Transfer of Marketing Authorisation

This page lists questions that marketing-authorisation holders (MAHs) may have on transfers of marketing authorisations. It provides an overview of the European Medicines Agency's position on issues that are typically addressed in discussions or meetings with MAHs in the post-authorisation phase. Revised topics are marked 'New' or 'Rev.' upon publication.

1. What is a transfer of marketing authorisation?

A transfer of marketing authorisation (MA) is the procedure by which the MA is transferred from the currently approved marketing authorisation holder (MAH) to a new MAH which is a different person/legal entity.

Such a transfer may result from the MAH's commercial decision to divest the MA, e.g. in the event of a merger/acquisition, or be needed in anticipation of the MAH ceasing to exist as a separate legal entity and the MA being taken over by another legal entity.

In case the same transfer is sought for several veterinary medicinal products, a common data package may be prepared but an application must be submitted for each marketing authorisation (i.e. 1 application per main EU authorisation number).

A change of name and/or address of the MAH is not a MA transfer if the holder remains the same person/legal entity. Such change would be notified through a variation not requiring assessment (VNRA), classification A.1.a of Commission Regulation (EU) 2021/17).

A transfer of MA can only be initiated once a MA has been granted. Where there is a need to change the proposed MAH during the initial Marketing Authorisation Application procedure, the applicant who initially applied for the MA is advised to contact the Agency via Service Now (see Q&A 14 below for more details).

From this point forward within these Q&As on transfers:

- the MAH of the MA to be transferred is termed the Transferor,
- the person/company to whom the transfer is to be granted is termed the Transferee.

References

- Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93

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- Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC

2. How shall I present my application for the transfer of my marketing authorisation?

Transfer applications consist of a cover letter accompanied by three attachments and other documents mentioned. The attachments (electronic documents) should be prepared following to a letter format bearing the name and contact details of the Transferor or Transferee, as appropriate. A template is provided for the cover letter and for each attachment to give guidance on the information expected to be included in each document.

1. Attachment 1: information concerning the Transferor, Transferee and concerned product(s) including date(s) of authorisation(s), and declarations that all the necessary information has been made available to the Transferee and that no other changes than those directly linked to the transfer were introduced in the product information – see 'Authorisation details' tab of the product-specific website on the European Medicines Agency website or as per the respective information in the Union product database.
2. Attachment 2: information about the product status on the market and a statement from the Transferee that they will take over all MAH responsibilities as of the date of the notification of the Commission Decision on the transfer OR agreement between the Transferor and the Transferee on a transitional period with a date for completion of the transitional period (referred to as the implementation date) - See also Q&A 5 below.
3. Attachment 3: information showing the capacity of Transferee to perform all the responsibilities required of a MAH under the Veterinary Medicinal Product Regulation.
4. A proof of establishment of the Transferee within the European Economic Area (EEA), issued in accordance with national provisions and dated within the last six months.
5. The summary of product characteristics and package leaflet bearing the name of the MAH to whom the transfer is to be granted must be provided electronically in Word format (highlighted using track changes) and in PDF format (clean), in all EU languages, Icelandic and Norwegian.

   Please be reminded that in accordance with Union data protection requirements, no personal data should be included in the annotated PIs. This applies to the English version and all the translations. Please submit annotated PIs in an anonymised format (i. e. names of the reviewers removed from the track-changes). If you do not wish to do so, please ensure that the individuals whose data is included consented to its sharing with EMA and its further sharing by EMA with third parties such as other applicants, marketing authorisation holders (MAH) and National Competent Authorities, as relevant. EMA expressly disclaims any liability or accountability for the presence of unnecessary personal data in the annotated PI submitted by the MAH.
6. It is recommended to include mock-ups of the outer and primary packaging bearing insert the name of the person to whom the transfer is to be granted the transfer application (see Q&A 9 below). More information on mock-ups can be found on the Agency website.

N.B.:

- The Cover letter must be signed by the Transferor.
- Attachments 1 and 2 must be signed by both the Transferor and the Transferee.
- Attachment 3 must be signed by the Transferee and the QPPV.

References

- Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93.
- Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC
- EU Implementation Guide on veterinary medicines product data in the Union Product Database Implementation of the requirements of Regulation (EU) 2019/6 for the Union database on veterinary medicinal products in the European Economic Area Chapter 2: Format for the electronic submission of veterinary medicinal product information(Vet EU IG Chapter 2 Initial submission (europa.eu))
- Mock-ups for veterinary medicines

3. How and to whom shall I submit my transfer of marketing authorisation application?

Applicants should closely follow any separate dedicated advice on the format/route of e-Submissions as this may change over time.

4. How shall my transfer of marketing authorisation application be handled (timetable)?

A transfer application follows a 30-day procedure following receipt of the application. There are no set submission dates. In order to choose the best submission date, especially in case of any other ongoing/expected procedures, the Transferor should contact the Agency via Service Now (for more details, see Q&A 14 below), at least 1 month before submission of the application.

Within 7 days upon receipt of the transfer application, the EMA will check whether the transfer application is correct and complete. In case the application is correct and complete, the Agency aims to finalise the procedure by Day 10. In case of an incorrect or incomplete application the applicant will be notified and required to provide the amended and/or additional documentation within 10 calendar days from the date of the EMA notification. The EMA will not be able to issue a favourable opinion on the transfer if the documentation is incomplete.

The Agency will finalize the procedure within 30 days from the receipt of a valid transfer application (or within 30 days upon receipt of the applicant's response if corrections or additional documentation were requested by the Agency to validate the application), provided fees were paid.

The transfer opinion will be sent to the Transferor, Transferee, the European Commission and national competent authorities. Subsequently, the European Commission will amend the initial marketing authorisation decision and notify both the transferor and the transferee. The transfer of the MA is authorised from the date of the notification of the Commission decision on the transfer.

Note: For products migrated to IRIS, the Opinion will be available to the Transferor through the IRIS Industry Portal. Please refer to the IRIS guidance page.

However, the Agency by mutual agreement with the Transferor and the Transferee can set an implementation date for the transfer (see also Q&A 5 below).

Reference

- Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93

5. How to choose the implementation date?

The implementation date is the date on which the Transferee takes over ALL responsibilities as the Holder of the MA.

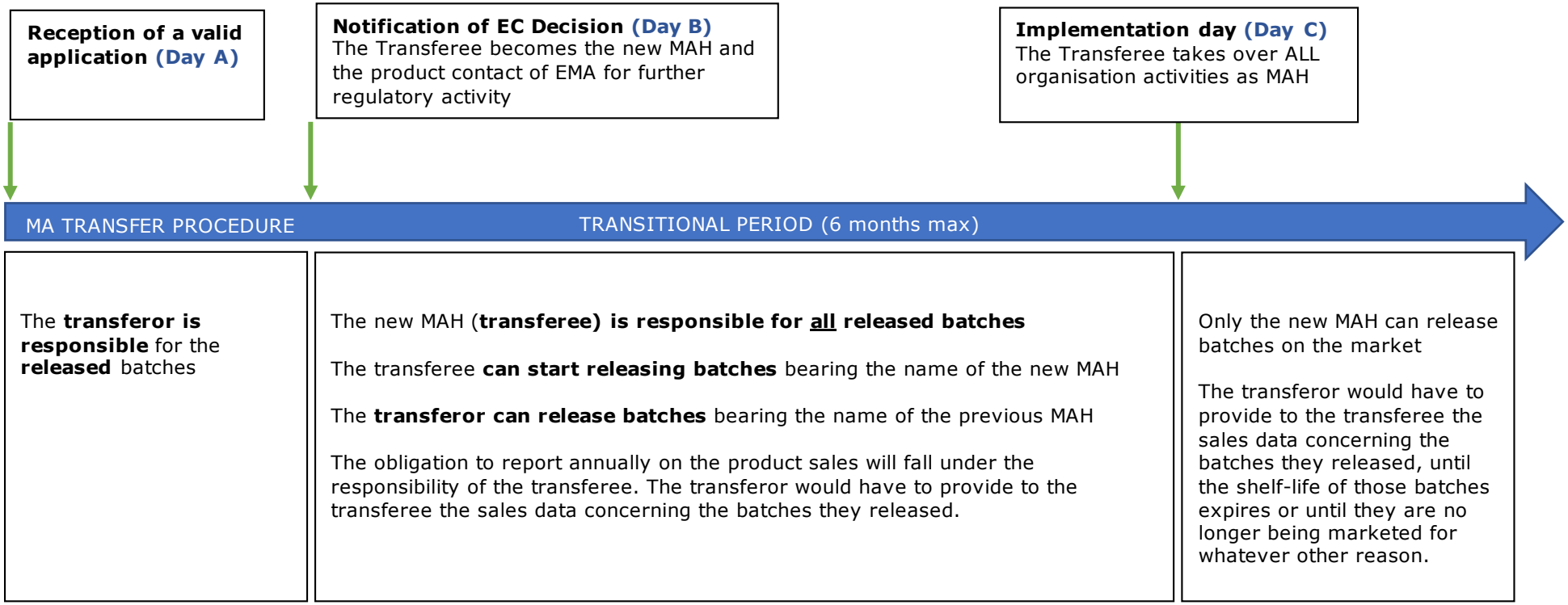
This date is proposed by the Transferor and Transferee in the transfer application (Attachment 2) and will be subject to agreement by the Agency. The implementation date will be stated in the opinion adopted by the Agency and also in the European Commission decision, and will be legally binding.

For the transfer of a marketing authorisation covering medicinal products already marketed by the Transferor, the proposed date should be set taking into account the following timelines (see also Q&A 4 above):

- The EMA timeframe for finalisation of the Opinion is 30 days from the receipt of a valid application (Day A)
- The Commission will subsequently issue a Commission decision on the Transfer of the marketing authorisation. As of the date of notification of the Commission Decision on the Transfer of the marketing authorisation (Day B), the Transfer is effective, and the Transferee becomes the new MAH of a concerned veterinary medicinal product.
- Between Day B and Day C (implementation day), there is a transitional period during which the previous MAH and the new MAH have to finalise their organisational arrangements, as defined in the Transfer application (e.g. contractual agreements as regards to batch release). The transfer application should include information as to the date on which the Transferor will release the last produced batch in the distribution chain, duly justifying why that particular date has been chosen. The transitional period between the notification of the Commission decision on the transfer of a marketing authorisation (Day B) and the implementation date (Day C) should be proportionate to the organisational activities that need to be performed by the Transferor and Transferee. Nevertheless, it should be noted that as of Day B, the Transferee becomes the new MAH of the medicinal product and the EMA will only deal with the new MAH for any further regulatory activity (e.g. variations applications).
- Before Day B the Transferor is responsible for released batches. As of Day B, the new MAH can start releasing batches. The batches released by the new MAH should be in accordance with the Annexes of the Commission decision on the transfer and therefore, these batches should have the name of the new MAH in the product information. During this transitional period and on the basis of the arrangements agreed between Transferor and Transferee, batches bearing the name of the previous MAH can be released as well. Nevertheless, it should be noted that as of Day B, the responsibility for all released batches falls on the new MAH.
- After day C only the new MAH (Transferee) can release batches on the market. The batches that have been released before Day C and that bear the name of the previous MAH can remain on the market.

  The obligation to report annually on the product sales will fall under the responsibility of the new MAH as of Day B. The Transferor would have to provide to the Transferee the sales data concerning the batches they released, until the shelf-life of those batches expires or until they are no longer being marketed for whatever other reason.

For the transfer of a marketing authorisation covering veterinary medicinal products not yet marketed by the Transferor, the proposed implementation date should refer to the day on which the Commission decision on the transfer will be issued.


Reception of a valid application (Day A)
Notification of EC Decision (Day B)
The Transferee becomes the new MAH and the product contact of EMA for further regulatory activity
Implementation day (Day C)
The Transferee takes over ALL organisation activities as MAH
MA TRANSFER PROCEDURE
TRANSITIONAL PERIOD (6 months max)
The transferor is responsible for the released batches
The new MAH (transferee) is responsible for all released batches
The transferee can start releasing batches bearing the name of the new MAH
The transferor can release batches bearing the name of the previous MAH
The obligation to report annually on the product sales will fall under the responsibility of the transferee. The transferor would have to provide to the transferee the sales data concerning the batches they released.
Only the new MAH can release batches on the market
The transferor would have to provide to the transferee the sales data concerning the batches they released, until the shelf-life of those batches expires or until they are no longer being marketed for whatever other reason.

6. What fee do I have to pay for my transfer of marketing authorisation application?

For information on the fee applicable for transfer applications, please refer to the fees payable to the European Medicines Agency.

References

- Fees payable to the European Medicines Agency
- How to pay

7. How to handle planned or ongoing variations procedures during the transfer of marketing authorisation?

MAHs should avoid submitting variation procedures in parallel to a transfer of MA application.

MAHs are strongly advised to contact the Agency in advance of the submission of the transfer of marketing authorisation application, in order to discuss how to handle any planned/ongoing procedures (especially when the product information is affected) or when there are variations linked to the transfer procedure (other than the variations not requiring assessment mentioned in the answer to question 12). Log any request related to the future Transfer via Service Now (see Q&A 14 below).

Variation applications should preferably be finalised prior to the submission of a transfer application. Where a procedure affecting the product information is not yet finalised at the time of the submission of the transfer application, the last product information accepted/adopted should be used at the submission of the transfer application by the MAH.

If a variation procedure is finalised during the finalisation of the transfer procedure, the accepted/adopted variation changes must be used in the product information of the transfer opinion. The MAH will be asked to submit the updated product information electronically in all languages.

8. How to handle remaining post-authorisation measures (PAMs) when transferring a marketing authorisation?

Post-authorisation measures (PAMs), including recommendations, conditions or specific obligations (specific obligations are only applicable to MAs granted in exceptional circumstances - Article 26 of Regulation (EU) 2019/6)) may have been agreed at the time the CVMP opinion was granted for the medicinal product to be transferred. When PAMs are still pending for the veterinary medicinal product concerned, it is the responsibility of the Transferee to complete them within the agreed timeframe (as specified in the CVMP opinion and/or assessment report). PAMs will be listed in Attachment 2. Detailed information on fulfilment of PAMs, as well as the letter of undertaking template can be found in the Agency's post-authorisation guidance on PAMs.

References

- Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93.
- Q&A: Post-authorisation measures

9. Do I have to submit mock-ups?

According to point 6 in the Annex to Regulation (EC) No 2141/96 on transfers of centrally authorised medicinal products, mock-ups are to be included in the transfer application. However, in line with the current EMA guidance on veterinary mock-up requirements, it is recommended (not mandatory) that applicants provide at submission an English and multi-lingual ('worst-case') colour mock-up of outer and immediate packaging for each pharmaceutical form in each container type (e.g. blister and bottle) in the smallest pack-size. If not available, relevant example mock-ups of the marketed presentation may be submitted instead.

If the transfer only affects the MAH details on the packaging without any impact on the overall artwork design, a declaration stating that only the details of the MAH have been modified should be provided and there would be no need for the recommended submission of mock-ups.

Please consult the Q&A on mock-ups.

References

- Q&A: Mock-ups

10. Can I include changes to manufacturers in my transfer of marketing authorisation application?

Changes to manufacturers resulting from the transfer of the MA are not considered part of the transfer procedure. Therefore, the appropriate variation(s) should be submitted and handled separately. In such case, the MAH is advised to contact the Agency via Service Now (see Q&A 14 below) prior to submitting a transfer application in order to discuss the appropriate timeframe of such variation(s).

In addition, when the need for GMP inspections is anticipated by the MAH, it is advisable to contact the Agency well in advance of the variation and transfer submission.

11. Can I change the Qualified Person for Pharmacovigilance and what information on the summary of the transferee's pharmacovigilance system update should I submit as part of my transfer of marketing authorisation application?

A change to the Qualified Person for Pharmacovigilance (QPPV) can be notified as part of the transfer application without the need for a separate variation (see also Q&A 2 above, Attachment 3). The EMA will update the necessary databases.

If a summary of pharmacovigilance system master file (Summary of PSMF), or information regarding the PSMF location and reference number was previously submitted to the EMA by the Transferor for the concerned product, the new MAH (i.e. the Transferee) will have to vary the PSMF information contained in UPD via the submission of separate VNRAs C.5 (PSMF location) and C.6 (PSMF number/other information contained in the Summary PSMF which are not covered by other VNRA), once the Notification of the EC is received (see "How shall my transfer of marketing authorisation application be handled?"). The variations can be grouped.

In case no information on PSMF was previously submitted by the transferor, the transferee is invited to file a VNRA C.6 to introduce a Summary of PSMF for the product.

References

- Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93.
- Commission Implementing Regulation 2021/1281 of 2 August 2021 laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products.
- Commission Implementing Regulation (EU) 2021/17 of 8 January 2021 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6
- Union Product Database | European Medicines Agency (europa.eu)

12. Can I change the name of a veterinary medicinal product as part of a transfer application?

The name of a medicinal product can be changed as part of the transfer of marketing authorisation procedure. In case the name of the product to be transferred bears the name of the Transferor, it must be changed as the result of the transfer application and all batches manufactured after Day B (see Q&A 5 above) will need to carry the name of the new MAH or the new invented name.

Whatever the chosen new name structure (invented name or International non-proprietary name (INN) / common name + name of the Transferee), the proposed names will have to undergo the EMA (invented) name check procedure to verify their acceptability.

Ideally, the new name should be agreed before the submission of the transfer application. The Transferee is therefore advised to plan the submission of the proposed name(s) so that the (invented) name-check procedure is completed by this time, especially if the name of the transferred product refers to the Transferor (see above), and/or when the submission of mock-ups is intended (see Q&A 9 above).

For more information on the procedure to change the name of a veterinary medicinal product, please refer to the Q&A on changing the (invented) name of a centrally authorised veterinary medicine. See also the Pre-submission Q&A.

After the transfer is agreed (e.g. Day B, Notification of the EC Decision), the new marketing authorisation holder will have to submit a VNRA type A.2 in UPD to change the product name in the database. The new name can be used as soon as the VNRA is approved by the Agency.

References

- Q&A on changing the (invented) name of a centrally authorised veterinary medicine
- Pre-submission Q&A
- Commission Implementing Regulation (EU) 2021/17 of 8 January 2021 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6
- Q&A on Variations not requiring assessment
- Union Product Database | European Medicines Agency (europa.eu)

13. Will there be any publication on the transfer of marketing authorisation?

Yes, the change in MAH will be reflected in the UPD.

References

- Union Product Database | European Medicines Agency (europa.eu)

14. Who should I contact if I have a question when preparing my application or during the procedure?

If you cannot find the answer to your question in the Q&A when preparing your application, please contact us by raising a ticket via Service Now. Select post -authorisation queries followed by the sub-option "MAH transfer".

If you do not have an EMA Account, you may create one via the EMA Account Management portal. For further information or guidance about how to create an EMA Account reference the guidance "Create an EMA Account". If you have any questions about registrations, please send an e-mail to Reset.Password@ema.europa.eu. Failure to register may cause delay in communication.

The Agency aims to respond to your query within 10 working days. To help us deal with your enquiry, please provide as much information as possible including the name of the product in your correspondence.