Coordination Group for Mutual Recognition and Decentralised Procedures for Veterinary Medicinal Products

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STANDARD OPERATING PROCEDURE

for

The Allocation of the Mutual Recognition/Decentralised Procedure Application Number

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01	18.03.2022		Implementation of Regulation (EU) 2019/6. Introduction of a numbering system for all procedure types in the Communication and Tracking System (CTS) database

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1. INTRODUCTION

Each Mutual Recognition (MR), Decentralised (DC) and Subsequent Recognition (SR, formerly known as Repeat Use - RUP) procedure and each variation requiring assessment (VRA) is recorded in the Communication and Tracking System (CTS) database. All these procedures are characterised by a unique and specific number (called procedure number in this document).

Depending on the procedure type, the number will be allocated by the RMS/Reference Authority of the procedure or by the Marketing authorisation Holder (MAH). Further detail is provided in chapter 5.2.

This approach will also apply to the re-examination procedure for limited market and exceptional circumstances authorisations, which will be developed at a later stage and therefore are not further detailed in this document.

2. AIM AND SCOPE

This Best Practice Guide (BPG) has been prepared for use by the RMS/MAH and in respect with veterinary medicinal products, in order to facilitate consistent allocation of the procedure numbers in accordance with the CMDv General Document Mutual Recognition and Decentralised Procedures.

3. REFERENCES and RELATED DOCUMENTS

- Minimum Data Input in CTS Database
- Best Practice Guide for Changing the Reference Member State
- Best Practice Guide for the MRP
- Best Practice Guide for the DCP
- Best Practice Guide for the subsequent recognition procedure
- Best Practice Guides for the SPC harmonisation procedures
- Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.
- Best Practice Guide for variations requiring assessment
- Best Practice Guide for worksharing
- Best Practice Guide for limited market Applications
- Best Practice Guide for exceptional circumstances applications

4. GENERAL

Abbreviations

CMS	Concerned Member State
CTS	Communication and Tracking System
DC DCP	Decentralised Decentralised Procedure
MAH	Marketing Authorisation Holder
MR MRP	Mutual Recognition Mutual Recognition Procedure
RMS	Reference Member State
SPC	Summary of Product Characteristics
SRP	Subsequent Recognition Procedure (formerly known as Repeat Use Procedure)
UPD	Union product database
VRA	Variation requiring assessment

5. DESCRIPTION OF PROCEDURE

5.1. The Procedure-Number

The procedure number is of the following form:

CC/D/nnnn/sss

in which the element (see also Annex I MRP/DCP Numbering System):

CC is the initial of the Reference Member State
D is the Domain, 'H' for medicinal products for human use or 'V' for medicinal products for veterinary use

nnnn is the 'Medicinal Product Number' or 'product counter' characterising the medicinal product, related to an active principle and to an applicant

sss is the 'Speciality Number' characterising the strength and/or pharmaceutical form and/or target species of a medicinal product

GENERAL PRINCIPLES

1. The system is intended for numbering the procedures.

2. The proposed numbering system has to be used.

3. The basic number (nnnn) is related to an active principle and to an applicant/MAH.

4. The three next digits (sss) are in relation with the strength and/or pharmaceutical form and/or target species.

5. The numbering system should comply with the provisions according to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products.

6. The numbering system should not limit the possibility for an applicant to vary a marketing authorisation.

5.2. The chronology of the Procedure Numbers

The purpose of this 'chronological number' (element 'vvv' of the Variation Number) is to enable the MAH and the competent authority/inspectorate of the Member States to receive information about the history of changes to a medicinal product.

Principles:

1. Irrespective of the timetable of the VRA, there is a continuous numbering of the submitted VRA applications (except for those under chapter "I"). This is also the case after a change of the reference member state for a medicinal product. Although the procedure number will change due to the RMS transfer the numbering of subsequently submitted VRA applications will be continued from the last chronological number.
2. Variations under chapter "I" - i.e. changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species – are counted according to a separate numbering line. To this end, a sequential VRA under chapter "I" counter is applied.
3. Basis for the continuous numbering is the medicinal product characterised by the 'Medicinal Product Number' (e.g. FR/V/0100) irrespective of its 'Speciality Number' (sss).
4. Only identical VRA applications are entitled to have the same chronological number.
5. No gaps in the continuous numbering are acceptable.
6. The numbering system for VRA applications is independent from the numbering system for Subsequent Recognition procedures and VRAs under the chapter "I". The numbering system is also independent for SPC harmonisation procedures (please be referred to chapter 5.3.4).
7. In case a RMS transfer occurred, the numbering for VRA/Subsequent Recognition procedures will be continued from the last chronological number. I.e. after a change of RMS, the numbering of VRA/Subsequent Recognition procedures in the new RMS will start with the next sequential number applicable for the respective procedure.
8. Applications for VRA that concern several veterinary medicinal products with the same RMS, or with different RMS, or that concern purely national marketing authorisations in several MS, are numbered independently from the numbering system for VRA concerning one veterinary medicinal product only. Please refer to chapter 5.3.3.3..

The RMS/Reference authority is responsible for allocating the procedure number.

See the following examples.

Example of chronological applications to a fictive product “Noname”:

VRA	Subsequent recognition Procedure
FR/V/0100/001-006/A/001	
FR/V/0100/001-003/A/002	
FR/V/0100/006/A/003	
FR/V/0100/001-006/A/004	
FR/V/0100/001-006/A/005	
	FR/V/0100/004-006/E/001
FR/V/0100/001-002/A/006	
	FR/V/0100/001-002/E/002
FR/V/0100/001-002/A/007	
FR/V/0100/006/A/008	

5.3. Practical Examples of the numbering system

5.3.1. The Procedure Number for new applications for marketing authorisation

The Procedure-Number for new applications will be extended by a further element:

CC/V/nnnn/sss/QQ/

where

QQ is MR for a Mutual Recognition Procedure and DC for a Decentralised Procedure (see Annex 1)

Examples:

A. Application number for “Noname” tablets for dogs and cats which include the following presentations:

aa.) MRP

10 mg tablet for cats and small dogs	FR/V/0100/001/MR
20 mg tablet for medium size dogs	FR/V/0100/002/MR
30 mg tablets for large dogs	FR/V/0100/003/MR

ab.) DCP

10 mg tablet for cats and small dogs	FR/V/0100/001/DC
20 mg tablet for medium size dogs	FR/V/0100/002/DC
30 mg tablets for large dogs	FR/V/0100/003/DC

B. Number given if a 10 mg oral suspension for cats was also included:

ba) MRP

FR/V/0100/004/MR

bb) DCP

FR/V/0100/004/DC

C. Number given in case of addition of a premix for pigs via VRA:

ca) MRP

FR/V/0100/005/MR

cb) DCP

FR/V/0100/005/DC

Number in case of addition of an injectable solution for cats, dogs and pigs via VRA:

da) MRP

FR/V/0100/006/MR

db) DCP

FR/V/0100/006/DC

D. Would a different number be requested if the above mentioned VRA for an injectable formulation also included cattle at the same time as cats, dogs and pigs?

No.

5.3.2. The Procedure Number for Subsequent Recognition Procedures

The Procedure Number will be extended by two further elements:

CC/V/nnnn/sss/QQ/vvv

where

QQ is E (see Annex 1)
vvv is a chronological number, independent from VRA/VRA under chapter "I"/SPC harmonisation procedures

- Number for a subsequent recognition procedure of the procedure for the Noname 10 mg tablet for cats and small dogs?

  FR/V/0100/001/E/001

5.3.3. The Variation Number

To characterise VRA applications for veterinary medicinal products within the scope of mutual recognition in a unique and specific way, the MRP-number will be extended by two further elements

CC/V/nnnn/sss/QQ/vvv

where

QQ is 'A' for VRA or "X" for changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species)

vvv is a chronological number, independent from Subsequent recognition procedure / VRA under the chapter "I" / SPC harmonisation procedures (VRA counter)

This refers to single VRA. For grouped and worksharing applications, please refer to chapter 5.3.3.3.

Example:

VRA	MR-VRA-Number
VRA other than Changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species	FR/V/0100/001/A/002
Changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species)*	FR/V/0100/001/X/004 FR/V/0100/002/X/001 *for further explanation see chapter 5.3.3.2

5.3.3.1. Identical VRA

If an identical change concerning different strengths and/or pharmaceutical forms of a medicinal product is applied for simultaneously, this single VRA application will receive the same chronological number. An identical VRA application is characterised by the combination of the title of the change, the procedure type and the identical content of this change.

Examples:

a) To add pack sizes (outside the approved pack size range) with 33 and 44 tablets to the SPC of the veterinary medicinal products “Noname” 10 mg tablet for cats and small dogs (FR/V/0100/001) and “Noname” 20 mg tablet for medium size dogs (FR/V/0100/002):

   As the change is identical for both veterinary medicinal products, the following VRA Numbers will apply:

   for “Noname” 10 mg tablet for cats and small dogs FR/V/0100/001/A/001

   for “Noname” 20 mg tablet for medium size dogs FR/V/0100/002/A/001

   or in a combined short form: FR/V/0100/001-002/A/001

b) To add pack sizes (outside the approved pack size) with 33 and 44 tablets to the SPC of the medicinal products “Noname” 10 mg tablets for cats and small dogs (FR/V/0100/001) and pack sizes (outside the approved pack size) with 33 and **55** tablets to the SPC of the medicinal product “Noname” 20 mg tablets for medium size dogs (FR/V/0100/002):

   As the change does not have identical content for the two medicinal products, VRA numbers with different chronological numbers have to be assigned:

   “Noname” 10 mg tablet for cats and small dogs FR/V/0100/001/A/001
   (for 33 and 44 tablets)
   and
   “Noname” 20 mg tablet for medium size dogs FR/V/0100/002/A/002
   (for 33 and 55 tablets)

5.3.3.2 The Procedure Number for a change of active substance(s), strength, pharmaceutical form, route of administration or food producing target species

Changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species are listed in the Annex - section I - to the EMA-CMDv Guidance on the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and associated documentation requirements.

The corresponding procedure will receive the following number:

CC/V/nnnn/sss/QQ/vvv

where
QQ is X
vvv is the next available sequential VRA under chapter “I” counter.

Based on the above examples:

E. Number for a VRA application to add the target species horse to the marketing authorisation of the solution for injection:

Introduction of a new food-producing species to the terms of a marketing authorisation is a “Change of active substance(s), strength, pharmaceutical form, route of administration or food producing target species” according to the above mentioned EMA-CMDv Guidance document.

Example:

“Noname” solution for injection for cats, dogs, cattle and pigs: FR/V/0100/006
New food-producing species:

“Noname” solution for injection for cats, dogs, cattle, horses and pigs:

FR/V/0100/006/X/003

if “003” is the next available VRA under chapter “I” counter.

NOTE:
This approach is not possible in the case where the applicant wants to have (for example) a separate medicinal product authorised specifically for horses. It is not possible to have the same speciality number for two medicinal products because a further variation could cover one medicinal product and not the other one.

In this case it is necessary to provide a different number for the medicinal product specific for horses:

FR/V/0100/007/X/003 (if a MRP timetable is used)
FR/V/0100/007/DX/003 (if a DCP timetable is used)

For changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species processed through a grouped or workshare VRA, please refer to 5.3.3.3.

5.3.3.3. VRA numbers for grouped and worksharing applications

Principles:

1. A grouped application or worksharing application is a single procedure for the VRA. It is not bulk or multiple single procedures.
2. For the purpose of handling grouping and worksharing procedures, the following definition of a marketing authorisation is used: all strengths and pharmaceutical forms of a certain product. For MRP/DCP products this would imply that all products belonging to e.g. FR/V/0100/001-sss will be considered to belong to the same marketing authorisation.
3. Grouping of VRA is legally foreseen according to Art. 64 "Groups of variations": Where several VRA apply to one marketing authorisation, these VRA may be grouped in a single application.
   Where one or several VRA identically apply to several different marketing authorisations held by one MAH, that MAH may submit one application for all products.
   According to Art. 65 "Work-sharing procedure", where one or more VRA identically apply to one or several marketing authorisations which are held by the same marketing authorisation holder and which have been granted by different competent authorities or by the Commission, an identical application shall be submitted to the competent authorities in all relevant Member States and, where a VRA to a centrally authorised veterinary medicinal product is included, to the Agency.
   The CMDv Best Practice Guide for worksharing provides further detail on the worksharing procedure.
   Where MAs held by different RMS are combined within one single application, a worksharing procedure shall apply.
4. Grouped and worksharing applications need to be visible in the lifecycle of each individual product. Therefore, it is required to identify each product and any speciality of a product included in the grouped or worksharing application. This means that in addition to the grouping or worksharing procedure number, a MRP variation number for each MRP/DCP authorised product has to be allocated in CTS. The MAH keeps the MRP variation number.

5.3.3.3.1 Grouping of several VRA that concern one veterinary medicinal product under MR/DC procedure

The following scheme is used for Grouped VRA:

CC/D/nnnn/QQ/vvv/G

Where:
CC = two letter country code of the RMS
V = Veterinary domain
nnnn = product counter
QQ = procedure qualifier (”A” for VRA or “X” for groupings that include changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species
vvv = chronological number: next available sequential VRA counter or VRA under chapter “I” counter
G = Grouping qualifier (G)

- number is composed of the RMS code, domain, product counter (nnnn) and the next available sequential VRA counter or VRA under chapter “I” counter (vvvv) and the grouping qualifier (G)
  (e.g. FR/V/0100/A/010/G)

Example:

Given
FR/V/0100/sss last variation chronological number: 009

If Grouped VRA FR/V/0100/A/010/G is for:
- FR/V/0100/002
- FR/V/0100/003

Then the MRP VRA numbers are:
- FR/V/0100/002/A/010/G
- FR/V/0100/003/A/010/G

5.3.3.3.2. Grouping of one or several VRA that concern several veterinary medicinal products with the same RMS

The following scheme is used for groupings of one or several VRA that concern several veterinary medicinal products with the same RMS:

CC/V/nnnn/QQ/vvv/G

Where:

CC	=	two letter country code of the RMS/competent authority assessing the VRA
V	=	Veterinary domain
nnnn	=	the product counter is replaced by the placeholder: “xxxx”
QQ	=	procedure qualifier: “A” for VRA or “X” for groupings that include changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species
vvv	=	sequential grouping counter* or VRA under chapter “I” counter
G	=	Grouping qualifier (G)

*grouping counter starting from 1 for each RMS

- For grouped procedures covering several veterinary medicinal products with the same RMS, the number is composed of the country code of the RMS, domain, a placeholder for the product counter (nnnn = xxxx) and new sequential grouping counter or VRA under chapter “I” counter.
  e.g. FR/V/xxxx/A/011/G
- A sequential grouping counter is assigned which generally starts from 1 (specific and sequential per RMS). All grouped applications covering several marketing authorisations with the same RMS will be sequentially counted irrespective of product or MAH.
- For groupings that include changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species, a sequential VRA under chapter “I” counter is applied.
- In addition to the grouping application number, for each MRP/DCP authorised product and each speciality included in the grouped procedure a MRP variation number is created and maintained in CTS.
  - The MRP VRA number consists of the RMS country code, domain, product counter, speciality counter of the product followed by the procedure qualifier “A” or “X” and the next available VRA sequence or VRA under chapter “I” counter of each product included.
  - Any MRP VRA number has to be kept by the MAH in order to know the next sequence counter for a VRA concerning the relevant product only.
  - The MRP VRA numbers are not to be listed on the cover letter or the first page of the application form. MRP VRA numbers should only be listed in the table ‘Products concerned by this application’ in the application form.
- Each grouped procedure covering several veterinary medicinal products with the same RMS has a unique number.

Example:

Given
Eleventh grouped VRA procedure for France:
FR/V/0100/sss last VRA chronological number: 011
FR/V/0103/sss last VRA chronological number: 003

If grouped VRA FR/V/xxxx/A/011/G is for
- FR/V/0100/001
- FR/V/0100/002
- FR/V/0103/001

Then the MRP VRA numbers are:
- FR/V/0100/001/A/012/G
- FR/V/0100/002 /A/012/G
- FR/V/0103/001/A/004/G

5.3.3.3.3. Worksharing application for one or several VRA that concern several veterinary medicinal products with different RMS, and/or purely national marketing authorisations in several MS

The following scheme is used for worksharing applications for one or several VRA that concern several veterinary medicinal products with different RMS, and/or purely national marketing authorisations in several MS:

CC/V/nnnn/QQ/vvv

Where:

CC	=	two letter country code of the RMS/competent authority assessing the VRA
V	=	Veterinary domain
nnnn	=	the product counter is replaced by the placeholder: “xxxx”
QQ	=	procedure qualifier: WS for worksharing procedure, WX for worksharing procedure including change(s) of active substance(s), strength, pharmaceutical form, route of administration or food producing target species
vvv counter	=	sequential worksharing counter* or VRA under chapter “I”

*new counter starting from 1 for each RMS/competent authority assessing the VRA

- For worksharing applications for one or several VRA that concern several veterinary medicinal products with different RMS, and/or purely national marketing authorisations in several MS, the number is composed of the country code of the RMS/competent authority assessing the VRA, domain, a placeholder for the product counter (nnnn = xxxx) and new sequential worksharing counter or VRA under chapter “I” counter - e.g. FR/V/xxxx/WS/011

- The coordination group shall agree upon a competent authority among those having granted the relevant marketing authorisations to assess the application. Details are provided in the CMDv Best Practice Guide for worksharing.
- A sequential worksharing counter is assigned which generally starts from 1 (specific and sequential per RMS/competent authority assessing the VRA). All worksharing applications will be sequentially counted irrespective of product or MAH.
- For worksharing applications that include changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species, a sequential VRA under chapter "I" counter is applied.
- In addition to the worksharing application number, for each speciality included in the worksharing a MRP VRA number is created and maintained in CTS.
    - The MRP VRA number consists of the RMS country code, domain, product counter, speciality counter of the product followed by the worksharing qualifier or qualifier for worksharing procedure including change(s) of active substance(s), strength, pharmaceutical form, route of administration or food producing target species and the next available VRA sequence or VRA under chapter "I" counter of each product included.
    - The MRP VRA numbers have to be kept by the MAH in order to know the next sequence counter for a VRA concerning the relevant product only.
    - The MRP VRA numbers are not to be listed on the cover letter or the first page of the application form. MRP VRA numbers should only be listed in the table 'Products concerned by this application' in the application form.
    - For purely national MAs participating in a worksharing application no MRP VRA number has to be allocated.
- Each worksharing has a unique number.

When at least one Centrally authorised product is involved in the worksharing procedure the EMA will be the reference authority.

Example:

Given

Eleventh WS procedure for France:

FR/V/0100/sss last VRA chronological number: 011

FR/V/0103/sss last VRA chronological number: 003

If Work sharing FR/V/xxxx/WS/011 is for

- FR/V/0100/001
- FR/V/0100/002
- IE/V/0103/001

Then the MRP VRA numbers are:

- FR/V/0100/001/WS/012
- FR/V/0100/002 /WS/012
- IE/V/0103/001/WS/004

5.3.4. Procedure number for SPC-Harmonisation

The procedure number for SPC harmonisation procedures of reference products according to Article 70 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC will be as follows:

CC/V/xxxx /SPC/vvv

in which the element (see also Annex I MRP/DCP Numbering System):

CC is the initial of the Reference Member State (rapporteur) of the procedure

V Veterinary domain

xxxx the product counter is replaced by the placeholder: “xxxx”

SPC SPC stands for SPC harmonsiation

vvv chronological number for the SPC harmonisation procedures managed by one RMS

Example:

IT/V/xxxx/SPC/001:

IT is the rapporteur of the procedure

v for “veterinary”

SPC stands for SPC Harmonisation

001 is the number of SPC harmonisation procedures managed by IT

When the product will be transferred to MRP the product number it will receive a medicinal product number , e. g. IT/V/0369/001 (if 0369 is the next sequential number). This number will be stored in the UPD.

The harmonisation of generic and hybrid veterinary products according to Article 71 of Regulation (EU) 2019/6 will be processed via a VRA procedure under category G.I.2.b (please be referred to EMA-CMDv Guidance on the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and associated documentation requirements.). The procedure numbers of the respective VRA will be allocated as described in chapter 5.3.3.

Annex

Annex I: MRP/DCP Numbering System

CC/D/nnnn/sss/QQ/vvv/g

Elements	Elements description
CC	Initials of the Reference Member State AT: Austria BE: Belgium BG: Bulgaria CY: Cyprus CZ: Czech Republic DE: Germany DK: Denmark EE: Estonia EL: Greece ES: Spain FI: Finland FR: France HR: Croatia HU: Hungary IE: Ireland IS: Iceland IT: Italy LI: Liechtenstein LT: Lithuania LU: Luxembourg LV: Latvia MT: Malta NL: Netherlands NO: Norway PL: Poland PT: Portugal RO: Romania SE: Sweden SI: Slovenia SK: Slovakia EMA: European Medicines Agency (in worksharing only)
D	**V** = Veterinary
nnnn	Medicinal Product Number (4 digits)
sss	3 digits Speciality Number (for strength, pharmaceutical form/target species)
QQ	Procedure qualifier which assumes one of the following values: **MR**: for Mutual Recognition Procedure **DC**: for Decentralised Procedure **A**: for VRA other than changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species **E:** for 'Repeat-Use' **X:** for changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species in MRP **WS**: for worksharing procedure **WX:** for worksharing procedure including change(s) of active substance(s), strength, pharmaceutical form, route of administration or food producing target species **SPC:** SPC harmonisation of reference products
vvv	Chronological Number (3 digits)
G	G: Grouping qualifier