



Federal Office of
Consumer Protection
and Food Safety

Paul-Ehrlich-Institut



Federal Institute for Vaccines
and Biomedicines



Austrian
Federal Office for
Safety in Health Care
BASG

famhp
federal agency for medicines and health products

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**GUIDANCE
FOR
HARMONISATION OF THE GERMAN LANGUAGE TRANSLATION OF
PRODUCT INFORMATION
FOR VETERINARY MEDICINAL PRODUCTS IN MRP/DCP**

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1. INTRODUCTION

Article 7 of Regulation (EU) 2019/6 permits, in its subsections (1) and (2), the use of multi-lingual (two or more languages) and multi-country (same language applicable for two or more Concerned Member States (CMS)) packaging, on condition that the same information appears in the product information of the veterinary medicinal product (VMP). The establishment of multi-lingual and/or -country packaging is an important mechanism for increasing and maintaining the number of VMPs on EU markets, especially on so called “small markets”. In particular, German language translations of product information for VMPs in MRP/DCP are increasingly requested. This document has been elaborated between Member States with German as official or allowed language in their countries to take up these developments and make allowance for the benefits of multi-country packaging for the availability of VMPs.

2. AIM AND SCOPE

This document aims to assist Applicants in preparation of shared German language packages for VMPs and to facilitate the translation harmonisation process between the affected NCAs within the scope of MRP/DCP for marketing authorisations, variations requiring assessment (VRA) and SPC harmonisations of reference VMP.

For harmonisation of product information of purely nationally authorised VMPs, the worksharing procedure according to Article 65 of Regulation (EU) 2019/6 will generally apply (see CMDv Best Practice Guide for the processing of SPC, Labelling and Package leaflet and the preparation of Multilingual/-country Packaging provided in support of MRP/DCP/SRP and Variations).

The procedure is of administrative nature and enables a co-ordinated joint linguistic review of German product information texts between the NCAs affected. It aims to avoid repetition of work and to improve the quality of translations due to review by all involved NCAs.

It will be initiated upon request by the Applicant, except for procedures according to section 6. of this guidance.

The translation harmonisation procedure in accordance with this guidance applies to the NCAs of AT/BE/DE as applicable. If the applicant intends to use the final harmonised German-language translation for further Member States, e.g. Luxembourg and/or the Netherlands, he may convey the harmonised German-language translation to those Member States after completion of the translation harmonisation procedure. Regarding the Concerned Member State Liechtenstein, AT acts on behalf of LI according to the Agreement BGBl. III No. 126/2010.

3. REFERENCES AND RELATED DOCUMENTS

This guidance should be read in conjunction with the following documents:

- CMDv Best Practice Guide for the processing of SPC, labelling and package leaflet and the preparation of multilingual/-country packaging provided in support of MRP/DCP/SRP and variations

- [EMA Veterinary product information \(QRD\) templates](#)
- CMDv Best Practice Guide for the submission of high-quality national translations for veterinary medicines
- CMDv guidance on national-specific labelling/ package leaflet information
- CMDv recommendations on labelling and packaging of veterinary medicinal products
- National guidance in German speaking Member States for processing of product information documents (SPC, labelling and package leaflet) (Annex 4 to this guidance document)
- CMDv procedural contact points
- CMDv overview of MS's requirements during national phase

4. PREREQUISITES FOR MULTI-COUNTRY PACKAGING

- Same (invented) name, pharmaceutical form, strength(s) and target species of the VMP
- The content of the approved text in the SPC/labelling (LAB)/package leaflet (PL) must be identical in the MSs except for national-specific requirements.

5. DESCRIPTION OF THE PROCEDURE

5.1 Submission of translation in German language

- Preparation of high-quality German translation in compliance with the documents listed in Annex 3 and Annex 4 to this guidance document.
- Submission of the German translation in line with the requirements for the respective procedure.
- For non-immunological VMPs, the submission of the proposed German product information texts for harmonising the translation must include the filled and signed request form for common translation procedure according to Annex I to this guidance.
- One combined text file of SPC/LAB/PL in word format (.docx) for each VMP must be submitted identically and simultaneously to all involved NCAs. The national-specific information must be clearly indicated per country using the respective country code (e.g. „AT:", „BE:", „DE:").
- The German translation should be sent to the involved NCAs according to the CMDv submission document and CMDv procedural contact points.

5.2 Revision of German translation between involved NCAs

5.2.1 Selection of Lead NCA

After simultaneous submission of German translations by the Applicant with the request of multi-country packaging, the involved authorities agree upon the “Lead NCA” which will start the

text review and take over the coordination of communication with “Affected NCA” authorities and the Applicant.

The following scenarios are considered for acting as the Lead NCA:

- a) A German-speaking NCA is RMS in the relevant MR-/DC-procedure.
- b) If all involved NCAs are CMSs, DE will act as Lead NCA in the translation harmonisation process.
- c) If all involved NCAs are CMSs and DE is not a CMS and/or not affected by multi-country-packaging, AT will start with the review and coordination between the Affected NCAs

Any German-speaking NCA involved but not acting as Lead NCA will generally act as Affected NCA. Where AT is involved in the MR-/DC-procedure but not acting as Lead NCA, AT will generally act as Affected NCA 1.

5.2.2 Review process

Only the common German texts corresponding to the approved final EN product information will be reviewed regarding correct linguistic and complete translation by all involved NCAs within the translation harmonisation procedure. The clearly marked national-specific information in the shared multi-country packaging will be reviewed solely by the respective NCA. In case of any changes concerning national-specific information, the Applicant shall inform the German-speaking NCAs involved in the multi-country packaging about the updated national-specific information. Any change of national-specific information approved by the respective NCA can be implemented immediately and will be taken into account within the next revision of the product information.

In general, for non-immunological VMPs, the following procedural steps and target timelines will be followed. Where a procedural step is not required in a specific case, the procedure may be shortened accordingly. Where technically and objectively feasible, the relevant NCAs may choose to apply shorter timelines.

D0:

The shared German translation harmonisation procedure will automatically start after simultaneous submission of the German translations by the Applicant with the request of multi-country packaging to all involved NCAs.

By D30:

The Lead NCA assesses the submitted German product information text, includes any proposed amendments in tc (track changes)-mode and sends the tc document to the Affected NCA(s).

By D37:

The Affected NCA 1 maintains the tc mode in the reviewed German product information text and adds any further changes or comments also in tc mode. The Affected NCA 1 sends the revised version to the Lead NCA and other Affected NCAs involved in the procedure.

Absence of comments will be considered as a silent agreement.

By D44 if applicable:

Other Affected NCAs, if any, include any further proposed amendments/comments in the text version circulated by the Affected NCA 1 in tc mode and send the document to the Lead NCA and to all Affected NCAs involved in the procedure.

Absence of comments will be considered as a silent agreement.

5.3 Agreement of revised German translation with the Applicant

By D44/51:

The Lead NCA forwards the German product information text as agreed between the involved NCAs in tc mode to the Applicant.

Clock-stop of 1 week

If the Applicant notices any necessary corrections in the reviewed product information text, the Applicant shall include the proposed corrections in tc mode and send the document to the Lead NCA and to all Affected NCAs within one week.

Absence of comments will be considered as a silent agreement.

By D51/58 as applicable:

The Lead NCA and all Affected NCAs evaluate the Applicant's proposed amendments, if any. Otherwise, the procedure will be finalised.

5.4 Finalisation of national phase by involved NCAs

By D56/63:

The Lead NCA closes the procedure and sends the final agreed German product information text to the Applicant and all Affected NCAs.

Subsequently, the Lead NCA and all Affected NCAs will close the national phase and issue or amend the national licence(s), as applicable.

Once the translation harmonisation procedure has been completed, further changes to the translation will generally require a subsequent variation.

6. HARMONISATION OF THE GERMAN LANGUAGE VERSION OF PRODUCT INFORMATION OF REFERENCE VMP AFTER SPC HARMONISATION WITHOUT APPLICANTS'S REQUEST

With regard to SPC harmonisation of reference VMP the following applies: Even if the Applicant does not request a common German translation for the product information texts and multi-country packaging, the alignment will be carried out concerning the German translation for the general, non-country specific information, because a common translation is relevant for the subsequent amendment of generics/hybrids to the reference VMP with regard to the German translations. This alignment also applies in case the reference VMP is not authorised in one of the countries as generics/hybrids might still be authorised there.

However, if the Applicant requests common German translations for product information texts and multi-country packaging, the procedure as described in section 5 is followed.

ANNEX 1: REQUEST FORM FOR THE HARMONISATION OF THE GERMAN-LANGUAGE TRANSLATION OF PRODUCT INFORMATION OF NON-IMMUNOLOGICAL VMPS IN MRP/DCP

Involved German Speaking Member State(s) selected by the Applicant

Please note the information in section 1 of the guidance regarding NL, LU and LI.

AT BE DE

Concerned Common Translation Procedure

Please note the prerequisites for multi-country packaging (according to guidance section 4):
Same (invented) name, pharmaceutical form, strength(s) and target species

EU procedure number: Klicken oder tippen Sie hier, um Text einzugeben.

Type of procedure: Marketing authorisation Variation SPC Harmonisation
of reference product

Full Name of VMP Klicken oder tippen Sie hier, um Text einzugeben.
(according to SPC Section 1.):

Applicant's contact details

Name and address: Klicken oder tippen Sie hier, um Text einzugeben.

Name of contact person: Klicken oder tippen Sie hier, um Text einzugeben.

E-Mail: Klicken oder tippen Sie hier, um Text einzugeben.

Declaration of the Applicant

I hereby apply for the common German-language translation harmonisation procedure and I declare that:

1. This application, including all relevant translations of product information texts, has been submitted identically and simultaneously to all participating Member States.
2. Due to the translation harmonisation procedure that I have requested, the notification of the MA may be/will be issued outside the statutory period.
3. The shared translation harmonisation procedure will be conducted according to the Guidance for the harmonisation of the German-language translation of product information of VMPS in MRP/DCP.
4. The involved NCAs may share the documentation/information relevant to this procedure.

Name _____

Job title _____

Date _____

Signature _____

ANNEX 2: LIST OF USED ABBREVIATIONS

CMDv	Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products
CMS	Concerned Member State
D	Day
DCP	Decentralised Procedure
EMA	European Medicines Agency
MRP	Mutual Recognition Procedure
MS	Member State(s)
NCA	National Competent Authority
LAB	Labelling
PL	Package leaflet
QRD	Quality Review of Documents
SPC	Summary of Product Characteristics
SRP	Subsequent Recognition Procedure
VRA	Variation requiring assessment
VMP	Veterinary Medicinal Product

ANNEX 3: LIST OF RELATED DOCUMENTS

EMA-QRD/CMDv	QRD veterinary product information annotated Template (English and translations)
EMA/CVMP/PhVWP/288284/2007	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse events in animals and humans
EMA/CVMP/PhVWP/10418/2009	Combined VeDDRA list of clinical terms for reporting suspected adverse events in animals and humans to veterinary medicinal products
EMA/CMDv/563813/2021	Best Practice Guide for the processing of SPC, Labelling and Package leaflet and the preparation of Multilingual/-country Packaging provided in support of MRP/DCP/SRP and Variations
EMA/CMDv/5098/2022	Best Practice Guide for the submission of high-quality national translations for veterinary medicines
EMA/776723/2017	QRD guidance on the use of adopted abbreviations and pictograms on the packaging of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised (DCP), subsequent recognition (SRP) and national procedures
EMA/364980/2017	Quick Response (QR) codes in the labelling and/or package leaflet of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised procedures (DCP) and national procedures
EMA/102667/2014	Mock-ups checklist - Guidance for checking mock-ups
EMA/27236/2003	Tables of non-standard abbreviations
EMA/315185/2010	List of official languages per country
EMA/CMDv/717493/2021	National requirements on submission of documents during the national phase for new marketing authorisation applications via MRP/DCP
EMA-CMDv-702142-2021	CMDv procedural contact points
EMA/CMDv/22456/2022	Guidance on national-specific labelling/package leaflet information
EMA/CMDv/308754/2021	Best Practice Guide for variations not requiring assessment
EMA/CMDv/144277/2021	Best Practice Guide for variations requiring assessment
EMA/CMDv/398214/2021	Best Practice Guide for the harmonisation of the SPC of the reference products

EMA/CMDv/398218/2021	Best Practice Guide for the harmonisation of the SPC of generic/hybrid veterinary medicinal products
EMA/CMDv/314348/2021	Q&A – List for the submission of variations according to the Regulation (EU) 2019/6
EMA/CMDv/717292/2021	Recommendations on labelling & packaging of veterinary medicinal products
EMA/CMDv/5116/2022	Position paper on agreeing the product name during the decentralised procedure

ANNEX 4: LIST OF PUBLISHED RELEVANT NATIONAL GUIDANCE IN GERMAN SPEAKING MEMBER STATES FOR PROCESSING OF PRODUCT INFORMATION DOCUMENTS (SPC; LABELLING AND PACKAGE LEAFLET)

Member State	Published national guidance documents
Austria	<p>Assistance for submission of high-quality national translations for human and veterinary medicinal products after approval of DCP/MRP: https://www.basg.gv.at/en/companies/marketing-authorisation-life-cycle/marketing-authorisation-procedure/mrp/dcp-authorisation/mrp/dcp-national-translations</p> <p>AT Guidance document – naming of medicinal products: https://www.basg.gv.at/en/companies/marketing-authorisation-life-cycle/faq-marketing-authorisation-life-cycle/naming-of-medicinal-products#c18978</p> <p>Accessible product information: https://www.basg.gv.at/en/companies/marketing-authorisation-life-cycle/marketing-authorisation-procedure/accessible-patient-information-leaflet</p>
Belgium	<p>Rule for the harmonisation of SPC, labelling and PL: https://www.famhp.be/en/belgian_rules_for_the_harmonisation_of_spc_labelling_and_patient_information_leaflet</p> <p>BE Guidance document – naming of medicinal products: https://www.fagg.be/sites/default/files/downloads/RL%20naamgeving%20dgm%20-%20V0_0_2-%20NL.pdf https://www.afmps.be/sites/default/files/downloads/RL%20naamgeving%20dgm%20-%20V0_0_2-FR%20(2).pdf</p>
Germany DE-BVL	<p>Hinweise zu Vorlagen für Produkttexte für Tierarzneimittel: DE: https://www.bvl.bund.de/DE/Arbeitsbereiche/05_Tierarzneimittel/04_AntragstellerUnternehmen/08_AllgemeineHinweise/01_Hinweise_Verfahren/05_Hinweise_TAM-Produkttexte/Hinweise_TAM-Produkttexte_node.html</p> <p>EN: https://www.bvl.bund.de/SharedDocs/Downloads/05_Tierarzneimittel/Rechtsgrundlagen/01_EU/Product-information-templates-Advice.html?nn=19452776</p>
Germany DE-PEI	<p>Für die Kennzeichnung eines immunologischen Tierarzneimittels bittet das PEI um die Verwendung der von der EMA veröffentlichten Formatvorlagen (Product information templates): https://www.ema.europa.eu/en/veterinary-regulatory/marketing-authorisation/product-information/veterinary-product-information-templates#current-template-(v.9)-section</p>