



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information and Communications Technology

PIM Data Validation Engine v 2.1.1

Release Notes

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1. About This Document

This document briefly describes the content of **release 2.1.1** of the PIM Data Validation Engine (PDVE). This release of the PDVE provides support for the latest **DES release 2.7.1 (QRD Templates v7.3.1)** as well as older DES releases starting from **DES v2.6**.

2. New and Changed Functionality

The table below summarizes the new functionality that has become available with release 2.1.1

Reference	Since	Description
3.3 DES v2.7.1 Support	2.1.1	Align to the latest DES version 2.7.1 aligning to the revised QRD Templates v7.3.1 in Dutch (NL) and French (FR):- For more details, see <ul style="list-style-type: none">- the PIM DES v2.7.1 Release Notes- the PIM DES Specifications v2.7.1- the PIM DES upgrade from DES 2.7 to DES 2.7.1- the PIM Data Validation Rules v2.72.1

3. Resolved Issues

Release 2.1.1

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4. Known Limitations

Reference	Description	Workaround (if any)
R02.05	While viewing the HTML format of the validation report, the user must be able to configure which rules should be shown/hidden (PDVE Stand-alone)	None. To be addressed in a future PDVE release.
R04.03	The system must support the possibility to generate a zip package with the PDF PI documents that correspond to the imported submission across all languages included in the submission. The tgz format will not be supported.	Manually zip the pdfs generated under <Storage-Area>/<Product/pdve/<submission-full>/pdve/ To be addressed in a future PDVE release.
R04.04	The PDVE should identify documents (i.e. generate filenames) when producing PDF using the same naming convention as the one adopted for the EPAR documents	The names of files generated by PDVE follow the name of the PIM submission. To be addressed in a future PDVE release.
R08.07	The user manual must be available as a PDF document that can be downloaded from the system.	An HTML format of the user manual is delivered along with the application and is accessible by pressing the "Help" button. A link exists within this Help page to download the PDF format from the EMEA website To be addressed in a future PDVE release.
	LCM related rules not implemented: P1, P2, P5,	To be addressed in a future PDVE

Reference	Description	Workaround (if any)
	P6, P8, P9, P10, P11, P16, P17	release.
	[Important] Usage of fixed widths in tables could cause problems in reviewing.	<p>Widths in table columns should be defined as percentages. An example is given below.</p> <pre data-bbox="957 560 1197 862"><table border="1"> <colgroup> <col width="30%" /> <col width="20%" /> <col width="50%" /> </colgroup></pre>
	PDF generation may fail if there is a table with cells that span multiple columns.	<p>Users should introduce a <code>colgroup</code> element just below the table, defining the number of columns and their width in percentages.</p> <p>See example above.</p>
	Defining the width of table columns at the TD element, is ignored in the generated PDF format.	<p>Users should introduce the <code>width</code> attribute at the level of each <code>col</code> element within a <code>colgroup</code> element, and not at the level of the <code>td</code>.</p> <p>See example above.</p>
	Large tables may not fit in A4.	<p>Applicant should configure the font size in all table cells, by adding a <code>span</code> element and a <code>style</code> attribute, e.g.</p> <pre data-bbox="957 1758 1332 1814"><TD>text</td></pre>
	If no width is specified for a table, there is an inconsistency between the PDF and the HTML	For tables that should not fill the width of the whole page (especially, if

Reference	Description	Workaround (if any)
	formats: PDF - the table fills the width of the full page, HTML - the table fills the minimum space required to render the contents of the cells	borders are also shown), the width should be defined as a %.
	Long templates (e.g. tables or lists) that can not fit in A4 get truncated in the PDF	Applicants should set the keep-together template attribute to 'auto'

5. Technical Updates

Since **PDVE v2.1**:

- Use latest version of Apache FOP engine (v0.95)
- Liberation Fonts for PDF embedded into the application

6. Document information

6.1. Open issues

None

6.2. Document location

EMA

6.3. Document id

EMA/498115/2010

6.4. Referenced documents

Doc id	Title
	Work Plan for PDVE 2 1 1 release

6.5. Document history

Version	Who	When	What
0.1	S.Gerogiannakis	25/05/2010	Initial draft (rc1)

6.6. Review history

			Remarks