EMA/CMDv/386218/2021

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| **BEST PRACTICE GUIDE**  **for**  **the selection of products for SPC harmonisation**  **Edition number: 01**  **Edition date: 8 October 2021**  **Implementation date: 28 January 2022** |

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## 1. INTRODUCTION

With the entry into application of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products (VMPs) and repealing Directive 2001/82/EC, a new procedure, the SPC harmonisation procedure, was created as per section 4 of this regulation.

The initial objectives of the Regulation (EU) 2019/6 should be taken into account, more specifically the objectives of reducing administrative burden, enhancing the functioning of the internal market, increasing availability and safeguarding public health, animal health, animal welfare and the environment.

## PROCEDURE PHASES

The SPC harmonisation procedure for veterinary medicinal products can be divided into three phases:

1. Selection phase

* 1. Examination phase for the reference veterinary medicinal product
  2. National phase for updating the SPC of the reference veterinary medicinal product
  3. Harmonisation of the SPCs of generic and hybrid veterinary medicinal products
  4. National phase for updating the SPCs of the generic and hybrid veterinary medicinal products

According to this procedure National Competent Authorities (NCA) as well as Marketing Authorisation Holders (MAH) may propose harmonisation of the SPCs of Reference Veterinary Medicinal Products (RVMPs) for which a marketing authorisation has been granted in accordance with Article 47.

The Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMDv) shall annually draw up a list of reference VMPs which shall be subject to SPC harmonisation and the CMDv shall also appoint a reference Member State (RMS) for each VMP concerned.

The purpose of this Best Practice Guide (BPG) is:

* + 1. To provide guidance to NCAs and MAHs on the procedure for proposing reference VMPs to be harmonised in accordance with article 70 of the Regulation (EU) 2019/6.
    2. To provide guidance for the CMDv and the NCAs on the selection of VMPs for SPC harmonisation and the designation of a reference Member State for each VMP concerned.

## AIM AND SCOPE

This BPG describes phase 1 of the SPC harmonisation procedure of the reference products on the selection of the VMPs for SPC harmonisation and the designation of a reference Member Sate for each VMP concerned.

The second phase of the SPC harmonisation procedure (the examination phase for the RVMP) is described in the BPG for the harmonisation of Reference Veterinary Medicinal Products. And the last phase (the harmonisation of the generics and hybrids) is described in the BPG for the harmonisation of generic and hybrid products . As a consequence, this document must be taken into consideration together with the BPGs for phase 2 and 3 of the SPC harmonisation procedure.

‘Reference veterinary medicinal products’ in the framework of this BPG as well in the other CMDv BPGs on SPC harmonisation may be considered as:

all VMPs that have obtained a marketing authorisation in several Member States following the procedure mentioned in article 47 of the regulation 2019/6/EC and that are not generics or hybrids. RVMPs have been authorised in accordance of the Article 8, 20 or 22 of Regulation.

In the scope of the SPC harmonisation procedure, immunological as well as non-immunological VMPs can be considered as RVMPs subject to SPC harmonisation in the framework of article 70 of the regulation 2019/6/EC. In the scope of the BPGs for SPC harmonisation the term ‘pharmaceutical products’ will be used to indicate non-immunological VMPs.

This BPG has been prepared by the CMDv to be used in SPC harmonisation procedures by Reference Member States (RMS), Concerned Member States (CMS) as well as the marketing authorisation holders (MAH), in order to facilitate the SPC harmonisation procedure.

## REFERENCES AND RELATED DOCUMENTS

* + Regulation (EU) 2019/6
  + BPG for the Harmonisation of Reference Veterinary Medicinal Products
  + BPG for the Harmonisation of generic and hybrid products

*The full list of CMDv documents related to this BPG can be found at the end of the document.*

## DESCRIPTION OF THE PROCEDURE

During the selection phase, reference VMPs for which SPC harmonisation is proposed are to be selected and, for each reference VMP that is selected, a Reference Member State is to be appointed to take the lead in the SPC harmonisation procedure of the product concerned.

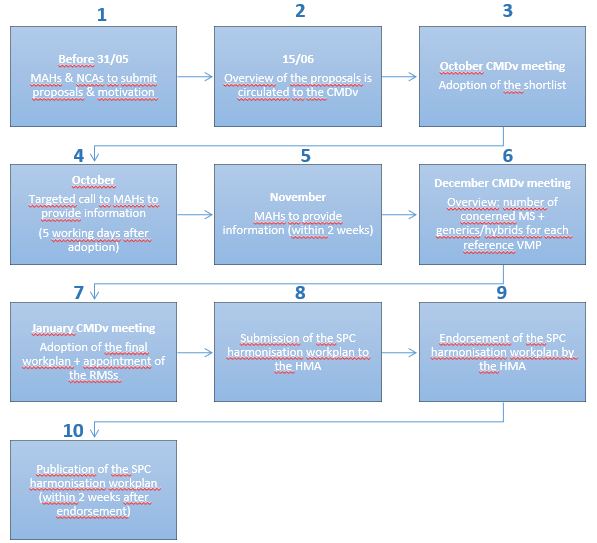
## Selection of the reference veterinary medicinal products

According to article 70 of Regulation (EU) 2019/6, NCAs may propose reference VMPs for SPC harmonisation or alternatively the MAH may apply for the procedure of SPC harmonisation for their reference VMPs.

The coordination group shall annually draw up a list of reference VMPs that will be harmonised and in accordance with Article 70.3 this list should be published.

The flow for the selection of reference veterinary medicinal products to be harmonised can be summarised as follows:

* + 1. NCAs and MAHs submit proposals of reference VMPs to be harmonised.
    2. An overview of all proposals made by NCAs and MAHs is made and circulated to the CMDv.
    3. Elaboration of the shortlist of reference VMPs proposed for SPC harmonisation
    4. A targeted request to provide information on generics, hybrids and informed consent MAs is sent to all MAHs having a marketing authorisation for a VMP with the same active substance as one of the reference VMPs on the shortlist.
    5. The MAHs submit the requested information
    6. An overview is made on all reference VMPs on the shortlist and their linked marketing authorisations.
    7. The CMDv elaborates a final list of the VMPs to be harmonised along with the proposed RMS and CMS.
    8. The list is submitted to the HMA for endorsement.
    9. Endorsement of the proposed workplan by the HMA.
    10. The list of the reference products and the generics/hybrids of the reference VMPs concerned is published on the CMDv website.



* + 1. NCAs and MAHs to propose reference VMPs to be harmonised

All NCAs and MAHs can annually submit proposals for reference veterinary medicinal products to be harmonised. MAHs and NCAs are requested to submit their proposals before the end of May each year in order to be taken into account for the exercise for the elaboration of the workplan of the upcoming year.

NCAs proposing reference VMPs for SPC harmonisation should circulate their proposal(s) to the dedicated mailing list for SPC harmonisation by using the NCA SPC harmonisation request form for NCAs as presented in annex 3 of this BPG. A separate form shall be used for each proposed reference VMP. A NCA that proposes a reference VMP for SPC harmonisation should be prepared to contribute to the work for the examination of the harmonised SPC as RMS or by contributing to the examination of the application.

MAHs proposing reference VMPs for SPC harmonisation can submit their proposal(s) to the CMDv secretariat by using the MAH SPC harmonisation request form for MAHs as presented in annex 4 of this BPG. A separate form shall be used for each proposed reference VMP. The MAH SPC harmonisation request form should be accompanied by a comparative table such as listed in annex 5 and the proposed harmonised SPC. A prerequisite for proposing a reference VMP for SPC harmonisation is that the applicant is the MAH for the VMP concerned.

In their forms for proposing reference VMPs to be harmonised, MAHs and NCAs must substantiate the reasoning for proposing a reference VMP for SPC harmonisation. The criteria as listed in section 4.1.3. can be used.

NCAs and MAHs proposing reference VMPs for SPC harmonisation should take into account Article 72 while proposing VMPs for SPC harmonisation.

The CMDv has agreed upon a pragmatic approach in determining which products may be considered as not falling within the scope of Article 72. The principles of this approach have been agreed upon by the CVMP ERA Working Party. The following types of products are considered as not falling within the scope of Article 72:

* Immunological VMPs.
* VMPs authorised for companion animals only.
* Reference VMPs for which a generic has been authorised with the same target species, same indications, same pharmaceutical form, same posology and an ecotox evaluation has been performed during the MA procedure of the generic; even if no ERA was performed for the reference VMP itself. Any measures to mitigate the risk to the environment, warning sentences and other information on environmental properties that apply to the generic should also be applied to the reference product in these cases. No information of the generic/hybrid dossier will be transferred to the MAH of the reference VMP and no questions can be raised to the MAH of the generic/hybrid at this stage.
* In the case where one or several NCAs have performed an ERA for a VMP subject to SPC harmonisation while other NCAs did not perform an ERA for this product, mutual trust will be applied. In these cases all the marketing authorisations for the VMP concerned will be taken into the scope of the harmonisation procedure, even if no ERA was performed in some of the MSs.
  + 1. Overview of the proposals

During the first 2 weeks of June the CMDv secretariat will make an overview of all proposals made by NCAs and MAHs. For the elaboration of this overview the table in annex 5 will be used. This overview will be circulated by the CMDv secretariat to the CMDv mailing list at the latest by June 15th of each year. CMDv members should discuss within their agency which products on the list are of interest for their market to be harmonised and for which they are willing to act as RMS or prepared to participate in the work for the examination of the SPC harmonisation. MSs may also identify potential risks linked to the SPC harmonisation of a reference VMP. Feedback on the global list should be provided at the latest for the July CMDv meeting.

The overview sent by the CMDv secretariat will include the following information:

name of the VMP, active substance and strength, pharmaceutical form, MAH, NCA or MAH proposing the product for SPC harmonisation and the reasoning for proposing the reference VMP for SPC harmonisation. Furthermore, all the NCA SPC harmonisation request forms will be circulated with the CMDv agenda stored in MMD.

* + 1. Elaboration of the shortlist of reference VMPs proposed for SPC harmonisation

Based on the feedback received from the CMDv members on the interest and risks of having a reference VMP harmonised and the preparedness to act as RMS, a dedicated working group will elaborate a shortlist of reference VMPs for SPC harmonisation. This shortlist will be circulated to the CMDv at the latest with the first mailing of the September meeting.

A number of criteria for the prioritisation of the SPC harmonisation have been identified:

* Significant differences in the clinical information of the SPC (Withdrawal periods, indications, posology, route of administration, target species);
* VMPs authorised by means of the National Procedure in some MSs and also authorised by means of MRP in other MSs;
* Harmonisation already finalised for a similar reference VMP (same active substance, same pharmaceutical form);
* VMPs with an SPC already partially harmonised after referral;
* VMPs for which the SPC has been revised at national level in a MS;
* Number of MSs where the product is nationally authorised;
* Number of related authorisations (generics, hybrids);
* Number of MSs with related authorisations (generics, hybrids);
* Reference VMPs authorised by means of the National Procedure in multiple Member States for which an application for a generic of the product is introduced by means of the Centralised Procedure;
* Voluntary harmonisation requests introduced by MAHs;
* Pharmaceutical classes with high risks for public/animal health and environment (antibiotics, antiparasitics);
* VMPs for food-producing species;
* VMPs with MUMS indications / indications of interest for NCAs;
* Issues identified during Pharmacovigilance evaluation (e.g. differences in contraindications);
* Extent of the use of the product/molecule (for example based on ESVAC data)

There is no hierarchy in the presentation of these criteria and during the first working years the VMPs on the shortlist will be selected based on a mix of criteria, in order to gain experience with different types of SPC harmonisations. Based on this experience, the criteria for selecting products and the procedure can be adjusted.

Taking into account the limited resources within the network and the uncertainty on the workload of this new procedure, the first working years, the number of reference VMPs on the shortlist will be limited to 5-6 products.

During the September CMDv meeting, a discussion will take place on the proposed shortlist. Based on the outcome of this discussion, the shortlist may be amended and circulated for adoption during the October CMDv meeting.

* + 1. Targeted call to MAHs to provide information

For the products on the CMDv shortlist, the CMDv working group on SPC harmonisation will identify in the Union Product Database all MAHs having a marketing authorisation for a VMP with the same active substance as those of the Reference VMPs identified on the shortlist. NCAs may also be requested to provide information on the contact points of the concerned MAHs.

Within 5 working days after adoption of the shortlist, a targeted request will be sent by the CMDv secretariat to all the identified MAHs to provide information on the link between the marketing authorisation of their product(s) and the products identified on the CMDv shortlist. The template in annex 7 can be used by the MAHs for providing the requested information.

For the reference VMPs listed in the CMDv shortlist for which the proposal for SPC harmonisation was not made by the MAH themselves, the MAH will be requested by the CMDv secretariat to provide the following information on their reference VMPs listed in the CMDv shortlist:

* + List of countries where the reference VMP is authorised
  + Product name(s) and name and address of the MAH in all the countries where the reference VMP is authorised
  + Type of marketing authorisation procedure in each of the MSs where the reference VMP is authorised
  + MRP number, if applicable
  + MAH contact point for the SPC harmonisation (name, email and telephone number)

MAHs of reference VMPs may also provide other information/comments on the products on the CMDv shortlist if they consider that this information is useful for the CMDv for the decision on the final list of VMPs to be harmonised (for example mitigation arguments and analysis of impact that are linked with the SPC harmonisation of the specific reference VMP or status of the harmonisation of part II of the VMP). Moreover MAHs of reference VMPs may also take the opportunity to suggest a timeline for the start of the SPC harmonisation procedure.

* + 1. MAHs to provide information

Within 2 weeks after the receipt of the call to provide information, all MAHs should provide the CMDv secretariat with the information requested for their VMPs.

In the case where a marketing authorisation has been granted in the scope of Articles 18,19 or 21 of the Regulation 2019/6/EC (generics, hybrids or informed consents) of one of the VMPs listed in the CMDv shortlist; the MAH should provide the following information:

* + Type of link with the reference VMP (generic, hybrid, informed consent)
  + List of countries where the VMP is authorised
  + Product name(s) and name and address of the MAH in all the countries where the product is authorised
  + Type of marketing authorisation procedure in each of the MSs where the product is authorised
  + For VMPs authorised by means of MRP/DCP: procedure number
  + For VMPs authorised by means of national procedure: preferred RMS for the SPC harmonisation
  + MAH contact point for the SPC harmonisation (name, email and telephone number)

For providing this information, the MAHs should use the form in annex 7 of this BPG.

In the case that a MAH does not provide an answer within the deadline set by the CMDv secretariat, a reminder will be sent by the CMDv secretariat.

The CMDv secretariat will forward all information received to the CMDv working group on SPC harmonisation.

* + 1. Overview of the proposals

For each of the VMPs on the CMDv shortlist, the CMDv working group on SPC harmonisation will collect all information received in the SPC harmonisation request forms, the information received on linked marketing authorisations (generics, hybrids and informed consent marketing authorisations) and the information received from the MAH. An overview table will be elaborated containing the information listed in annex 8.

This overview will be circulated to the CMDv for the December CMDv meeting and MSs will be requested to confirm at the latest before the 2nd mailing of the January meeting their willingness to act as RMS for the SPC harmonisation (for the reference VMP and the generics/hybrids). MSs that accept to act as RMS for the SPC harmonisation of a reference VMP should also indicate a preferred timeframe for the start of the SPC harmonisation procedure. This indicative timeframe does not need to be specific (for example, Q1 202x). In order to allow the MAH of the RVMP enough time to prepare the documentation referred to in Article 70.5 of Regulation 2019/6/EC, there should be at least 6 months between the intended start date and the publication of the final workplan. In the case where the MAH and the RMS agree upon an earlier start of the procedure, this 6-month timeframe can be shortened.

* + 1. Adoption of the workplan

At the January CMDv meeting a discussion will take place on the final list of reference VMPs to be harmonised. For this discussion the CMDv will take into account the availability of the RMS, the criteria for prioritisation and the risks identified by NCAs and/or MAHs. In the case where there are multiple NCA’s willing to act as RMS for the SPC harmonisation of a reference VMP or there are no NCAs volunteering to take the RMSship, while the SPC harmonisation of the reference VMP is considered as important; the criteria listed in section

* 1. will be used to agree upon an RMS.

Taking into account the limited resources within the network and the uncertainty on the workload of this new procedure, for the first working years the number of reference VMPs to be harmonised will be limited to a maximum of 2-3 products. This maximum number will be reviewed based on the first experiences.

The CMDv can decide that products that were included in the shortlist and that are considered as good candidates for SPC harmonisation, but that could not be retained in the final list due to resource issues, will be put on the potential list for SPC harmonisation for the next year.

Based on the outcome of the discussion during the January CMDv meeting and the timeframe preferred by the RMSs, a workplan will be made in order to ensure a suitable distribution of the harmonisation procedures over the year. This workplan will be circulated by means of a written procedure for adoption during the February CMDv meeting.

* + 1. Submission of the SPC harmonisation workplan to the HMA

After adoption by the CMDv, the CMDv chair will circulate the proposed workplan to the HMA for endorsement by means of written procedure.

This SPC harmonisation workplan will contain the following information:

* Product name(s), pharmaceutical form and name of the MAH of each of the reference VMPs
* For each reference product a list of NCAs where the product is authorised
* For each reference product the name of the NCA(s) that have indicated they are prepared to act as RMS and the indicated timeframe for start of the procedure
* For each reference VMP a list of all generic and hybrid marketing authorisations: name(s) of the VMPs and the MSs where the product is authorised + the NCA that will act as RMS for the SPC harmonisation procedure of the generic/hybrid (if applicable)
  + 1. Endorsement of the SPC harmonisation workplan by the HMA

In order to ensure that all NCAs make the necessary resources available, the CMDv SPC harmonisation workplan will be submitted to HMA for endorsement by means of a written procedure. In the case that a NCA does not agree upon the proposed workplan, this could be discussed during a HMA plenary meeting.

* + 1. Publication of the SPC harmonisation workplan on the CMDv website

Within 2 weeks after endorsement by the HMA, the CMDv secretariat will publish the SPC harmonisation workplan on the CMDv website.

According to Article 70. of Regulation (EU) 2019/6 only a list of the reference VMPs that will be harmonised needs to be published. However the CMDv has decided to publish a complete list that also includes the generics/hybrids of the reference VMPs that will be harmonised in accordance with Article 71, including an indicative period for the start of the SPC harmonisation procedure of the reference VMP. Publication of this complete list allows MAHs to start the preparation for the respective SPC harmonisation procedure.

The list published on the CMDv website needs to be considered as being current at the time of publication and may not reflect subsequent changes, for example, the granting of a new MA or the withdrawal of a MA in one or multiple MSs. No updated overview will be published but a disclaimer will be added that subsequently authorised generics and hybrids are considered to fall within the scope.

NCAs that are RMS for an ongoing MR/DC procedure for a new marketing authorisation of a generic/hybrid VMP of one of the reference VMPs on the workplan and NCAs that have an ongoing national procedure for a generic/hybrid VMP of one of the reference VMPs on the workplan should inform the applicant of the generic/hybrid on the need for a variation requiring assessment to harmonise their SPC with the harmonised SPC of the RVMP. However, it should be noted that the MAHs of generics/hybrids do have the legal obligation to harmonise the SPCs of their products in accordance with Article 71 of Regulation (EU) 2019/6/EC and that the NCA concerned cannot be held responsible for ensuring the timely submission of the variation requiring assessment by the MAH.

* + 1. SPC harmonisation of Informed Consent applications

Since the SPC harmonisation of Informed Consent marketing authorisations is not covered by the scope of Article 71 of the Regulation (EU) 2019/6, the SPC harmonisation of these

Informed Consent MAs has to be done under the scope of Article 70 as a separate procedure of the SPC harmonisation of the reference VMP. However, since Informed Consent MAs are linked to the VMP with regard to which consent is given, it is preferable to keep the SPCs of both VMPs aligned as much as possible.

In the case where the MAH of the Informed Consent MA is the same as the MAH of the reference VMP (or belongs to the same group of companies), the SPC harmonisation should preferably be run in parallel to the SPC harmonisation of the reference VMP. However, taking into account the workload related to these procedures, both the MAH and the RMS should agree to run both procedures in parallel.

In all other cases, the SPC harmonisation of the Informed Consent MA will be run separately from the SPC harmonisation of the reference VMP after the completion of the harmonisation of the reference VMP. This procedure has to be run in accordance with article 70 with a 180- day procedure, with the option to close the procedure earlier in case there is an agreement before D180.

The CMDv will take into account these principles while elaborating the workplan as described in section 4.1.7.

## Selection of the RMS for the harmonisation of a veterinary medicinal product

* + 1. Selection of the RMS for the harmonisation of a reference veterinary medicinal product

Taking into account that for the establishment of the workplan the commitment of the RMS to provide the required resources for the SPC harmonisation is needed, the decision on the selection of the products to be harmonised and the appointment of an RMS for each of the reference VMPs to be harmonised are interlinked and should be discussed together.

A pre-requisite for being RMS for a SPC harmonisation procedure is that the product is authorised in the Member State acting as RMS.

For the designation of a RMS for a SPC harmonisation procedure, the following criteria should be taken into account:

* MS that requested the harmonisation of the product
* Voluntary candidates;
* The NCA is RMS for the same product in a MRP/DCP;

Other criteria that can be taken into account:

* RMSship for a generic/hybrid of the proposed reference product or similar product;
* Rapporteurship for a centralised marketing authorisation application for the same molecule or a rapporteurship for the MRL of the active substance;
* Number of linked MAs (generics/hybrids) authorised in the MS;
* The Member State acting as lead-authority for signal management;
* Preference of the MAH;
* Reasonable workload repartition between the MSs in the framework of the SPC harmonisation procedures
  + 1. Selection of the RMS for the harmonisation of a generic/hybrid VMP

For the designation of RMSs for the subsequent harmonisation of the generics/hybrids, there are multiple cases:

1. The generic/hybrid veterinary medicinal product is authorised in just 1 MS:

The subsequent harmonisation is a purely national procedure in the MS concerned and no designation of a RMS is required.

1. The generic/hybrid veterinary medicinal product is authorised by means of a DCP: The subsequent harmonisation will be done by means of a MRP variation under coordination of the RMS of the generic/hybrid.
2. The generic/hybrid veterinary medicinal product is authorised by means of national procedures in multiple MSs or by national procedure in at least 1 MS and by MRP/DCP in at least 2 other MSs:

The subsequent harmonisation will be done by means of a MRP variation under coordination of the RMS of the MRP/DCP authorised VMPs.

1. The generic/hybrid veterinary medicinal product is authorised by means of national procedures in multiple MSs:

The harmonisation of the SPCs of the national products must be done by means of a worksharing procedure.

In the cases where the SPC harmonisation of a generic/hybrid will be done by means of a worksharing procedure, the designation of the RMS will be done in the same way as for other WS procedures: the MAH should propose a National Competent Authority (NCA) to act as the Reference Authority. However, the CMDv may choose to appoint a different Reference Authority if this is more appropriate to the marketing authorisations involved in the worksharing procedure. An MAH that wishes to propose an RMS, should provide this information, while providing the information listed in section 4.1.5.

## ANNEX 1 LIST OF RELATED DOCUMENTS

* + BPG for the harmonisation of reference products
  + BPG for the harmonisation of generics and hybrids
  + CMDv Rules of Procedure
  + Management of e-mail use during procedures and standardisation of Subheadings
  + Guideline on the definition of a potential serious risk to human or animal health or for the environment in the context of Article 33(1) and (2) of Directive 2001/82/EC — March 2006

## ANNEX 2: LIST OF USED ABBREVIATIONS

BPG Best Practice Guide

CMDv Co-ordination Group for Mutual Recognition and Decentralised Procedures – veterinary

DCP Decentralised Procedure

HMA Heads of Medicines Agencies

MA Marketing Authorisation

MAH(s) Marketing Authorisation Holder(s) MMD Managing Meeting Documents system MS(S) Member State(s)

MRP Mutual Recognition Procedure NCA(S) National Competent authority(s) RMS Reference Member State(s)

RVMP(s) Reference Veterinary medicinal product(s) SPC Summary of Product Characteristics VMP(s) veterinary medicinal product(s)

**ANNEX 3: NCA SPC harmonisation request form**

Request for SPC harmonisation according to article 70 of the Regulation (EU) 2019/6 for a reference medicinal product

***This form should be sent to*** [***CMDv@ema.europa.eu***](mailto:CMDv@ema.europa.eu)

|  |
| --- |
| **NATIONAL COMPETENT AUTHORITY**: ………… |
| **REFERENCE VETERINARY MEDICINAL PRODUCT FOR WHICH AN SPC HARMONISATION IS PROPOSED**  Product name(s): ...............................................................  Pharmaceutical form: ........................................................  Strength: ............................................................................  Type of the veterinary medicinal product: Pharmaceutical Immunological  ATC-vet code: ....................................................................  Date of first authorisation in the Member State: ................  Authorisation number: .......................................................  Name of active Substance(s) and quantity: Excipient(s):  ………………………………………… …………………………………………  ………………………………………… …………………………………………  INN: …………………………………………  ………………………………………… …………………………………………  ………………………………………… …………………………………………  …………………………………………  Name & Address of the active substance manufacturer(s): ……………………………………………  ………………………………………………………………………………………………………………….  Name & Address of the finished product manufacturer(s): ……………………………………………  …………………………………………………………………………………………………………………. |
| **CLINICAL INFORMATION OF THE REFERENCE VMP** |

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|  |  |  |  |
| --- | --- | --- | --- |
|  | **Indications** |  |  |
|  | **Dose and duration of treatment** |  |  |
|  | **Target species** |  |  |
|  | **Withdrawal period(s)** |  |  |
|  | **Route of administration** |  |  |
| **MOTIVATION FOR REQUESTING SPC HARMONISATION**  …………………………………………………………………………………………………………………..  …………………………………………………………………………………………………………………..  ………………………………………………………………………………………………………………….. | | | |
| **LIST OF GENERICS/HYBRIDS OF THE REFERENCE VMP AUTHORISED IN THE NCA**   |  |  |  | | --- | --- | --- | | **Product Name** | **Generic/hybrid** | **Name & Address of the MAH** | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | | | | |
| **ENVIRONMENTAL SAFETY DOCUMENTATION**  An environmental safety assessment has been performed and the VMP is considered as not being harmful to the environment  Yes No N/A  Comments:  …………………………………………………………………………………………………………………..  …………………………………………………………………………………………………………………..  ………………………………………………………………………………………………………………….. | | | |
| **MARKETING AUTHORISATION HOLDER OF THE REFERENCE VMP** | | | |
| Company name in this NCA: ............................................  address: ..............................................................................  …………………………………………………………………..  Contact point: ....................................................................  Email: .................................................................................  Tel: .................................................................................... | | | |

**ANNEX 4: MAH SPC harmonisation request form**

Request for SPC harmonisation according to article 70 of the Regulation (EU) 2019/6 for a reference medicinal product

# This form should be sent to [CMDv@ema.europa.eu](mailto:CMDv@ema.europa.eu)

|  |
| --- |
| **MARKETING AUTHORISATION HOLDER PROPOSING THE SPC HARMONISATION OF A REFERENCE VMP**  Company name: .................................................................  address: ..............................................................................  …………………………………………………………………..  Contact point: ....................................................................  Email: .................................................................................  Tel: .................................................................................... |
| **REFERENCE VETERINARY MEDICINAL PRODUCT FOR WHICH AN SPC HARMONISATION IS PROPOSED**  Product name(s): ...............................................................  Pharmaceutical form: ........................................................  Strength: ............................................................................  Type of the veterinary medicinal product: Pharmaceutical Immunological  ATC-vet code: ....................................................................  MRP number (if applicable): ..............................................  Name of active Substance(s) and quantity: Excipient(s):  ………………………………………… …………………………………………  ………………………………………… …………………………………………  INN: …………………………………………  ………………………………………… …………………………………………  ………………………………………… …………………………………………  …………………………………………  Name & Address of the active substance manufacturer(s): ……………………………………………  ………………………………………………………………………………………………………………….  Name & Address of the finished product manufacturer(s): ……………………………………………  …………………………………………………………………………………………………………………. |
| **INFORMATION ON THE MARKETING AUTHORISATION IN ALL MEMBER STATES**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **MS** | **Product Name** | **Authorisation date** | **Authorisation number** | **Authorisation type: MRP/NP** | | AT |  |  |  |  | | BE |  |  |  |  | | BG |  |  |  |  | | CY |  |  |  |  | | CZ |  |  |  |  | | DE |  |  |  |  | | DK |  |  |  |  | | EE |  |  |  |  | | EL |  |  |  |  | | ES |  |  |  |  | | FI |  |  |  |  | | FR |  |  |  |  | | HR |  |  |  |  | | HU |  |  |  |  | | IE |  |  |  |  | | IS |  |  |  |  | | IT |  |  |  |  | | LT |  |  |  |  | | LU |  |  |  |  | | LV |  |  |  |  | | MT |  |  |  |  | | NL |  |  |  |  | | NO |  |  |  |  | | PL |  |  |  |  | | PT |  |  |  |  | | RO |  |  |  |  | | SE |  |  |  |  | | SI |  |  |  |  | | SK |  |  |  |  | | UK(NI) |  |  |  |  |   Earliest possible start date for the SPC harmonisation procedure: *mm/yyyy* |

|  |
| --- |
| Part II is currently harmonised between all Member States:  Yes No  Preferred RMS after MRP transfer: …………… |
| **MOTIVATION FOR REQUESTING SPC HARMONISATION**  …………………………………………………………………………………………………………………..  …………………………………………………………………………………………………………………..  ………………………………………………………………………………………………………………….. |
| **ENVIRONMENTAL SAFETY DOCUMENTATION**  An environmental safety assessment has been performed and the VMP was evaluated as not being harmful to the environment  Yes No N/A  Comments:  …………………………………………………………………………………………………………………..  ………………………………………………………………………………………………………………….  …………………………………………………………………………………………………………………..  Member State(s) that did perform an environmental safety assessment:  ………………………………………………………………………………………………………………….. |



## ANNEX 5 : COMPARATIVE TABLE to be submitted by the MAH

Following information should be included in the comparative table to be submitted by the MAH at the moment of application in the case of a reference veterinary medicinal product being proposed for SPC harmonisation by the MAH.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Presentations in Member States | | | | | | | | | | | |
| **MS** | Product Name & Pharmaceutical  form(s) | Strength(s) | Indication(s) | Target Species | Routes of administration | Dose and duration of treatment | Withdrawal period(s) if appropriate | Contra‐ indications | Special precautions for use | Adverse reactions | Environmental warnings |
| AT |  |  |  |  |  |  |  |  |  |  |  |
| BE |  |  |  |  |  |  |  |  |  |  |  |
| BG |  |  |  |  |  |  |  |  |  |  |  |
| CY |  |  |  |  |  |  |  |  |  |  |  |
| CZ |  |  |  |  |  |  |  |  |  |  |  |
| DE |  |  |  |  |  |  |  |  |  |  |  |
| DK |  |  |  |  |  |  |  |  |  |  |  |
| EE |  |  |  |  |  |  |  |  |  |  |  |
| EL |  |  |  |  |  |  |  |  |  |  |  |
| ES |  |  |  |  |  |  |  |  |  |  |  |
| FI |  |  |  |  |  |  |  |  |  |  |  |
| FR |  |  |  |  |  |  |  |  |  |  |  |
| HR |  |  |  |  |  |  |  |  |  |  |  |
| HU |  |  |  |  |  |  |  |  |  |  |  |
| IE |  |  |  |  |  |  |  |  |  |  |  |
| IS |  |  |  |  |  |  |  |  |  |  |  |
| IT |  |  |  |  |  |  |  |  |  |  |  |
| LI |  |  |  |  |  |  |  |  |  |  |  |
| LT |  |  |  |  |  |  |  |  |  |  |  |
| LU |  |  |  |  |  |  |  |  |  |  |  |
| LV |  |  |  |  |  |  |  |  |  |  |  |
| MT |  |  |  |  |  |  |  |  |  |  |  |
| NL |  |  |  |  |  |  |  |  |  |  |  |
| NO |  |  |  |  |  |  |  |  |  |  |  |
| PL |  |  |  |  |  |  |  |  |  |  |  |
| PT |  |  |  |  |  |  |  |  |  |  |  |
| RO |  |  |  |  |  |  |  |  |  |  |  |
| SE |  |  |  |  |  |  |  |  |  |  |  |
| SI |  |  |  |  |  |  |  |  |  |  |  |
| SK |  |  |  |  |  |  |  |  |  |  |  |
| UK(NI) |  |  |  |  |  |  |  |  |  |  |  |

## ANNEX 6 : TABLE with overview of all proposals received from MAHs and NCAs

The excel table in annex can be used by the CMDv secretariat for compiling an overview of all the proposals for SPC harmonisation received by MAHs and NCAs.



**ANNEX 7: Form to be used by MAHs of linked Marketing Authorisations**

Information on linked marketing authorisations in the framework of SPC harmonisation according section 4 of the Regulation (EU) 2019/6

# This form should be sent to [CMDv@ema.europa.eu](mailto:CMDv@ema.europa.eu)

|  |
| --- |
| Email: .................................................................................  Tel: .................................................................................... |
| **INFORMATION ON VETERINARY MEDICINAL PRODUCT THAT IS LINKED WITH A REFERENCE VMP**  **ON THE CMDV SHORTLIST**  Product name(s) of the linked VMP: .................................  Pharmaceutical form: ........................................................  Strength: ............................................................................  Product name of the reference VMP listed in the CMDv shortlist:  …………………………………………………………………..  Type of link with the reference veterinary medicinal product: Generic Hybrid Informed Consent  MRP number (if applicable): .............................................. |
| **INFORMATION ON THE MARKETING AUTHORISATION IN ALL MEMBER STATES**   |  |  |  |  | | --- | --- | --- | --- | | **MS** | **Product Name** | **Name and address of the MAH** | **Authorisation type: DCP/MRP/NP** | | AT |  |  |  | | BE |  |  |  | | BG |  |  |  | | CY |  |  |  | | CZ |  |  |  | | DE |  |  |  | | DK |  |  |  | | EE |  |  |  | | EL |  |  |  | | ES |  |  |  | | FI |  |  |  | | FR |  |  |  | | HR |  |  |  | | HU |  |  |  | | IE |  |  |  | | IS |  |  |  | | IT |  |  |  | | LT |  |  |  | | LU |  |  |  | | LV |  |  |  | | MT |  |  |  | | NL |  |  |  | | NO |  |  |  | | PL |  |  |  | | PT |  |  |  | | RO |  |  |  | | SE |  |  |  | | SI |  |  |  | | SK |  |  |  | | UK(NI) |  |  |  | |
| **FOR VMPS AUTHORISED BY MEANS OF THE NATIONAL PROCEDURE IN MULTIPLE MEMBER STATES**  Preferred RMS for the SPC harmonisation by means of a Worksharing Procedure: ……………  A Part II harmonisation and MRP transfer is considered: Yes No  If Part II harmonisation and MRP transfer is considered, please indicate the expected timeframe for the submission of the part II harmonization and MRP transfer: …………… |

|  |  |
| --- | --- |
| BEST PRACTICE GUIDE  For the selection of the products for the SPC harmonisation | CMDv/BPG/XXX |
| Ed.: 00 |
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## ANNEX 8: TABLE with CMDv proposals for SPC harmonization

The excel table in annex can be used by the CMDv SPC harmonisation working group for the overview of the VMPs proposed for SPC harmonisation.

