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## PIM Data Validation Engine v 2.1.1

User Manual

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# 1. Introduction

## 1.1. Purpose of this Document

This User's Guide reviews the graphical user interface (GUI) and functionalities of the PIM Data Validation Engine (PDVE). It provides a description of the application's pages and information on how applicants may use the application to validate PIM submission, in the frame of a marketing authorisation application (MAA). It also provides guidance on how to generate a PDF format of the product information documents.

The next section introduces the PIM concept and places the PDVE application within the context of the software environment which has been put at the disposal of both applicants and Regulatory authorities.

**Chapter 2.** provides guidance on how to manually copy the PIM submissions (packages) under an external **storage area**.

**Chapter 3.** provides guidance on how to **launch** the application.

**Chapter 4.** provides guidance on how to **validate** a PIM submission and retrieve the associated validation report in either HTML or PDF format.

**Chapter 5.** provides guidance on how to **view** the full contents of a PIM submission in **HTML** format, including delta submissions. This operation assumes that the validate operation has already been performed.

**Chapter 6.** provides guidance on how to generate and retrieve the **HTML** and **PDF** files with the complete product information from all documents. This operation assumes that the validate operation has already been performed.

**Chapter 7.** , summarizes the rest of the operations supported by PDVE, i.e. how to consult an HTML version of this **user manual** and how to **exit** the application

**Note:** Users are advised to also check the Release Notes that accompany each new PDVE release. The Release Notes summarize all new functionality along with any resolved issues and known limitations.

## 1.2. Scope

This user manual details functionality available in **PDVE version 2.1.1**<sup>1</sup> which supports all DES versions starting from **DES version 2.6** and including the **latest DES version 2.7.1**.

This version of the PDVE supports the latest version of validation rules as defined in the document **"PIM Data Validation Rules version 2.7.1"**.

## 1.3. The PIM Concept

The concept of PIM appeared in 1999 while the EMEA was starting to devise a new way of handling product information in the European Regulatory context.

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<sup>1</sup>Although a version 1.0 of the PDVE was created in the past, it was only made available internally at EMEA without being distributed to the Applicants. That version supported a limited functionality since it validated only full packages against a very limited set of the PDVE rules, while PDF generation was not supported.

### **1.3.1. PIM is a Standard**

Primarily PIM is a standard for the electronic exchange of medicinal product information. It describes how the required information should be created and validated so that it can be exchanged successfully between applicants and competent authorities.

PIM's guiding design principle is to store any distinct piece of information only once while allowing to re-use it as many times as necessary in order to generate the required documents. The PIM standard obviates the need to supply either paper or MS Word documents when applying for the market authorization of a medicinal product.

The standard is based on XML (eXtensible Markup Language) to structure and control the exchanged product information. The scientific content and the layout of the required documents defined by PIM are compliant with the Quality Review of Documents (QRD) templates version 7, 7.2, 7.3 and 7.3.1 and with the DES 2.2 and DES 2.3.2 / 2.4 / 2.5.1 / 2.6.1 / 2.7 / 2.7.1 respectively.

### **1.3.2. PIM is a Process**

In support of the exchange of PIM submissions between applicant and EMEA, and the review of the product information, a number of processes have been defined, which in several aspects differ from the process for the exchange of product information currently used for paper and Word electronic documents.

### **1.3.3. PIM is a Project**

As a project, PIM was initiated in 1999 to develop a new way of handling product information. Its membership has been drawn from EMEA, Member State Competent Authorities (MSCAs) and The European Federation of Pharmaceutical Industries and Associations (EFPIA) members. It has gone through several phases, which have culminated in the publication of the PIM standard. The project continues to be directed by a Core Team, which is currently leading the implementation of the standard, the development of the system, the definition of the business processes and the further refinement of the standard.

### **1.3.4. PIM is a System**

In order to support the Regulatory review of product information produced using the PIM standard, a computer system is being developed for use by applicants, the EMEA and the MSCAs. This PIM system consists of three applications, all based on PIM's Data Exchange Standard (DES) for structuring and storing Product Information data (PI) in XML format:

- PIM Data Validation Engine (PDVE)
- PIM Light Authoring Tool (LAT)
- PIM Review System (PRS)

See the next three subsections for a brief introduction of these applications.

### **1.3.5. PDVE – PIM Data Validation Engine**

The PDVE is part of the EMEA's initiative to provide increased administrative assistance for small and medium sized enterprises (SMEs) to enable them to adapt to changes and to new operating procedures arising from European Union Regulatory and legislative change. The underlying legislative basis of this initiative may be found in Regulation (EC) No. 726/2004.

The PDVE is intended to be used by applicants who prefer to build their PIM submissions without relying on the LAT, which has already built-in validation features. PDVE is thus expected to be used a supplementary tool to other PIM authoring solutions to cover the validation of a PIM submission according to the PIM data validation rules. It also aims to support the need to generate a PDF version of the product information which is exactly the same as the one generated in the PRS, especially with regards to paging and other layout issues (ISO216 A4 size).

### **1.3.6. LAT – PIM Light Authoring Tool**

The LAT is part of the EMEA's initiative to provide increased administrative assistance for small and medium sized enterprises (SMEs) to enable them to adapt to changes and to new operating procedures arising from European Union Regulatory and legislative change. The underlying legislative basis of this initiative may be found in Regulation (EC) No. 726/2004.

LAT provides a superset of the functionality available in the PDVE. It allows applicants to author new PIM submissions which comply with the DES and export PIM packages that serve as input for the PRS. LAT also includes built-in validation features when exporting or importing submissions. LAT also allows the generation of a PDF version of the product information with and without track changes.

LAT however is more complex to deploy and maintain compared to the PDVE since it relies on third-party application server and database modules, even if their deployment is done automatically during the LAT installation process.

### **1.3.7. PRS - PIM Review System**

The PRS module is the review part of the PIM system for use by the EMEA and the National Competent Authorities.

It is composed of:

1. A central database located at the EMEA;
2. A Web application hosted by the EMEA and accessible to all competent authorities involved in the review of medicinal products within the European Economic Area (EEC).

The PRS master data is always stored in the database at the EMEA. Typically, the PI data accessible in the PRS application is loaded (imported) into the PRS database by authorised EMEA staff and may originate from either of the following sources:

1. PI data exported using the LAT provided freely to the industry by the EMEA.
2. PI data created and packaged by any software tool used or developed by applicants or any other institution or company, provided it can format, export and package XML data according to the PIM DES.

Thus, applicants using their own authoring tools may prefer to use the PDVE application in order to validate their PIM submissions as well as generate a PDF version of the product information before officially submitting the PIM package to the EMEA.

### 1.4. Conventions

This manual uses the following typographical conventions:

**[bold]** A link or a button, on which the user can click to go to another part of the application or to perform an action.

## 2. External Storage Area

PDVE usage assumes that PIM submissions are placed under an external storage area (i.e. system folder) that the PDVE engine has both read and write operating system access: read access to retrieve the packages and write access to generate the various output formats (e.g. validation reports in html or pdf format, reconstructed pim.xml in case of delta submissions, complete product information documents in html or pdf format). For each product a single folder should be created containing all the PIM packages submitted under this product. The products folders do not have to be located under the PDVE deployment directory, as long as they are system accessible.

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 by the applicant under this folder (one zip in this example).



Although the name of the folder does not have to be exactly the same as the one of the product, doing so will make maintenance of this repository easier (e.g. moving files around or navigating in the product directory structure).

Since PIM submissions may have references to previous ones, it is important that all valid product packages, applicant and regulator ones are located under this product folder. The same applies for packages submitted under different procedures. It is thus important that no specific folder is created per procedure.

All PDVE operations presented in Chapters 3 to 5 assume that the user first selects a PIM package from this storage area. That is before, pressing the **[Validate]**, **[View Report]**, **[View]**, **[View Full]**, **[Generated PDF]**, and **[View PDF]** buttons, a target package has been selected via the **[Browse]** button.

### 3. Launching the Application

Launching the PDVE application can be done through various means as explained in the options below. Under options 1 and 2 the system first checks whether a new release is available so as to automatically download and install this release before launching the application. For more details on how to deploy and launch the application see the **PDVE User Installation Manual**.

#### 3.1. Option 1 – EMEA web site download page

User should visit the EMEA web site download page and the click on the icon as shown in the figure below.

To download the latest version of the PDVE application, click on the icon below



**Note**

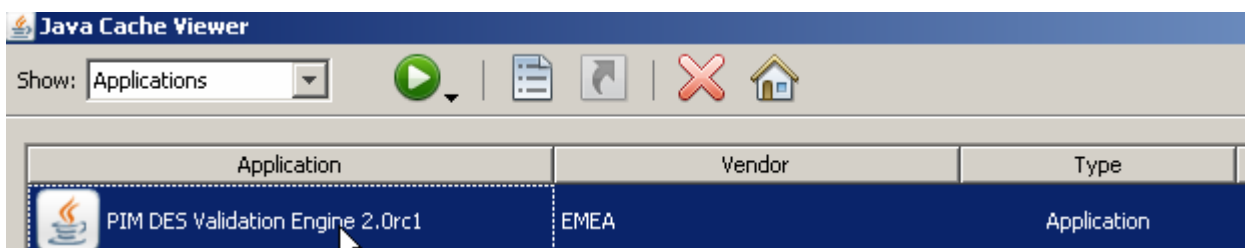
If Java is not launched automatically, you will need to install it on your PC!  
Get it [here](#).

The first time the user downloads the application he will be prompted to select a deployment directory where the application files (e.g. jar, libraries, etc.) will be placed.

Once the application is deployed, starting the PDVE through this option will check every time if there is a new release available in which case it will also download and install it under the predefined deployment folder.

#### 3.2. Option 2 – Java Web Start console or desktop shortcut

User should use the desktop shortcut created when the application was downloaded from the EMEA web site and deployed on the local machine (option 1). If no shortcut exists, the user may open the Java Web Start Console and select the PDVE application as shown in the figure below.



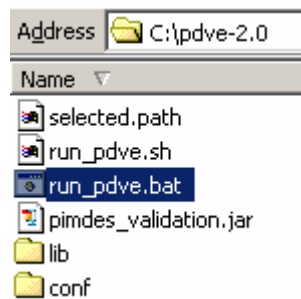
Starting the PDVE through this option will also check if there is a new release available in which case it will also download and install it.

### **3.3. Option 3 – Command line or batch file**

The user may open a command line system window, change the path to the PDVE deployment directory where the jar file is located and finally give the following command:

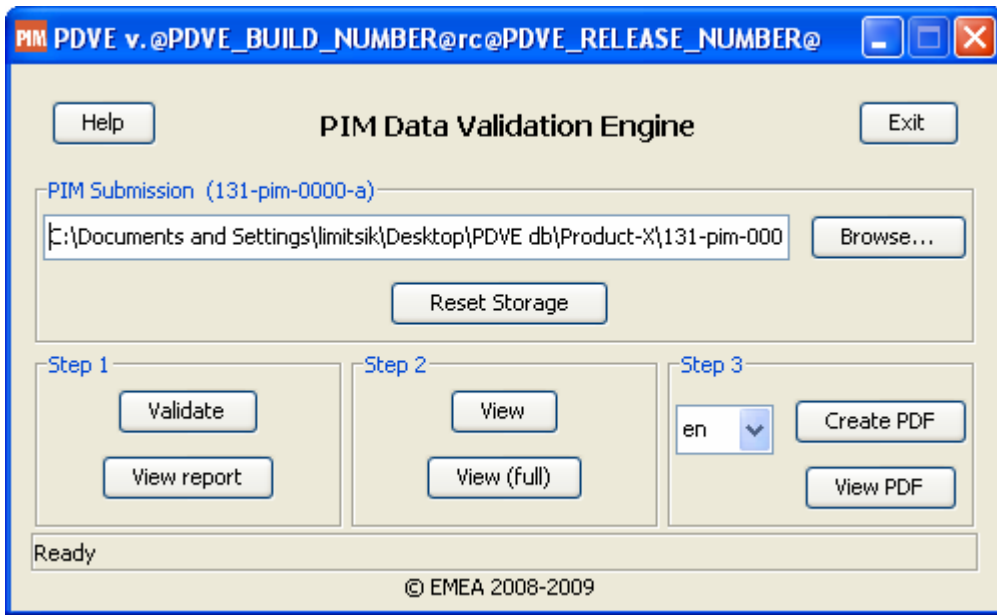
```
java -Xms128m -Xmx512m -jar pimdes_validation.jar
```

Alternatively, the user may execute the batch file "run\_pdve.bat" (Windows) or "run\_pdve.sh" (X systems, e.g. Linux etc.).

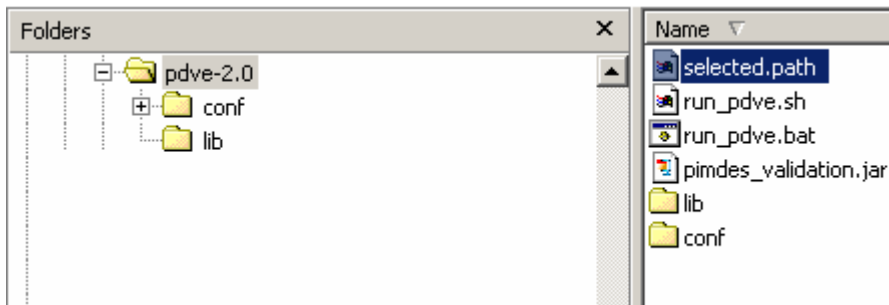


Starting the PDVE through this option ensures that always the currently deployed release will be launched even if there is a new release available. That is, this option does not download and deploy any new release.

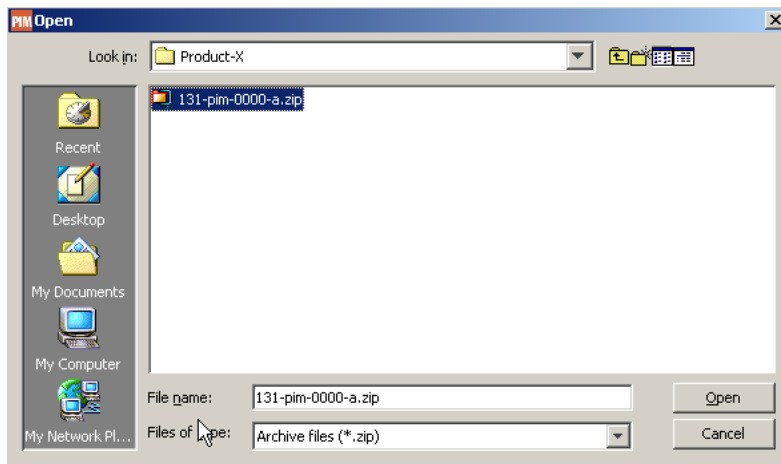
Once the application is launched the following screen will display:



The system automatically “remembers” the last selected submission as stored in the `selected.path` file under the deployment folder.

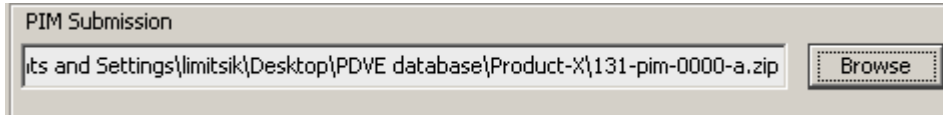


The user will have to use the **[Browse]** button to locate the package before attempting to perform any of the PDVE operations presented in the following chapters.

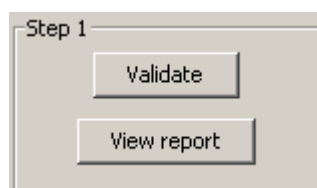


## 4. Validating a PIM Submission

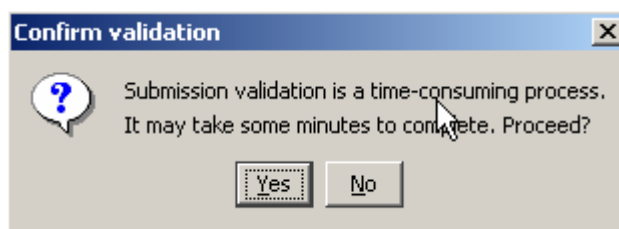
The user should have already selected a PIM submission from the storage area using the **[Browse]** button.



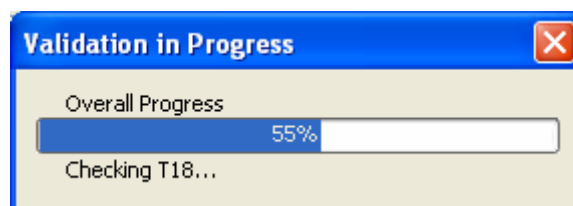
By pressing the **[Validate]** button the system will validate the submission against the PIM Data validation rules.



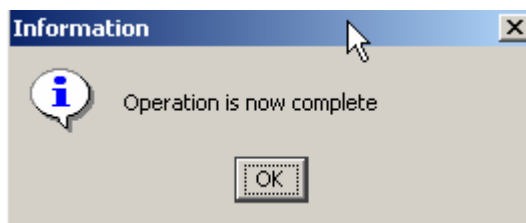
The user must first confirm the request by pressing the **[Yes]** button and then wait until the operation completes.



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



Once the validation operation completes the following message is shown.



The number of violated rules per type (e.g. Errors, Warnings etc.) is shown at the PDVE status bar.

Validation completed (9 sec) - Fatal:0, **Error:1**, Warning:1, Info:0

In order to view the validation report the user should press the **[View Report]** button. This will launch the default browser with an HTML version of the report as shown in the figure below.

## PIM DES VALIDATION ENGINE - VALIDATION REPORT

[View in PDF](#)

Date:08-12-2008 05:38:17  
 Product: **PIM Example 2**  
 Submission: **0000-a**

**Validation Results: FAILED**

DES business validation checks (PDVE Version@PDVE\_DES\_RULES\_VERSION@)

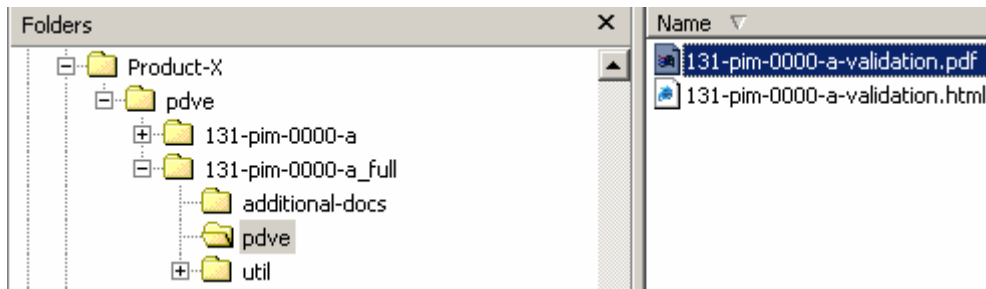
ERROR: 1  
 WARNING: 1  
 SUCCESS: 97  
 DISABLED: 3

Validation Rules::ERROR		
Identifier	Description	Outcome
F04	The file "pim-md5.txt" must contain the 128-bit hexadecimal-encoded MD5 checksum of the pim.xml file. The message digest must contain a combination of 32 digits and/or lowercase letters from "a" to "f"	Rule F04 failed. The MD5 checksum of the pim.xml in the "pim-md5.txt" (4f6627637e78e04e0da1db1885c713a3) does not match with the calculate checksum of pim.xml file (c8b3e877e12b3db6b8f96679d8c728a6).
Validation Rules::WARNING		
Identifier	Description	Outcome
		Rule T19 failed. A table was found without col elements! A table was found without col elements! A table was found without col elements! A table col element was found without setting width within attribute style! A table col element was found without setting width within

The validation report will display any violations of the PDVE rules. Errors are displayed first grouped by severity (e.g. fatal, severe, error) followed by any warnings or information ones. Rules executed successfully, i.e. without any violation, are appended at the end of the report. For each rule, its identifier and description is shown followed by the outcome of the validation, giving more details on the reason a particular rule failed. The validation is stopped if any of the rules defined as "fatal" fails (e.g. missing or invalid pim.xml file).

The user may also access a PDF version of this validation report by pressing 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.



Once the validation report has been generated, there is no need to execute the Validate operation again in order to view the report. Clicking on the **[View Report]** button or browsing to the relevant folder outside PDVE is all that is needed. However, if a new version of the same package (i.e. same sequence) needs to be validated again then the PIM submission (e.g. zip package) should be placed under the storage area overwriting the previous one and the **[Validate]** operation executed again. The operation will produce a new HTML and PDF version of the validation report overwriting any existing ones. Finally, viewing the validation report from old PIM submissions is also possible without having to execute the **[Validate]** operation again, assuming of course that the external storage is not cleared outside the PDVE.

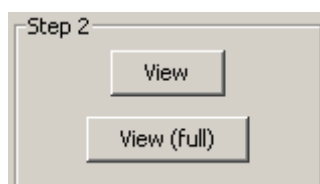
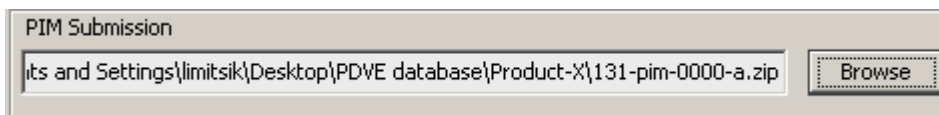
Delta packages are the ones using DES Life Cycle Management (LCM) operations which refer to previous PIM submissions. For these packages, the validation may take more time to complete since the PDVE needs to load the referenced PIM submissions from the storage area. Thus, all previous packages must be kept under the storage area in order to correctly validate future PIM submissions.

#### Notes:

- 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/<submission_filename>_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.
- Although packages in DES v2.7 or higher are full, the PDVE still follows the same approach and reconstructs the complete XML. The PDF generation utility always uses as input the file located under this `<Product>/pdve/<submission_filename>_full/` folder.

## 5. Viewing a PIM submission (HTML)

The user 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).



By pressing the **[View]** button the system will launch the default browser showing the product structure as this is rendered by the DES PIM Viewer stylesheets (see example below).

**PIM Submission (Ver. 2.6.1)**

Application :	EME A/H/C/107/II/30	Submission :	Var. Type IA (Article 61(3))	Inn :	Lamivudine
Applicant :	MAH-3	Procedure :	Centralised Day 0	eCTD Seq. :	-
Agency :	EMEA	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 

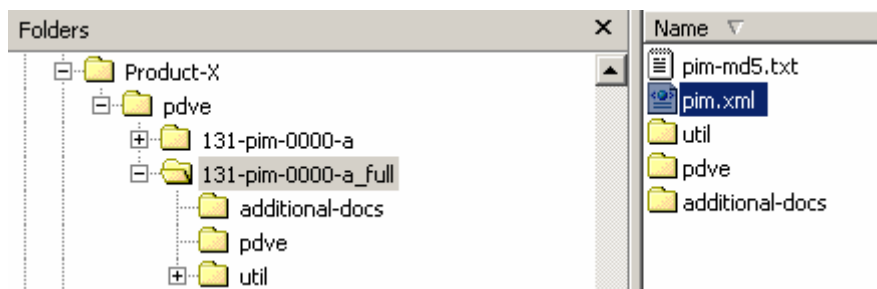
The user may select the applicable language from the ones listed above the product structure and then click on a particular document icon in order to view its contents, in another pop-up window.

For “delta” packages, only the templates exchanged as part of the submission will be shown. In order to view the complete reconstructed text the user should press the **[View Full]** button instead. The

outcome is the same as before, however any referenced templates from previous PIM submissions will also be displayed.

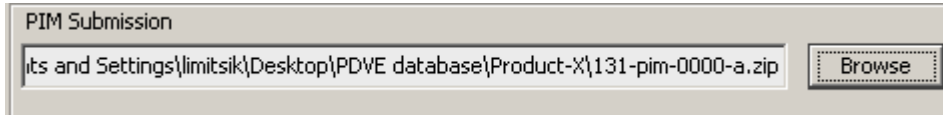
**Note:** System launches by default the application associated with the “xml” file types in the user machine. In order for the product structure to display as shown in the examples above, a browser should have been designated as the application to open xml files. Furthermore, due to a known limitation with the handling of entities by the FireFox’s underlying XSL engine, the PIM Viewer works properly only with the Internet Explorer browser.

**Note:** The reconstructed pim.xml file with the complete set of templates can be found under the folder <Product>/pdve/<submission\_filename>\_full/.

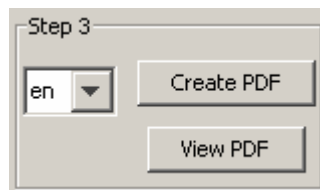


## 6. Generating the PDF version of Product Information

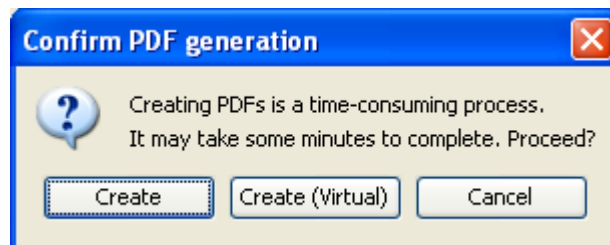
The user should have already selected a PIM submission from the storage area using the **[Browse]** button and also validated the submission (at least once in the past).



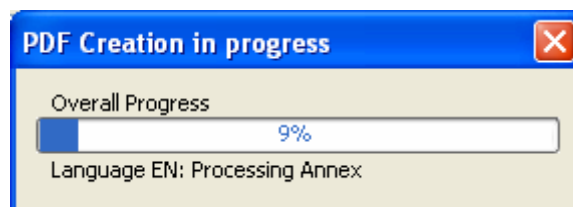
By selecting a language from the drop-down menu and then pressing the **[PDF]** button the system will generate a complete HTML and PDF with content from all product information documents.



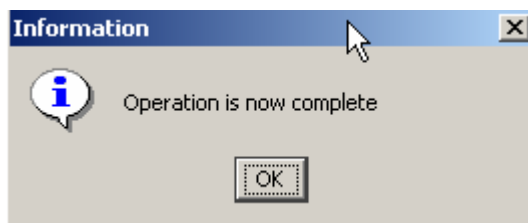
The user must first confirm the request by pressing either the **Create** or the **Create (Virtual)** button and then wait until the operations finishes. The **Create (Virtual)** button is similar to the **Create** one but also includes any virtual documents in the PDF (if defined).



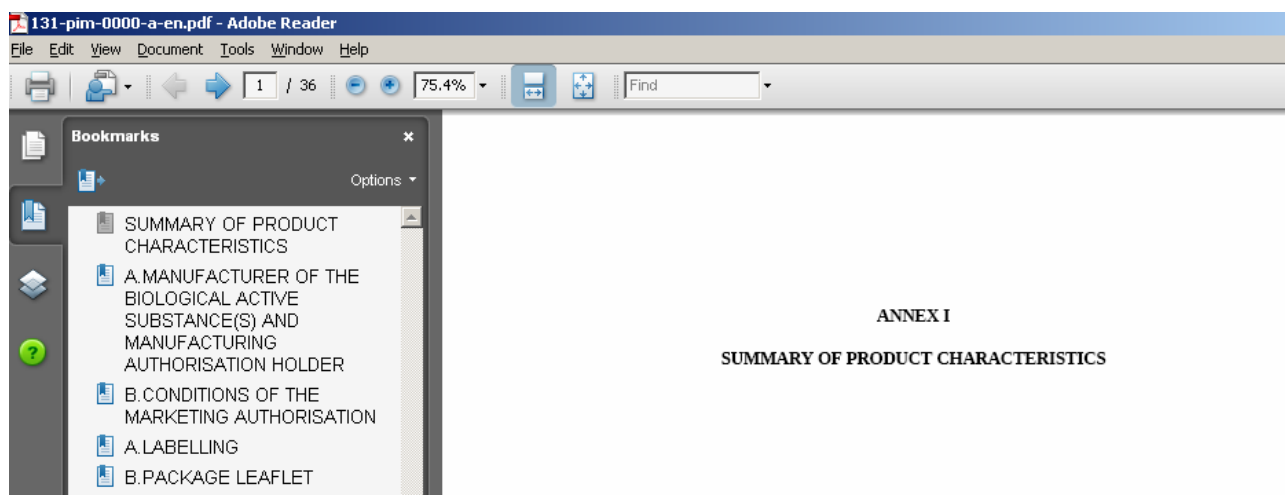
A progress bar pops-up showing the current language/document as well as the overall progress while the PDF generation is in progress.



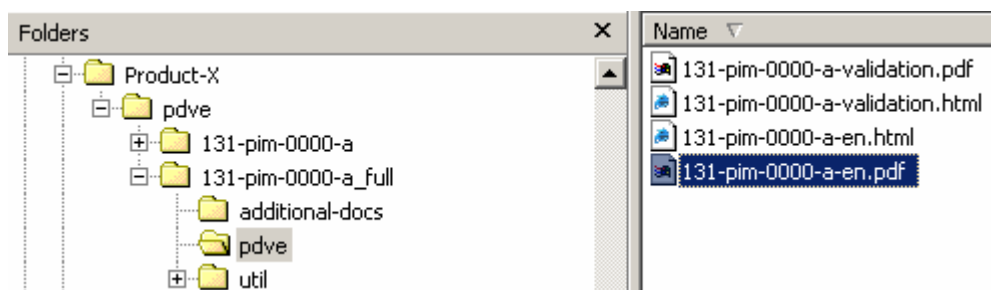
Once the PDF generation operation is finished the following message is displayed.



In order to view the PDF file the user should press the **[View PDF]** button. The system will launch the application associated with the PDF extension in the user machine (e.g. Acrobat Reader).




**Note:** 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.



## 7. Other

The user may retrieve an HTML version of this User Manual by pressing the **[Help]** button.

The user may exit the PDVE application, by pressing the **[Exit]** button or by simply closing the window .

## 8. Version History

### 8.1. Change Record

Version	Date	Author	Remarks
0.1	17/12/2008	Kostas Limitsios	Initial Draft
0.2	18/12/2008	Kostas Limitsios	Updated
0.3	04/02/2009	Kostas Limitsios	Corrections in headings
0.4	10/08/2009	Kostas Limitsios	Updated for PDVE v2.1
0.5	19/8/2010	Charles Humble	Updated for PDVE v2.1.1

### 8.2. Reviewers

Version	Date	Reviewer	Remarks

### 8.3. Distribution

Name	Date	Version

### 8.4. Referenced Documentation

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