



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 August 2010

Information and Communications Technology

PIM Data Validation Engine v 2.1.1

Quick Reference Guide

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom

Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8420

E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union



© European Medicines Agency, 2010. Reproduction is authorised provided the source is acknowledged.

Table of contents

| | |
|--|----------|
| 1. Pre-Requisites | 3 |
| 1.1. Tools/Technologies | 3 |
| 1.2. Storage Area | 3 |
| 1.3. Launching the Application..... | 3 |
| 2. Operations..... | 4 |
| 2.1. Validating a PIM Submission | 4 |
| 2.2. Viewing a PIM submission (HTML)..... | 5 |
| 2.3. Generating the PDF version of Product Information | 6 |
| 2.4. Help & Exit..... | 8 |
| 3. Version History | 9 |
| 3.1. Change Record | 9 |
| 3.2. Reviewers | 9 |
| 3.3. Distribution | 9 |
| 3.4. Referenced Documentation..... | 9 |

1. Pre-Requisites

1.1. Tools/Technologies

The following Software is necessary in order to run the PIM Data Validation Engine:

- Java Run Time Environment from Sun (**version 1.5 or higher**).
- Web browser to view the HTML version of the product information via the PIM Viewer (Internet explorer version 6 or higher recommended)
- RedHat Liberation fonts to generate the PDF format
- PDF reader (e.g. Adobe Reader) to view the PDF format

1.2. Storage Area

PDVE requires that PIM submissions are placed under a storage area (i.e. folder) that the PDVE engine has both read and write operating system access. A separate folder should be created per product.

In the example below, a single folder has been created for the product-X and all PIM submissions (e.g. zip packages) have been manually copied under this folder (one zip package in this example).



1.3. Launching the Application

To launch the PDVE application you may follow any of the following options:

Option 1 – Visiting the EMEA web site download page

Option 2 – Through the WebStart Console

Option 3 – Through the command-line by using the batch file "run_pdve.bat" (Windows) or "run_pdve.sh" (X systems, e.g. Linux etc.) located under the deployment folder.

Notes:

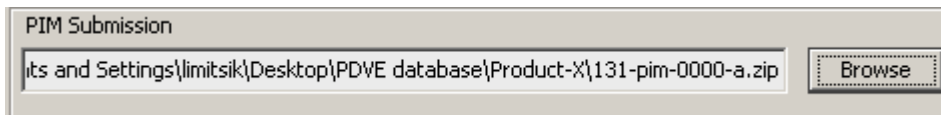
- Under options 1 and 2 the system will also automatically download and install any new PDVE release available from the EMEA website.
- It is possible to copy the complete PDVE deployment folder to a new location (or even move it to another machine) but in this case only option 3 should be used to launch the application.

2. Operations

2.1. Validating a PIM Submission

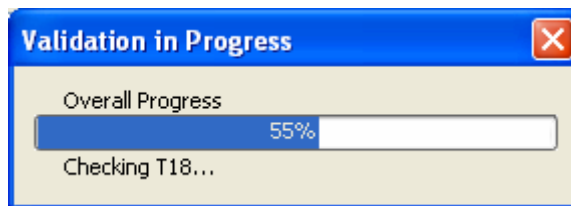
Note: PDVE v2.0 supports **DES version v2.6 or higher**. Validation is performed against the **PIM Data Validation Rules v2.7.1**.

To validate a PIM submission first select the package from the storage area using the **[Browse]** button ...

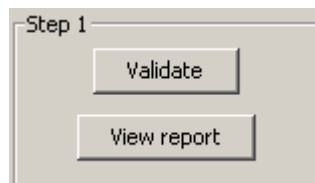


and then press the **[Validate]** button.

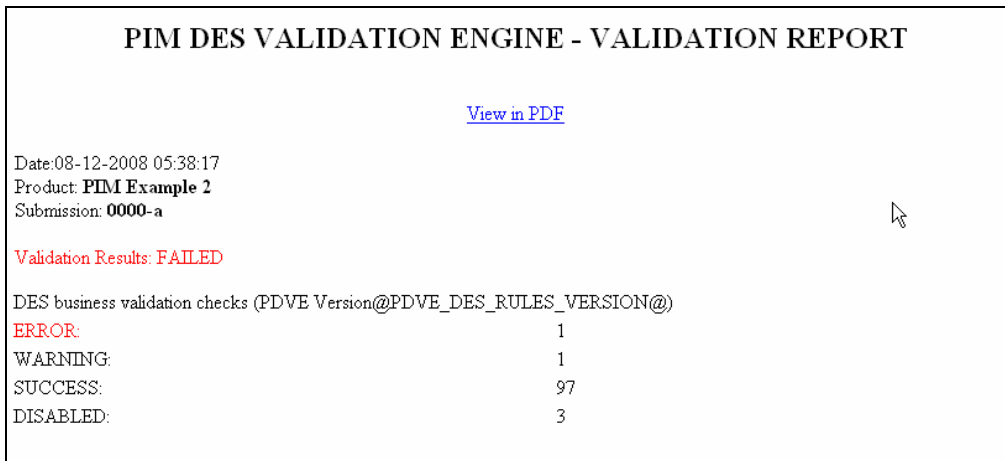
A progress bar pops-up showing the current rule under validation as well as the overall progress.



Once the system validation finishes press the **[View Report]** button.

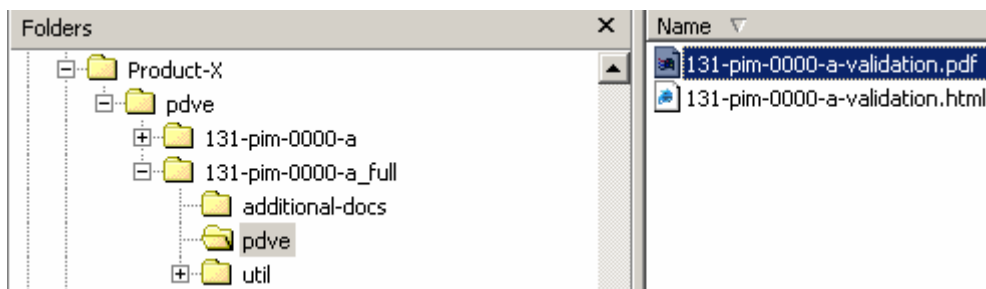


The Validation Report will display in a new window.



To access a PDF version of the validation report click on the **[View in PDF]** link from within the HTML version of the report.

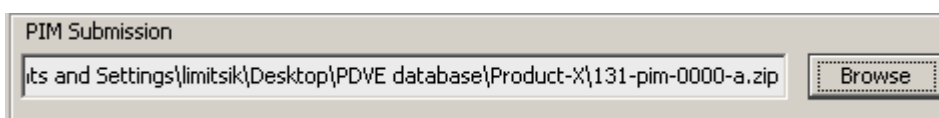
Tip: The HTML and PDF formats of the validation report are automatically generated under the folder <Product>/pdve/<submission_filename>_full>/pdve so that they can be retrieved even without launching the PDVE application.



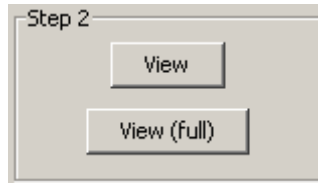
Note: The **[Validate]** operation also extracts the contents of the PIM submission (package) under the storage area and reconstructs a new `pim.xml` file under <Product>/pdve/<131-pim-XXXX-a_full>/ with templates from previous submissions (if any). This reconstructed xml is the one used by the PDVE when the user presses any of the **[View Full]** or **[Generate PDF]** buttons.

2.2. Viewing a PIM submission (HTML)

Pre-requisite: You should have already selected a PIM submission from the storage area using the **[Browse]** button and also validated the submission (at least once in the past).






In order to view the contents of the PIM submission press the **[View]** button to launch the default application associated with the XML file extension in the system.








If this application is a browser, then the DES PIM Viewer will be launched, as shown below.

PIM Submission (Ver. 2.6.1)



| | | | | | |
|---|-------------------|-----------------|--|----------------|------------|
| Application : | EMA/H/C/107/11/30 | Submission : | Var. Type IA (Article 61(3)) | Inn : | Lamivudine |
| Applicant : | MAH-3 | Procedure : | Centralised Day 0 | eCTD Seq. : | - |
| Agency : | EMA | Invented Name : | Product-X | PIM Seq. : | 0000-a |
| Status : | - | ATC Code : | J05A F05 | Related Seq. : | - |
| Description : | | | | | |
| Additional Information to Labelling : | | |  Additional Information O | | |
| Additional Information to Package Leaflet : | | |  Additional Information P | | |

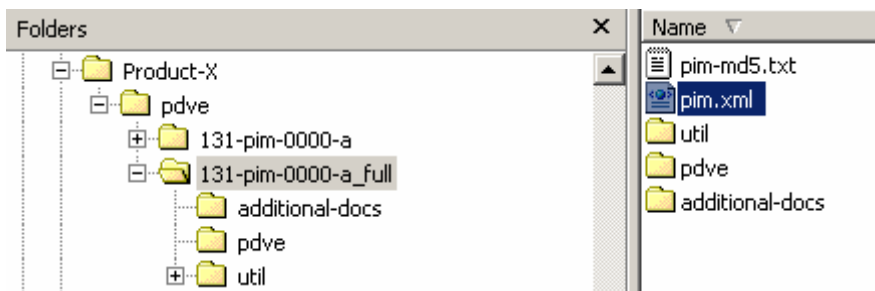
Provided languages: **en** EPAR

| Product | Form | Strength | Presentation |
|---------|---|--|--|
| | Oral Solution  | 10 mg/ml  | Bottle  |
| | | 150 mg  | Blister  |

Note: If an editor application however has been associated with the xml extension, then the source XML code will display instead.

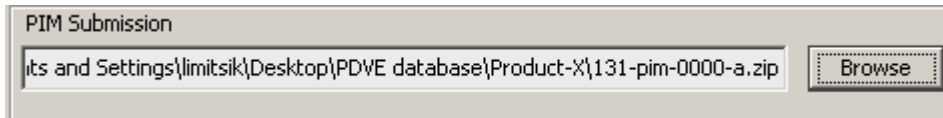
[DES v2.6.1 only] For a delta submission, the **[View Full]** button will display the full reconstructed content after retrieving the templates exchanged in previous delta submissions.

Tip: The reconstructed pim.xml file with the complete set of templates can be found under the folder <Product>/pdve/<submission_filename>_full/>.

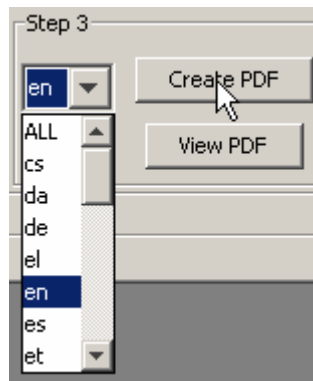


2.3. Generating the PDF version of Product Information

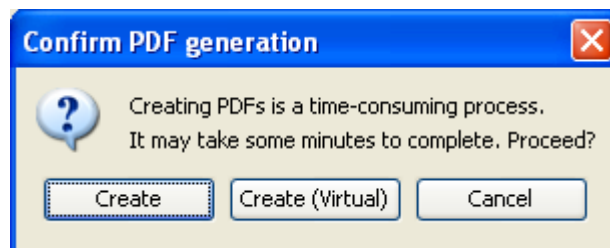
Pre-requisite: You should have already selected a PIM submission from the storage area using the **[Browse]** button and also validated the submission (at least once in the past).



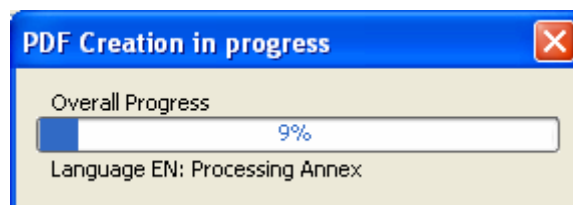
To generate the PDF format of the product information first select a language from the drop-down menu, or the "all" option, and then press the **[Create PDF]** button to generate a complete HTML and PDF with content from all product information documents.



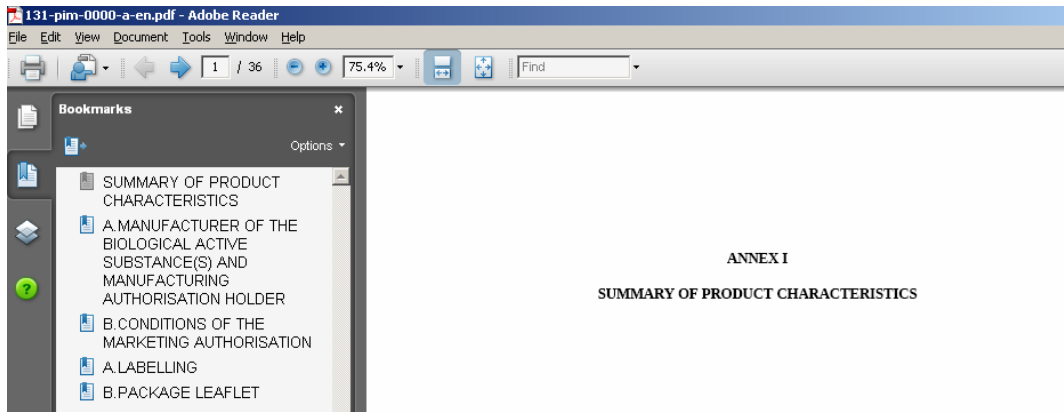
You must first confirm the request by pressing either the **Create** or the **Create (Virtual)** button and then wait until the operations finishes. The **Create (Virtual)** button is similar to the **Create** one but also includes any virtual documents in the PDF (if defined).



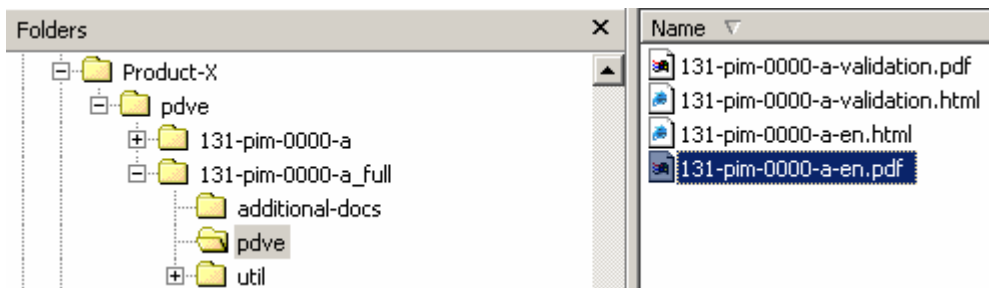
A progress bar pops-up showing the current language/document as well as the overall progress while the PDF generation is in progress.



To access the generated PDF(s) simply press the **[View PDF]** button (but also select a language first, if the "all" option was selected). The system will launch the application associated with the PDF extension in the user machine (e.g. Acrobat Reader) as shown below.



Tip: The HTML and PDF formats of the product information from all documents are automatically generated under the folder <Product>/pdve/<submission_filename>_full>/pdve so that they can be retrieved even without launching the PDVE application.



2.4. Help & Exit

To retrieve detailed guidance press the **[Help]** button. The User Manual will display in a new window (HTML format).

To exit the PDVE application press the **[Exit]** button or by simply close the window .

3. Version History

3.1. Change Record

| Version | Date | Author | Remarks |
|---------|------------|------------------|---------------------------|
| 0.1 | 09/01/2009 | Kostas Limitsios | Initial Draft (PDVE v2.0) |
| 0.2 | 10/08/2009 | Kostas Limitsios | Updated for PDVE v2.1 |
| 0.3 | 19/8/2010 | Charles Humble | Updated for PDVE v2.1.1 |
| | | | |
| | | | |

3.2. Reviewers

| Version | Date | Reviewer | Remarks |
|---------|------|----------|---------|
| | | | |
| | | | |
| | | | |
| | | | |

3.3. Distribution

| Name | Date | Version |
|------|------|---------|
| | | |
| | | |
| | | |
| | | |

3.4. Referenced Documentation

| Document Name | Location | Version |
|---------------------------------|---|---------|
| PIM Data Validation Rules | http://pim.ema.europa.eu/PDFs/PIM%20Data%20Validation%20Rules%20v2[1].7.1.pdf | 2.7.1 |
| PDVE - User Installation Manual | | |