OBP DIVESTITURE & ACQUISITION GUIDE

Revision History

Version Date	Version	Author	Reason For Changes
03/MAY/2019	1.0	Stefan Artlich	Initial Document
22/NOV/2019	2.0	Stefan Artlich	Complete review based on insights gained through compilation of user requirements for system enhancements • Sec. 3.2, Footnote 2 added • Sec. 5.2: Specifics for Poland added • Sec. 5.3: Uniqueness of Batch ID added • Sec. 5.4 renamed and rewritten • Sec. 5.5 added • Annex II added
04/NOV/2022	3.0	Tracy Slosse	Update to reflect the changes from CR_21833 and include PC Transfer Request process

Contents

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 a 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. 4.2.3)
- Access to product history in European Hub and NMVSs (sec. 6)

Throughout the document original pack manufacturers 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 the Marketing Authorization (MA) transfer to Health Authorities (HA)
2. Between submission of the MA transfer and the Implementation Date of the MA transfer
3. After the Implementation Date of the MA transfer

Here, 'Implementation Date of the 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.

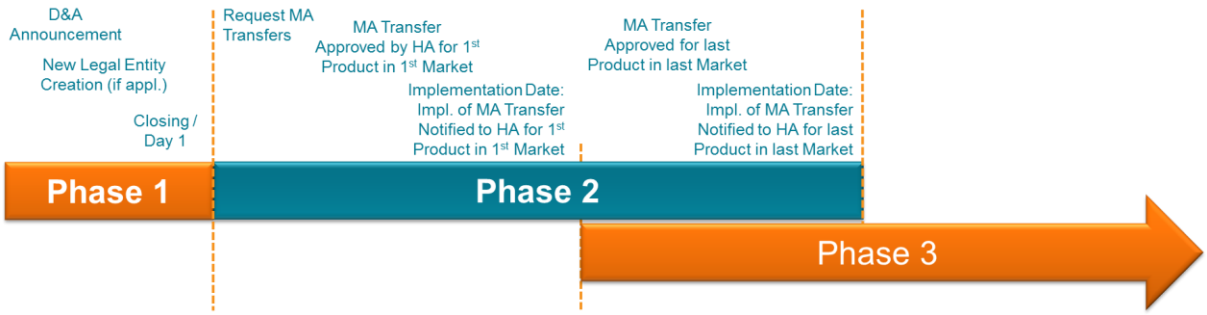

Figure 1: D&A phases derived from the activities regarding the transfer of the marketing authorizations from Transferor to Acquirer

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 to an already existing legal entity within his corporation 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. This phase 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, the 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) Once uploaded to the EU Hub, product codes are always assigned to one OBP and technically 'blocked' for usage by other OBPs. Therefore, a product code ownership change must be requested should the Acquirer continue using product codes previously uploaded by the Transferor.

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 the MA Transfer

Activity	Actor	Description
Notify EMVO	Transferor, Acquirer	Actors to notify EMVO upon signature of the transaction agreement between Transferor and Acquirer or clearance of business transfer agreement by authorities, if required, by submitting a ticket to the EMVO Helpdesk. The ticket 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 the completion of the 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.

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 for 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[2]: • Update list of MAHs in EMVO OBP Portal • Get 'Letter of Adhesion to OBP-EMVO Participation Agreement' signed by said additional MAH[3] 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 the list of affiliated MAHs in the EMVO OBP Portal

[2] As per the OBP-EMVO Participation Agreement, Appendix 2, a supplementary On-boarding Fee might apply if such additional MAH leads to the OBP reaching a higher OBP category (e.g. from '3-5 …' to '6-12 MAHs in Europe'.

[3] 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.

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

4. Data Upload to European Hub

4.1 Overview

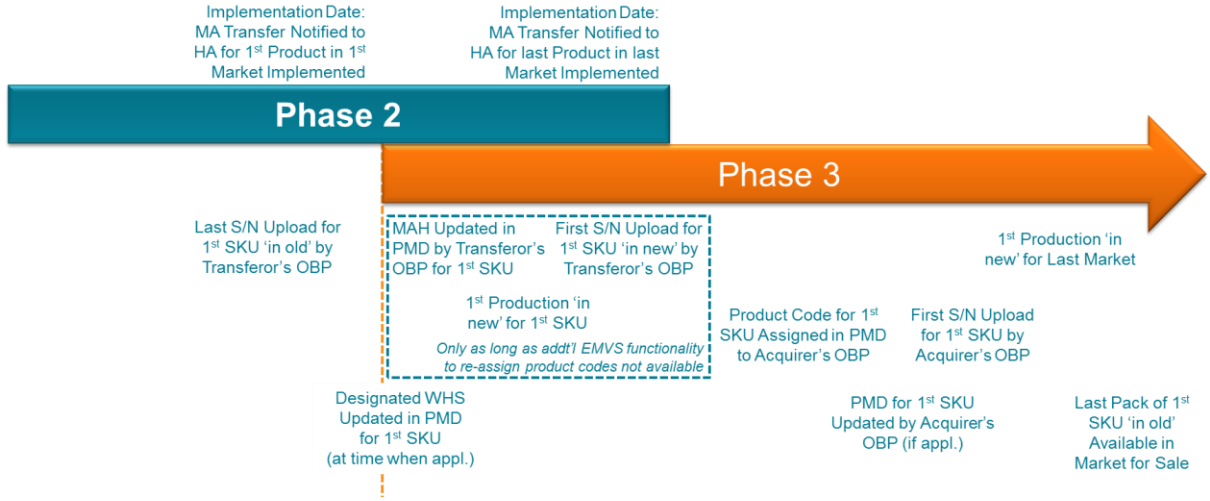

Figure 2: Activities related to the data upload by OBPs to the European Hub

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.[4]

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

[4] 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.

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.

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. 7 '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 table apply for NTINs. Furthermore, they apply for GTINs if the company prefix that is used in the GTINs is divested to the Acquirer.

Activity	Actor	Description
Assign Product Code to Acquirer's OBP	EMVO	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 OBP to Acquirer OBP See section 4.2 for detailed process.
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,
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

4.2 Process to assign the PC to Acquirer OBP

4.2.1 Request Introduction

Upon completion of the implementation of the MA transfer on the packaging and prior to the first production with the revised artwork, the Transferor and the Acquirer must submit the request to EMVO to switch the Product Code ownership.

The request must be sent to the EMVO Helpdesk (helpdesk@emvo-medicines.eu) with the ticket title "PC Transfer Request CP XXXX – [Date]". It can come from either the Transferor and the Acquirer, as long as all respective SPOCs, and SPOC assistants if applicable, are included in the email thread.

The email must contain:

- The consent forms, duly completed by both parties. See Annex III: Product Code Ownership Transfer Consent Forms
- The Invoicing Information Form, duly completed by the relevant party. Available here.
- The list of affected product code in CSV format, duly completed. Available here.

4.2.2 Fill in the CSV template

For each product code, the following information must be provided in the file in one row (separate by a comma value):

- The product code number
- The product code scheme
- The ORG ID of the Transferor
- The ORG ID of the Acquirer
- The transfer date (format YYYY-MM-DD) *Note: only one date can apply for multi-country products*
- The scenario ("1" or "2", see 4.2.3)
- The escalation date (format YYYY-MM-DD)

Important note: If you choose scenario 2, please leave the field "escalation date" empty; otherwise the transfer will not be processed.

4.2.3 Define Receipt and Processing of Alerts

To define the alert reception following the transfer, two different scenarios are possible:

- Scenario 1
  - Each alert triggered **on or after "Escalation date"** shall be routed to the **Acquirer** independent of the batch that the alert is related to. In particular, this includes *#A2 'Batch not Found'* alerts.
  - Each alert triggered **prior to "Escalation date"** shall be routed to the **Transferor** independent of the batch that the alert is related to. In particular, this includes *#A2 'Batch not Found'* alerts.

- Scenario 2
    - Each alert shall be routed (a) to the **Acquirer** for those batches where the **Acquirer** has uploaded the PPD for and (b) to the **Transferor** for those batches where the **Transferor** has uploaded the PPD for.
    - Each *#A2 'Batch not Found'* alerts triggered **on or after the "Transfer Date"** shall be routed to the **Acquirer**
    - Each *#A68 'Batch Identifier Mismatch'* alert shall be routed to the party to which the batch that exists in the NMVS belongs to (rather than routing it to the party to which the batch contained in the verification request belongs to)

Scenario 2 implies that for all batches uploaded prior to "Transfer Date", the Transferor continues to receive the alerts. Furthermore, for batches that the Transferor has uploaded the PPD for after "Transfer Date" (using a PMD version that is assigned to him), the Transferor will receive the alerts as well.

In **Scenario 1**, if for "Escalation date" a date is chosen that lies after "Transfer Date" and the Acquirer has already uploaded PPD (which inevitably will have taken place after "Transfer Date"), the Transferor will continue to receive alerts for the Acquirer batches until "Escalation date" is reached.

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 Poland, it might be required to keep the product codes unchanged until the applicable reimbursement decision is due for renewal,

- 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 and Batch IDs

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[5] for that same product code. The requirements of DR 2016/161, Art. 4 (d) apply.

Likewise, Transferor and Acquirer must ensure that batch IDs are not re-used for the same product code.

5.4 Serial Number Exchange between Transferor and 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.

Likewise, such connection will be required if Acquirer acts as CMO for Transferor for products that were not transferred e.g. in case that Transferor has divested a packaging site to Acquirer and that divested site continues to produce non-transferred products for Transferor.

And finally, a connection for S/N exchange might be required only for an interim period an example being where Transferor continues to upload the S/Ns until the MA transfer is implemented on the packaging but the packaging site was transferred to Acquirer on Day 1. In this case, the transferred site will **temporarily** act similar to a CMO for Transferor during the period between Day 1 and the implementation of the MA transfer on the packaging.

5.5 Divestiture and Acquisition of Parallel Import Product Licenses

Upon transfer of a Parallel Import Product License (PIPL), the data reconciliation buffer (aka 'For repack' buffer) held in the European Hub cannot be transferred from the Transferor to the Acquirer. Therefore, any product already marked by the Transferor for repackaging i.e. decommissioned with attribute 'checked out' should be repacked by the Transferor including the corresponding product pack data upload.
Any inventory where the product pack data upload to the European Hub has taken place shall be either sold off by the Transferor or – subject to contractual agreement – by the Acquirer.

[5] This could be achieved through different lengths that Transferor and Acquirer are using for their serial numbers or a leading prefix that would be different.

6. Access to Product History in European Hub and NMVSs

Access to product and batch history will be available to the party that originally created the record.

7. Glossary

Acquirer	Company which has entered into a definitive agreement with the Transferor to acquire products from the Transferor.
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
Transferor	Company which has entered into a definitive agreement with the Acquirer to transfer products to the Acquirer.

8. Annexes

8.1 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[6]	[...]	[...]

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

8.2 Annex II: For Illustration Purposes: D&A Sample Scenario with Regard to Serialization

This annex describes different milestones that might be relevant in a D&A scenario. It is based on a real-life example taken from a D&A case that two companies have went through. For confidentiality reasons, the example has been anonymized. DISCLAIMER: By its nature, this practical example does neither include all scenarios conceivable in a D&A activity nor should it be considered 'normative' in the sense that companies undergoing a D&A would have to adhere to the decisions taken by the parties in the example.

Scenario Description

Company A ('Transferor') with businesses in all EU Member States has decided to divest a defined part of its product portfolio. Company B ('Acquirer') with businesses in all EU Member States has decided to acquire the divested products from Company A.

The divested products are nationally registered by different Marketing Authorization Holders belonging to Transferor's Group of companies. The products are packaged by different manufacturing sites belonging to Transferor's Group of companies and by contract manufacturers (CMOs). Since one of Transferor's manufacturing sites mostly produces products belonging to the divested portfolio, Transferor has decided to divest this site, the 'Transferred Site', to the Acquirer as well. After completion of the divestiture, the 'Transferred Site' will serve as a CMO for Transferor for products that remain in Transferor's product portfolio. Likewise, one of Transferor's manufacturing sites will serve as a CMO for Acquirer for parts of the divested product portfolio.

'Transferred Site' has also worked as a CMO for Transferor's customers who will become Acquirer's customers on Day 1.

The CMOs working for Transferor for the manufacturing of products belonging to the divested portfolio will become CMOs for Acquirer.

Some of the products are registered by Transferor's affiliated legal entity 'Transferred MAH'. Only products to be transferred are registered by this legal entity. Therefore, the legal entity 'Transferred MAH' is transferred to Acquirer on Day 1.

To summarize, the following changes in business relationship occur:

- As of Day 1, Transferor's legal entity 'Transferred MAH' becomes a legal entity of Acquirer,
- As of Day 1, Transferor's manufacturing site 'Transferred Site' becomes a manufacturing site of Acquirer,
- Acquirer becomes a CMO for Transferor, Transferor becomes a CMO for Acquirer,
- CMO for Transferor becomes CMO for Acquirer, customer of Transferor (in its role as a CMO at 'Transferred Site') becomes customer of Acquirer.

Product Transition EMVS – Transition Approaches

As part of the carve-out project between Transferor and Acquirer, the two parties discussed how to best re-assign in the EU Hub those product codes (from the Transferor to the Acquirer) that will be kept (rather than replaced by Acquirer product codes) such as NTINs in Germany in France. Two approaches for this re-assignment were considered together with the pros and cons:

	Option 1	**Option 2**
Approach	All SKU in one shot as of Day 1	Per country at the time when MA transfer is granted by nat'l authorities
Advantages	• Easier planning • Processing the complete set of SKUs right at the start	• Product master data and product pack data upload to EU Hub consistently done by applicable MAH at time of data upload
Disadvantages	• Early definition of master data by Acquirer in his systems even though Acquirer is not yet the MAH • Acquirer acting on behalf of Transferor until MA transfer is granted.	• Higher traffic on S/N exchange applications since for all products from 'Transferred Site', Acquirer has to deliver S/Ns to Transferor for data upload to EU Hub as long as MA transfer is not granted

The parties decided for **Option 2** considering the following specifics and limitations:

- Transfer of data ownership was only required for the few NTIN countries (since the product codes do not change in this case)
- For GTIN countries, the Acquirer assigned new GTINs and the existing product codes weren't re-assigned. As a result, no transfer of the history in EMVS for the Transferor's product codes took place.

Evolvement of Responsibility Split between Transferor and Acquirer for Packaging, Data Exchange, And Data Upload to EU Hub

The planning exercise in the work stream 'Serialization' of the carve-out project revealed that beyond agreement on the transfer of products codes in the EU Hub, a common understanding was required in detail on other aspects such as 'When will the artwork be changed?', 'Who is responsible for the packaging?', 'Are S/Ns to be exchanged?', 'Does the S/N format of the Transferor or that of the Acquirer apply?', and finally 'Who is responsible for the product pack data upload to the EU Hub?'.

The following table outlines these aspects for those of the divested products that are manufactured at the 'Transferred Site' and detailed according to the different Phases of a D&A activity as described in sec. 2 of this document.

Product Code Type	Transfer of Product Code Assignment in EU Hub		Phase 1: Prior to Day 1	Phase 2a: From Day 1 until MAH Transfer was Granted	Phase 2b: After MAH Transfer was Granted	Phase 3: After switch to Acquirer's Artwork
GTIN	No	MAH	Transferor	Transferor	*Acquirer*	Acquirer
		Product Code	Transferor's GTIN	Transferor's GTIN	Transferor's GTIN	*Acquirer's GTIN*
		Artwork	Transferor	Transferor	Transferor	*Acquirer*
		Packaging by	Transferor	*Acquirer*	Acquirer	Acquirer
		S/N Exchange Connection	No	Yes	Yes	*No*
		S/N format	Transferor	Transferor	Transferor	*Acquirer*
		EU Upload by	Transferor	Transferor	Transferor	*Acquirer*
NTIN	Yes	MAH	Transferor	Transferor	*Acquirer*	Acquirer
		Product Code	NTIN	NTIN	NTIN	NTIN
		Artwork	Transferor	Transferor	Transferor	*Acquirer*
		Packaging by	Transferor	*Acquirer*	Acquirer	Acquirer
		S/N Exchange Connection	No	Yes	*No*	No
		S/N format	Transferor	Transferor	*Acquirer*	Acquirer
		EU Upload by	Transferor	Transferor	*Acquirer*	Acquirer

Table 1: Responsibility Split for Divested Products Packaged at 'Transferred Site' (Changes compared to previous columns highlighted in Italics)

It should to be noted that such detailing is required as well for all other packaging sites considering both the divested and the non-divested product portfolio and the applicable CMO – Customer relationships between Transferor and Acquirer as well as other customers i.e.

- Non-divested products packaged at 'Transferred Site' i.e. Acquirer acting as CMO for Transferor,
- Divested products with Transferor's non-divested site(s) becoming CMO for Acquirer,
- Divested products with Transferor's CMO becoming Acquirer's CMO,
- Non-divested products with customer of Transferor's 'Transferred Site' becoming customer of Acquirer upon site transfer.

8.3 Annex III: Product Code Ownership Transfer Consent Forms

8.3.1 Form Representative Acquirer OBP

"I (Forename + Name), (Role: SPOC, AR) of the OBP (CP Number + Name of Acquirer OBP) with the Organisation ID (please provide Organisation ID of the Acquirer OBP) confirm that the OBP (CP Number + Name of Acquirer OBP) will take over the full responsibility for the data uploaded by the previous PC owner (Name of Transferor OBP), as specified for the scenario (Scenario 1/Scenario 2). I am fully aware that this responsibility relates also to possible alerts regarding the data uploaded by the previous PC owner (Name of Transferor OBP). Furthermore, I am aware that the algorithm used for the SNs, uploaded by the previous PC owner (Name of Transferor OBP) might differ from the algorithm used by the new PC Owner. In addition, I acknowledge that EMVO will reserve its right to apply and invoice the resulting costs.

Hence, I (Forename + Name), (Role: SPOC, AR) of the OBP (CP Number + Name of Acquirer OBP) request EMVO to switch the PC Ownership in the affected environment(s) of the following product codes from (Name of Transferor OBP) to (CP Number + Name of Acquirer OBP) with the Organisation ID (please provide Organisation ID of the Acquirer OBP):

Affected Product Code(s)
XXXXXXXXXXXX with product name XXXXXXXXXXXXXXX

Affected Environment(s)
Integrated Test Environment (ITE)
Integrated Quality Environment (IQE)
Production Environment (PRD)"

8.3.2 Form Representative Transferor OBP

"I (Forename + Name), (Role: SPOC, AR) of the OBP (CP Number + Name of Transferor OBP) with the Organisation ID (please provide Organisation ID of the Transferor OBP) confirm that the OBP (Name of Acquirer OBP) will take over the full responsibility for the data uploaded by the previous PC owner (Name of Transferor OBP), as specified for the scenario (Scenario 1/Scenario 2). I am fully aware that this responsibility relates also to possible alerts regarding the data uploaded by the previous PC owner (Name of Transferor OBP). Furthermore, I am aware that the algorithm used for the SNs, uploaded by the previous PC owner (Name of Transferor OBP) might differ from the algorithm used by the new PC Owner

Hence, I (Forename + Name), (Role: SPOC, AR) of the OBP (CP Number + Name of Transferor OBP) confirm the request to EMVO to switch the PC Ownership of the following product codes from (CP Number + Name of Transferor OBP) with the organisation ID (please provide Organisation ID of the Transferor OBP) to (Name of Acquirer OBP) in the affected environment(s).

Affected Product Code(s)
XXXXXXXXXXXX with product name XXXXXXXXXXXXXXX

Affected Environment(s)
Integrated Test Environment (ITE)
Integrated Quality Environment (IQE)
Production Environment (PRD)

8.3.3 Form Information

- **Role**: Please note that only the Single Point of Contact (SPOC), SPOC Assistant or Authorised Representative (AR) listed in the OBP Portal at the time of the transfer can fill in the form.
- **CP Number**: The CP Number is the contract partner number. It follows the format "CPXXXX" (with X=number) and can be found in the top right corner of any page in the Participation Agreement.
- **Organisation ID**: The organization ID is the identifier in the EU Hub. It follows the format "XXXX" (with X=number) and can be found by clicking on "Open" in several steps of the OBP Portal: 4.2.3.1, 4.2.4.1, 4.3.3.1 or 4.3.4.1, depending on your environment and connection number.
- **Scenario**: Please choose between scenario 1 or 2 to define the receipt and processing of Alerts, as described in section 4.2.3 of this document.