OBP Guideline for Divestitures and Acquisitions

1. Executive Summary

The purpose of this document is to provide guidance on aspects of the EMVS which might be impacted in Divestiture & Acquisition (D&A) activities (e.g. data upload to European Hub, contract of Transferor and Acquirer with EMVO and NMVOs, Quality Assurance Agreement between D&A partners related to data exchange with European Hub) of marketing authorisation holders.

This guidance document has been prepared considering D&A scenarios such as

- Acquisition / divestiture of a part of the business affecting a set of products for a set of markets (i.e. affecting a set of SKUs),
- Merger of two companies,
- Acquisition of a company by another company,
- Scenarios where a new legal entity is created by Transferor prior to divestiture in order to carve out the divested business.

In case of the merger of two companies or the acquisition of a company in whole by another company, the merged company or the acquirer respectively might decide – either long-term or for a limited period of time – not to file transfers of marketing authorizations with the authorities and not to touch established contracts with EMVO and NMVO(s). With regard to EMVO, this means to maintain two separate OBPs and that the affiliation of marketing authorization holders to each of the two OBPs remains unchanged. If these conditions are fulfilled, the activities outlined in the guidance document on hand do not apply.

The document outlines the following areas as to be considered in a D&A scenario:

- Establish/update contracts with EMVO / NMVOs (sec. 3)
- Data upload (product master data, product pack data) to European Hub (sec. 4)
- Production-related topics (sec. 5)
- Receipt and processing of alerts e.g. suspicious pack alerts (sec. 6)
- Access to product history in European Hub and NMVSs (sec. 7)

Throughout the document marketing authorization holders and parallel distributors are treated equally. For both of them, the term 'Marketing Authorization Holder' applies.

2. Introduction

For the purpose of this document, a Divestiture & Acquisition (D&A) activity has been structured into 3 phases as set out in Figure 1 and guided by the following timeline:

1. Prior to submission of Marketing Authorization (MA) transfer to Health Authorities
2. Between submission of MA transfer and Implementation Date of MA transfer
3. After Implementation Date of MA transfer

Here, 'Implementation Date of MA Transfer' means the completion of the MA transfer implementation on the packaging. This implementation date might vary from country to country and product to product.

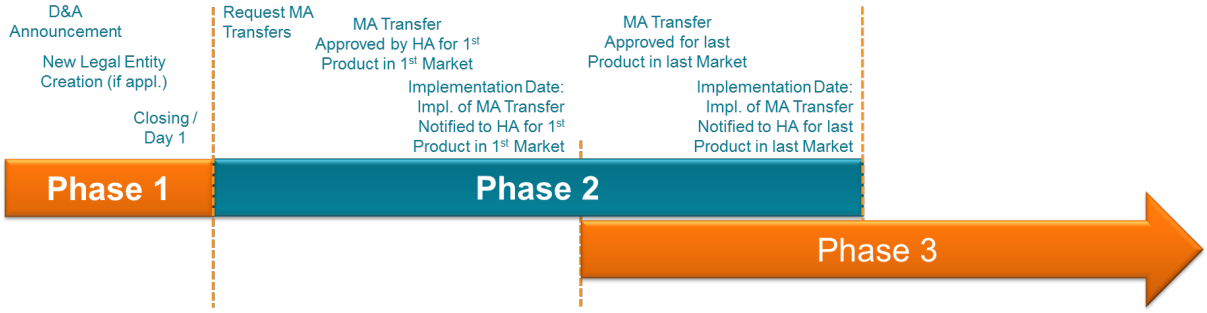

Figure 1: D&A phases derived from the activities regarding the transfer of the marketing authorizations from Transferor to Acquirer

Phase 1 starts with the announcement of the D&A activity by the Transferor and/or the Acquirer and includes the so-called Day 1. During that phase, the Transferor might establish a new legal entity in order to carve out the business that is divested to the Acquirer. Prior to Day 1, the Transferor might at first transfer his marketing authorizations to this new or an already existing legal entity that is subsequently transferred to the Acquirer.

Phase 2 starts with the submission of the request to the authorities to transfer the marketing authorizations for the first product to the Acquirer and lasts until the MA transfer for the last product is implemented on the packaging. Key considerations for Phase 2 are:

a) During implementation of the MA transfer on the packaging, Transferor OBP shall continue to upload data to the European Hub and to receive alerts,
b) NTINs remain unchanged upon MA transfers (cf. sec. 5.1)
c) Product codes are assigned to an OBP and assignment cannot be changed currently. This means that NTINs are technically 'blocked' by Transferor OBP and Acquirer OBP cannot take over from Transferor OBP and start to upload product master data and serial numbers for an NTIN product after implementation of MA transfer is complete.

a) and c) are the reason for the Transitional Service Agreement outlined in the next section.

Phase 3 starts with the implementation of the MA transfer on the packaging for the first product which precedes the first production of this first product with the new packaging layout. It lasts until the last pack of the transferred products in the 'old' packaging layout is available for sale.

3. Contractual Topics

3.1 Phase 1: Prior to Submission of MA Transfer

Activity	Actor	Description
Notify EMVO	Transferor, Acquirer	Actors to notify EMVO upon signature of transaction agreement between Transferor and Acquirer or clearance of business transfer agreement by authorities, if required, by placing a ticket with EMVO Helpdesk. The notification shall include the below information: • Involved actors • If a new entity has been or will be created as outlined in sec. 2 – provided this is already known to the Transferor at the moment of notification – and the details of this entity, if already known • If an existing MAH has been or will be transferred – provided this is already known to the Transferor at the moment of notification – and the details of this MAH • Type of D&A activity (for examples cf. sec. 1) • Estimation of the overall timeline of transfer
Notify NMVO	Nat'l Representative of Transferor, Nat'l Representative of Acquirer	Actors to notify applicable NMVOs similar to 'Notify EMVO' as described above
Update EMVO Contract	Transferor	If a new legal entity is created prior to divestment where MAs are transferred to by the Transferor, then the newly created legal entity shall be added to the list of affiliated MAHs in the EMVO OBP Portal
Update NMVO Contract(s)	Nat'l Representative of Transferor	If a new legal entity is created prior to divestment where MAs are transferred to by the Transferor, Transferor has to ensure that participation agreement(s) exist in relevant countries between Nat'l Representative(s) of Transferor and applicable NMVO(s); participation agreement(s) need to cover the newly created legal entity

Activity	Actor	Description
Establish EMVO Contract	Acquirer	The Acquirer needs to ensure that an OBP Participation Agreement exists between EMVO and a legal entity that the Acquirer is affiliated to (as per the Affiliation definition set out in the Participation Agreement) and which will act as the OBP vis-à-vis EMVO. This activity can be completed in Phase 2 but must be in place prior to completion of implementation of the MA transfer for the very 1st product in any of the EEA countries.
Establish NMVO Contracts	Nat'l Representative(s) of Acquirer	The Acquirer needs to ensure that participation agreements exist in relevant countries between Nat'l Representative(s) of Acquirer and applicable NMVO(s). This activity can be completed in Phase 2 but must be in place in each country prior to completion of implementation of the MA transfer for the 1st product in that country.
Establish Transitional Service Agreement between Transferor and Acquirer	Transferor, Acquirer	Mandates Transferor to take care of data upload and alert receipt on behalf of Acquirer during the phase where Acquirer is already the owner of the product but the implementation of the MA transfer is not completed[1] (for a conceivable wording cf. Annex I)
Side Letter to Transferor's OBP Participation Agreement	Transferor	Transferor OBP to request from EMVO the right to exceptionally upload data to the European Hub on behalf of the Acquirer until the MA transfer implementation is completed as described in the Side Letter template made available by EMVO.
Side Letter to Acquirer's OBP Participation Agreement	Acquirer	Acquirer OBP to request from EMVO the right to exceptionally deviate from the OBP Participation Agreement, Art. 5.9.2, by the scenario that Acquirer performs wholesaler transactions on products that he does not hold the MA for. This is needed to cover the situation where the distribution change from the Transferor to the Acquirer takes place prior to the transfer of the marketing authorization

[1] The applicable period for the Transitional Service Agreement needs to be chosen appropriately to cover the phasing and the different cases outlined in sec. 4 of this document.

As long as the necessary functionality in EU Hub and NMVSs to change the assignment of a product code to the Acquirer's OBP is not available: (functionality not to be expected in 2019)

Activity	Actor	Description
Establish Transitional Service Agreement (Amended)	Transferor, Acquirer	Amendment in addition to the corresponding activity above: Mandates Transferor to take care of data upload and alert receipt and to access product history data on behalf of Acquirer and to inform Acquirer as appropriate even after completion of MA transfer for products carrying an NTIN.
Side Letter to Transferor's OBP Participation Agreement (Amended)	Transferor	Amendment in addition to the corresponding activity above: Entitles Transferor to take care of data upload on behalf of Acquirer even after completion of the MA transfer implementation for products carrying (i) an NTIN and/or (ii) a GTIN in cases where Transferor transfers the applicable GS1 company prefix to the Acquirer and the Acquirer continues to use the GTINs previously used by the Transferor. This amendment is contained in the Side Letter template made available by EMVO which is referred to above.

3.2 Phase 2: Between submission of MA transfer to HAs and Implementation Date of MA transfer

Activities listed for Phase 2 need to be replicated per each market since both the submission of the MA transfer and the Implementation Date may vary between markets.

Activity	Actor	Description
Update EMVO Contract	Acquirer	If an additional MAH (now) belonging to the Acquirer becomes relevant in any of the markets: • Update list of MAHs in EMVO OBP Portal • Get 'Letter of Adhesion to OBP-EMVO Participation Agreement' signed by said additional MAH[2] If an additional Nat'l Representative (e.g. sales affiliate) (now) belonging to the Acquirer becomes relevant in any of the markets: • Delegate 'Designated Wholesaler Appointment' to Nat'l Representative of Acquirer Both 'Letter of Adhesion' and 'Designated Wholesaler Appointment' constitute internal documents of the OBP. A scanned copy of the 'Letter of Adhesion' is to be made available to EMVO upon request.
Update NMVO Contract(s)	Nat'l Representative of Acquirer	If an additional MAH belonging to the Acquirer becomes relevant in a market: • Update list of MAHs in NMVO contracts • Provide to NMVOs revised business figures for calculation of applicable NMVO fee. Note that the potential need to establish a contract between the additional MAH and the relevant NMVOs is addressed in activity 'Establish NMVO Contracts' in sec. 3.1.

3.3 Phase 3: After Implementation Date of MA transfer

Activity	Actor	Description
Update EMVO Contract	Transferor	If an MAH is no longer relevant in any of the markets: • Delete MAH from list of affiliated MAHs in EMVO OBP Portal
Update NMVO Contract(s)	Nat'l Representative of Transferor	If an MAH is no longer relevant in a market: • Delete MAH from list of affiliated MAHs in NMVO contract(s) • Provide to NMVOs revised business figures for calculation of applicable NMVO fee.

[2] Note that the 'Letter of Adhesion' is to be signed by affiliated MAHs – rather than Acquirer's sales affiliates – to authorise the Acquirer's OBP to perform the upload of data onto the European Hub according to DR 2016/161, Art. 33 (1) on behalf of MAHs affiliated to the Acquirer's OBP.

4. Data Upload to European Hub

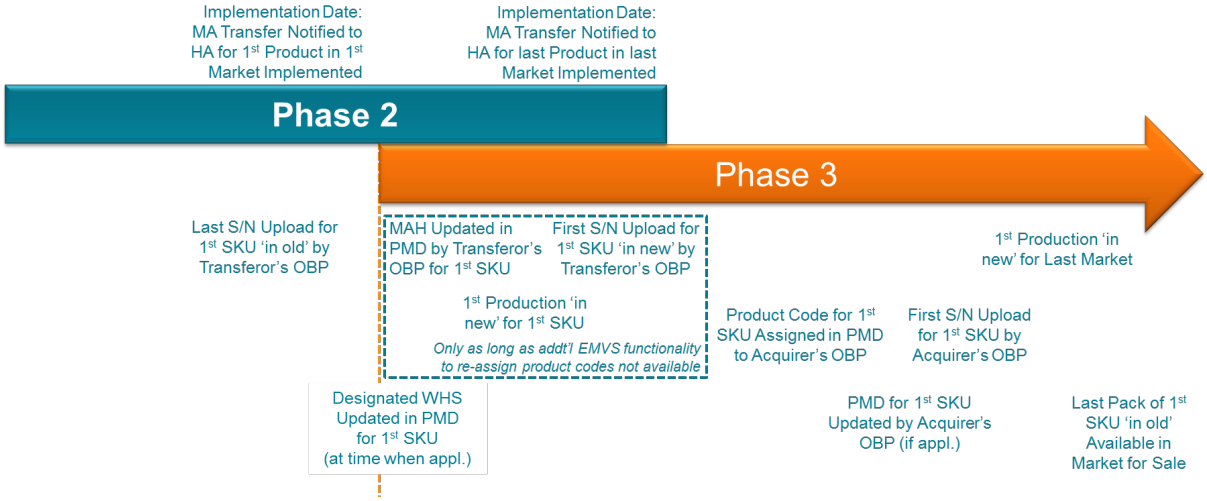

Figure 2: Activities related to the data upload by OBPs to the European Hub

This section deals with the upload of data to the European Hub and the synchronization with implementation of the MA transfer on the packaging. As a general rule, Transferor and Acquirer need to define responsibilities to ensure that the product master data as described in the document EMVO 0122 'EMVO Master Data Guide' is kept accurate. In this regard, in particular the 'Marketing Authorization Holder', the product-related Art. 57 code and the 'Designated Wholesaler' information need to be considered.

The activities outlined address the fact that for an interim period, the Transferor might upload pack data on behalf of the Acquirer for products that are already owned by the Acquirer. The underlying assumption is that the Transferor uploads the product pack data until the MA transfer is implemented on the packaging material i.e. the Transferor will upload the data up to the last batch of a product that is produced with the old artwork and the Acquirer will start with the data upload with the first production that takes place with the revised artwork.[3]

For NTINs or in cases where Transferor transfers the applicable GS1 company prefix to the Acquirer and the Acquirer continues to use the GTINs previously used by the Transferor, the 'Marketing Authorization Holder information' in the product master data must be changed prior to the first production with the revised artwork. For the decision at which point in time to actually change the product master data, the time of transfer of the MAH in the registration and the MAH information found in the patient information leaflet might be considered.

Likewise, it needs to be decided when to enter the new product-related Art. 57 code (EV code) that is received by the Acquirer when the MA transfer is granted.

[3] If the Transferor and the Acquirer agree upon a different point in time where the Acquirer's OBP starts the data upload, Transferor and Acquirer must re-assign the activities outlined in this section accordingly.

Furthermore, for the time until the functionality in EU Hub and NMVSs to change the assignment of a product code from the Transferor's OBP to the Acquirer's OBP becomes available, the Transferor's OBP will need to continue the pack data upload for products carrying an NTIN (and if the company prefix in use is divested to the Acquirer) even after the implementation of the MA transfer.

Activity	Actor	Description
Update Designated Wholesaler Master Data	Transferor or Acquirer	Update the 'Designated Wholesaler' information for each product-country combination at the time when the Distribution Switch (cf. sec. 8 'Glossary') takes place. Depending on the way the Distribution Switch is implemented the existing Transferor's 'Designated Wholesaler' master data is either to be amended by or to be replaced with the applicable master data of the Acquirer. In case of amendment, it needs to be ensured that the product master data is updated once the Transferor's 'Designated Wholesaler' master data is no longer applicable. The update needs to be carried out by either the Transferor or the Acquirer depending on to whom the product is assigned in the EU Hub at the time where the Distribution Switch takes place.

The activities in the following two tables apply for NTINs. Furthermore, they apply for GTINs if the company prefix that is used in the GTINs is divested to the Acquirer.

A) As long as the necessary functionality in EU Hub and NMVSs to change the assignment of a product code to the Acquirer's OBP is not available: (functionality not to be expected in 2019) or if Transferor and Acquirer agree to change the product master data prior to the change of the assignment of the product code

Activity	Actor	Description
Update Marketing Authorization Holder Master Data	Transferor	Update marketing authorization holder information in product master data reported to EU Hub at the time as agree upon between Acquirer and Transferor and in any case prior to the first production with the revised artwork.
Update Art. 57 Master Data	Transferor	Update product-related Art. 57 information in product master data reported to EU Hub at the time as agree upon between Acquirer and Transferor and in any case prior to the first production with the revised artwork.

B) As soon as the necessary functionality in EU Hub and NMVSs to change the assignment of a product code to the Acquirer's OBP is available: (functionality not to be expected in 2019)

Activity	Actor	Description
Assign Product Code to Acquirer's OBP	tbd	Upon completion of the implementation of the MA transfer on the packaging and prior to the first production with the revised artwork, switch assignment of product code from Transferor's OBP to Acquirer's OBP Detailed process incl. Actor tbd upon compilation of the user requirements for changing the assignment of a product code to the Acquirer's OBP
Update Marketing Authorization Holder Master Data	Acquirer	Update marketing authorization holder information in product master data reported to EU Hub at the time as decided by Acquirer and in any case prior to the first production with the revised artwork, provided that this update is not performed by Transferor on behalf of Acquirer as outlined under A) above
Update Art. 57 Master Data	Acquirer	Update product-related Art. 57 information in product master data reported to EU Hub at the time as decided by Acquirer and in any case prior to the first production with the revised artwork, provided that this update is not performed by Transferor on behalf of Acquirer as outlined under A) above

5. Production-Related Topics

The following sections contain production-related topics that are to be considered by the Acquirer:

5.1 Rules for Product Code Changes

Guidance on how to manage product code changes in D&A scenarios is provided in the GS1 General Specifications, sec. 1.6 'Allocation' and in the GS1 Healthcare GTIN Allocation Rules. In particular, it needs to be considered that

- Upon implementation of the MA transfers, new GTINs are to be assigned out of the Acquirer's GTIN number range,
- In case of a 1:1 relationship between the products divested and the GS1 company prefix used in the GTINs for these products (i.e. no products with same company prefix as the divested products remain with Transferor), the Transferor can transfer the GS1 company prefix to the Acquirer. In this case, GTINs do not need to be changed upon implementation of the transfer of the marketing authorizations.
- National numbers remain unchanged as follows:

- NTINs / nat'l numbers in Austria (PZN-AT), France (CIP), Germany (PZN-DE), Spain (Código Nacional), Switzerland (Swissmedic no.) remain unchanged upon transfer of the marketing authorization,
- No requirement exists to change the NTIN (with Nordic VNR embedded) in the Nordics upon MA transfer,
- In Portugal, the Número de Registo that is to be encoded in the DataMatrix code remains unchanged while the product code that is a GTIN shall change upon implementation of the MA transfer,
- In the UK, the AMPP code is retained when the MA for a product is transferred.

5.2 Implementation of MA Transfer in Case of Alternate Packaging Sites

If a product is manufactured in alternate production sites, the changes to implement the MA transfer need to be synchronized to ensure that after implementation of the MA transfer in the first site, all subsequent productions in the alternate production site(s) use the same revised artwork.

5.3 Uniqueness of Serial Numbers

Two packs with the same product code must never carry the same serial number. This includes the time before and after an MA transfer i.e. the Acquirer's MAH must never re-use serial numbers that were previously used by the Transferor's MAH. The requirements of DR 2016/161, Art. 4 (d) apply.

5.4 Transferor Acting as CMO for Acquirer

If the Transferor acts as a CMO for a (set of) product(s) after implementation of the MA transfer, a connection between the Acquirer and the Transferor for the exchange of serial numbers needs to be established.

6. Receipt and Processing of Alerts

Until necessary functionality in EU Hub and NMVSs to change the assignment for receipt and processing of alerts to Acquirer is available, Transferor will receive alerts for all batches (of the divested products) that Transferor has uploaded the batch data incl. serial numbers for.

7. Access to Product History in European Hub and NMVSs

Until necessary functionality in EU Hub and NMVSs to change assignment for access to product history to Acquirer is available, Transferor will have access to product history for all batches (of the divested products) that Transferor has uploaded the batch data incl. serial numbers for.

8. Glossary

CMO	Contract Manufacturing Organization; a company manufacturing a product on behalf of the Marketing Authorization Holder
Distribution Switch	The change in the supply chain setup where the distribution of the divested/acquired products is transferred to the distribution channels of the Acquirer. Such distribution change might take place prior to the transfer of the marketing authorization to the Acquirer
DR 2016/161	EU Delegated Regulation 2016/161; the regulation laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use
Implementation Date	'Implementation Date of MA Transfer' means the completion of the MA transfer implementation on the packaging. This implementation date might vary from country to country and product to product.
EMVO	European Medicines Verification Organization; the legal entity established to set up and manage the European Hub
EMVS	European Medicines Verification System; the European system for medicines verification set up and managed in accordance with Chapter VII of the Delegated Regulation
EU Hub	European Hub; the component of the EMVS under the responsibility of EMVO that serves as the central information and data router according to DR 2016/161, Article 32, para. 1, a)
GTIN	Global Trade Item Number; a GS1 conformant unique product code containing a company prefix and a assigned to a product following the rules of the standardization body GS1
HA	Health Authority
MA	Marketing Authorization
MAH	Marketing Authorization Holder; for the purpose of this document, the term includes the holders of parallel import or parallel distribution licenses
NMVO(s)	National Medicines Verification Organization(s); the legal entity (entities) responsible to set up and manage a national and/or supranational repository(-ies) in accordance with the provisions of DR 2016/161
NMVS	National Medicines Verification System; a national or supranational repository of the EMVS according to Article 32, para. 1, b) of the Delegated Regulation under the responsibility of one NMVO

NTIN	National Trade Item Number; a GS1 conformant unique product code that – other than a GTIN – does not contain a company prefix. Usually, NTINs are used in countries where legacy numbering schemes in the healthcare sector were to be embedded into a GS1-compliant data element
OBP	Onboarding Partner; the legal entity holding the participation agreement with EMVO for itself and on behalf of affiliated companies
OBP Participation Agreement	Agreement between OBP and EMVO that e.g. entitles the OBP to upload data to the EMVS

Annex I: Draft Input for Transitional Service Agreement

The following is a conceivable wording for the related activities outlined in sec. 3.1. This wording might be used in a Transitional Service Agreement. The Legal Disclaimer governing the guidance document applies.

Service Supplier	Type of Service	Description of Service	Transitional Period (from Day 1/ Closing)	Charge	Additional Terms
[Name of Transferor]	Supply Chain – Serialization	Always in accordance with: 1. the conditions set out in the respective Agreement for Participation of Onboarding Partners in the European Medicines Verification System ("OBP Participation Agreement") between [Insert Transferor OBP's name] and the European Medicines Verification Organization ('EMVO') with Effective Date [Insert Month Day, Year] on the one hand; and the OBP Participation Agreement between [Insert Acquirer OBP's name] and the EMVO with Effective Date [Insert Month Day, Year] on the other hand (both as supplemented by any applicable Side Letter(s)); and 2. the EU Directive on Falsified Medicines; and 3. the EU Delegated Regulation 2016/161 Transferor shall, on behalf of Acquirer: • Upload Data to the European Hub regarding the Products.	Up until the completion of the MA transfer implementation on the packaging[4]	[...]	[...]

[4] Note that this 'Transitional Period' needs to be chosen appropriately to cover the applicable actual timelines agreed upon Transferor and Acquirer.

Service Supplier	Type of Service	Description of Service	Transitional Period (from Day 1/ Closing)	Charge	Additional Terms
[Name of Transferor]	Supply Chain – Serialization	Always in accordance with: 1. the conditions set out in the respective Agreement for Participation of Onboarding Partners in the European Medicines Verification System ("OBP Participation Agreement") between [Insert Transferor OBP's name] and the European Medicines Verification Organization ('EMVO') with Effective Date [Insert Month Day, Year] on the one hand; and the OBP Participation Agreement between [Insert Acquirer OBP's name] and the EMVO with Effective Date [Insert Month Day, Year] on the other hand (both as supplemented by any applicable Side Letter(s)); and 2. the EU Directive on Falsified Medicines; and 3. the EU Delegated Regulation 2016/161 Transferor shall, on behalf of Acquirer: • Receive alerts generated by any NMVS and routed to the Transferor via the European Hub regarding the Products for all batches that Transferor has uploaded the batch data for to the European Hub • Access Product history data in the European Hub. Transferor shall inform Acquirer of any such alerts within [Insert number of days for notification to Acquirer] days. Processing of such alerts shall be Transferor's / Acquirer's [select the responsible party] responsibility.	Until necessary functionality in EU Hub and NMVSs to change assignment to Acquirer (i) for access to product history and (ii) for receipt and processing of alerts is available	[…]	[…]