	SOP – Pilot phase approach – Marketing Authorization Holders (MAH)	
	Document Number: MVOPT-0053	Version: 3.0
	Effective Date: 07-August-2018	Page 1 of 1

Author Signature

<i>Name</i>	<i>Role</i>	<i>Date</i>	<i>Signature</i>
Nuno Lages	Author	07-August-2018	

Approver Signatures

<i>Name</i>	<i>Role</i>	<i>Date</i>	<i>Signature</i>
Ricardo Valente	Approver	07-August-2018	

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
2.0	10-July-2018	Information added	Added the contact details available for support and the information on availability of the Production Environment
3.0	07-August-2018	Information added	Detail on different options for testing (section 4.3)

THE SOLE FUNCTION OF THE ABOVE TEXT IS TO APPROVE THE VERSION OF THIS USER ACCEPTANCE TEST PLAN PTMVS TEMPLATE (MAH 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.



	SOP – Pilot phase approach – Marketing Authorization Holders (MAH)	
	Document Number: MVOPT-0053	Version: 3.0
	Effective Date: 07-August-2018	Page 1 of 19

Table of Contents

1.	Purpose.....	2
2.	Scope.....	2
3.	Pilot phase general goals.....	2
4.	Approach and governance	3
4.1	Pilot phase duration	3
4.2	Preconditions to participate.....	3
4.3	Testing environment and data for testing	3
4.4	Testing process.....	4
4.4.1	Test planning	4
4.4.2	Test execution.....	5
4.4.3	Test abortion criteria	5
4.4.4	Test results, discussion and follow-up	5
4.5	Exit criteria for the Pilot phase	5
5.	Definitions.....	6
6.	Test cases	7
6.1	Attributes to be tested.....	7
6.2	Test cases – Product Master Data	8
6.2.1	PTMVS-M-01 Master Data Upload	8
6.2.2	PTMVS-M-02 Upload incomplete Product Master Data	9
6.3	Test cases – Batch and Pack Data	10
6.3.1	PTMVS-M-03 Product Pack Data Upload	10
6.3.2	PTMVS-M-04 Upload incomplete Pack Data	11
6.3.3	PTMVS-M-05 Creation of Duplicate Pack Data.....	12
6.3.4	PTMVS-M-06 Upload serial number with small and capital letters.....	13
6.3.5	PTMVS-M-07 Upload batch data with small and capital letters	14
6.3.6	PTMVS-M-08 Change Product Pack Data	15
6.3.7	PTMVS-M-09 Upload large batch (>250.000 packs) in 3 parts	16
6.3.8	PTMVS-M-10 Upload large batch (>250.000 packs) in 1 part.....	17
6.3.9	PTMVS-M-11 Batch Recall	18
7.	Related documents	19

	SOP – Pilot phase approach – Marketing Authorization Holders (MAH)	
	Document Number: MVOPT-0053	Version: 3.0
	Effective Date: 07-August-2018	Page 2 of 19

1. Purpose

The purpose of this document is to describe the objectives, approach, requirements, procedures and expected results for the Pilot phase, for Marketing Authorization Holders (MAH).

In the Pilot phase, the integration between PTMVS and IT systems of selected Authorization Holders and selected End Users will be the main focus of the tests to be performed.

PTMVO is categorized as a GxP system and is connected to the EU Hub, a subsystem of the European Medicines Verification System (EMVS). MAH will not access PTMVS, but the EU Hub. The data uploaded to EU Hub will be automatically transferred to PTMVS.

2. Scope

The scope of this document consists of the description of the objectives, approach, requirements, entry criteria, test scenarios, exit criteria, test abortion criteria and documentation criteria applicable to Marketing Authorization Holders (MAH). If the MAH is an OBP itself, it will use its own OBP system, otherwise it will use the system of its associated OBP.

The internal organization and processes of the MAH (or OBP) will not be assessed by PTMVO in any way. Each MAH (or OBP) is responsible for defining and implementing its own internal organization, processes and procedures in order to comply with the Delegated Regulation and other applicable legislation.


The test scenarios described in this document are considered sufficient to verify the correct functioning of the data exchange between PTMVS and the OBP system. Despite available for MAH, the transactions related to pack verification and decommissioning will not be part of the testing, as those will very unlikely be performed by the MAH or OBP directly, but via a pre-wholesaler instead. The MAH (or OBP) can perform any other tests it may consider relevant. Those additional tests will not be followed-up by PTMVO.

No software audit or certification whatsoever will be granted by PTMVO to any piece of software of any MAH nor OBP.

Certain system functionalities may not be available for testing during the Pilot period. Those functionalities will be tested by PTMVO when available, and PTMVO may invite MAH (or OBP) for testing. Performance testing will not be part of the Pilot period scope, once those tests will be assured by Arvato directly.

3. Pilot phase general goals

The overall objective of the Pilot phase is to simulate, as similar to real world conditions as possible, the utilization of the national verification system. For MAH (or OBP) specifically, the main goal is to verify the system interface and the success of the data exchange performed between MAH (or OBP) and EMVS, and the consequence in the interface between EMVS and PTMVS, according to predefined test scenarios.

	SOP – Pilot phase approach – Marketing Authorization Holders (MAH)	
	Document Number: MVOPT-0053	Version: 3.0
	Effective Date: 07-August-2018	Page 3 of 19

4. Approach and governance

The conditions for testing the integration between MAH or OBP IT system and PTMVS (through the EU Hub) are to be set as similar to real world utilization as possible. Those conditions are described in the following sections.

4.1 Pilot phase duration

- The Pilot phase will occur between July 2nd 2018 and October 31st 2018.
- Despite the fixed time interval for the Pilot Phase, each MAH can decide on the date to start executing the tests. It is not necessary to start on July 2nd. A joint planning must be in place between the MAH (or OBP) and PTMVO concerning testing dates so PTMVO can assure proper support (see section 4.5.1 of this document).

4.2 Preconditions to participate

The participation in the Pilot phase is voluntary. MAH willing to participate in the Pilot phase must inform PTMVO by sending an email to mvo.portugal@mvoportugal.pt. This manifestation of interest can be done at any moment.

The MAH and OBP willing to participate in the Pilot phase must complete the onboarding processes with both EMVO and PTMVO.

In regards to the onboarding with EMVO, having completed the onboarding process is necessary as otherwise the OBP would not be able to upload data to the system (IQE environment will be used for testing - see section 4.3 of this document). The onboarding process with EMVO is managed by EMVO directly. More information can be found in the following link: <https://emvo-medicines.eu/pharmaceutical-companies/>.

In regards to the onboarding with PTMVO, the process is described in the document MVOPT-0044_Onboarding of Authorization Holders. By having completed the onboarding process with PTMVO is understood that the MAH has completed the following actions:

- Having provided two signed hardcopies of the Cooperation Agreement to PTMVO postal address (Avenida Dom Vasco da Gama 34, 1400-128 Lisboa). The MAH may use the English Version (MVOPT-0045_Cooperation agreement draft) or the Portuguese Version (MVOPT-0046_Cooperation agreement draft (PT)). A scanned version of the signed Services Agreement can be sent to mvo.portugal@mvoportugal.pt to accelerate the onboarding process;
- Having paid the participation costs, in accordance to the fee model as described in the document MVOPT-0044_Onboarding of Authorization Holders.

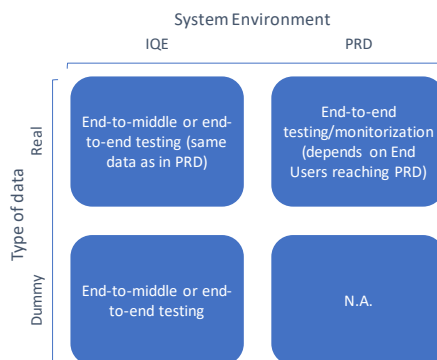
The number of MAH participating in the Pilot phase will be limited and PTMVO reserves its right to make decisions on the participants, considering the number of MAH interested to participate, the project needs and PTMVO capacity.

4.3 Testing environment and data for testing

- The tests can be performed on either PTMVS's Integrated Quality Environment (IQE) or on the Production Environment (PRD), or both. Both are already available and connected to the EU Hub.
- The software version to be used during the pilot phase is identical to the software version to be deployed on the Production Environment (PRD). Eventual enhancements, resulting from the testing phase, may be included in the software version to be used once the system is in production.
- Each MAH (or OBP) will use its own data, either dummy data or real data. Alternatively, PTMVO can supply the MAH participating in the Pilot phase with product data to be used (GTIN, Serial Number, Batch Number, Expiry date and National Reimbursement Code). In case of data to be supplied by PTMVO, it will fulfill the requirements defined for Portuguese market, as per the

published legislation and GS1 guidelines. In the planning phase (see section 4.4.1 of this document) the decision on the data to be used will be taken.

In brief, the following options are available for MAH (or OBP) in regard to testing their solutions against PTMVS:



By end-to-middle testing is understood as the tests performed between the MAH (or OBP) and the PTMVS. In the IQE, and if necessary, PTMVO can act as End User. The end-to-end testing is understood as the tests performed between the MAH (or OBP) and the End User (Wholesaler, Pharmacy or Hospital). In the specific case of the PRD environment, for end-to-end testing or monitorization, there is the dependency on End Users to complete the onboarding process and reach the Production Environment.

4.4 Testing process

The testing process has been structured as described in the following sections.

4.4.1 Test planning

The MAH (or OBP) and PTMVO will establish a specific timeframe (i.e. a specific week or weeks) for the MAH (or OBP) perform the tests. It is aimed with this approach to assure availability by PTMVO to the MAH (or OBP) during the testing period. However, the MAH (or OBP) is free to perform the tests at any other time. In addition, it will be decided what data to use in the testing. The MAH (or OBP) will inform PTMVO about the following:

- Which environment will be used for testing – PTMVS’s Integrated Quality Environment (IQE), or the Production Environment (PRD), or both;
- Which type of data will be used (dummy or real, or both);
- What data will be used (at least the GTINs to be used). In case of the data to be used in IQE for end-to-end testing, the data is to be sent in Excel (xlsx or csv) format to mvo.portugal@mvoportugal.pt. No real data shall circulate outside the system;
- Whether physical packs will be used.

4.4.2 Test execution

The MAH (or OBP) performs the tests as per the distributed test scenarios and documents the results for ulterior discussion, using the template MVOPT-0051_Pilot Report - MAH. The test scenarios are described on section 8 of this document.

PTMVO and the PTMVS IT supplier (Arvato) will be available to support during the testing period. Technical support is available via email and telephone. The available contacts are the following:

- Technical support – Arvato:
 - Email address: support@sws-nmvs.eu
 - Telephone: + 49 5241 80 79900
- Support to test execution – MVO Portugal:
 - Email address: mvo.portugal@mvoportugal.pt
 - Telephone: +351 21 121 4967

4.4.3 Test abortion criteria

The testing may be stopped if:

- Disturbances/interference in the connection between OBP IT system and EU Hub and/or EU Hub and PTMVS emerge after the testing has been commenced preventing the exchange of information.
- Disturbances/malfunctions in the IT infrastructure of OBP, EU Hub or PTMVS IT systems emerge after the testing has been commenced preventing the normal operation of either system.
- The resources allocated for testing become unavailable after the testing has been commenced preventing the continuation of testing.

4.4.4 Test results, discussion and follow-up

At the end of the testing period, the MAH (or OBP) and PTMVO will discuss the test results. These discussions may happen with more than one MAH (or OBP) at the same time. The scheduling of the discussions will occur upon agreement between the MAH (or OBP) and PTMVO.


4.5 Exit criteria for the Pilot phase

The Pilot phase may end in different moments for different MAH (or OBP). The Pilot phase will end for a given MAH (or OBP) when:

- The test scenarios described in section 8 of this document have been successfully performed, or
- If not all test scenarios have been successful, the problems encountered are documented for analysis and resolution, or
- The Pilot phase has reached the final date (see section 4.1 of this document).

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 wholesaler systems and to the pharmacy 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.).
OBP	On Boarding Partner.
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 (Pharmacies, Wholesalers, 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.

	SOP – Pilot phase approach – Marketing Authorization Holders (MAH)	
	Document Number: MVOPT-0053	Version: 3.0
	Effective Date: 07-August-2018	Page 7 of 19

6. Test cases

The MAH is primarily responsible for the initial interaction with the system, with the transmission of product data (master data and pack data) from the original product manufacturers to the European Hub. The data upload is performed by the respective OBP. No facility or mechanism is provided to load master data from the National System (Blueprint or otherwise) to the European Hub.

6.1 Attributes to be tested

The following attributes will be tested:


Process ID	Description
G511	Upload master data
G520	Upload batch and pack data or modify batch data from EU Hub
G530	Batch recall via EU Hub

6.2 Test cases – Product Master Data

6.2.1 PTMVS-M-01 Master Data Upload

Description	Test case to verify if can be successfully performed via the MAH system interface the MAH Master Data Upload in the European Hub and the transmission of Product Master Data from the European Hub Product Catalogue to the PTMVS.		
Transactions	G511 Upload master data		
Precondition	The MAH has been created in PTMVS and PTMVS has prior knowledge of the entitlement for the MAH to do this transaction. Definition of the Product Master Data must be prepared by the MAH. Articulation with PTMVO to execute the upload.		
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.		
Performed by			

Step	Description	Expected result	Actual result
1	Load the master data for a predefined product. Take a screenshot showing the result.	Receive a "Data Receipt Confirmation" from EU Hub.	
		Receive a "Data Check Confirmation" from EU Hub. (If the Check "failed", related error information is sent with the information that the data received has been rejected).	
		If "Data Check Confirmation" is OK, MAH will receive a "Data Load Confirmation" (to the Product Catalogue)	
2	EU Hub performs the operation "Select Product Master Data for Transmission" to PTMVS.	Receive via EU Hub a "Data Transmission Confirmation".	
3	PTMVO will compare "Product Master Data" upload with the data received.	Product Master Data upload by MAH (or OBP) is in accordance with the original data reported.	
4	Take a screenshot showing the message received from PTMVS.		

	SOP – Pilot phase approach – Marketing Authorization Holders (MAH)	
	Document Number: MVOPT-0053	Version: 3.0
	Effective Date: 07-August-2018	Page 9 of 19

6.2.2 PTMVS-M-02 Upload incomplete Product Master Data

Description	Test case to verify if in case of "Incomplete Product Master Data" the European Hub signalized "INVALID" Data and the PTMVS do not receive any information regarding this data.	
Transactions	G511 Upload master data	
Precondition	The MAH has been created in PTMVS and PTMVS has prior knowledge of the entitlement for the MAH to do this transaction. Definition of the Product Master Data must be prepared by the MAH. Articulation with PTMVO to execute the upload.	
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.	
Performed by		

Step	Description	Expected result	Actual result
1	Load the Master Data for a predefined product with incomplete data. Take a screenshot showing the result.	Receive a "Data Receipt Confirmation" from EU Hub.	
		Receive a check "failed", related error information with the information that the data received has been rejected.	
2	PTMVO checks that no data was created.	No data created.	

6.3 Test cases – Batch and Pack Data

6.3.1 PTMVS-M-03 Product Pack Data Upload

Description	Test case to verify if can be successfully performed via the MAH system interface the MAH "Product Pack Data Upload" in the European Hub and the transmission of Product Pack Data from the European Hub to the PTMVS.
Transactions	G520 Upload batch and pack data or modify batch data from EU Hub.
Precondition	Applicable product Master Data available in the EU Hub. Product Packs Data available for transmission does not contain any duplicates in itself. File uniqueness: The (same) file containing the Product Packs Data has not already previously transmitted. Articulation with PTMVO to execute the upload.
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.
Performed by	

Step	Description	Expected result	Actual result
1	Load Product Pack Data for a predefined product. Take a screenshot showing the result.	Receive a "Data Receipt Confirmation - Valid" from EU Hub.	
		Receive a "Data Check Confirmation - Loaded" from EU Hub. (If the Check "failed", related error information is sent with the information that the data received has been rejected).	
2	EU Hub perform the operation "Select Product Pack Data for Transmission" to PTMVS. Take a screenshot showing the result.	Receive via EU Hub a "Data Distribution Confirmation – Transmitted".	
3	PTMVO will compare data created in PTMVS with MAH transmitted data.	Pack data uploaded by the MAH to the EU Hub is in accordance with the original.	
4	PTMVO will check the status of the product uploaded.	Product status "ACTIVE".	



SOP – Pilot phase approach – Marketing Authorization Holders (MAH)

Document Number: MVOPT-0053

Version: 3.0

Effective Date: 07-August-2018

Page 11 of 19

6.3.2 PTMVS-M-04 Upload incomplete Pack Data

Description	Test case to verify if in case of "Incomplete Product Master Data" the European Hub signaled "INVALID" Data and the PTMVS do not receive any information regarding this data.	
Transactions	G520 Upload batch and pack data or modify batch data from EU Hub.	
Precondition	The MAH has been created in PTMVS and PTMVS has prior knowledge of the entitlement for the MAH to do this transaction. Definition of the Product Master Data must be prepared by the MAH. Articulation with PTMVO to execute the upload.	
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.	
Performed by		

Step	Description	Expected result	Actual result
1	Load Pack Data for a predefined product with incomplete data. Take a screenshot showing the result.	Receive a "Data Receipt Confirmation" from EU Hub.	
		Receive a check "Error" and the related error information. (e.g. "invalid format" – related with batch expired date format)	
2	PTMVO check that no data was created.	No data created.	



SOP – Pilot phase approach – Marketing Authorization Holders (MAH)

Document Number: MVOPT-0053

Version: 3.0


Effective Date: 07-August-2018

Page 12 of 19

6.3.3 PTMVS-M-05 Creation of Duplicate Pack Data

Description	Test case to verify if MAH can duplicate Pack Data in the European Hub with reflex in the PTMVS.		
Transactions	G520 Upload batch and pack data or modify batch data from EU Hub.		
Precondition	Applicable product Master Data available in the EU Hub. Articulation with PTMVO to execute the upload.		
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.		
Performed by			


Step	Description	Expected result	Actual result
1	Load Pack Data for a predefined product with batch ID, product code, and serial numbers that already exist in the system. Take a screenshot showing the result.	Receive a "Data Receipt Confirmation" from EU Hub.	
		Receive a "Data Check Confirmation" from EU Hub with a return code "Duplicate Serial Number".	
3	PTMVO will check that any data will be not created.	No data created.	

	SOP – Pilot phase approach – Marketing Authorization Holders (MAH)	
	Document Number: MVOPT-0053	Version: 3.0
	Effective Date: 07-August-2018	Page 13 of 19

6.3.4 PTMVS-M-06 Upload serial number with small and capital letters

Description	Test case to verify if in case of using small and capital letters in the Product Pack Data file, the European Hub signals Pack Created Partially and the PTMVS receive information regarding this status.
Transactions	G520 Upload batch and pack data or modify batch data from EU Hub.
Precondition	The MAH has been created in PTMVS and PTMVS has prior knowledge of the entitlement for the MAH to do this transaction. Definition of the Product Master Data must be prepared by the MAH. Articulation with PTMVO to execute the upload.
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.
Performed by	

Step	Description	Expected result	Actual result
1	Load Pack Data for a predefined product with small and capital letters. 3 Product Pack Data: - serial number only with lower case characters. - serial number only with upper case characters. - serial number with mixes upper and lower-case characters. Take a screenshot showing the result.	Receive a "Data Receipt Confirmation" from EU Hub. Receive a "Data Check Confirmation" with a message with an "Partial Pack Data creation". Error "invalid serial number" for packs with small letters in the serial number.	
2	PTMVO will checks that specific pack data uploaded by MAH has been created in the PTMVS.	All the 3 packs uploaded are created in the PTMVS with Small and Capital Letters.	

	SOP – Pilot phase approach – Marketing Authorization Holders (MAH)	
	Document Number: MVOPT-0053	Version: 3.0
	Effective Date: 07-August-2018	Page 14 of 19

6.3.5 PTMVS-M-07 Upload batch data with small and capital letters

Description	Test case to verify if in case of using small and capital letters in the Product Pack Data file, the European Hub signals Pack Created Partially and the PTMVS receive information regarding this status.
Transactions	G520 Upload batch and pack data or modify batch data from EU Hub.
Precondition	The MAH has been created in PTMVS and PTMVS has prior knowledge of the entitlement for the MAH to do this transaction. Definition of the Product Master Data must be prepared by the MAH. Articulation with PTMVO to execute the upload.
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.
Performed by	

Step	Description	Expected result	Actual result
1	Load Product Data for a predefined product with batch number with small and capital letters. Take a screenshot showing the result.	Receive a "Data Receipt Confirmation" from EU Hub.	
		Receive a "Data Check Confirmation" with a message with an "Incomplete file transmitted".	
2	PTMVO will checks that specific pack data uploaded by MAH has been created in the PTMVS but not the batch field.	Checks that specific batch data has not been created in PTMVS.	

6.3.6 PTMVS-M-08 Change Product Pack Data

Description	Test case to verify if can be successfully performed via the MAH system interfaces the changes in the initial Product Pack Data and if the change is reflected from the European Hub to the PTMVS.
Transactions	G520 Upload batch and pack data or modify batch data from EU Hub.
Precondition	Applicable product Master Data available in the EU Hub. Product Packs Data available for transmission does not contain any duplicates in itself. Articulation with PTMVO to execute the upload.
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.
Performed by	

Step	Description	Expected result	Actual result
1	Perform the operation "Modify Product Pack Data" for a predefined product. Test for each possibility: - Change Product Code - Change Serial Number - Change Batch ID - Change Expiry Date - Change Manufacturer ID - Change Manufacturer Name - Change Manufacturer Address Take a screenshot showing the result.	Receive a "Data Receipt Confirmation" from EU Hub. Change Product Code Change Serial Number Change Batch ID Change Expiry Date Change Manufacturer ID Change Manufacturer Name Change Manufacturer Address	
2	PTMVO will compare the new PTMVS Data with Modify Product Pack Data uploaded by the MAH.	No changes to Product Code nor to Serial Number New Product Pack Data created to Batch ID, Expiry Date, Manufacturer ID, Manufacturer Name, Manufacturer Address	

6.3.7 PTMVS-M-09 Upload large batch (>250.000 packs) in 3 parts

Description	Large batches have to be uploaded to the EU-Hub in several parts. Currently, there is a maximum of 250,000 packs per upload. Test case to verify if in case of using "Upload large batch" (>250.000 packs in 3 parts, each part with less than 250.000 packs) in the Product Pack Data file, the European Hub signals "Batch with more than 250.000 Packs" is created.	
Transactions	G520 Upload batch and pack data or modify batch data from EU Hub.	
Precondition	The MAH has been created in PTMVS and PTMVS has prior knowledge of the entitlement for the MAH to do this transaction. Definition of the Product Master Data must be prepared by the MAH. Articulation with PTMVO to execute the upload.	
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.	
Performed by		

Step	Description	Expected result	Actual result
1	Load batch for a predefined product in 3 parts to ensure that the 3 sections of the full upload are interpreted correctly & the packs all belong to the same batch. Take a screenshot showing the result.	Receive a "Data Receipt Confirmation" from EU Hub.	
		Receive a "Data Check Confirmation" with a message with a "Batch created". (Batch with more than 250.000 packs is created).	
2	PTMVO will checks that specific batch data uploaded by MAH has been created in the PTMVS. (Sends batch & pack data sent to the EU Hub at previous step in a file to PTMVO).	Checks that specific batch data has been created in PTMVS and is "Active".	



SOP – Pilot phase approach – Marketing Authorization Holders (MAH)

Document Number: MVOPT-0053

Version: 3.0

Effective Date: 07-August-2018

Page 17 of 19

6.3.8 PTMVS-M-10 Upload large batch (>250.000 packs) in 1 part

Description	Large batches have to be uploaded to the EU-Hub in several parts. Currently, there is a maximum of 250,000 packs per upload. Test case to verify if in case of using "Upload large batch" (>250.000 packs in 1 part) in the Product Pack Data file, the European Hub signals "Batch with more than 250.000 Packs" is created.			
Transactions	G520 Upload batch and pack data or modify batch data from EU Hub.			
Precondition	The MAH has been created in PTMVS and PTMVS has prior knowledge of the entitlement for the MAH to do this transaction. Definition of the Product Master Data must be prepared by the MAH. Articulation with PTMVO to execute the upload.			
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.			
Performed by				

Step	Description	Expected result	Actual result
1	Perform the operation 'Upload Large Batch' for a batch with more than 250.000 packs, for a predefined product in 1 part. Take a screenshot showing the result.	Receive a "Data Receipt Confirmation" from EU Hub.	
		Receive a "Data Check Confirmation" with a message "Batch too large".	
2	PTMVO will check that specific batch data uploaded by MAH has not been created in the PTMVS. (Sends batch & pack data sent to the EU Hub at previous step in a file to PTMVO).	No data created.	



SOP – Pilot phase approach – Marketing Authorization Holders (MAH)

Document Number: MVOPT-0053

Version: 3.0


Effective Date: 07-August-2018

Page 18 of 19

6.3.9 PTMVS-M-11 Batch Recall

Description	Test case to verify that transactions 'Batch Recall' can be successfully performed via the MAH IT system interface and verify if the change is reflected from the European Hub to the PTMVS. It is not advisable to perform this test scenario in the PRD environment.	
Transactions	G530 Batch recall via EU Hub.	
Precondition	The MAH has been created in PTMVS and PTMVS has prior knowledge of the entitlement for the MAH to do this transaction. Applicable Product Master Data and Pack Master Data available in the EU Hub. Batch Recall information available in MAH system.	
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.	
Performed by		

Step	Description	Expected result	Actual result
1	Perform the operation "Batch Recall" for a predefined product. Take a screenshot showing the result.	Receive a "Confirmation Message" from EU Hub.	
		Receive a "Markets List" (valid and invalid) from EU Hub and confirm PT Market in the list.	
2	EU Hub performs the operation "Batch Recall Information" to PTMVS. Take a screenshot showing the result.	Receive via EU Hub a "Batch Recall Confirmation for PT Market".	
3	PTMVO will checks that specific batch data uploaded by MAH has been created in the PTMVS.	Status have been change to "Batch Recall"	

	SOP – Pilot phase approach – Marketing Authorization Holders (MAH)	
	Document Number: MVOPT-0053	Version: 3.0
	Effective Date: 07-August-2018	Page 19 of 19

7. Related documents

Document Identification	Title
MVOPT-0044	Onboarding of Authorization Holders
MVOPT-0048	Services Agreement
MVOPT-0049	Services Agreement (PT)
MVOPT-0051	Pilot Report - MAH