MASTER DATA MAINTENANCE: VERSIONING AND RETROSPECTIVE UPLOAD

VERSION 1.0
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INTRODUCTION

WHY DO MASTER DATA VERSIONING EXISTS

The retrospective upload of serialized products is only relevant for multi-market products where not all associated NMVS are live yet;

This functionality makes use of the Product Master Data versioning and it is used to re-upload Product Master Data and Pack Data to new markets that were not included in previous versions of Product Master Data;

This way OBPs will have the means to upload their serialized data to all NMVS where their products are sold;

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WHEN SHOULD I DO THE RETROSPECTIVE UPLOAD

o **New markets where my product is to be sold**

This scenario can contemplate different cases:

- New markets that will onboard in the EMVS;
- A new market already part of the EMVS where my product can now be sold in;

o **Update Product Master Data elements**

This scenario contemplates the situations where master data elements were incorrectly uploaded into the EMVS and need to be corrected;

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WHY SHOULD I DO THE RETROSPECTIVE UPLOAD

o **FMD-COMPLIANCE**

As per the Delegated Regulation (DR), the MAHs (OBPs) are responsible for introducing all information about the serialized products into the data repositories (EMVS). For products bearing a unique identifier, the Member State(s) where the medicinal product is intended to be placed must be identified.

o **EMVS TRAFFIC**

The incorrect retrospective upload leads ultimately to data missing from some or all (national) systems composing the EMVS, which is in not in line with the DR. Extra resources are required to verify whether the data is present in other systems. This functionality is called "Intermarket Transaction". This function shall be used, for instance, for compassionate use purposes only, or in cases markets are dependent on products which are originally to be distributed in other markets.

o **EMVS ALERTS**

The incomplete retrospective upload can lead also to false positive alerts.

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GLOSSARY

The use of versioning requires the understanding of fundamental concepts of the following Master Data attributes:

Attribute	Described
Product Code	The Product Code is the logistics code on the pack contained within the Data Matrix code. The function of the EU-Hub to upload a Product Code into the EMVS is called "Product Master Data".
Product Code Version	Product Codes can have different versions. The Product Code Version is an optional field that shall be used by OBPs to associate the Product Master Data with specific versions. When not specified, the EU-Hub might increase the version number automatically according with the versioning rules.
Batch	A Batch represents a set of packs to be serialized. A Batch is linked to a single combination of Product Code and Product Code Version. When a new batch is uploaded, the EU-Hub will associate it with the latest version of the Product Code. If new packs are added to a Batch, they will remains associated with the original Product Code Version.
Market List	List of markets where products can be sold. The markets are associated with the combination of Product Code and Product Code Version.

*EMVO recommends the reading of the document EMVO_0122 EMVS Master Data Guide for more information

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HOW TO DO THE RETROSPECTIVE UPLOAD

The retrospective upload needs to be done in two phases:

o **Phase 1: Re-upload of Product Master Data**

The Product Master Data describes the attributes of the products to be serialized. It also indicates the markets where the product is to be sold and the market specific elements*. The complete record of Master Data is composed by all versions uploaded into the EMVS.

Phase 2: Re-upload of Product Pack Data

The Product Pack Data is the function that allows OBPs to place the actual batches and packs into the markets. When transmitted for the first time, the European Hub will associate the batch with the last version of Product Master Data uploaded into the data repository.

*EMVO recommends the reading of the document EMVO_0122 EMVS Master Data Guide for more information

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HOW TO DO THE RETROSPECTIVE UPLOAD

○ **1. OBP Uploads Product Master Data**

   • **Result:** Product A, Version 1, Markets: PT;

○ **2. OBP Uploads Product Pack Data**

   • **Result:** Batch A distributed and associated with Version 1;

HOW TO DO THE RETROSPECTIVE UPLOAD

○ **3. OBP initiates a retrospective upload of Product Master Data**

OBP needs to send the same product, including the version to be updated (in this case Version 1) and the list of countries where this version is to be uploaded:

- Product A, Version 1, Markets: PT, FR; **(NOTE: BOTH COUNTRIES NEED TO BE SPECIFIED)**

- **Result**: Product has been successfully uploaded to PT and FR but the batch A is only distributed in PT

| Phase 1 | PT Product A [Batch A Version 1] | FR Product A | Product Pack Data to be issued |

○ **4. Re-upload of Product Pack retrospectively**

OBP needs to send the same product and batch, which is linked to the version to be updated (in this case Version 1). The EU-Hub will automatically send the batch to all countries associated with this version.

- **Result**: Batch A is re-uploaded retrospectively

| Phase 2 | PT Product A [Batch A Version 1] | FR Product A [Batch A Version 1] | Correct Retrospective Upload |

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HOW DO I CHECK WHICH VERSIONS OF PRODUCT MASTER DATA EXIST?

o **Product Master Data Report**

- The Product Master Data Report can be issued for that purpose;

- This report lists the complete record of Product Master Data including all versions uploaded into the EMVS and the date when the uploads occurred;

- This report allows OBPs to identify which versions exist in the EMVS and validate whether the information is consistent within the different versions.

SCENARIOS - EXAMPLES

#	Description	Risks	EMVO Recommendation
1	**Incorrect Retrospective Upload**	• Unnecessary effort is put into the EMVS systems • It might affect the EMVS performance and lead to timeout messages	EMVO recommends OBPs to do the retrospective upload of Product Master Data to all countries where the product has been distributed, followed by the retrospective upload of the batches affected.
2	**Incomplete Retrospective Upload**	• False positive alerts raised • Potential patient safety at stake: serialised pack cannot be dispensed to a patient	EMVO recommends OBPs to do the retrospective upload of Product Master Data to all countries where the product has been distributed, followed by the retrospective upload of the batches affected.
3	**Retrospective Upload not performed**	• Unnecessary effort is put into the EMVS systems • It might affect the EMVS performance and lead to timeout messages	EMVO recommends OBPs to do the retrospective upload of Product Master Data to all countries where the product has been distributed, followed by the retrospective upload of the batches affected.
4	**Remove a country**	• In case either the Batch or the Product are not active (i.e. Batch is recalled, and Product is withdrawn), the pack will not be dispensed and patient safe is at stake;	EMVO recommends OBPs to do the retrospective upload of Product Master Data to all countries where the product has been distributed, followed by the retrospective upload of the batches affected.

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S1. INCORRECT RETROSPECTIVE UPLOAD (1/4)

o **INITIAL SITUATION.**

- Product A, Version 1, Markets: PT;

o **Description**

- OBP wants to add a new country, FR, so that the batch A can be dispensed in all countries where the product can be sold in.

- **Error:** OBP does not mention the version of the retrospective upload or creates a Version 2;

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S1. INCORRECT RETROSPECTIVE UPLOAD (2/4)

○ **INITIAL SITUATION.**

- Product A, Version 1, Markets: PT;

PT — Product A Version 1 — Batch A Version 1

○ **1. OBP initiates a retrospective upload of Product Master Data**

- Product A, Version 1, Markets: PT;
- Product A, Version 2, Markets: FR;

PT — Product A Version 1 — Batch A Version 1

FR — Product A Version 2

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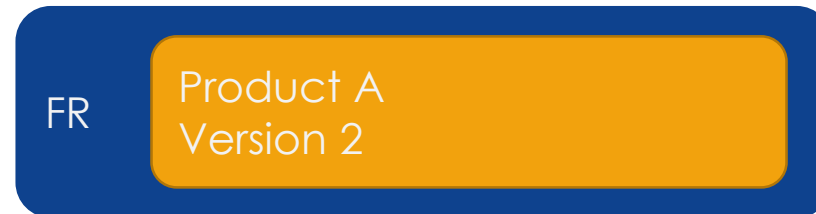
S1. INCORRECT RETROSPECTIVE UPLOAD (3/4)

o **2. Re-upload of Product Pack retrospectively**

  - Batch A, associated with version 1 is sent only to PT

PT — Product A Version 1 — Batch A Version 1

FR — Product A Version 2

Batch A Version 1 → ✖

Distribution Failed
Markets: PT
Message: Duplicated Serial Numbers
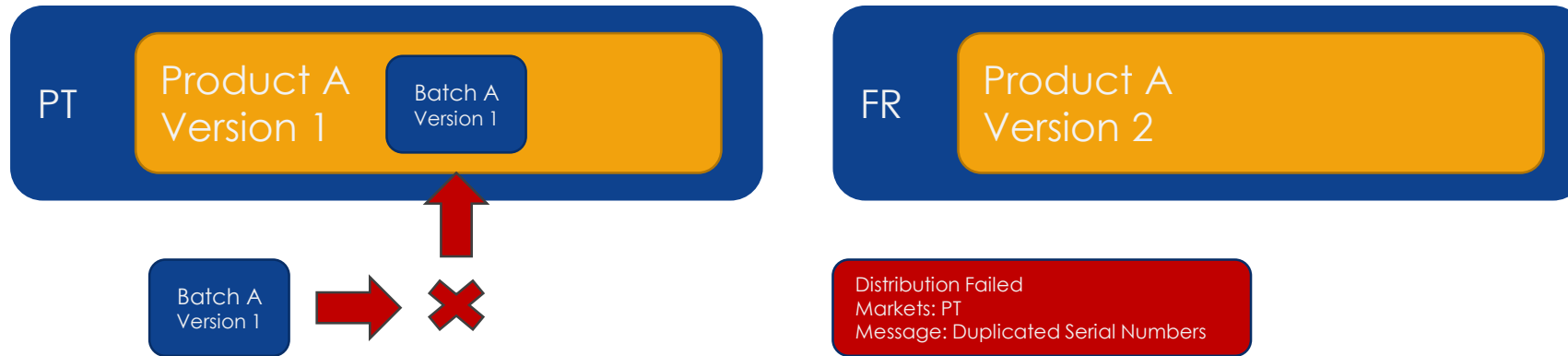
o **3. Upload of New Product Pack Batch**

  - Batch B, associated with version 2 is sent only to FR

PT — Product A Version 1 — Batch A Version 1

FR — Product A Version 2 — Batch B Version 2

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S1. INCORRECT RETROSPECTIVE UPLOAD (4/4)

o **FINAL SITUATION**

| PT | Product A Version 1 | Batch A Version 1 |

| FR | Product A Version 2 | Batch A Version 2 |

o **Risk**

- Given that the Batch A is found in FR, the packs can only be decommissioned via an IMT;
- IMT uses at least 4 message flows between the EMVS systems;
- This extra effort impacts the health of the EMVS system;

o **EMVO Recommendation**

- EMVO recommends OBPs to do the retrospective upload of Product Master Data to all countries where the product has been distributed, followed by the retrospective upload of the batches affected.

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S2. INCOMPLETE RETROSPECTIVE UPLOAD (1/4)

○ **INITIAL SITUATION.**

- Product A, Version 1, Markets: BE;

BE — Product A Version 1 — Batch A Version 1

○ **Description**

- OBP wants to add a new country, DE, so that the batch A can be dispensed in all countries where the product can be sold in.
- **Error:** OBP retrospectively upload the Product Master Data successfully but not the product pack data.

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S2. INCOMPLETE RETROSPECTIVE UPLOAD (2/4)

○ **INITIAL SITUATION.**

- Product A, Version 1, Markets: BE;

BE

Product A
Version 1

Batch A
Version 1

○ **1. OBP initiates a retrospective upload of Product Master Data**

- Product A, Version 1, Markets: BE, DE;

BE

Product A
Version 1

Batch A
Version 1

DE

Product A
Version 1

Retrospective upload of
Product Pack Data not performed

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S2. INCOMPLETE RETROSPECTIVE UPLOAD (3/4)

- **2.1 OBP change the Pack Status**
  - The EU-Hub transmits the data to the two markets associated with Version 1;

BE | Product A Version 1 | Batch A Version 1

OBP → EU-HUB Product A, Version 1, Batch A, Markets: BE; DE

DE | Product A Version 1

ALERT RAISED
Markets: DE
Message: Pack Not Found

- **2.2 End-user in FR initiates an Intermarket Transaction**
  - The EU-Hub will randomly choose one of the two markets. DE is chosen for the example purpose;

BE | Product A Version 1

FR → EU-HUB Product A, Version 1, Batch A, Markets: BE; DE

DE | Product A Version 1

EU HUB will randomly choose one of the countries.

PACK CANNOT BE DISPENSED + ALERT RAISED
Markets: DE
Message: Pack Not Found

Pack cannot be dispensed to a patient

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S2. INCOMPLETE RETROSPECTIVE UPLOAD (4/4)

o **FINAL SITUATION**

BE	Product A Version 1	Batch A Version 1

DE	Product A Version 1	**PACK CANNOT BE DISPENSED + ALERT RAISED** Markets: DE Message: Pack Not Found

OBP → EU-HUB Product A, Version 1, Batch A, Markets: BE; DE

Patient Safety at Stake: serialised pack cannot be dispensed to a patient

o **Risk**
- • False positive alerts raised
- • Potential patient safety at stake: serialized pack cannot be dispensed

o **EMVO Recommendation**
- • EMVO recommends OBPs to do the retrospective upload of Product Master Data to all countries where the product has been distributed, followed by the retrospective upload of the batches affected.

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S3. RETROSPECTIVE UPLOAD NOT PERFORMED (1/4)

o **INITIAL SITUATION.**

- Product A, Version 1, Markets: PT;

PT | Product A Version 1 | Batch A Version 1

o **Description**

- OBP wants to add a new country, FR, so that the batch A can be dispensed in all countries where the product can be sold in.

- **Error:** OBP does not retrospectively upload the Product Master Data, instead, creates a Version 2 distributed in two markets;

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S3. RETROSPECTIVE UPLOAD NOT PERFORMED (2/4)

o **INITIAL SITUATION.**

- Product A, Version 1, Markets: PT;

PT | Product A Version 1 | Batch A Version 1

o **1. OBP initiates the upload of Product Master Data**

- Product A, Version 1, Markets: PT;
- Product A, Version 2, Markets: PT,FR;

PT | Product A Version 1, 2 | Batch A Version 1

FR | Product A Version 2

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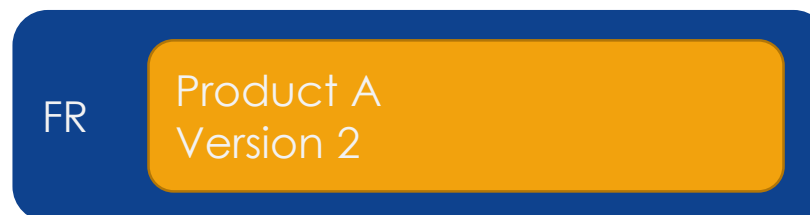
S3. RETROSPECTIVE UPLOAD NOT PERFORMED (3/4)
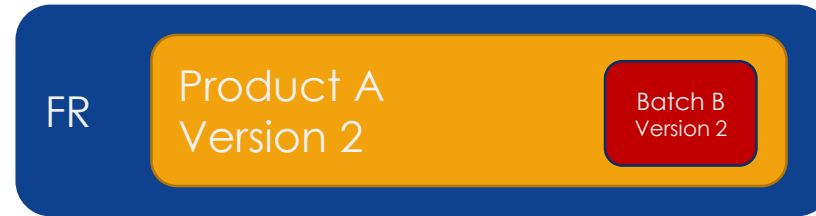
- o **2. OBP initiates the upload of Product Pack Data**
  - Product A, Version 1, Markets: PT;
  - Product A, Version 2, Markets: PT, FR;
  - Batch A associated with Version 1, Batch B associated with version 2;

| PT | Product A Version 1, 2 | Batch A Version 1 | Batch B Version 2 |

| FR | Product A Version 2 | Batch B Version 2 |

Note: Versions are only relevant for the EU-Hub. The National Systems do not make any use of it.

- o **3. Pack associated with the Batch A is decommissioned in FR, which does not have this record**
  - Intermarket Transaction is thus initiated by FR

| PT | Product A Version 1, 2 | Batch A Version 1 | Batch B Version 2 |

| FR | Product A Version 2 | BATCH NOT FOUND | Batch B Version 2 |
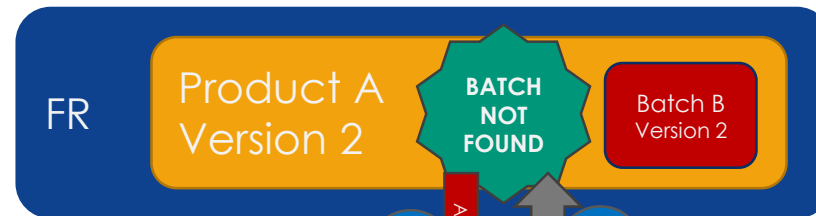
Batch A creates an extra effort in the EMVS. 4 transactions were necessary to decommission the pack.

2 ANSWER **3** RESPONSE

1 ANSWER **4** RESPONSE

EU-HUB Product A, Version 1, Batch A, Markets: PT; FR

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S3. RETROSPECTIVE UPLOAD NOT PERFORMED (4/4)

o **FINAL SITUATION**

PT | Product A Version 1, 2 | Batch A Version 1 | Batch B Version 2

EU-HUB Product A, Version 1, Batch A, Markets: PT; FR

FR | Product A Version 2 | BATCH NOT FOUND | Batch B Version 2

o **Risk**
- Unnecessary effort (i.e. system load) is put into the EMVS systems
- It might affect the EMVS performance and lead to timeout messages

o **EMVO Recommendation**
- EMVO recommends OBPs to do the retrospective upload of Product Master Data to all countries where the product has been distributed, followed by the retrospective upload of the batches affected.

S4. REMOVE A COUNTRY (1/5)

○ **INITIAL SITUATION.**

- Product A, Version 1, Markets: PT, FR;
- Product A, Version 2, Markets: PT, FR;

PT	Product A Version 1,2	Batch A Version 1	Batch B Version 2

FR	Product A Version 1, 2	Batch A Version 1	Batch B Version 2

○ **Description**

- OBP wants to remove the market FR from the Version 2;

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S4. REMOVE A COUNTRY (2/5)

○ **INITIAL SITUATION.**

- Product A, Version 1, Markets: PT, FR;
- Product A, Version 2, Markets: PT, FR;

PT	Product A Version 1,2	Batch A Version 1	Batch B Version 2

FR	Product A Version 1, 2	Batch A Version 1	Batch B Version 2

○ **1. OBP initiates a retrospective upload of Product Master Data**

- Product A, Version 1, Markets: PT;

PT	Product A Version 1,2	Batch A Version 1	Batch B Version 2

FR	Product A Version 1, 2	Batch A Version 1	Batch B Version 2

Distribution Failed at the EU-Hub. FR cannot be removed from the version 1, as markets cannot be removed from specific versions.

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S4. REMOVE A COUNTRY (3/5)

o **EMVO RECOMMENDATION FOR FOLLOWING STEPS**
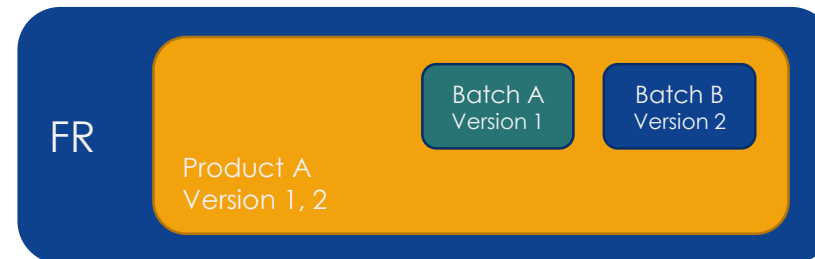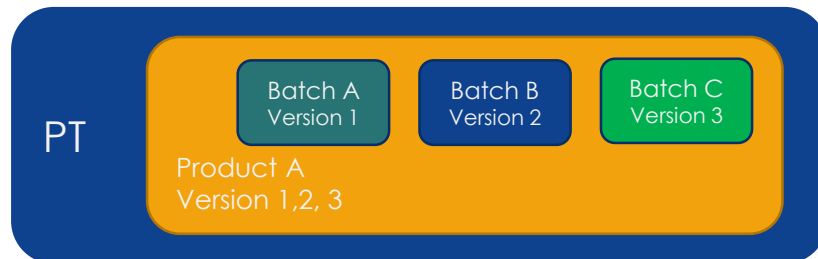
o **2. OBP initiates an upload of Product Master Data**
- Product A, Version 1 and 2, Markets: PT, FR;
- Product A, Version 3, Markets: PT;

PT | Product A Version 1, 2, 3 | Batch A Version 1 | Batch B Version 2

FR | Product A Version 1, 2 | Batch A Version 1 | Batch B Version 2

o **3. OBP initiates an upload of Product Pack Data**
- Batch A, B associated with version 2 distributed in
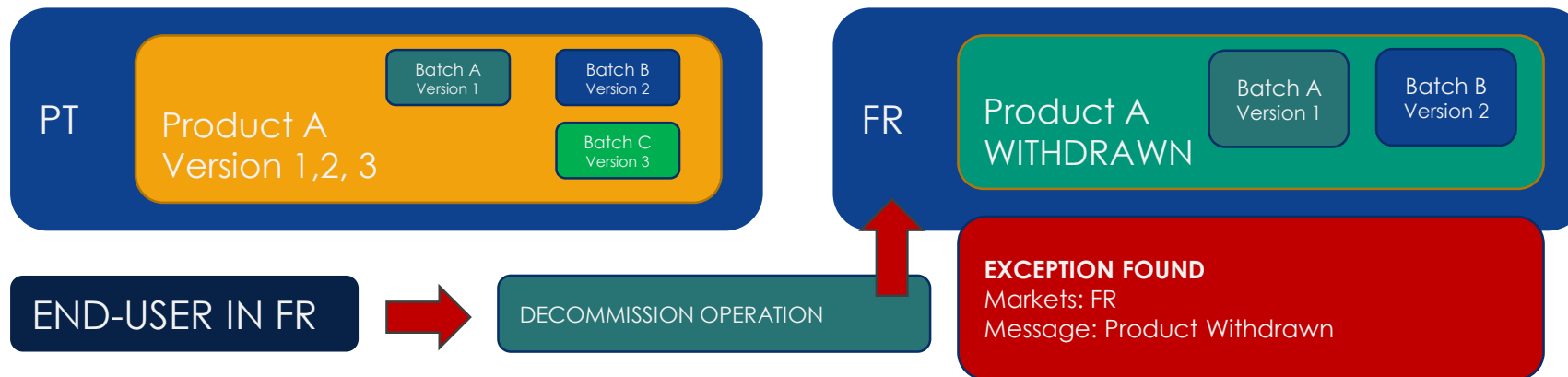- Batch C associated with version 3

PT | Batch A Version 1 | Batch B Version 2 | Batch C Version 3 — Product A Version 1,2, 3

FR | Batch A Version 1 | Batch B Version 2 — Product A Version 1, 2

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S4. REMOVE A COUNTRY (4/5)

NON-RECOMMENDATION

- o **2. OBP initiates a withdraw of product from market FR**
  - Product A, Version 1 and 2, Markets: PT;
  - Product A, Version 3, Markets: PT;

PT — Product A Version 1,2, 3 — Batch A Version 1 — Batch B Version 2 — Batch C Version 3

FR — Product A WITHDRAWN — Batch A Version 1 — Batch B Version 2

- o **3. Pack needs to be decommissioned in FR (for any reason)**

PT — Product A Version 1,2, 3 — Batch A Version 1 — Batch B Version 2 — Batch C Version 3

FR — Product A WITHDRAWN — Batch A Version 1 — Batch B Version 2

END-USER IN FR → DECOMMISSION OPERATION

EXCEPTION FOUND
Markets: FR
Message: Product Withdrawn

S4. REMOVE A COUNTRY (5/5)

o **FINAL SITUATION**

o **Risk**

- In case either the Batch or the Product are not active (i.e. Batch is recalled and Product is Withdrawn), the pack will not be dispensed and patient safe is at stake;

o **EMVO Recommendation**

- EMVO recommends the OBP to increase the version of the Product Master Data, as all future batches and packs will be associated with that version.
- EMVO does not recommend any recall or withdraw operations

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UPDATE MASTER DATA ELEMENTS (1/3)

o **Description**

In case the retrospective upload is used to correct any data, the OBP should do the following steps:

- **1. Identify the Product and the data elements that need to be corrected**
  - Product Code A, Version 1

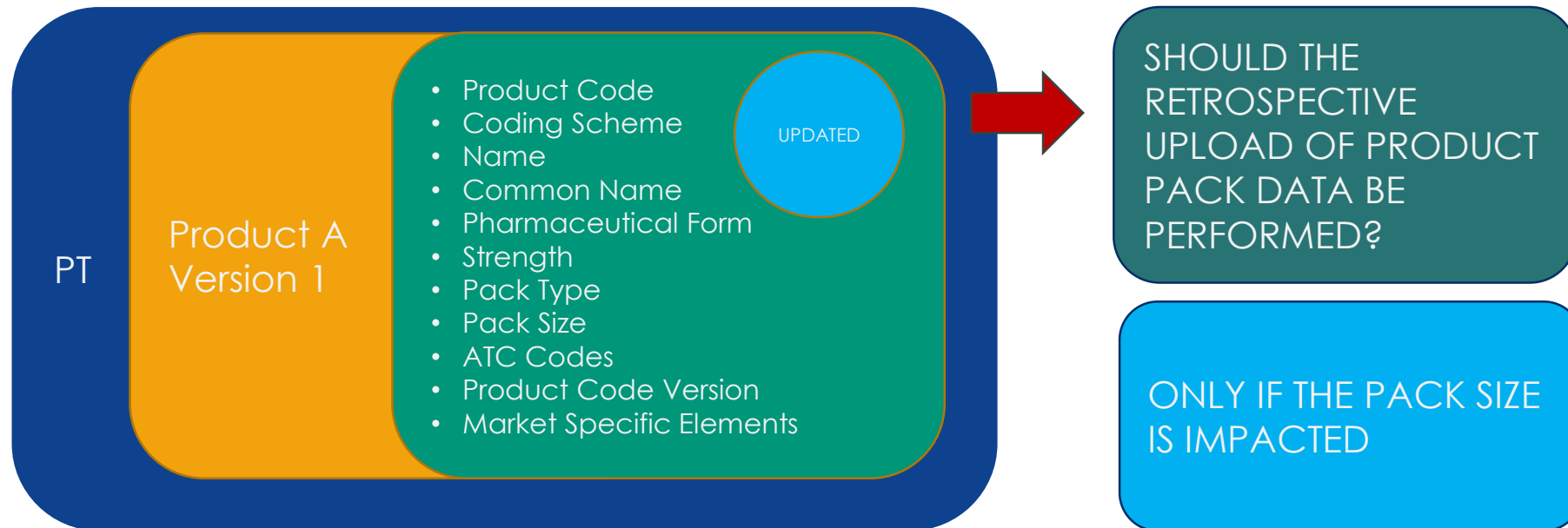**PT**

Product A Version 1

- Product Code
- Coding Scheme
- Name
- Common Name
- Pharmaceutical Form
- Strength
- Pack Type
- Pack Size
- ATC Codes
- Product Code Version
- Market Specific Elements

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UPDATE MASTER DATA ELEMENTS (2/3)

o **Description**

In case the retrospective upload is used to correct any data, the OBP should do the following steps:

- **2. Retrospectively upload the Product Master Data**
  - Product Code A, Version 1

PT

Product A
Version 1

- Product Code
- Coding Scheme
- Name
- Common Name
- Pharmaceutical Form
- Strength
- Pack Type
- Pack Size
- ATC Codes
- Product Code Version
- Market Specific Elements

UPDATED

SHOULD THE RETROSPECTIVE UPLOAD OF PRODUCT PACK DATA BE PERFORMED?

ONLY IF THE PACK SIZE IS IMPACTED

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UPDATE MASTER DATA ELEMENTS (3/3)

o **FINAL SITUATION**

PT | Product A Version 1 | Master Data Elements | UPDATED

o **Risk**

- If the Pack Size is not updated there will be a mismatch between Pack Size in the Product Master Data and the Pack Size uploaded in the Product Pack Data

- Affect the repack buffer used for Parallel Distributors uploads of packs

o **EMVO Recommendation**

- EMVO recommends the OBP to upload retrospectively product pack data only in case the packs size is to be modified.

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