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Revision History

<i>Version</i>	<i>Date</i>	<i>Reason for changes</i>	<i>Description of changes made</i>
1.0	07-June-2018	Initial document	N/A

THE SOLE FUNCTION OF THE ABOVE TEXT IS TO APPROVE THE VERSION OF THIS USER ACCEPTANCE TEST PLAN PTMVS TEMPLATE (HOSPITAL TEST CASES) AND TO MAINTAIN THE REVISION HISTORY. IT IS NOT PART OF THE PILOT PHASE APPROACH AND PLAN ITSELF. NOTE THAT A SEPARATE HEADER AND FOOTER IS USED ON THIS FIRST PAGE.

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1. Purpose

The purpose of this document is to describe the tests required to be performed in the IQE environment, in order to access the Production environment.

Access to PTMVS will be granted by PTMVO to each individual person using a unique system account. PTMVO is categorized as a GxP system and is connected to the EU Hub, a subsystem of the European Medicines Verification System (EMVS). End User IT systems will be connected to PTMVS via an interface or a web portal.

2. Access to test environment

Only after having completed the onboarding process the End User will be eligible for receiving the access credentials to IQE environment of PTMVS. The access credentials will consist of username, initial password and a certificate. These credentials will be supplied to the End User via email. The provided credentials will have administrator privileges. Each End User will create and manage its own users. The instructions to operate user management are described in the document MVOPT-0062_User Management.

The tests will occur on PTMVS's Integrated Quality Environment (IQE), which is connected to EU Hub IQE environment.

The data to be used will be supplied by PTMVO to each End User. That will allow the determination of which set of data to be used in each test scenario, and thus better grasp the behavior of the systems. The data to be used may or may not be real pack data. If no real pack data is to be used, the data to be used will fulfill the requirements defined for Portuguese market, as per the published legislation and GS1 guidelines.

3. Access to Production Environment (PRD)

Access to the Production Environment will be granted to all End Users that successfully accomplish the tests described in this document. In order to be eligible for access to the Production Environment (PRD), the End User must provide the following documents:

- Report summarizing the results of the test including a table of all test cases, screenshots, list of all defects, description of open defects/issues and final test conclusion. The screenshots of the output of the tested IT system as defined in respective test cases to be added to the Pilot report. For this, the template MVOPT-0066_IQE Test Pilot Report – Hospitals is to be used by the End User.
- Defect reports concerning all defects detected during testing. For this, the template MVOPT-0035_Defect Report Template is to be used by the End User.

4. System description

PTMVS will serve as the verification platform to which Hospital connects in order to verify the authenticity of medicinal products. Each Hospital has chosen an IT service provider that will deliver the Hospital system and the interface between the Hospital system and PTMVS. For the purpose of this document, the IT service provider can be an internal entity (i.e. the internal IT Department) or an external supplier. In case of unavailability of the connection between the End User IT system and the PTMVS via the webservices, it will be possible the use of a web-based portal, a graphical user interface (GUI), for the purposes of verifying the authenticity of the unique identifier and decommissioning. In the test scenarios described on section 6 of this document including the expression "manual entry" the GUI will be used.

5. Definitions


Term/Acronym	Definition
Authorisation Holders	The group composed by Marketing Authorisation Holders and Parallel Importer Holders.
EMVS	European Medicines Verification System. The European system for medicines verification consisting of the European Hub, the NMVS, the interface between those two, and the interfaces to the manufacturer / parallel distributor systems, to the Hospital systems and to the Hospital systems.
EU Hub	The subsystem of the European Medicines Verification System that serves as a gateway for the transmission of manufacturer and parallel importer data to the national systems. Furthermore; data reconciliation on repackaging activities is performed on the EU Hub.
GxP System	A system that is subject to GxP regulations (x can mean: Clinical, Laboratory, Manufacturing, Pharmaceutical, etc...). The company must ensure that such systems comply with appropriate regulations.
End User	End User shall mean any wholesaler, pharmacy, hospital or other person authorized or entitled to supply medicinal products to the public as foreseen under the EU Directive on Falsified Medicines and the Delegated Regulation.
IQE	Integrated Quality Environment.
ITE	Integrated Test Environment.
IT Service Provider	The service provider that delivers the interface between the End User system and PTMVS. Is contracted by the End User.
MAH	Marketing Authorisation Holder.
NCA	National Competent Authority (In Portugal, INFARMED I.P.).
PIAH	Parallel Importer Authorisation Holder.
PRD	Production Environment.
PTMVO	Portuguese Medicines Verification Organisation.
PTMVS	Portuguese Medicines Verification System. A system in the European Medicines Verification landscape that serves as the verification platform for Portugal. The End Users registered (Hospitals, Hospitals, Hospitals or Other kind of End Users in the Portuguese context) check the authenticity of a product using a connection to this system.
SOP	Standard Operational Procedure.

6. Test cases for Hospitals

6.1 Attributes to be tested

The following attributes will be tested:

Process ID	Description
Download product master data	
G101	Download product master data
Single pack transactions	
G110	Verify single pack
G120	Dispense single pack
G121	Undo dispense single pack
G122	Dispense single pack manual entry
G130	Destroy single pack
G150	Sample single pack
G151	Undo sample single pack
Homogenous bulk transactions	
G115	Bulk verify packs
G125	Bulk dispense packs
G127	Bulk undo dispense packs
G135	Bulk destroy packs
G155	Bulk sample packs
G157	Bulk undo sample packs
G188	Request bulk transaction result
G195	Submit mixed bulk transaction
G916	Request mixed bulk transaction

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6.2 Test cases – Single pack transactions

6.2.1 PTMVS-H-01 Verify, dispense and undo dispense single pack

Description	Test case to verify that transactions 'Verify single pack', 'Dispense single pack' and 'Undo dispense single pack' can be successfully performed via the Hospital IT system interface.	
Transactions	G110 Verify single pack G120 Dispense single pack G121 Undo dispense single pack	
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs has been uploaded in PTMVS.	
Acceptance criteria	All steps could be successfully completed.	
Successfully completed	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Packs used	Send file to PTMVO with the packs used.	
Defect report reference		
Performed by		

Step	Description	Expected result	Actual result
1	Perform the operation 'Verify single pack' for the predefined packs. Take a screenshot showing the result.	The status of the pack is ACTIVE and the operation is successfully completed.	
2	Perform the operation 'Dispense single pack' for the packs verified in Step 1. Take a screenshot showing the result.	The operation is successfully completed.	
3	Perform the operation 'Verify single pack' for the packs dispensed in Step 2. Take a screenshot showing the result.	The status of the pack is INACTIVE (DISPENSED) and the operation is successfully completed.	
4	Perform the operation 'Undo dispense single pack' for the packs verified in Step 3. Take a screenshot showing the result.	The operation is successfully completed.	
5	Perform the operation 'Verify single pack' for the packs used in Step 4. Take a screenshot showing the result.	The status of the pack is ACTIVE and the operation is successfully completed.	

6.2.2 PTMVS-H-02 Dispense single pack manual entry


Description	Test case to verify that transaction 'Dispense single pack manual entry' can be successfully performed by manually introducing the data into the system.			
Transactions	G122 Dispense single pack manual entry			
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs has been uploaded in PTMVS.			
Acceptance criteria	All steps could be successfully completed.			
Successfully completed	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Packs used	Send file to PTMVO with the packs used.			
Defect report reference				
Performed by				

Step	Description	Expected result	Actual result
1	Perform the operation 'Dispense single pack manual entry' for a predefined pack. Take a screenshot showing the result.	The operation is successfully completed.	
2	Perform the operation 'Verify single pack' for the pack dispensed in Step 1. Take a screenshot showing the result.	The status of the pack is INACTIVE (DISPENSED) and the operation is successfully completed.	

6.2.3 PTMVS-H-03 Sample single pack and undo sample single pack

Description	Test case to verify that transactions 'Sample single pack' and 'Undo sample single pack' can be successfully performed via the Hospital IT system interface.	
Transactions	G150 Sample single pack G151 Undo sample single pack	
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs has been uploaded in PTMVS.	
Acceptance criteria	All steps could be successfully completed.	
Successfully completed	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Packs used	Send file to PTMVO with the packs used.	
Defect report reference		
Performed by		


Step	Description	Expected result	Actual result
1	Perform the operation 'Sample single pack' for a predefined pack. Take a screenshot showing the result.	The operation is successfully completed.	
2	Perform the operation 'Verify single pack' for the pack sampled in Step 1. Take a screenshot showing the result.	The status of the pack is INACTIVE (SAMPLE) and the operation is successfully completed.	
3	Perform the operation 'Undo sample single pack' for the pack verified in Step 3. Take a screenshot showing the result.	The operation is successfully completed.	
4	Perform the operation 'Verify single pack' for the pack used in Step 4. Take a screenshot showing the result.	The status of the pack is ACTIVE and the operation is successfully completed.	

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6.2.4 PTMVS-H-04 Destroy single pack

Description	Test case to verify that transaction 'Destroy single pack' can be successfully performed via the Hospital IT system interface.	
Transactions	G130 Destroy single pack	
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs has been uploaded in PTMVS.	
Acceptance criteria	All steps could be successfully completed.	
Successfully completed	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Packs used	Send file to PTMVO with the packs used.	
Defect report reference		
Performed by		

Step	Description	Expected result	Actual result
1	Perform the operation 'Destroy single pack' for a predefined pack. Take a screenshot showing the result.	The operation is successfully completed.	
2	Perform the operation 'Verify single pack' for the pack destroyed in Step 1. Take a screenshot showing the result.	The status of the pack is INACTIVE (DESTROYED) and the operation is successfully completed.	

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6.2.5 PTMVS-H-05 Alarm generation

Description	Test case to verify that a predefined pack not previously uploaded to the system generates an alarm.			
Transactions	G110 Verify single pack			
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs has been uploaded in PTMVS.			
Acceptance criteria	All steps could be successfully completed.			
Successfully completed	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Packs used	Send file to PTMVO with the packs used.			
Defect report reference				
Performed by				

Step	Description	Expected result	Actual result
1	Perform the operation 'Verify single pack' for a predefined pack. Take a screenshot showing the result.	The pack does not exist in the system and an alarm should be generated.	

6.3 Test cases – Bulk transactions

6.3.1 PTMVS-H-06 Bulk verify packs, bulk dispense packs, bulk undo dispense packs and request bulk transaction result

Description	Test case to verify that transactions 'Bulk verify packs', 'Bulk dispense packs', 'Bulk undo dispense packs' and 'Request bulk transaction result' can be successfully performed via the Hospital IT system interface.
Transactions	G115 Bulk verify packs G125 Bulk dispense packs G127 Bulk undo dispense packs G188 Request bulk transaction result
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs has been uploaded in PTMVS.
Acceptance criteria	All steps could be successfully completed.
Successfully completed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Packs used	Send file to PTMVO with the packs used.
Defect report reference	
Performed by	

Step	Description	Expected result	Actual result
1	Perform the operation 'Bulk verify packs' for the predefined packs. Take a screenshot showing the result.	A confirmation of receipt containing a transaction ID is returned and the operation is successfully completed.	
2	Perform the operation 'Request bulk transaction result' by using the transaction ID received in Step 1. Take a screenshot showing the result.	The status of all the packs is ACTIVE and the operation is successfully completed.	
3	Perform the operation 'Bulk dispense packs' for packs verified in Step 2. Take a screenshot showing the result.	A confirmation of receipt containing a transaction ID is returned and the operation is successfully completed.	
4	Perform the operation 'Request bulk transaction result' by using the transaction ID received in Step 3. Take a screenshot showing the result.	The status of all the packs is INACTIVE (DISPENSED) and the operation is successfully completed.	
5	Perform the operation 'Bulk undo dispense packs' for packs dispensed in Step 4. Take a screenshot showing the result.	A confirmation of receipt containing a transaction ID is returned and the operation is successfully completed.	



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6	Perform the operation 'Request bulk transaction result' by using the transaction ID received in Step 5. Take a screenshot showing the result.	The status of all the packs is ACTIVE and the operation is successfully completed.	
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6.3.2 PTMVS-H-07 Bulk sample packs and bulk undo sample packs


Description	Test case to verify that transactions 'Bulk sample packs' and 'Bulk undo sample packs' can be successfully performed via the Hospital IT system interface.	
Transactions	G155 Bulk sample packs G157 Bulk undo sample packs	
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs has been uploaded in PTMVS.	
Acceptance criteria	All steps could be successfully completed.	
Successfully completed	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Packs used	Send file to PTMVO with the packs used.	
Defect report reference		
Performed by		

Step	Description	Expected result	Actual result
1	Perform the operation 'Bulk sample packs' for the predefined packs. Take a screenshot showing the result.	A confirmation of receipt containing a transaction ID is returned and the operation is successfully completed.	
2	Perform the operation 'Request bulk transaction result' by using the transaction ID received in Step 1. Take a screenshot showing the result.	The status of all the packs is INACTIVE (SAMPLE) and the operation is successfully completed.	
3	Perform the operation 'Bulk undo sample packs' for packs used in Step 2. Take a screenshot showing the result.	A confirmation of receipt containing a transaction ID is returned and the operation is successfully completed.	
4	Perform the operation 'Request bulk transaction result' by using the transaction ID received in Step 3. Take a screenshot showing the result.	The status of all the packs is ACTIVE and the operation is successfully completed.	

6.3.3 PTMVS-H-08 Bulk destroy packs

Description	Test case to verify that transaction 'Bulk destroy packs' can be successfully performed via the Hospital IT system interface.			
Transactions	G135 Bulk destroy packs			
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs have been uploaded in PTMVS.			
Acceptance criteria	All steps could be successfully completed.			
Successfully completed	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Packs used	Send file to PTMVO with the packs used.			
Defect report reference				
Performed by				

Step	Description	Expected result	Actual result
1	Perform the operation 'Bulk destroy packs' for the predefined packs. Take a screenshot showing the result.	A confirmation of receipt containing a transaction ID is returned and the operation is successfully completed.	
2	Perform the operation 'Request bulk transaction result' by using the transaction ID received in Step 1. Take a screenshot showing the result.	The status of all the packs is INACTIVE (DESTROYED) and the operation is successfully completed.	

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6.4 Test cases – Mixed Bulk transactions

6.4.1 PTMVS-H-09 Submit mixed bulk transaction and request mixed bulk transaction result

Description	Test case to verify that transactions 'Submit mixed bulk transaction' and 'Request mixed bulk transaction result' can be successfully performed via the Hospital IT system interface.	
Transactions	G195 Submit mixed bulk transaction G196 Request mixed bulk transaction result	
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs have been uploaded in PTMVS.	
Acceptance criteria	All steps could be successfully completed.	
Successfully completed	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Packs used	Send file to PTMVO with the packs used.	
Defect report reference		
Performed by		

Step	Description	Expected result	Actual result
1	Disconnect the Hospital IT system from PTMVS. Perform the operation 'Dispense single pack' for a predefined pack. Take a screenshot showing the result.	The transaction is cached on the Hospital IT system.	
2	Perform the operation 'Undo dispense single pack' for the pack dispensed in Step 1. Take a screenshot showing the result.	The transaction is cached on the Hospital IT system.	
3	Perform the operation 'Destroy single pack' for the pack used in Step 2. Take a screenshot showing the result.	The transaction is cached on the Hospital IT system.	
4	Reconnect the Hospital IT system to PTMVS. Perform the operation 'Submit mixed bulk transaction'. Take a screenshot showing the result.	A confirmation of receipt containing a transaction ID is returned and the operation is successfully completed.	
5	Perform the operation 'Request mixed bulk transaction result' by using the transaction ID received in Step 4. Take a screenshot showing the result.	All transactions are correctly listed on the report.	



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6	Perform the operation 'Verify single pack' for the pack used in Steps 1-3. Take a screenshot showing the result.	The status of the pack is INACTIVE (DESTROYED) and the operation is successfully completed.	
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6.5 Test cases – Undo single pack transactions (10 days after the initial transaction)

6.5.1 PTMVS-H-10 Undo dispense single pack (10 days after the initial transaction)


Description	Test case to verify “Undo dispense single pack” after 10 days of a “dispense single pack” can´t be successfully performed via the Hospital IT system interface. This test case must be performed after 10 days of the initial transaction.
Transactions	G110 Verify single pack G120 Dispense single pack G121 Undo dispense single pack
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs have been uploaded in PTMVS.
Acceptance criteria	All steps could be successfully completed.
Successfully completed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Packs used	Send file to PTMVO with the packs used.
Defect report reference	
Performed by	

Step	Description	Expected result	Actual result
1	Perform the operation ‘Verify single pack’ for the predefined packs. Take a screenshot showing the result.	The status of the pack is ACTIVE and the operation is successfully completed.	
2	Perform the operation ‘Dispense single pack’ for the packs verified in Step 1. Take a screenshot showing the result.	The operation is successfully completed.	
3	Perform the operation ‘Verify single pack’ for the packs dispensed in Step 2. Take a screenshot showing the result.	The status of the pack is INACTIVE (DISPENSED) and the operation is successfully completed.	
4	Wait for 10 days	-	
5	Perform the operation ‘Undo dispense single pack’ for a predefined pack. Take a screenshot showing the result.	The status of the pack is INACTIVE (DISPENSED) and the Undo operation is not possible to complete.	

6.5.2 PTMVS-H-11 Undo sample single pack (10 days after the initial transaction)

Description	Test case to verify that transactions “Undo sample single pack” can’t be successfully performed via the Hospital IT system interface. This test case must be performed after 10 days of the initial transaction.	
Transactions	G150 Sample single pack G151 Undo sample single pack	
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs have been uploaded in PTMVS.	
Acceptance criteria	All steps could be successfully completed.	
Successfully completed	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Packs used	Send file to PTMVO with the packs used.	
Defect report reference		
Performed by		

Step	Description	Expected result	Actual result
1	Perform the operation ‘Sample single pack’ for a predefined pack. Take a screenshot showing the result.	The operation is successfully completed.	
2	Perform the operation ‘Verify single pack’ for the pack sampled in Step 1. Take a screenshot showing the result.	The status of the pack is INACTIVE (SAMPLE) and the operation is successfully completed.	
3	Wait for 10 days	-	
4	Perform the operation ‘Undo sample single pack’ for a pre-defined pack. Take a screenshot showing the result.	The status of the pack is INACTIVE (SAMPLE) and the Undo operation is not possible to complete.	

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6.6 Test cases – Undo bulk pack transactions (10 days after the initial transaction)

6.6.1 PTMVS-H-12 Bulk dispense packs and Undo dispense packs (10 days after the initial transaction)

Description	Test case to verify that transactions, “Bulk undo dispense packs” can´t be successfully performed via the Hospital IT system interface. This test case must be performed after 10 days of the initial transaction.
Transactions	G115 Bulk verify packs G125 Bulk dispense packs G127 Bulk undo dispense packs G188 Request bulk transaction result
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs has been uploaded in PTMVS.
Acceptance criteria	All steps could be successfully completed.
Successfully completed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Packs used	Send file to PTMVO with the packs used.
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Step	Description	Expected result	Actual result
1	Perform the operation ‘Bulk verify packs’ for the predefined packs. Take a screenshot showing the result.	A confirmation of receipt containing a transaction ID is returned and the operation is successfully completed.	
2	Perform the operation ‘Request bulk transaction result’ by using the transaction ID received in Step 1. Take a screenshot showing the result.	The status of all the packs is ACTIVE and the operation is successfully completed.	
3	Perform the operation ‘Bulk dispense packs’ for packs verified in Step 2. Take a screenshot showing the result.	A confirmation of receipt containing a transaction ID is returned and the operation is successfully completed.	
4	Perform the operation ‘Request bulk transaction result’ by using the transaction ID received in Step 3. Take a screenshot showing the result.	The status of all the packs is INACTIVE (DISPENSED) and the operation is successfully completed.	
5	Wait for 10 days	-	
6	Perform the operation ‘Bulk verify packs’ for the packs used in Step 1.	The status of all the packs is INACTIVE	



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	Take a screenshot showing the result.	(DISPENSED) and the Undo operation is not possible to complete.	
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6.6.2 PTMVS-H-13 Bulk sample packs and bulk undo sample packs (10 days after the initial transaction)

Description	Test case to verify that transactions “Bulk undo sample packs” can’t be successfully performed via the Hospital IT system interface. This test case must be performed after 10 days of the initial transaction.
Transactions	G155 Bulk sample packs G157 Bulk undo sample packs
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs has been uploaded in PTMVS.
Acceptance criteria	All steps could be successfully completed.
Successfully completed	<input type="checkbox"/> Yes <input type="checkbox"/> No
Packs used	Send file to PTMVO with the packs used.
Defect report reference	
Performed by	

Step	Description	Expected result	Actual result
1	Perform the operation ‘Bulk sample packs’ for the predefined packs. Take a screenshot showing the result.	A confirmation of receipt containing a transaction ID is returned and the operation is successfully completed.	
2	Perform the operation ‘Request bulk transaction result’ by using the transaction ID received in Step 1. Take a screenshot showing the result.	The status of all the packs is INACTIVE (SAMPLE) and the operation is successfully completed.	
3	Wait for 10 days	-	
4	Perform the operation ‘Bulk sample packs’ for the packs used in Step 1. Take a screenshot showing the result.	The status of all the packs is INACTIVE (SAMPLE) and the Undo operation is not possible to complete.	

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6.7 Test cases – Download product master data

6.7.1 PTMVS-H-14 Download product master data – 1 code

Description	Test case to verify that the Hospital can download product master data stored in PTMVS.		
Transactions	G101 Download product master data		
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs has been uploaded in PTMVS.		
Acceptance criteria	All steps could be successfully completed.		
Successfully completed	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Packs used	Send file to PTMVO with the packs used.		
Defect report reference			
Performed by			

Step	Description	Expected result	Actual result
1	Request the download of the product master data for a predefined product. Take a screenshot showing the result.	The product master data is successfully downloaded. The data received is: - Product code - National product code - MAH registration number - List of contracted wholesalers (empty if product code not found).	



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6.7.2 PTMVS-H-15 Download product master data – all codes

Description	Test case to verify that the Hospital can download product master data stored in PTMVS.			
Transactions	G101 Download product master data			
Precondition	The Hospital has been created in PTMVS. A sufficient number of products/packs has been uploaded in PTMVS.			
Acceptance criteria	All steps could be successfully completed.			
Successfully completed	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Packs used	Send file to PTMVO with the packs used.			
Defect report reference				
Performed by				

Step	Description	Expected result	Actual result
1	Request the download of all product master data available in the system. Take a screenshot showing the result.	The product master data is successfully downloaded. The data received is: - Product code - National product code - MAH registration number - List of contracted wholesalers	

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7. Related documents

Document Identification	Title
MVOPT-0035	Defect Report Template
MVOPT-0037	Access Request Form
MVOPT-0039	Access Request Form (PT)
MVOPT-0057	Onboarding of Hospitals
MVOPT-0048	Services Agreement
MVOPT-0049	Services Agreement (PT)
MVOPT-0066	IQE Test Report - Hospital