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PEI-C Rebuild

PEI's new portal for the submission
of batch release applications



Agenda

- Overview
- Status of the project
- Registration and login
- **Functionality of the portal**
- Support
- Prospects

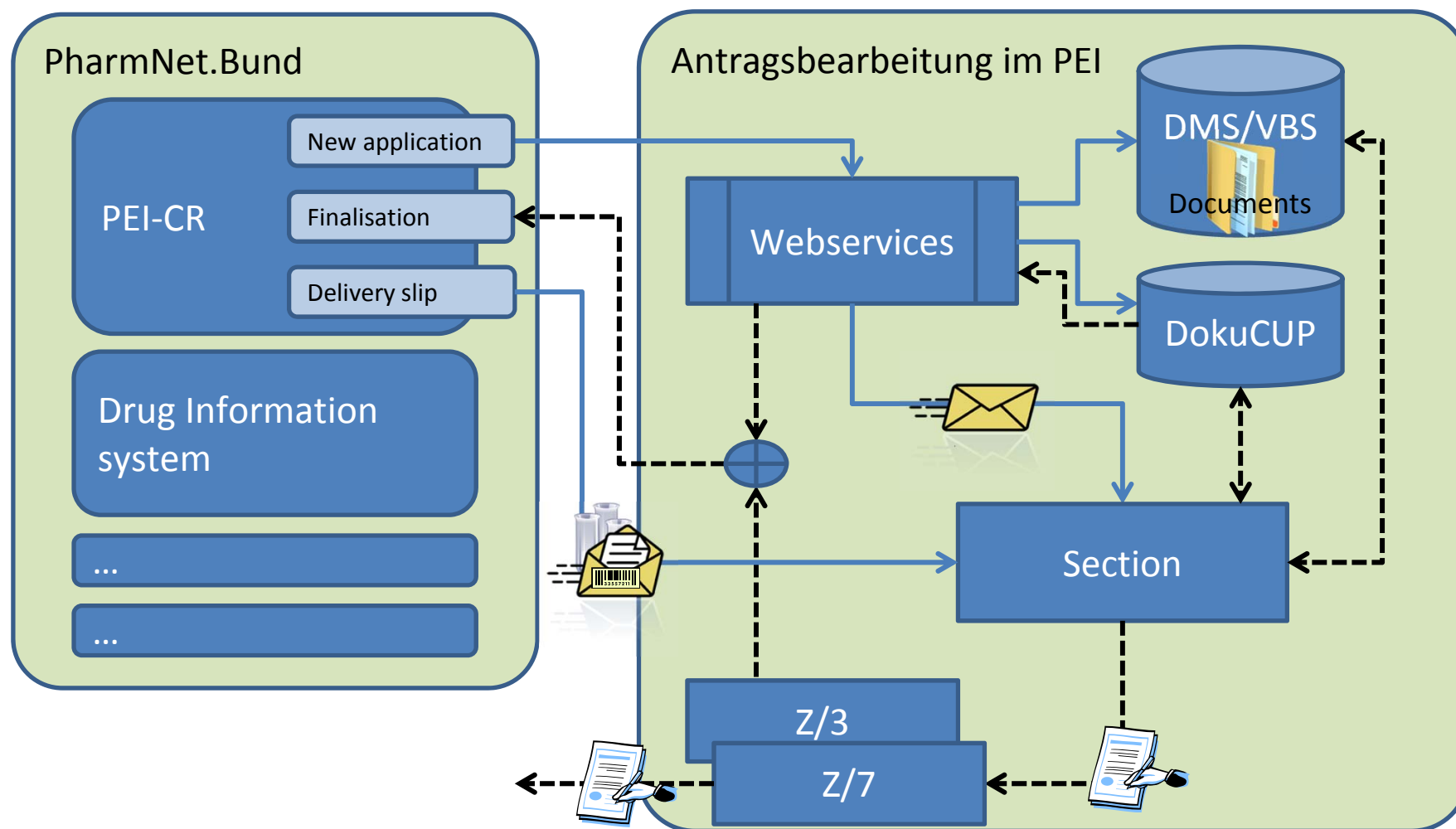


Overview

- The application PEI-C Rebuild contains of a portal, a database and of interfaces to and from related applications
- The portal allows the electronic submission of batch release applications
- The batch release database contains all metadata related to batches. It provides these data to all relevant user groups.
- Data and documents are provided also automatically to PEI-internal systems responsible for processing batch release applications.
- No media discontinuity from submission to the presentation of the related data after having processed the application data.
- Discontinuity still exists for sending the certificates
- Integration into the PharmNet.Bund portal
<http://www.pharmnet-bund.de/dynamic/de/index.html>
- Providing only the relevant data for a user is achieved by using interfaces to databases containing data of medicinal products and data of MAHs



How the process works





Status of the project

- Training of the batch release application in 02.2014
- First availability of the applications
 - Registration and user administration (RuBen) 20.03.2014
 - Portal for the submission of batch release applications(PEI-C Rebuild) 28.03.2014
- Starting phase is beginning in 04.2014



Registration and login (1)

- 2-factor authentication
 - Usercode and password
 - Plus an additional component
- X.509 certificates
 - Purchasing a certificate from an appropriate provider
 - Certificate's public key -> DIMDI
 - Certificate's private key -> own browser
 - Certificate per account
 - No private PKI (Public Key Infrastructure) for generating certificates
 - List of appropriate providers will be published by DIMDI, see documentation on PEI homepage




Registration and login (2)

- Acess zu RuBen
 - DIMDI Design, because it will be used not only in the PharmNet.Bund context
- Registration
 - Application filed by user
 - Mail as confirmation
 - Evaluation done by an PEI employee
 - Usercode and password are sent via different letters



Registration and login (3)

- Change of the one time password

Passwort ändern 

Bitte geben Sie ein neues Passwort ein:

Altes Passwort:

Das neue Passwort muss 8 bis 16 Stellen lang sein und neben Buchstaben mindestens eine Zahl oder ein Sonderzeichen **innerhalb** des Passworts sein. Beispiel: Geheimnis1 falsch, Geheimni1s richtig.

Es werden Klein- und Großbuchstaben unterschieden. Erlaubte Sonderzeichen sind: ! # \$ % () + ? @ [] _ { } | ~

Bitte wählen Sie Ihr Passwort sorgfältig aus, um Missbrauch zu vermeiden.

Neues Passwort:

Neues Passwort wiederholen:

Speichern >

- Administration of additional users





Registration and login (4)



- Dimdi
- PharmNet.Bund
- Benutzerverwaltung
- Meine Daten
- Benutzerverwaltung
- Passwort ändern
- Abmelden

Version: 1.0.140



Benutzer hinzufügen	
Person	
Bitte füllen Sie alle Felder aus, die mit einem Stern (*) gekennzeichnet sind.	
PNR (Partner-Nr)	0000000
Unternehmen	Pharmazeutischer Unternehmer Mustermann
Anrede:	<input type="text"/>
Vorname: *	<input type="text"/>
Nachname: *	<input type="text"/>
Telefon: z.B. +49 221/77879-23	<input type="text"/>
E-Mail Adresse: *	<input type="text"/>
Straße:	<input type="text"/>
PLZ:	<input type="text"/>
Stadt:	<input type="text"/>
Land:	<input type="text" value="Deutschland"/>
Status	
Status	<input type="text" value="ACTIVE"/>
Berechtigte Fachanwendungen 	
Elektronische Chargenfreigabebeanträge	<input checked="" type="checkbox"/> Elektr. Chargeneinreichung <input checked="" type="checkbox"/> Elektr. Chargeneinreichung Anträge erstellen <input checked="" type="checkbox"/> Elektr. Chargeneinreichung Anträge senden



Registration and login (5)

– Zuständigkeit

Anzahl pro Seite

<< 1-10 von 40 >>

ENR	Arzneimittelname
<input type="checkbox"/> 2670879	Benlysta - 120 mg - 1 Durchstechflasche
<input type="checkbox"/> 2670880	Benlysta - 400 mg - 1 Durchstechflasche
<input type="checkbox"/> 2188162	Chlorhexidindigluconat Baggerman 20 mg/ml imprägniertes Tuch
<input type="checkbox"/> 2708338	Clopidogrel Teva Generics B.V. 75 mg Filmtabletten - KALP28(28x1)
<input type="checkbox"/> 2708336	Clopidogrel Teva Generics B.V. 75 mg Filmtabletten - OP100
<input type="checkbox"/> 2708344	Clopidogrel Teva Generics B.V. 75 mg Filmtabletten - OP100(100x1)
<input type="checkbox"/> 2708330	Clopidogrel Teva Generics B.V. 75 mg Filmtabletten - OP28
<input type="checkbox"/> 2708337	Clopidogrel Teva Generics B.V. 75 mg Filmtabletten - OP28(28x1)
<input type="checkbox"/> 2708331	Clopidogrel Teva Generics B.V. 75 mg Filmtabletten - OP30
<input type="checkbox"/> 2708339	Clopidogrel Teva Generics B.V. 75 mg Filmtabletten - OP30(30x1)

alle 40 ☐

– Zertifikat

Zertifikat

kein Zertifikat vorhanden

Zertifikat hochladen:

Keine Datei ausgewählt.





Registration and login(6)

- Testaccounts for this introduction
 - Paul-Muster-Pharm GmbH
 - User Code: GQUS8QYR
 - Rights:
 - Edit an application for all of his medicinal products
 - File an application for all of his medicinal products
 - Create accounts
 - Paul Ehrlich GmbH
 - User Code: PQN3L3R6
 - Rights :
 - Edit an application for one medicinal product
 - File an application for one medicinal product
 - Peter Ehrlich
 - User Code: UTXGE8LS
 - Rights :
 - Edit an application for all medicinal products of the Paul-Muster-Pharm GmbH



Functionality of the portal

- The live demo is done using three different users
 - The original registered account
 - Account, which is allowed to edit applications only
 - Account, which has access to a shortened list of medicinal products only

- German version
- English version



Support

- Helpdesk
 - functional e-mail-Address of the helpdesk team:
pei_cr_support@pei.de
 - Automatted generation of a ticket
 - Standard confirmation after filing the request
 - If necessary an employee of PEI or DIMDI contacts you via telephone or e-mail
 - An e-mail ist sent after the ticket is closed
- Homepage
 - [Informations concerning the batch release portal](#)
 - News
 - User guide
 - Links



Perspective

Further developments planned:

- Withdrawal of applications and batches
- Enhancement of the portal for european parallel sales
- Electronic transmission of certificates where possible and reasonable



Conclusion

We are on the way to paperless processing of applications

