CMDv/GUI/031

GUIDANCE

for

Marketing Authorisation Transfer – National Requirements

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AUSTRIA (AT)

**Type of procedure**

National procedure: Change of Ownership/Transfer of Title for marketing authorisations and registrations according to Art 25 Medicinal Products Act (Arzneimittelgesetz AMG)

**Documents to be provided**

- waiver declaration of the current marketing authorisation/registration holder
- take-over declaration of the future marketing authorisation/registration holder
- Proof of establishment of the new MAH
- Commitment to submit a variation for the change of the DDPS
- updated texts (SPC, PIL, LAB)
- MockUps

**Follow up requirements**

Along with the transfer, the DDPS will change. A variation classified according to the Classification Guideline is required. In case the product was first authorized through MRP or DCP, the variation is considered to go through MR.
BELGIUM (BE)

**Type of procedure**
Type IA variation, classified N.I.1. National administrative change – transfer MAH

**Documents to be provided**

- Application form

- Signed letter wherein the new MAH agrees to fulfill all duties for the concerned product(s)

- A letter signed by both parties and confirming/detailing the transfer of Pharmacovigilance data to the new MAH

- In case the distributor is to be changed a national variation type IA classified N.I.2. Change of distributor is requested.

- In case the language of the marketing authorization document needs to be amended (this depends on the linguistic role of the MAH), a national variation type IA classified N.I.3. Switch in language is requested.

- Along with the transfer, the DDPS changes. A variation classified under CII7 is required and will be handled as a type IB or type II depending whether the DDPS has already been assessed or not. This variation should be submitted in parallel with the transfer MAH.

In case the product was first authorized through MRP or DCP, the variation is considered to go through MR. In case the variation cannot be submitted in parallel with the transfer MAH, a commitment should be provided.
BULGARIA (BG)

Type of procedure

Documents to be provided: Application form

Follow up requirements
CROATIA (HR)

**Type of procedure**

**Documents to be provided**

- Application form
- Names and addresses of the old and new MAH
- Proof of establishment of the new MAH where his address is
- Agreement from the old MAH with transfer of MA to the new MAH
- Statement from the new MAH of acceptance of the transfer of MA
- List of VMP subject to a transfer with details (name, strength, packaging, MA number, validity of the license)
- Date of transfer
- Detail description of the PhV system of the new MAH
- Name, address, education of qualified person for PhV

**Follow up requirements**
CYPRUS (CY)

Type of procedure

Documents to be provided: Application form

Follow up requirements
CZECH REPUBLIC (CZ)

Type of procedure
A Transfer of Marketing Authorisation from the existing Marketing Authorisation Holder to a new Marketing Authorisation Holder has to be submitted nationally in spite of the original authorisation procedure (NP/MRP/DCP) and is handled as a specific national procedure via “Application for transfer of the marketing authorisation”. This specific national procedure falls outside of variations classification.

Fees
The fee amount should be paid according to the “CZ Fee Guideline” ÚSKVBL/UST 4/2008/Rev.3 to the appropriate account numbers.
Administrative fee: 2 000 CZK
Assessment fee: 4 900 CZK

Documents to be provided
- Declaration of the current marketing authorisation holder
- Declaration of the proposed marketing authorisation holder
- Written authority of the person authorised to communication by the proposed marketing authorisation holder
- Schedule for pharmacovigilance obligations transfer
- Document identifying the qualified person responsible for pharmacovigilance together with a curriculum vitae, the address, telephone and fax number and email
- Detailed description of the pharmacovigilance system of appropriate veterinary medicinal product, which will be introduced by the proposed marketing authorisation holder after transfer of marketing authorisation
- Proposal for Summary of Product Characteristics in Czech (hard copy and e-version)
- Proposal for Package Leaflet in Czech (hard copy and e-version)
- Proposal for labelling in Czech (hard copy and e-version)
- Proof of payment of the administrative fee
- Proof of payment of the costs reimbursement

Follow up requirements
None.
DENMARK (DK)

Type of procedure
A Transfer of Marketing Authorisation (MA) from the existing Marketing Authorisation Holder (MAH) to a new MAH has to be submitted nationally (also for MRP or DCP) as type IB variation no A.z. When a medicinal product is transferred from one holder to another, the entire medicinal product must be transferred, i.e. all pharmaceutical forms and strengths.

Please refer to the Danish guideline on variations to marketing authorisations for medicinal products

Documents to be provided-
1. Confirmations from both the entity holding the marketing authorisation and the entity to which ownership is to be transferred
2. Revised SmPC, package leaflet and labelling as word files

Follow up requirements
If the name of the MAH is included in the name of the medicinal product (the generic name), an application to transfer the ownership of the marketing authorisation to another holder must be accompanied by an application to change the name of the medicinal product at the same time. An application to transfer the ownership of a marketing authorisation and change the generic name can be applied for as a grouping on the same application form if the medicinal product has been authorised under the purely national procedure.
ESTONIA (EE)

Type of procedure

A Transfer of Marketing Authorisation (MA) from the existing Marketing Authorisation Holder (MAH) to a new MAH has to be submitted nationally (also for MRP or DCP) as type II variation no A.z – Transfer of marketing authorisation to different legal entity

Documents to be provided

1. Declaration stating the date on which the Transferor and the Transferee finalise the transitional organisational arrangements and the Transferee takes over all responsibilities (must be signed by both the Transferor and the Transferee).

2. Contact details of the person responsible for communication between the MAH and State Agency of Medicines and letter of authorisation.

3. Information on whether the pharmacovigilance system and Qualified Person for pharmacovigilance remain the same or are changed.

4. Revised product information and the implementation date of the variation.

5. Proof of establishment of the MAH in the EEA.

Follow up requirements

To introduce a new pharmacovigilance system of the new MAH a suitable variation should be submitted. For products registered through MRP or DCP, it is processed at MRP level.
FINLAND (FI)

Type of procedure
According to the FIMEA administrative regulation 2/2018

Documents to be provided
- Cover letter stating the name of the product, its strength, pharmaceutical form, marketing authorisation or registration number and to whom the marketing authorisation or registration is to be transferred (i.e. the new holder’s name, address and the contact person).
- An agreement on the transfer showing that the marketing authorisation or registration and the associated responsibilities and liability will be transferred to the new holder in their entirety shall also be annexed to the application
- Proposals for Summaries of Product Characteristics, package leaflets and labelling (including mock-ups)
- If the transfer to the new holder of responsibilities and liability relating to the packages of the old holder in connection with the transfer of the marketing authorisation or registration has been included in the contract between the holders, the packages of the old holder and the new one can be released simultaneously to the market for a maximum of six months. In this case the marketing authorisation or registration holder shall present the request for simultaneous marketing and the justification in connection with the transfer application

Follow up requirements
- The new marketing authorisation or registration holder shall submit the name and contact information of the person responsible for pharmacovigilance to Fimea.
- Final new mock-ups have to be submitted via type IB variation II.C.6 by the new MAH if these have not been submitted with the transfer application.
- It is the duty of the new MAH to submit DDPs variation
FRANCE (FR)

Type of procedure

Documents to be provided

A cover letter containing:
1. Names of the VMP concerned by the authorization transfer, the authorization number(s) and the date(s) on which the authorization(s) was (were) granted.
2. The information concerning the person authorized for communication during the procedure (name, telephone and e-mail).
3. The identification (name and address) of the holder of the MA to be transferred (proof of establishment in the EEA).
4. A document certifying that the complete and up-to-date file concerning the MA or a copy of this file has been made available to or has been transferred to the person whom the transfer is to be granted.
5. The commitment of the qualified person of all manufacturers to apply the conditions that have been identified by the MA, including the respect of the methods of manufacture and control.
6. Detailed description of PhV system that the new MAH plans to put in place.
7. The summary of the product’s characteristics : SPC/PL.

Follow up requirements
GERMANY (DE)

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)

Type of procedure
National variation application in accordance with the German drug law (§ 29 AMG)

Documents to be provided
- Application form

A complete national variation application form (national or EU application form) - in paper and originally signed – has to be sent to the BVL (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Mauerstraße 39 – 42, 10117 Berlin)

The originally signed paper version of the application form can be dismissed if the variation application is provided via CESP.

The variation type should be clearly indicated with the code number: “SKNR 0013, Zulassungsinhaber”.

In case the distributor is to be changed, an additional national variation type should be clearly indicated with the code number: “SKNR 0299, Mitvertreiber”.

Contact details of the old and new MAH.

The application must be submitted by the old MAH or the new MAH with a power of attorney from the current MAH authorizing the transfer.

- Additionally to the application form, the modified product information texts (SPC, labeling and PIL texts) have to be submitted to the BVL (track changes).

There is a choice between the submission of the texts according to the AMG-Einreichungsverordnung (AMG-EV) dated 21.12.2000 in electronic form to: tam-zulassung@amg-zulassung.de or alternatively the submission via CD-ROM or via CESP.

Instructions for electronic submission can be found on the homepage of the BVL or following the link http://www.bvl.bund.de/SharedDocs/Downloads/05_Tierarzneimittel/amg_ev/amg-ev.pdf?jsessionid=2F239F3B71032AAEEB710C01FE2FAAF1.2_cid332?__blob=publicationFile&v=3

English version:
- For introduction of a new MAH which is unknown to BVL legal details of the new MAH (e.g. proof of establishment, local representative) may be required.

**Follow up requirements**

For the PhV system, the new MAH submits its DDPS for approval.

**Paul-Ehrlich-Institut (PEI)**

**Type of procedure**

A Transfer of Marketing Authorisation from the existing Marketing Authorisation Holder to a new Marketing Authorisation Holder has to be submitted nationally in spite of the original authorisation procedure (NP/MRP/DCP) and is handled as a specific national procedure via “Application for transfer of the marketing authorisation”.

This specific national procedure falls outside of variations classification.

**Documents to be provided**

- Application letter
- Valid excerpt from the commercial register
- Updated national product information
- (word files – a) track-change mode version, b) clean version)
- Declarations from present and proposed MAH
- Statement of the implementation date of the MAH change
- Statement regarding possible changes in contact details of the QPPV and/or DDPS (in case of changes, these have to be applied for separately as variation following the MAH change*)

* Please note that although the change of the MAH is a purely national variation (notification) outside the Variation Regulation (EC) No 1234/2004 there might be a need for a follow up MRP variation in case the product has been authorised nationally following mutual recognition or decentralised procedure (MRP, DCP) and the change of MAH results in a change of DDPS / QPPV.
GREECE (EL)

Greece accepts applications via the CESP platform. Submission of a cover letter as a hard copy is mandatory. Declaration forms are accessible under www.eof.gr

**Type of procedure**

- Applications/declarations of current and proposed MAH (duly apostilled)

(Fees to be payed upon application, as type IB)

**Documents to be provided**

- Copy of the current greek MA
- A signed declaration of the current MAH about the transfer of the MA, a signed declaration of the proposed MAH accepting the MA and the inbetween agreement
- Should the trademark owner change, a A- other variation, type IA, is required
- A signed declaration of the new MAH:
  a) a listing of all pending measures or specific obligations; should neither be the case it must be mentioned that no pending measures or specific obligations exist
  b) that no other changes have been made to the product information (SPC, Labelling and Package leaflet) other than those to the details of the MAH and, if appropriate, the new details of the batch release site (variation B.II.b.2.c, type IA) and the local representative (variation C.II.6.a type IA)
- The SPC, the labelling, and the package leaflet (in clean mode and Track Changes)
- Changes of the DDPS. A variation classified under CII7 is required and will be handled as a type IB or type II depending whether the DDPS has already been assessed or not.

**Follow up requirements**

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HUNGARY (HU)

Type of procedure

Documents to be provided

- Application form
- Updated products literature
- Contract between the old and the new MAH
- List of affected products

Follow up requirements

- Updated DDPS if necessary should be submitted
ICELAND (IS)

Type of procedure

Documents to be provided

- Application form

- SPC, PL and labelling text with tracked changes (if applicable)

- Updated mock-up to be provided within time limits set in IMA’s approval letter

- In case there is a local representative for the new MAH, this should be mentioned in connection with the transfer

- Statement from the old and the new MAH confirming as of which date the transfer takes place, thereby transferring all responsibilities to the new MAH

Follow up requirements

- If the new MAH does not already hold a MA in Iceland, a DDPS should be submitted
IRELAND (IE)

Type of procedure
Transfer. Please find link to national documentation.

Documents to be provided
- Covering letter.
- Relevant transfer application form. For bulk transfer applications, only one application form is required. If necessary, provide an annex listing the VPA numbers, full product names and strengths.
- Signed statement from the old MAH/applicant and the new one.
- Information relating to the recall procedures of the new MAH as detailed in transfer forms.
- Evidence of establishment in the European Union, e.g certificate of incorporation or equivalent – only for companies or individuals not already holding a MA in Ireland.
- Proof of payment.

Note:
The existing MA must have a remaining period of validity at least three months. If the period is less than three months, the existing MA must be renewed before the transfer application can be processed.

Only the VPA number and the MAH’s name and address (and distributor if applicable) may be amended.

Follow up requirements
- Once the transfer has been completed no further stocks bearing the old MA number may be manufactured or released for sale by the qualified person. This is extended to six months for transfers directly relating to the UKs decision to exit the EU. Batches of the original product may be supplied from wholesale level for a period of twelve months after issue of the transferred authorisation. At the end of this period, any remaining stocks of the original product must be recalled from wholesale level.
- Evidence must be provided that a variation to replace or change an existing DDPS has been submitted or an explanation provided as to why no change or variation is necessary.
ITALY (IT)

Type of procedure

Type IB variation

Documents to be provided

- Request of the company (Transferee), equipped with a stamp duty (marca da bollo) of € 16,00;
- Proof of payment of the fee;
- SPC in MS Word format;
- Document with the header of both the old and the new owner, signed by both, as they declare the sale / purchase of medicine (notary deed or private deed authenticated);
- Declaration on the current pharmacovigilance system and commitment by new MAH to modify the DDPS and the QP as soon as received the MA transfer;
- Proof that the new MA holder is located in the EEA territory;
- Communication of the contact point for the recall of the batch in the case of quality defect;
- Declaration of the new company that nothing else is changed at the time of purchase;
- Letter of access to the DMF modified or CEP with "declaration of access" properly filled in with the new holder name;
- Copy of written confirmation from the manufacturer of active substances to inform Applicant in case of modification of the manufacturing process or specifications according to annex I Directive 2001/82/EC;
- Declaration of acceptance to manufacture for the new holder by the manufacturer site's Qualified Person (QP);
- CD-ROM complete with documentation.
LATVIA (LV)

**Type of procedure**

Type II variations

**Documents to be provided**

- Application for variation pointing a variation point. C.II.z *;
- Proof of payment **;
- Proof of establishment of the new MAH in the European Economic Area;
- Declaration regarding MA transfer procedure signed by the old MAH and the new MAH containing name, established address, telephone, fax and email address of the old MAH and the new MAH;
- Declaration that all complete and up to date files, including previous variations, have been transferred or made available to the new MAH by the old MAH;
- Contact details and power of attorney for the new person authorised for communication with NCA on behalf of the new MAH;
- The new MAH declares to have a suitable Pharmacovigilance system in place that allow to safeguard its responsibilities with respect to the products and, if necessary, can take appropriate action;
- Name, contact details and CV of the Qualified Person for Pharmacovigilance for the new MAH;
- Modified SPC, labeling and PIL texts (clean and track version);

* No more than 5 VMPs in one application form
** Separate charge for each VMP

**Follow up requirements**

- Variation to change the DDPS if necessary. The Guidelines on the details of the various categories of variations C(2013)28041 classifies a change in DDPS as C.II.7 : Introduction of a new Pharmacovigilance system. Depending on whether the DDPS of
the new MAH has already been assessed or not, the new MAH should apply for a type IB or II variation application respectively.

- Submit updated mock-ups for approval.
LIECHTENSTEIN (LI)

Type of procedure

Documents to be provided: Application form

Follow up requirements
LITHUANIA (LT)

**Type of procedure**
National procedure: in accordance with Article 1(2) of Commission Regulation (EC) No 1234/2008, this regulation shall not apply to the transfer of a MA from one marketing authorisation holder to another.

**Documents to be provided**

- Cover letter clearly stating the procedure requested, the name of the medicinal product concerned by the authorisation transfer, the authorisation number.
- The identifications (name, address and email) of the Transferor (current MAH) and the Transferee (proposed MAH).
- A document certifying that the complete and up-to-date file concerning the medicinal product or a copy of this file has been made available to or has been transferred to the Transferee.
- A document stating the date on which the Transferor and the Transferee finalize the transitional organizational arrangements. This is referred to as the implementation date.
- Proof of establishment of the Transferee within the EEA (the fees and details of payment may be found here: [http://www.nmvrvl.lt/en/authorization.of.vmrs/fees/](http://www.nmvrvl.lt/en/authorization.of.vmrs/)).
- Documents showing the capacity of the Transferee to perform all the responsibilities required of a MAH under Community Pharmaceutical legislation:
  - A document identifying the Qualified Person responsible for Pharmacovigilance (QPPV) together with his/her Curriculum Vitae, address, email address, telephone and fax number. The Where a Detailed Description of the Pharmacovigilance System (DDPS – Module 1.8.1) is authorised as part of the Marketing Authorisation, and the transfer has resulted in a change of the QPPV, a signed statement from the Transferee and new QPPV must be included, confirming that the Transferee has the services of the new QPPV and has the necessary means for the collection and notification of any adverse reaction occurring either in the Community or in a third country. However, changes to the DDPS resulting from the transfer other than the above mentioned require the submission of a separate variation by the new MAH, once the transfer has been finalized. The authorised DDPS would remain in force until the DDPS variation is finalized.
  - A document identifying the person/company authorised for communication between the Transferee and the Agency after authorisation on the Transfer of MA.
  - A document identifying the contact details of the person responsible for quality defects and batch recall including the Name, address, telephone, fax and E-mail address.
A signed statement that no other changes have been made to the product information (SPC, Labelling and Package leaflet) other than those to the details of the MAH and, if appropriate, the details of the local representatives.

- The SPC, the labelling, and the package leaflet bearing the name of the person to whom the transfer is to be granted (in Track Changes).

**Follow up requirements**

Once the transfer procedure has been finalized, application for variation to introduce Pharmacovigilance system of new MAH (C.II.7 (either C.II.7.a or C.II.7.b) depending on whether Pharmacovigilance system has been assessed by our Authority or not) should be submitted by a new MAH.
LUXEMBOURG (LU)

Type of procedure

Documents to be provided: Application form

Follow up requirements
MALTA (MT)

Type of procedure

**Documents to be provided** - Application form

Follow up requirements
NETHERLANDS (THE) (NL)

Type of procedure

Type IA variation

Documents to be provided

- Application form

- Submission letter clearly stating that it concerns a change of MA, producttype 313

- Name, established address, telephone, fax and email address of the old MAH

- Proof of establishment of the new MAH in the European Economic Area

- The new MAH must possess the appropriate licenses for production and/or distribution if applicable

- Amended SPC and product information

- Name, established address, telephone, fax and email address of the new MAH and name of contact person for defects and recalls after transfer

- The products for which the MA will change. If this is a long list of product this information may be provided as an appendix

- Declaration that the SPC, package leaflet and labeling texts will not be changed other than the marketing authorization and (of applicable) the product name

- A declaration from the old MAH agreeing to the transfer

- A declaration from the new MAH that they are taking over all rights and duties with regard to the MA

Follow up requirements

- Declaration of the new MAH that they will submit a variation to change the pharmacovigilance system (if applicable) as soon as possible during or after the transfer
With regard to the pharmacovigilance system, CII7 of the classification guideline applies – a type II or type IB, which depends on the fact whether the pharmacovigilance system has been assessed previously or not.
Type of procedure
Type IB
A. Administrative variation z) other variation

Documents to be provided
- Application form
- SmPC, patient information leaflet, PIL, labeling (mock-up)
- Confirmation from both parties on the agreement of transfer. It should also be confirmed that the transfer do not imply other changes to the product

Follow up requirements
- If the name of the medicinal product contains the names of the MA holder, a notification of change in name must also be submitted. This is classified as an administrative variation A2 in the variation regulation
- Change in MAH will also imply variation to the pharmacovigilance system. This is in the new variation regulation classified as a variation C.I.8 “Introduction of a new pharmacovigilance system”.
- If the product is approved via the MR or DCP, the transfer of MA to a new legal entity is regarded a purely national variation, while the change in name and variation to the pharmacovigilance system will have to be notified through the EU-procedure
POLAND (PL)

**Type of procedure**

**Documents to be provided**

- Application for change of MAH (letter with request for variation) – application is to be submitted by new MAH

- Current extract from the Chamber of Commerce for old MAH (original or notarized copy, with sworn translation in Polish) with the information on person(s) authorized to represent the company – the attached extract from company register should be issued not later than 6 months, before submitting the application of variation

- Current extract from the Chamber of Commerce for new MAH (original or notarized copy, with sworn translation in Polish) with the information on person(s) authorized to represent the company – the attached extract from company register should be issued not later than 6 months, before submitting the application of variation

- In case when the company (new MAH) is represented by the plenipotentiary, the Power of Attorney for this person has to be attached to the application for change of MAH (original or notarized copy, with sworn translation in Polish)

- Modified SPC, labeling and PIL text, clean and track change versions

- Mock-up

- Original (or notarized copy) of agreement between new and old MAH concerning passing of rights and responsibilities of MAH for the VMP, with sworn translation into Polish. The document has to be signed by the person authorized by the companies to sign this kind of documents. This has to be stated in the Extracts from the Chamber of Commerce for both companies.

- Statement of the new MAH that no other elements of MA for the product and registration documentation were changed.

- List of VMP including numbers of marketing authorization which are covered by the application for change of MAH

- Confirmation of fee payment for change in MAH

- Confirmation of duty fee payment for submission of Power of Attorney

**Follow up requirements**
PORTUGAL (PT)

Type of procedure
A transfer of a marketing authorization is a purely national procedure (including MRP, DCP), which falls outside of variations classification.

Fees
Proof of payment with the amount of 300 €. When the same transfer concerns more than one veterinary medicinal product, the cost of each supplementary act is reduced by 25% (225 €).

Documents to be provided

1. For the transfer of the market authorization holder is necessary the following documentation:
   a) Name of veterinary medicine that the transfer of the market authorization relates, number (s) of authorisation and date (s) in which the permission was granted.
   b) Identification (name and address) of the market authorization holder to transfer and identification (name and address) of the holder for which the transfer is made.

2. The application referred to in the preceding paragraph shall be accompanied by the following documents:
   a) proof that the process complete and updated on veterinary medicine in question has been or will be made available to the holder for whom the transfer is made;
   b) Document to propose the date set for the transfer and from which, without prejudice to the final decision, the holder for whom the transfer is made can physically take all responsibilities of the market authorization holder concerned to replace the previous holder.
   c) Summary of product characteristics, label and package leaf left containing the name of the holder for whom the transfer is made in word format (with the changes in track changes).

3. The documents referred to in points of the preceding paragraph shall be signed by the market authorization holder and the holder for whom the transfer is made.

4. The request for transfer of the market authorization holder should also be accompanied by the necessary documents, supplied and signed by the holder for whom the transfer is made to demonstrate their competence to assume the responsibilities regularly assigned to the market authorization holder, including:
a) A document that identifies the responsible for pharmacovigilance, curriculum vitae, indicating the address and phone numbers.

b) Document identifying the department responsible for scientific information on veterinary medicinal products

c) The new holder shall inform the national competent authority that it will replace or amend an existing detailed description of the pharmacovigilance system (DDPS) or provide a justification if no change or variation is necessary.

For all National procedures the contact is: national@dgav.pt

**Follow up requirements**

Once the transfer is finalized, an application for a variation to introduce a new DDPS should be submitted depending if the MAH is new and no information about the MAH is present in the agency.
Type of procedure
National procedure

Documents to be provided

- request for transfer of MA for a veterinary medicinal product:

The following documents should accompany the request for the transfer of MA for a veterinary medicinal product:

1. the marketing authorization of the product for which the transfer is requested,
2. the statutory declaration of the MAH, indicating that the full dossier of the veterinary medicinal product or a copy of this dossier was made available or transferred to the new MAH,
3. the statutory declaration regarding the date from which the applicant takes over, through the transfer, all responsibilities from the MAH of veterinary medicinal product
4. the written consent of the MAH and applicant, as regards the date of implementation of the transfer of MA
5. documents emphasizing the capacity of the applicant to fulfill all responsibilities of a MAH, according to the specific legislation in force, namely:
   a. power of attorney of the responsible person with pharmacovigilance, indicating name, surname, address, telephone, fax, e-mail and CV; the responsible person with pharmacovigilance should be permanent at the disposal of the new MAH, to have the head office in Romania or EU;
   b. identification document (identity card / articles of incorporation) of the self employed person or legal person authorized for communication between the new MAH and Institute for Control of Veterinary Biological Products and Medicines, after the approval of the transfer of MA;
   c. mandate for the contact person responsible for ulterior complaints regarding the product, indicating the name, address, telephone, fax, e-mail.
6. statutory declaration of the MAH, mentioning that the veterinary medicinal product for which a transfer is requested has not been placed yet on the market, in any of its presentation forms
7. statutory declaration of the applicant of the transfer of AC as regards remaining measures or specific obligations; if none of the two aspects is valid, in declaration will be mentioned the fact that no more remaining measures or specific obligations are to be fulfilled,
8. statutory declaration mentioning that no other changes related to product information were made, except those involving the MAH, and details regarding the local representative, if necessary,
9. package leaflet of the product,
10. summary of product characteristics
11. label

**Follow up requirements**
Updated DDPS if necessary should be submitted
SLOVAK REPUBLIC (SK)

Type of procedure
A transfer is a purely national procedure (including MRP, DCP), which falls outside of variations classification. There is a separate application form - Application for transfer of the marketing authorisation.

Documents to be provided

- Written consent of the proposed marketing authorisation holder to fill obligations mentioned in § 98 of Act No.362/2011 about Medicaments and Medical Devices
- Written authority of the person authorised to communication by the proposed marketing authorisation holder
- Schedule for pharmacovigilance obligation transfer
- Confirmation that the proposed marketing authorisation holder has a qualified person responsible for pharmacovigilance (QPPV), contact information, curriculum vitae
- Description of the pharmacovigilance system of the proposed marketing authorisation holder
- Summary of Product Characteristics in Slovak language
- Proposed labelling in Slovak language
- Proposed Package Leaflet in Slovak language
- Proof of payment of the administrative fee

Follow up requirements

None.
SLOVENIA (SI)

Type of procedure

Documents to be provided

To transfer the MA an application including following documents is required:
- Cover letter (signed, containing following data: name and address of current MAH, name and address of proposed MAH, type of application -> transfer of MA, name of VMP(s), pharmaceutical form and strength, proposed date of the implementation of MAH transfer, signed by authorised person of the current MAH).
- Documentation for MAH transfer:
  o Table with all VMPs which are subject of the transfer
  o Statement of the current MAH that they agree with the transfer and that they are transferring all the obligations considering the MA
  o Statement of the proposed MAH that they accept the transfer and they are aware of the obligations
  o Updated SPC, PIL and labelling
  o DDPS of the proposed MAH

The application for transfer of MA has to be submitted by the current MAH.

The fee is 250€ for a transfer of a single VMP and not more than 1.000€ in case of multiple transfers. The fee is not required in advance, the applicant will receive an invoice after the submission of application. Please see: http://www.jazmp.si/en/fees/#c1534

The transfer is implemented after approval, the transition period is six months.

Follow up requirements

-
SPAIN (ES)

**Type of procedure**
Type II variation, special fee.

**Documents to be provided**
- Application form
- Cover letter describing the change
- Identification (name and address) of the market authorization holder to transfer and identification (name and address) of the holder for which the transfer is made
- Proof of sale of the medical product subject of the change
- Declaration of the new holder to fulfil the marketing authorization conditions including to obey the current manufacturing and control processes
- Proposal for mocks-ups, summary of product characteristics, packaging, labelling and package insert.
- For MR/DCP products, detailed and clear documented contractual arrangements between the MAH, in which the holders should allow a harmonised surveillance at EU level and designate only one Qualified Person for Pharmacovigilance (EU-QPPV) for this product, in charge of EU surveillance.
- For pure national products, the DDPS of the new MAH should be included in the variation for the MAH transfer.

**Follow up requirements**
Only for MR/DCP products:
- The new MAH should submit the DDPS including a product specific addendum specifying that, for this product, the main pharmacovigilance tasks, in particular signal detection and PSURs at EU level are subcontracted to the old MAH or that the new MAH is in charge of EU surveillance, including MS where the MAH is the old one. EU variation is needed.

- If the MAH remains unchanged in Spain, the DDPS from the old MAH should be submitted including a product specific addendum stating that, for this product, the old MAH is in charge of EU surveillance, including countries where the MAH is the new one or that the main pharmacovigilance tasks, in particular signal detection and PSURs at EU level are subcontracted to the new MAH. For this change either a variation or a notification is needed according to the national requirements.
**Type of procedure**
National notification.

If the transfer should be implemented on a specific date in that case the notification should be submitted three months in advance.

For more information please refer to the FAQ on MPA’s website:

**Documents to be provided**

- Application form
- Wholesale license for the new MAH
- Proof of establishment for new MAH
- SmPC, PIL and labeling text with tracked changes (if applicable)
- Latest approved version of the mockups and the new final version (if applicable)

**Follow up requirements**

- In the approval letter, the MAH is requested to submit the new DDPS for the new MAH
UNITED KINGDOM (UK)

Type of procedure
Type IB variation

Documents to be provided
- Application form

- Confirmation that the new MAH has considered the DDPS either by confirming that this will not change or that they have or are going to submit a new DDPS to add to the dossier to reflect the change in holder.

- Formal letters of transfer from the current and proposed MAH

- Proof of establishment of the company; only applicable if the new MAH does not already hold any current marketing authorisations

Follow up requirements
- EU variation to change the DDPS