	Bulk number / Component number	
Preferences		
Logout	date of manufacture(mm/dd/yyyy)	
Version: 1.3.1635 UC: GQUS8QYR	date of start of period of validity(mm/dd/yyyy)	
CNR: PUR00222 PNR: 4609991	date of potency test by	
Role: admin	manufacturer(mm/dd/yyyy) Date of expiry •(mm/dd/yyyy)	12/12/2016
	230 5. 5.1 (, 25, /////	12/12/2010
	Number of containers produced	
	Number of containers to be released	
	batch number diluent/solvent	
	date of expiry diluent/solvent [](mm/dd/yyyy)	
	Volume per Container	
	Unit of volume	microgram(s)
	Nominal dose per container	
	Type of container	Durchstechflasche + Durchstechflasche
- Comment		
Included Co ⊢⊞ bn: bu		
└⊞ pn: —⊞ pn: 00 —⊞ ch: CO	0000370021 02670024 M2233 com4477 - PP887 447	
< back		save as draft >

Fig. 32: Regular Application - page 3 - with included components

The *edit* icon (pencil) will always return you to the screen of the appropriate component or plasmapool. Use the *carbage can* to delete the component / plasmapool in the appropriate line. Click on the (+) - *symbol* before a component to display more detailed information on the component.





Fig. 33: Regular Application - page 3 - with components on / off

In the display showing details on the component, you can view the bulk number (bn) and the type of the component included or its name.

Click on the (-) - symbol to hide the component details again.

Confirm all data in the application by clicking *continue*. The **Report** is displayed.

The Report shows the information entered by you, subdivided into paragraphs. You can use the pencil icon, which you will find next to each paragraph heading, to retrieve incorrect or incomplete paragraphs back into the edit mode. Alternatively, edit mode can be reopened using the *back* button.



polication Information		
pplication Information 🏒		
pplicant		
rganisation	Paul-Muster-Pharm GmbH	
treet	Mustergasse 15	
ostbox		
p code	63225	
ity	Langen	
ountry	Germany	
oplication Information		
ype of application	Regular Application	
ate of application	Mar 14, 2014	
ate sample received		
umber of sample containers ubmitted	4	
quested certificates	EU-Certificate (Number of duplicates 0)	
umber of containers to be released		
Medicinal Product		
Name of medicinal Product	Faktor VIII - Testarzneimittel (PEI)	
Name of medicinal Product product identifier	2670675	
Name of medicinal Product product identifier Marketing authorisation number	2670675 PEI.99998.01.1	
Name of medicinal Product product identifier Marketing authorisation number Valid until	2670675	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder	2670675 PEI.99998.01.1	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder PNR	2670675 PEI.99998.01.1 Jan 5, 2018 4609991	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder PNR Organisation	2670675 PEI.99998.01.1 Jan 5, 2018 4609991 Paul-Muster-Pharm GmbH	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder PNR Organisation Street	2670675 PEI.99998.01.1 Jan 5, 2018 4609991 Paul-Muster-Pharm GmbH Mustergasse 15	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder PNR Organisation	2670675 PEI.99998.01.1 Jan 5, 2018 4609991 Paul-Muster-Pharm GmbH Mustergasse 15 63225	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder PNR Organisation Street Zip code City	2670675 PEI.99998.01.1 Jan 5, 2018 4609991 Paul-Muster-Pharm GmbH Mustergasse 15	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder PNR Organisation Street Zip code City Country	2670675 PEI.99998.01.1 Jan 5, 2018 4609991 Paul-Muster-Pharm GmbH Mustergasse 15 63225	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder PNR Organisation Street Zip code City	2670675 PEI.99998.01.1 Jan 5, 2018 4609991 Paul-Muster-Pharm GmbH Mustergasse 15 63225 Langen	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder PNR Organisation Street Zip code City Country Valid until Manufacturer	2670675 PEI.99998.01.1 Jan 5, 2018 4609991 Paul-Muster-Pharm GmbH Mustergasse 15 63225 Langen	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder PNR Organisation Street Zip code City Country Valid until Manufacturer PNR	2670675 PEI.99998.01.1 Jan 5, 2018 4609991 Paul-Muster-Pharm GmbH Mustergasse 15 63225 Langen	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder PNR Organisation Street Zip code City Country Valid until Manufacturer	2670675 PEI.99998.01.1 Jan 5, 2018 4609991 Paul-Muster-Pharm GmbH Mustergasse 15 63225 Langen Germany	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder PNR Organisation Street Zip code City Country Valid until Manufacturer PNR	2670675 PEI.99998.01.1 Jan 5, 2018 4609991 Paul-Muster-Pharm GmbH Mustergasse 15 63225 Langen Germany 4609991 Paul-Muster-Pharm GmbH Mustergasse 15	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder PNR Organisation Street Zip code City Country Valid until Manufacturer PNR Organisation	2670675 PEI.99998.01.1 Jan 5, 2018 4609991 Paul-Muster-Pharm GmbH Mustergasse 15 63225 Langen Germany 4609991 Paul-Muster-Pharm GmbH	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder PNR Organisation Street Zip code City Country Valid until Manufacturer PNR Organisation Street	2670675 PEI.99998.01.1 Jan 5, 2018 4609991 Paul-Muster-Pharm GmbH Mustergasse 15 63225 Langen Germany 4609991 Paul-Muster-Pharm GmbH Mustergasse 15	
Name of medicinal Product product identifier Marketing authorisation number Valid until Marketing Authorization Holder PNR Organisation Street Zip code City Country Valid until Manufacturer PNR Organisation Street	2670675 PEI.99998.01.1 Jan 5, 2018 4609991 Paul-Muster-Pharm GmbH Mustergasse 15 63225 Langen Germany 4609991 Paul-Muster-Pharm GmbH Mustergasse 15 63225 63225	

Fig. 34: Regular Application - report part 1 (with uploaded documents)



Batch Information					
Bulk					
Duik					
State					
Processing ID					
Batch number	CHAR123A				
Bulk number / Component number					
date of manufacture					
date of start of period of validity					
date of potency test by manufacturer					
Date of expiry	May 12, 2018				
Number of containers produced					
Number of containers to be released					
batch number diluent/solvent					
date of expiry diluent/solvent					
Volume per Container					
Unit of volume	microgram(s)				
Nominal dose per container					
Type of container	Durchstechflasche + Durchstechflasche				

Included Components

∟⊞ ch: 20120226ATIII1 └⊞ ch: 20120226Huhn1 └⊞ bn: bulkHuhn1

ch: 20120226ATIII1

Batch number	20120226ATIII1
Bulk number / Component number	
Bulk type	Bulk
Internal name of bulk / component	
Name of medicinal Product	AT III - Testarzneimittel (PEI)
Released by OMCL	
date of start of period of validity	
date of manufacture	
date of potency test by manufacturer	
Date of expiry	Dec 12, 2016
Comments	

ch: 20120226Huhn1

Batch number	20120226Huhn1
Bulk number / Component number	
Bulk type	
Internal name of bulk / component	
Name of medicinal Product	Hühnerimpfstoff 1ml - Testarzneimittel (PEI)
Released by OMCL	
date of start of period of validity	
date of manufacture	
date of potency test by manufacturer	
Date of expiry	Dec 12, 2016
Comments	

Fig. 35: Regular Application - report part 2



Batch number		
Bulk number / Component number	bulkHuhn1	
Bulk type		
Internal name of bulk / component	bulkHuhn1Bez	
Name of medicinal Product		
Released by OMCL		
date of start of period of validity		
date of manufacture		
date of potency test by manufacture	r	
Date of expiry	Dec 12, 2017	
Comments		
< back		save Application

Fig. 36: Regular Application - report part 3

Click *save application* to return to the start page. This page will show a message which says that the application has been updated.

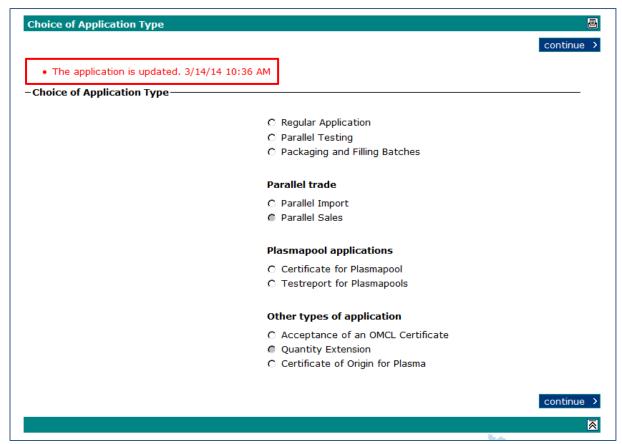


Fig. 37: Regular Application - affirmative answer



4.2.2. Parallel Testing

This type of application enables you to submit samples and to have them tested before you make a regular application as follow-up. As mentioned above, in this section we will only address the differences between this type of application and the regular type.

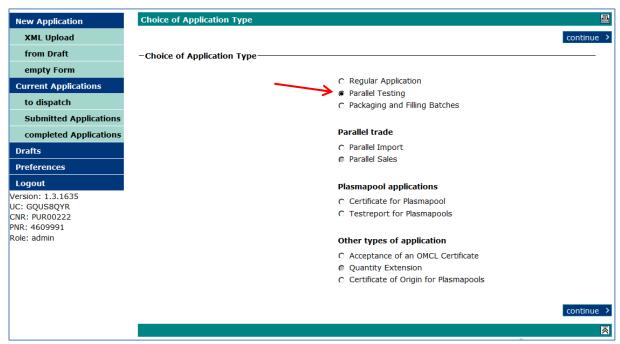


Fig. 38: Choice of Application Type - Parallel Testing

Since, in the event of Parallel Testing, you place an order for testing the samples before making a Regular Application, the subsequent application pages will only contain the essential required fields. Thus, the section for the application for releases will not be shown on the first page. On the third page, the *number of containers to be released* field is missing. The Report is created as in the section for a Regular Application, and can be edited by you in the same way.



Caution!

Parallel Testing must always be followed by a Regular Application or a withdrawal of the application. Parallel Testing alone will not replace an application for a batch release. In the event of submitting parallel testing, please **never** submit a Regular Application as **new** application. Always submit the latter as a follow-up application (Section 8.3) using the appropriate button of the overview of **submitted Applications.**

After sending the application, you will have the option to print a *delivery slip* to make it easier for you to assign the sample. (Section 7).

4.2.3. Packaging and Filling Batches

The term **Packaging Batches** refers to batches already filled into containers, which will then be packed into package sizes in different numbers. **Filling Batches** refer to a bulk which, depending on the package size, is filled into containers. Batch release applications for this special type can be submitted only in rare cases.



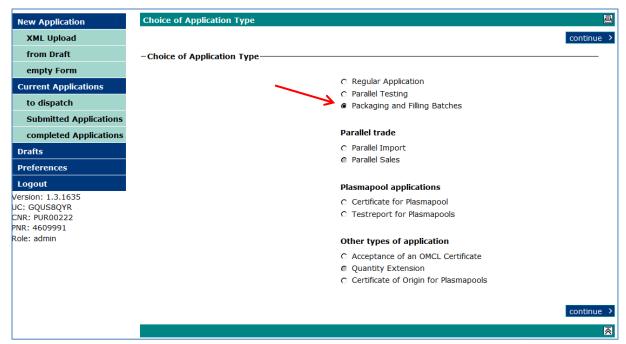


Fig. 39: Choice of Application Type - Packaging and Filling Batches

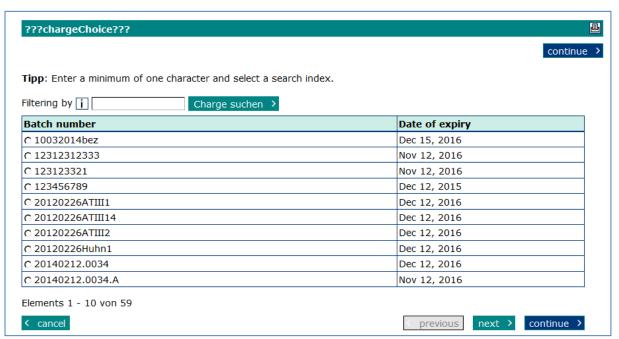


Fig. 40: Packaging and Filling Batches - page 1 - choice of Batch

The basic difference between this type of application and the Regular Application is this first page placed before the pages known for the Regular Application. In this page, select the reference batch for which you wish to make an application for a packaging or a filling batch. Confirm by clicking *continue*, to view the subsequent pages.

You will no longer have the option to choose a product on the third page (similarly to the second page of the Regular Application). These fields are preselected by the system and contain the appropriate information from your selection of the reference batch.



Packaging and Filling Batches							₽
< back						contin	ue >
					save	as dr	aft >
							_
Processing ID							
Reference Batche							_
Reference batch	20120226ATIII1						
referenced batch type/number •	Packaging Batch	▼					
-Batch Information-							_
Batch number •	20120226ATIII1						
Released by OMCL			select >				
date of manufacture(mm/dd/yyyy)							
date of potency test by manufacturer(mm/dd/yyyy)							
Date of expiry •(mm/dd/yyyy)	12/12/2016						
Number of containers produced							
Number of containers to be released							
batch number diluent/solvent							
date of expiry diluent/solvent [](mm/dd/yyyy)							
Valuma per Cantainer			1				
Volume per Container Unit of volume							
	microgram(s)		1				
Nominal dose per container]				
Type of container	Glas-Flasche + Glas-Flasche						
-Comments-							-
Included Components							
└⊞ ch: 20120226Huhn1 └⊞ bn: bulkHuhn1			C.	P.	D		
□ bn: bulkHuhn1			C+	P+	J.	Î	
< back						contir	NIO >
- Dack					save	e as dr	
							uit •

Fig. 41: packaging and Filling Batches - page 4

The last page of this application, too, is largely familiar to you from the Regular Application. In the upper section of the page, the information on the reference batch selected is automatically retrieved from the database. The structure of the component tree is also adopted from the reference batch and can no longer be altered.

After confirming your data, click *continue* to view the Report which you can edit or print, similarly to the Regular Application.



4.2.4. Parallel import

Use this type of application, if you wish to make an application for a batch release of a parallel import.

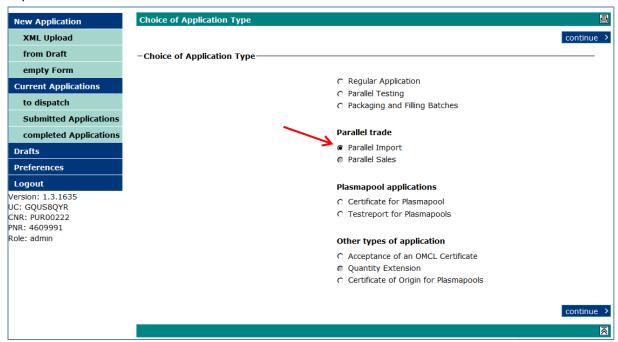


Fig. 42: Choice of Application type - Parallel Import



Parallel Import		
< back		continue
		save as draft
Applicant		
Organisation	Paul-Muster-Pharm GmbH	
Street	Mustergasse 15	
Postbox		
Zip code	63225	
City	Langen	
Country	Germany	
address for certificate dispatch		
Organisation		
Street		
Zip code		
City		
Country	Germany	•
Contact information		
-Application Information		
Date of application(mm/dd/yyyy)	03/14/2014	
Number of sample containers submitted		
requested certificates		
requested certificates •	✓ National Certificate	Number of duplicates 0
C back		continue
		save as draft

Fig. 43: Parallel Import- page 1

In accordance with the type of application selected by you, it will only be possible to apply for a national release on the first page. While the second page is entirely identical with the second page of the Regular Application, page 3 essentially differs in its batch information section.



Parallel Import			
< back			continue >
			save as draft >
Processing ID			
-Reference Batche			
Reference batch •		select >	
referenced batch type/number •	Packaging Parallelimport Batch		
country of origin for parallelimport / -trade $ullet$	No country of origin has been chosen.		
	Select Countries >		
-Batch Information			
Batch number •			
date of start of period of validity(mm/dd/yyyy)			
Date of expiry •(mm/dd/yyyy)			
Number of containers to be released			
batch number diluent/solvent			
date of expiry diluent/solvent [i](mm/dd/yyy	y)		
_			
Volume per Container			
Unit of volume	microgram(s)	-	
Nominal dose per container			
Type of container •	Fertigspritze		
- Comments			
/ book			a oution.
< back			continue >
			save as draft >

Fig. 44: Parallel Import - page 3

The batch name selected must be unambiguous for each pharmaceutical company. In spite of this, it can be possible that a batch name is identical with two different pharmaceutical companies. To assure unambiguousness of a batch name, the name of the reference batch (your imported batch for which you submit the application for release) must be entered via a filter function. Click *select* reference batch. You will see this screen on which you enter the **exact batch name** of your reference batch in search field (1). This name will in all probability not be available in the database. You will then see the message in the search template below (2). Click *continue* to adopt the name of the reference batch into the main screen.



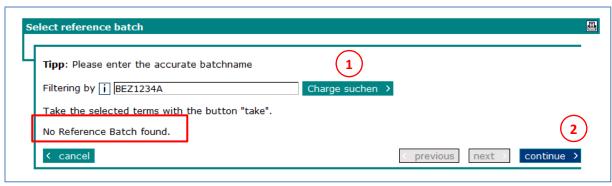


Fig. 45: Parallel Import - select Reference Batch

Then select the country of origin for parallel import, by clicking *select country*. A list of countries of the European Economic Area will be displayed in which you can select your country. After completing all other required fields, create the Report by clicking *continue*. You will then be able to edit the report as usual.

4.2.5. Certificate for Plasmapool

The application type *Certificate for Plasmapool* gives you the option to apply for the issuance of a certificate for a plasmapool.

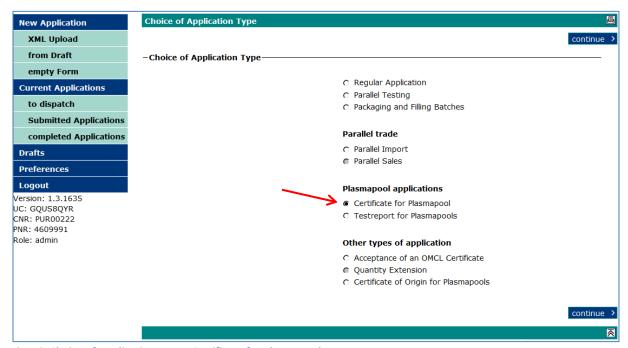


Fig. 46: Choice of Application Type - Certificate for Plasmapool

While the first page agrees with that of the Regular Application, the subsequent one solely gives you the choice to upload documents for the application and submit notes.



Certificate for Plasmapool		E
< back		continue >
		save as draft >
—Uploaded documents		
Add more documnets:		
1. Step: select document	Durchsuchen	
2. Step: description (optional)		
3. Step: add document	add document >	
- Comments Comments		^
< back		continue >
		⊼

Fig. 47: Certificate for Plasmapool - page 2

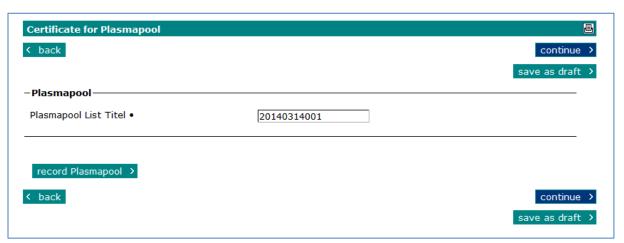


Fig. 48: Certificate for Plasmapool - page 3

As in the Regular Application, the third page gives you the choice to add a plasmapool. The name of the plasmapool or plasmapool list is given by the system with the current date and a number in ascending order. You can overwrite this field if required. Clicking *record Plasmapool* opens the page for plasmapool information with which you are already familiar from the Section on the Regular Application.



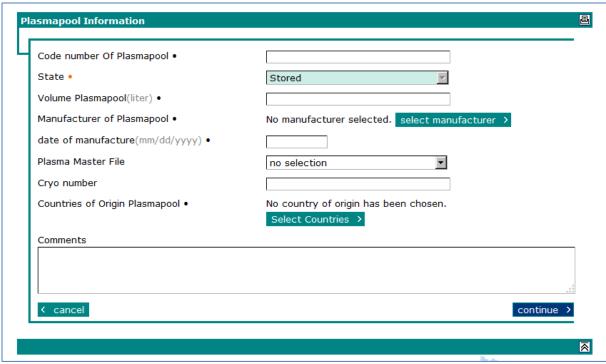


Fig. 49: Certificate for Plasmapool - add Plasmapool

After selecting *Manufacturer of Plasmapool* und *countries of origin Plasmapool* on this page, similarly to the Regular Application, and after completing all other required fields, confirm your entries by clicking *continue*.

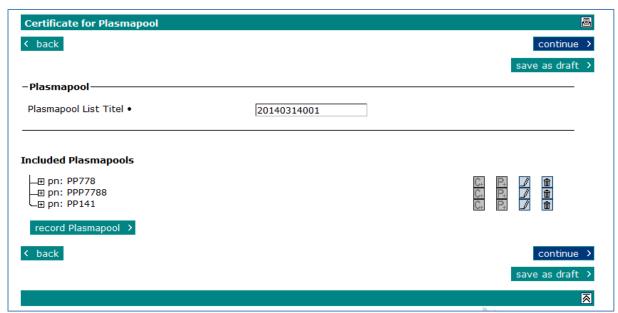


Fig. 50: Certificate for Plasmapool - page 3 - with Plasmapools

On the main page, you can now add other plasmapools or retrieve the plasmapool information or delete the plasmapool using the appropriate buttons at the end of each line. The two other buttons are greyed out, since it will not be possible to add components or plasmapools within a plasmapool. Confirm this last page of your application by clicking *continue*. You will again receive the Report which you can edit as described above.



4.2.6. Test report for Plasmapools

Use this type of application to receive a certification on a test for your plasmapool.

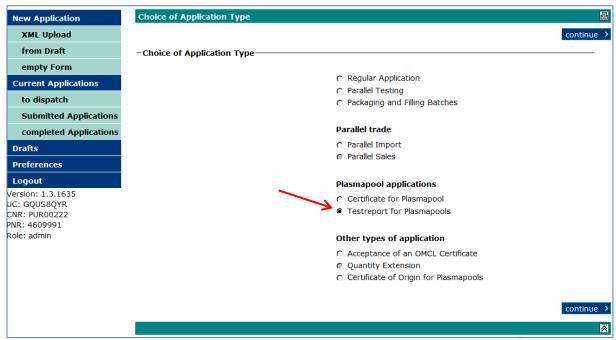


Fig. 51: Choice of Application Type - Testreport for Plasmapools

The first page is identical with that of the Regular Application. On the second page, you can upload documents and make notes.

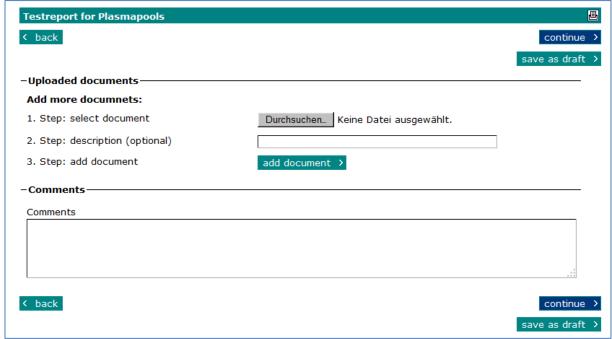


Fig. 52: Testreport for Plasmapools - page 2

On the third page, you can add one or more plasmapools and assign titles. The system completes the field for the title with the current date and a number (in ascending order). You can overwrite this field if required.



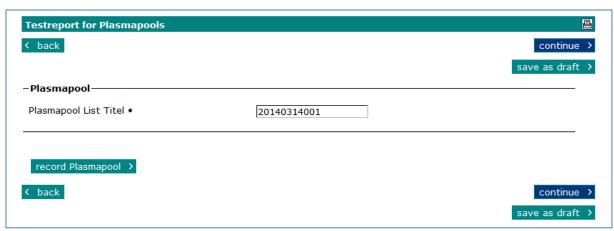


Fig. 53: Testreport for Plasmapools - page 3

If you click the **record Plasmapool** button, the page for plasmapool information will open. On this page, please select the manufacturer and a country of origin.

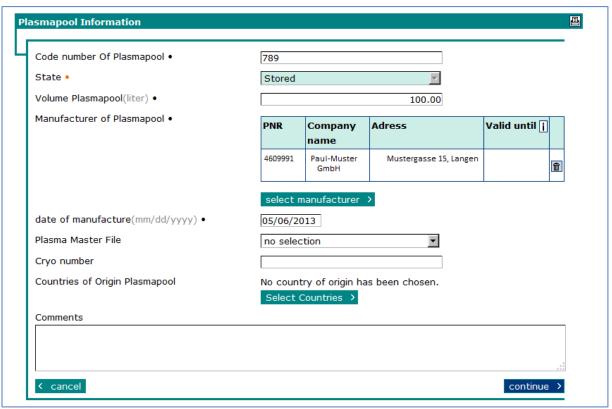


Fig. 54: Testreport for Plasmapools - add Plasmapool

After completing the required fields, confirm the information with *continue* to return to the main page of the application, on which you can retrieve the plasmapool information line by line to edit it or to delete the plasmapool. The two other buttons are greyed out, since it will not be possible to add components or plasmapools within a plasmapool.

The report is created similarly to the Regular Application if you confirm this page with *continue*.



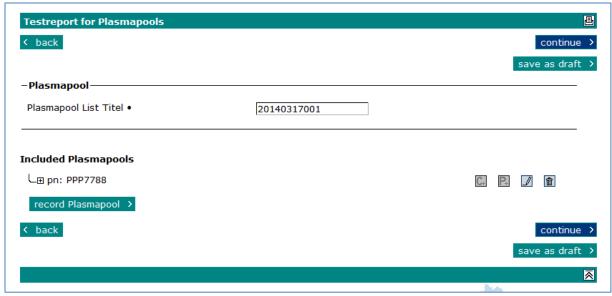


Fig. 55: Testreport for Plasmapools - page 3 with plasmapool

4.2.7. Acceptance of an OMCL Certificate

You can select this type of application if a batch release certificate for the respective batch is already available from another country, and you wish to market it also in Germany.

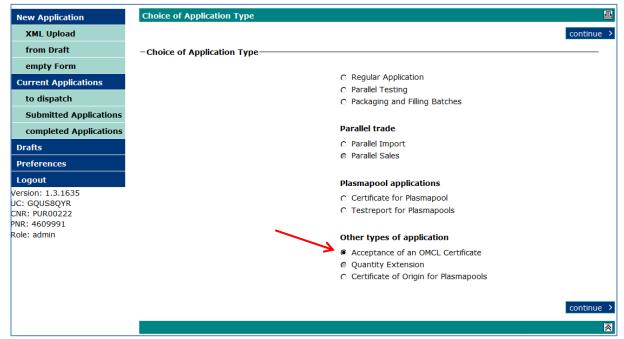


Fig. 56: Choice of Application Type - Acceptance of an OMCL Certificate

While the first two pages are largely the same as for the Regular Application, on page 3, select the OMCL from which you previously received the release for the batch.



Acceptance of an OMCL Certificate			B
< back			continue >
			save as draft >
Proceeding ID		1	
Processing ID			
-Batch Information			
Batch number •			
Bulk number / Component number			
Released by OMCL •		select >	
OMCL certificate number			
date of manufacture(mm/dd/yyyy)			
date of start of period of validity(mm/dd/yyyy)			
date of potency test by manufacturer(mm/dd/yyyy)			
Date of expiry •(mm/dd/yyyy)			
Number of containers produced			
Number of containers to be released			
batch number diluent/solvent			
date of expiry diluent/solvent $[i]$ (mm/dd/yyyy)			
Volume per Container			
Unit of volume	microgram(s)		
Nominal dose per container			
Type of container	Fertigspritze		
- Comments			
Comments			
			.:
record Component >			
< back			continue >
			save as draft >
			≅

Fig. 57: OMCL-Certificate - page 3

Click on the *released by OMCL* button and you will see a list of OMCLs in which you can either scroll back or forward or select an OMCL using the search function.



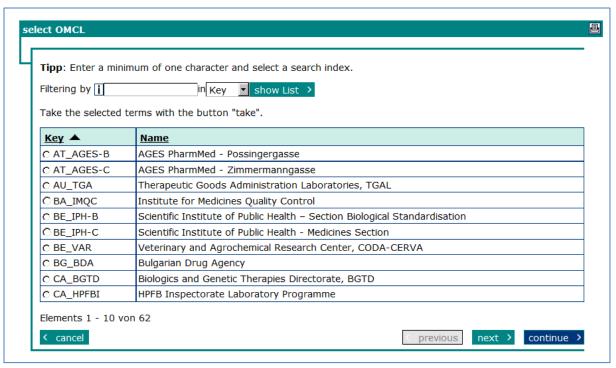


Fig. 58: select OMCL

After confirming with *continue* proceed in the same way as for the Regular Application. Finally, you will receive the report which you can edit as usual.

4.2.8. Certificate of Origin for Plasmapools

This function will give you the option to apply for a Certificate of Origin.

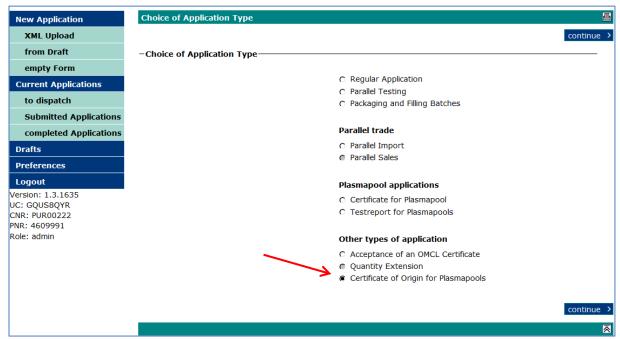


Fig. 59: Choice of Application Type - Certificate of Origin for Plasmapools

The first two pages are the same as for the Regular Application. On the second page, the field for the note is required. Here, you will enter the importing or requesting agency or country, the name of the product abroad and the pharmaceutical form.



After completing the required fields on the third page in the same way as for the Regular Application, click *continue* to view the Report for the application, which you can edit or print as described above.

4.3. Submit an application with a Multi ZNR Range

For some types of application, instead of selecting the product, you have the option to form so-called Multi ZNR Ranges (**A-Z-Chargen**). This function can above all be used for medicinal products which have a centralised marketing authorisation. However, only those marketing authorisation numbers can be consolidated into a group, in which the product will later be filled into the same type of container.

After selecting the appropriate product on page 2 of the regular application, you will see another button: *select additional Medicinal Products*.

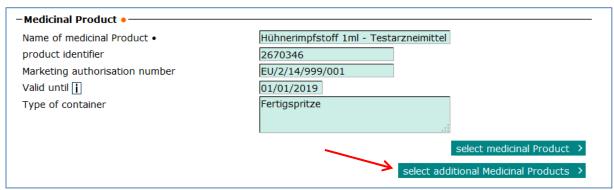


Fig. 60: Regular Application - page 2 - select additional medicinal products

Click this button. You will see a selection of the marketing authorisation numbers to be grouped.

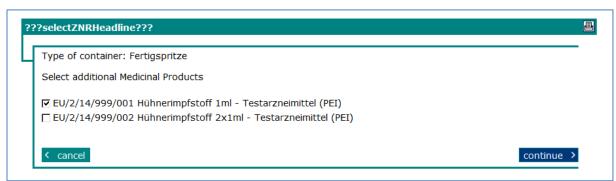


Fig. 61: Regular Application - select ZNR

After confirming the selection with *continue*, the display of the product on the main screen will be updated and presented in the form of a table.



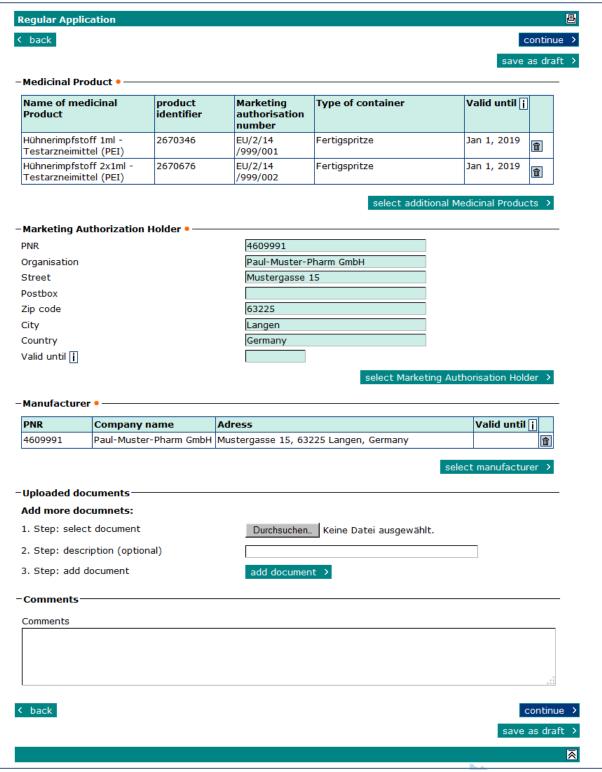


Fig. 62: Regular Application - page 2 - with additional medicinal products

After you have selected several ZNRs that way, you will – on the third page of the Regular Application where you submitted the batch number – be given the option to attach a suffix to the appropriate package sizes (A-Z batch).



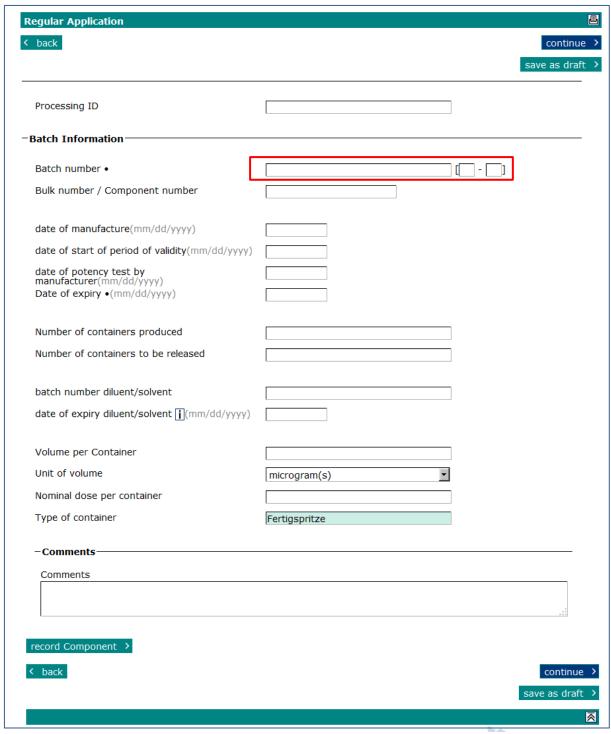


Fig. 63: Regular Application - page 3 - with ZNR-Range



In the final analysis, the decision as to whether a multi ZNR batch release application can be submitted is made by the section in charge at the Paul-Ehrlich-Institut.



5. View applications

The menu item *Current Applications* in the navigation menu on the left of the screen gives you the choice to view your applications.



Fig. 64: Menu for Navigation - Button to display the current Applications

These applications are each displayed in a list, which you can sort by column headings in ascending or descending order. On each page, you will also find the familiar search function, which enables you to search for individual applications in a targeted manner. In the right column of the list, you will find various different icons which show you what you can do with each individual application.



5.1. Applications to dispatch

An application is accepted in the **to dispatch** list, after you have saved the application at the end of the report and have received a message on the start screen that your submission was successful.



Fig. 65: Applications to dispatch

The following actions are available using the icons below:

- show Report
- edit Application (retrieve the Report in which you can open the individual sections for editing, as described in the Section on Regular Applications)
- submit Application (if you have the appropriate rights, see Section 6)
- delete Application



5.2. Submitted Applications

After submitting the applications you will see them in the list submitted Applications.

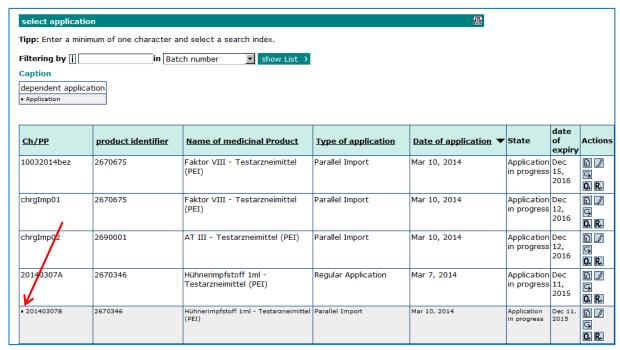


Fig. 66: submitted Applications

This figure shows how a "dependent" follow-up application is shown in the list. At the beginning of the line where the follow-up application is shown, a dot is displayed, the text is displayed smaller and the line is marked with a darker colour.

Use the icons below to select the actions which you wish to execute in the application selected.

- show Report
- edit Application (retrieve the Report in which you can open the individual sections for editing, as described in the Section on Regular Applications.)
- make a follow-up application for a Quantity Extension (Section 8.1)
- make a follow-up application for additional Releases (Section 8.2)
- make a Regular Application as follow-up application of Parallel Testing (Section 8.3)



disclaim (This function has not yet been activated in the current version. If you wish to withdraw an application, please contact the section in charge at the Paul-Ehrlich-Institut by email or phone.)



5.3. Completed Applications

This list shows those applications the processing of which has been completed at the Paul-Ehrlich-Institut.

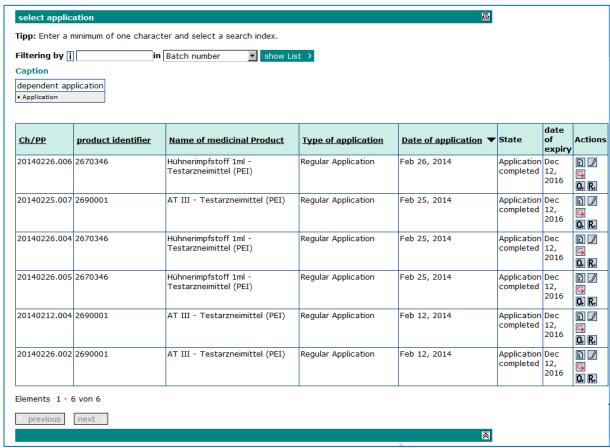


Fig. 67: completed Applications

Use the icons below to select the actions which you wish to execute in the application selected.

- show Report
- edit Application (In the current version, the presence of this button is a programming error)



- disclaim (This function has not yet been activated in the current version. If you wish to withdraw an application, please contact the section in charge at the Paul-Ehrlich-Institut by email or phone.)
- make a follow-up application for a Quantity Extension (Section 8.1)
- make a follow-up application for additional Releases (Section 8.2)



6. Submit Application (Four Eye Principal Rule)



The concept of roles and rights of this application involves the assignment of two roles to meet the requirements of the **Four Eye Principal Rule** of your company. The role "edit applications" enables you to edit, save and modify applications. However, it does not give you the right to submit an application. For this purpose, there is another role allowing the user to submit saved applications to the Paul-Ehrlich-Institut.

Even if you have all rights, you will not be able to edit and send an application within the same role.

Although you will see the letter icon in the listing after editing the application, you will receive the message below after clicking the Report:

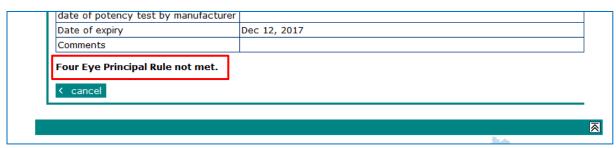


Fig. 68: alarm message: Four Eye Principal Rule not met

If you have the right to send applications and have not edited the application to be submitted yourself, you will receive the Report after clicking the letter icon. At the bottom of the report, you will find the request to accept the Terms and Conditions of Use of the application. You will be able to read these Terms and Conditions, as well as the Statutory Cost Regulations of the PEI on the PEI website by following the appropriate link.

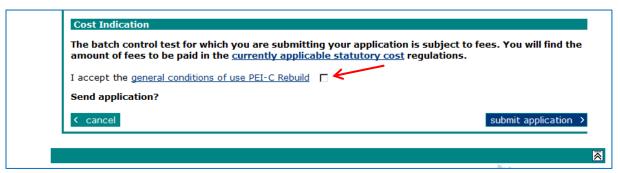


Fig. 69: Report of an Application to dispatch with the general conditions of use



After sending, you will receive a send confirmation on the start page of the application. The application will be moved to the list of applications submitted.

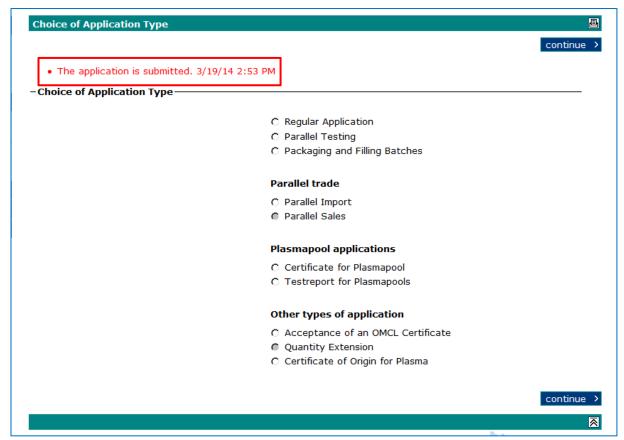


Fig. 70: send confirmation



7. Print delivery slip

When selecting an application from the list of submitted applications and clicking on the icon with which you open the report, you will see several buttons at the bottom of the report.

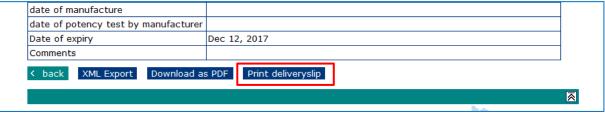


Fig. 71: print the delivery slip

Here, you can save the application as a pdf, download it as an xml or print the delivery slip by clicking *print delivery slip*. A pdf file is then generated which contains all important data from your application. The section of the Paul-Ehrlich-Institut in charge of testing and release of your batch will be loaded into the address from the medicines data base. The bar code, too, facilitates the assignment of the samples to the application. This can speed up the beginning of the batch testing procedure.

Paul-Muster-Pharm GmbH Mustergasse 15 63225 Langen Germany

Paul-Ehrlich-Institut Fachgebiet 7/4 Paul-Ehrlich Str. 51-59 63225 Langen



Lieferschein zum Chargenantrag "Regular Application" vom 14.03.2014

Fig. 72: Heading of delivery slip

Datum: 19.03.2014



8. Submitting follow-up applications

You can submit follow-up applications using the overview function for submitted and completed applications. Each application includes those icons you can use to add follow-up applications directly to an existing application.



It is absolutely necessary to assure that you submit follow-up applications exclusively via these icons, since, at worst, the PEI will be unable to assign your applications, which may lead to delays and unnecessary expenses.

In the overview tables, follow-up applications are always listed independently from the way the lists are sorted, and are always listed directly below the main application. Applications which are dependent on other applications are marked in a specific colour and with a dot.

If you wish to make more than one follow-up application for one main application (e.g. several increases in the item number for one batch), always make these follow-up applications with the same main application.

8.1.Application of Quantity Extension

The **Quantity Extension** button can be used to increase the quantity, e.g. of parallel imports.

Click the appropriate button to retrieve the original application. You will then be able to enter data only in few fields. The master data cannot be edited and are highlighted green.

On the second page, enter the number of containers to be released in addition. You can upload documents and post remarks. Then click the *continue* button to display the Report, which contains the entire information on the application.



umber of additional containers to be eleased • • Comments		
Comments		
Uploaded documents		
•		.::
Add more documnets:	Keine Datei ausgewählt.	.:
Add more documnets: 1. Step: select document	Keine Datei ausgewählt.	
Add more documnets: 1. Step: select document 2. Step: description (optional)	Durchsuchen_ Keine Datei ausgewählt. add document >	.:
-Uploaded documents -Add more documnets: 1. Step: select document 2. Step: description (optional) 3. Step: add document		continu

Fig. 73: Quantity Extension

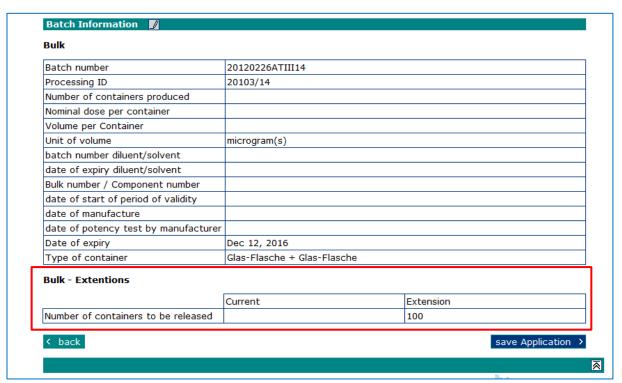


Fig. 74: Report of Quantity Extension

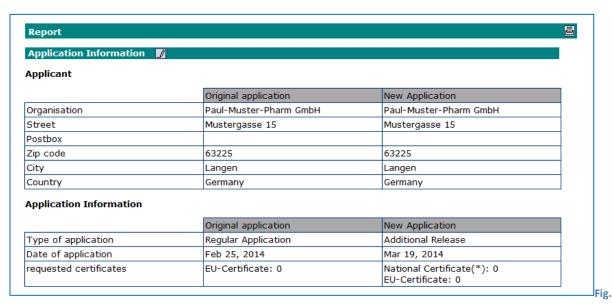


8.2. Application for additional Releases

Use the *additional Releases* button to receive additional release certificates for an application already submitted.

In the overview of applications submitted and completed, select the application required from the list or by means of the search function and retrieve the first page of the application using the action button. Here, check the box for the additional releases required, and indicate an additional shipping address if applicable.

Confirm by clicking the *continue* button. This will open the Report containing the additional releases submitted.



75: Report of additional releases

8.3. Submit a regular application as a follow-up application for parallel testing



For parallel testing, it is especially important that you make the **Regular application as follow-up application** – not starting from the start page of the software application where the main types of application are listed for choice.

In the list of applications submitted, choose the appropriate application for Parallel Testing and click on the icon for the Regular Application in the right column. The template for a Regular Application as described in Section 4.2.1 will be opened. The data entered in the appropriate application for Parallel Testing will be loaded automatically in the appropriate place. Please supplement the information entered so far. Saving and submitting of the application is performed in the same way as described in the Section for a Regular Application.

In the listing of applications submitted and completed, this Regular Application will be marked with a dot as "dependent application". Besides, the line is highlighted in colour and will always be displayed directly below the corresponding application for parallel testing despite the change in the sorting order.



9. Working with drafts

9.1. Save as draft

To use a draft, you must first create it. For this purpose, retrieve the type of application required, enter the data to be included into the draft, and click the *save as draft* button, which you will find on the right edge of the page at the top and the bottom of each application page. Thus, you can save each edit status of an application as draft. Uploaded documents, too, can be included in the draft.



Fig. 76: save as draft

On the pages below, you will be requested to give a name for your draft.

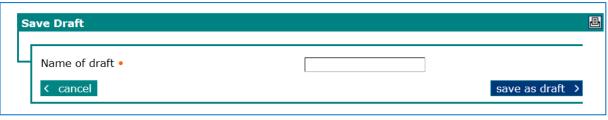


Fig. 77: Name of draft

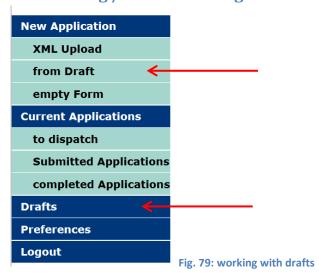
When clicking save as draft, you will receive a confirmation of the saving procedure.



Fig. 78: confirmation: draft is saved



9.2. Using / administrating a draft



You can use the menu item *drafts* in the navigation menu to retrieve the overview of the saved drafts. You will obtain the same screen by selecting *new Application from draft* in the navigation menu.

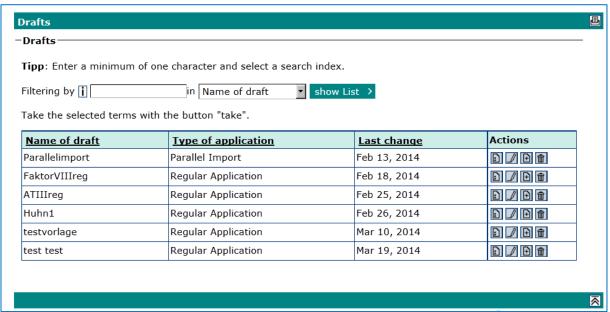


Fig. 80: Overview drafts

The following actions are available:

- Show draft: shows the draft as Report.
- Edit draft:shows the draft as Report. Here, you can retrieve the individual areas using the edit icon for editing. However, this will only complete the data within the draft. No regular batch release application is made.
- New Application from draft: will accept the draft in the application acceptance
- Delete draft: will delete the draft in the appropriate line



10. XML upload

This function gives you the option to upload an application in the XML format directly from your PC. For this purpose, you will receive the XSD file on our homepage www.pei.de.

When selecting Upload New Application XML in the navigation menu, you will see the dialogue for the document to be uploaded.



Fig. 81: XML upload

To facilitate filling out the fields before submitting the application, we give you the option to download the appropriate XML file from an existing application.

When selecting an application from the list of submitted applications and clicking on the action icon with which you open the report, you will, among other things, see the buttons for the XML export at the bottom of the report.



Fig. 82: Button for XML export

11. Change Preferences

There is currently no option to make configurations in the navigation item *preferences*. The menu item is a wildcard designed to allow any configuration functions required for the future.



12. Error messages

This section will not list all possible error messages. It rather serves to give you a better idea of error messages which may be issued. You will not need to report them to us.

An error message usually appears at the top of the screen and, again, where a required field may be overlooked or a day's date has been indicated incorrectly.

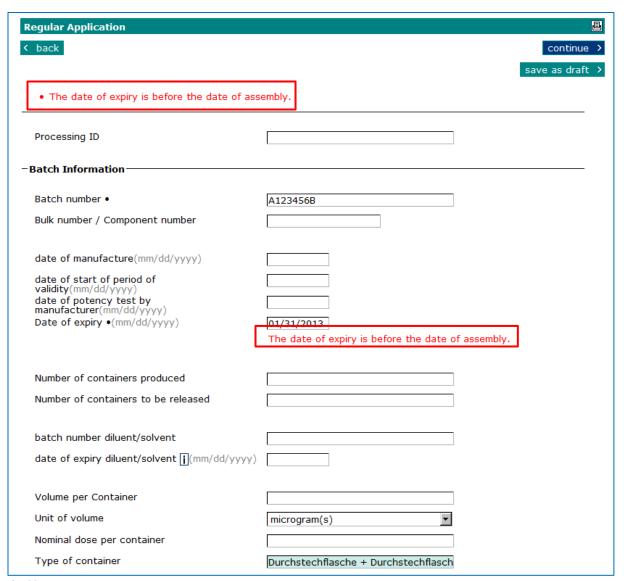


Fig. 83: Error message