EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

05th October 2012
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Release notes

EudraCT Version: 8.4.2

Goal: Major Release

Release Date: 09/10/2012

Environment: Production

Release Contents:

This is an enhancements release to production of the EudraCT application. It includes the following main functional changes:

- Selection of an active substance: When searching for a substance the user must now search exclusively by either the substance name or the exact EV code.

- Registration of an active substance: When creating a Clinical Trial Application using EudraCT, it is necessary to identify the Active Substances for each IMP in the study. The user must select the Substance from those previously registered. If the substance does not appear in the list it must be possible to start a process of requesting a new substance to be added the Medicinal Product Dictionary.

- Help text updates

- Migration of the application from Oracle OC4J application server to weblogic application server

The impacted use cases are listed below:

Functionality / Use case	Comments
System use case select substance	Selection of active substances
System use case register new substance	Request that a new substance should be added to the medicinal product directory

Below is a list of the new features including improvements and help text changes, defect fixes identified and addressed in this release and technical improvements in this release.

Issue Type	Key	Summary	Priority
Bug	ECT-3764	A spelling correction in the main text when selecting to register	Trivial
Bug	ECT-3727	Add Active Substance:The button to Select the path for attachment is disabled if once upload a file and then clear it	Major
Bug	ECT-3806	CBD details does not contain all the information as it is displayed on EUTCT Substance CBD field	Major
Bug	ECT-3797	CLONE - v8.3.0.1 Save As PDF on validation screen and you are unable to open the file. The attached error message is displayed	Major
Change Request	ECT-3782	Change the file formats of the Approved substance attachment.	Major
Task	ECT-3787	Default Search in EudraCT Main	Major
Task	ECT-3695	EUTCT Integration for substance selection	Major
Bug	ECT-3746	Error on screen when requesting to add an active substance without entering correct image for captcha and an attachment is added	Minor
Bug	ECT-3783	Error on screen when submiting a request to add a new active substance	Major
Bug	ECT-3807	Field 'PostCode or Zip code' under Sponsor details and 3rd party Provider for development substances should not be mandatory	Major
Sub-task	ECT-3771	ECT-3304 First Refactoring stage	Major
Improvement	ECT-3775	Fix the EudraVigilance registration link to open a standard-sized window with no statusbar and menubar	Major
New Feature	ECT-3777	Introduce separate registration properties file	Major
Change Request	ECT-3778	Label change - EV Code	Trivial
Bug	ECT-3752	No scrollbar appears on the modal panel shown when clicking on "Names" on the Substance Select Search results.	Minor
Bug	ECT-3726	On Add Active substance screen, the Return button takes the user back to the IMP screen instead of the MPD search results	Minor
Bug	ECT-3766	Only one of the fields Substance name and Substance code have to be provided for development substances	Minor
Bug	ECT-3731	Organisation Name is not included in the eudralink message for registered Development Substances	Minor
Bug	ECT-3729	Proposed EudraVigilance Organisation ID is not validated on new substance form	Major
Sub-task	ECT-3748	ECT-3684 Register New Substance - Test Case preparation	Major
Change Request	ECT-3833	Remove green dot from E.8.6.4	Major
Bug	ECT-3794	Search by Active Substance Name or EV Code does not work correctly	Major
Task	ECT-3717	Select Substance Use Case, clarification	Major

Issue Type	Key	Summary	Priority
Bug	ECT-3769	Some minor corrections in the eudralink package for development substances	Minor
Improvement	ECT-3694	Substance registration - Eudralink Error handling	Major
Sub-task	ECT-3774	ECT-3684 System Testing	Major
Improvement	ECT-3781	The "Chemical/Biological description" field on Approved substances form does not display the total number of characters allowed	Trivial
Bug	ECT-3779	The CBD column should not provide a sort user interface control enabling the user to sort the results	Trivial
Bug	ECT-3800	The CBD details is empty for active substances that have information on that field	Major
Bug	ECT-3808	The Menu panel containing the extensions after search results should open by default	Minor
Bug	ECT-3795	The Source field on Active substances should show the INN or non-INN term	Major
Bug	ECT-3768	The hyperlink to register to Eudravigilance is missing from the confirmation page	Minor
Bug	ECT-3798	The label Substance Name on MPD results should display in parenthesis the abbreviation EN	Trivial
Bug	ECT-3751	The list of values for 'Substance source' should be wider because some values cannot be displayed	Major
Improvement	ECT-3780	The total number of matching results should be centre aligned above the MPD Search Results	Trivial
Bug	ECT-3770	The validation error message for the Proposed Organisation Identifier needs to be updated	Minor
Bug	ECT-3733	Timeout exception for the transaction that includes eudralink access	Major
Bug	ECT-3763	Unable to attach tif files for approved substances	Major
Change Request	ECT-3743	Update Eudralink package meta-data	Major
Bug	ECT-3744	Update Substance registration forms and validations	Major
Improvement	ECT-3776	Update texts for active substance registration	Major
Sub-task	ECT-3784	ECT-3695 User interface change on substance search	Major
Bug	ECT-3831	V8.4.0.2 - Substance Source value "BANM" the reference source description should be: Banque de Données Automatisée sur les Médicaments however some of the accent marks incorrect on the screen	Major
Bug	ECT-3734	Wrong error message if leaving empty the fields Substance source and class	Minor
Sub-task	ECT-3786	ECT-3683 XEVMPD - Substance Selection -Test Case Preparation	Major
Bug	ECT-3757	v8.3.0.2 - Compare Results - Clicking to view section H gives a java exception error	Major
Bug	ECT-3801	v8.4.0 Substance search result screen - Text displayed when the concertina is clicked, the word "mean time" should be one word "meantime"	Minor
Bug	ECT-3810	v8.4.0.1 - Incorrect spelling of "Authorization Holder" on the organisation category. It should be "Authorisation Holder"	Minor
Bug	ECT-3813	v8.4.0.1 - java exception error encountered when "Send Request" button and Eudralink is unavailable	Major
Change Request	ECT-3816	v8.4.0.1 - substance search result screen - update information displayed when the concertina is expanded	Major

Issue Type	Key	Summary	Priority
Bug	ECT-3812	v8.4.0.1 On the Request addition of new substance screen the field "Email Address" should be "Email address for reply"	Minor
Bug	ECT-3815	v8.4.0.1 Register New Susbstance Screen: Remove the upper case "C" in PostCode. Should be Postcode	Minor
Change Request	ECT-3818	v8.4.0.1 Substances search should only return substances in which the status are Provisional or Current	Major
Bug	ECT-3839	v8.4.0.2 - "Send Request" and "Return" buttons should be a bit far apart. Please see Use Case WF4 & WF5	Minor
Bug	ECT-3840	v8.4.0.2 - Align the "Enter the characters shown" field with the rest of the text fields on the "Request addition of new substance"	Trivial
Bug	ECT-3823	v8.4.0.2 - Funny characters showing within some of the names under the "substance class" list	Major
Bug	ECT-3825	v8.4.0.2 - Incorrect page opens when click on the hyperlink "register with Eudravigilance" on substance request confirmation screen	Major
Bug	ECT-3837	v8.4.0.2 - The text "If none of the above are successful......" should be configurable. However when the update is done in the properties file, the text is still displayed	Major
Bug	ECT-3830	v8.4.0.2 - Validation error incorrectly displayed when a particular substance source is selected	Major
Bug	ECT-3824	v8.4.0.2 . Please use the exact wordings as shown in WF5 - New substance request confirmation screen	Minor
Bug	ECT-3822	v8.4.0.2 According to WF3 & WF4 under attachment the file format and maximum size file should be displayed	Minor
Change Request	ECT-3828	v8.4.0.2 According to register new substance use case the only attachment allowed should be PDF, DoC or Docx	Major
Bug	ECT-3829	v8.4.0.2 CAPCHA fields allows using previously issued image to whats currently displayed on the form when completing the request to add a new substance	Major
Change Request	ECT-3832	v8.4.0.2 Organisation Category: No value should be the default so the user has to select the value appropriate to them	Major
Bug	ECT-3821	v8.4.0.2 The word "with" is missing from the text information displayed for the options in registerising a new substance	Minor
Bug	ECT-3827	v8.4.0.2 if over the maximum size attachement is added, no error message is displayed on the screen as it happens if chemical/biological field has more than the allowed characters	Major
Bug	ECT-3826	v8.4.0.2 mistakenly leaving leading or trailing spaces at the end of an email, this is not ignore. Message is displayed that email address is not valid	Minor
Bug	ECT-3693	version page not working	Minor

Additional information

None.

Installation steps deviating from the deployment guide

None.