

## **PRODUCT TYPES + RATES VETERINARY**

**as per 01 January 2025**

<b>Reader's guide .....</b>	<b>2</b>
<b>Veterinary medicinal products .....</b>	<b>2</b>
<b>National procedures .....</b>	<b>2</b>
National - Application for marketing authorisation for veterinary medicinal products.....	2
National - Application for variation not requiring assessment (VNRA - submission via UPD) .....	2
National - Application for a variation requiring assessment (VRA) .....	3
National - National worksharing procedure (in which only national procedures are involved) NL is not the Reference Authority <sup>1,2</sup> .....	3
National - Transfer of marketing authorisation to another Marketing Authorisation Holder (MAH).....	4
National - Application and variations for homeopathic veterinary medicinal products .....	4
National - Application and variations for parallel trade licence .....	4
National - Application and variations for veterinary medicinal products intended for animals exclusively kept as pets .....	5
National - Other procedures .....	5
<b>Netherlands = Reference Member State (RMS).....</b>	<b>6</b>
RMS - Decentralised procedure - Application for marketing authorisation (DCP-RMS) .....	6
RMS - Mutual recognition procedure - Application for marketing authorisation (MRP-RMS) .....	6
RMS - Application for a variation not requiring assessment (VNRA submission via UPD) .....	6
RMS or Reference Authority in a Worksharing (RA) - Application for a variation requiring assessment (VRA) .....	7
<b>Netherlands = Concerned Member State (CMS).....</b>	<b>7</b>
CMS - Decentralised procedure - Application for marketing authorisation (DCP-CMS) .....	7
CMS - Mutual Recognition Procedure - Application for Marketing Authorisation (MRP-CMS) .....	7
CMS - Application for a variation not requiring assessment (VNRA submission via UPD) .....	8
CMS - Application for a variation requiring assessment (VRA).....	8
<b>SPC harmonisation .....</b>	<b>9</b>
<b>Annual fees veterinary medicinal product .....</b>	<b>9</b>
<b>Licenses for production and distribution .....</b>	<b>9</b>
Rates for licenses for manufacturing, import, wholesale and/or retail in veterinary medicinal products ....	9
<b>Annual fee per license or activity .....</b>	<b>10</b>

## Reader's guide

In the column 'VMPD Article' reference is made to the corresponding articles, which have been laid down by the [Dutch Veterinary Medicinal Products Decree 2022](#).

In the column '[Regulation. \(EU\) 2019/6](#) Article' lists the article(s) in which the type of application is described in more detail.

## Veterinary medicinal products

### National procedures

#### National - Application for marketing authorisation for veterinary medicinal products

Product type	Type of application	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1000	Application for marketing authorisation full dossier* (food producing animals)	€ 26.048,-	4.3.1	8/20/22/23
1001	Application for marketing authorisation full dossier* (non-food producing animals)	€ 17.049,-	4.9.1	8/20/22/23
1002	Application for marketing authorisation generic or hybrid dossier	€ 6.767,-	4.4.2/ 4.10.2	18/19
1003	Application for marketing authorisation informed consent	€ 1.594,-	4.3.5/4.9.5	2
264	Conversion of marketing authorisation to MRP-RMS full dossier* (food producing animals)	€ 17.049,-	4.7.1	52 8/20/22/23
265	Conversion of marketing authorisation to MRP-RMS full dossier* (non-food producing animals)	€ 13.194,-	4.13.1	52 8/20/22/23
266	Conversion of marketing authorisation to MRP-RMS generic/hybrid dossier (food producing animals)	€ 4.773,-	4.7.2	52 18/19
1005	Conversion of marketing authorisation to MRP-RMS generic/hybrid dossier (non-food-producing animals)	€ 3.751,-	4.13.2	52 18/19

\* This also includes bibliographical, fixed combination, duplicate and limited market applications.

#### National - Application for variation not requiring assessment (VNRA - submission via UPD)

Product type	Type of application	Rate (€)	VMP D Article	Regulation. (EU) 2019/6 Article
1011	VNRA*	€ 398,-	4.14.1	60.1 and 61
1012	VNRA mass change**	€ 3.546,-	4.15	60.1 and 61
1106	VNRA Supergrouping	€ 3.546,-	4.15	60.1 and 61

\* If the same application covers several marketing authorisations, € 398,- will be charged for each marketing authorisation for the administrative processing, see also \*\*;

\*\* If the applicant submits simultaneously identical variations for 9 or more marketing authorisations in the UPD, the total cost will not exceed € 3.546,-.

## National - Application for a variation requiring assessment (VRA)

Product type	Type of application**	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1013	VRA-Reduced*	€ 2.320,-	4.14.4.a	62/64
1014	VRA-Standard*	€ 7.673,-	4.14.3.a	62/64
1082	VRA-Standard G.I.18 update QRD template 9.0*	€ 2.320,-	4.14.4.a	62/64
1015	VRA - administrative ( <b>only for internal use, after intake BD-CM</b> )*	€ 398,-	4.14.4.c	
1016	VRA-E in case initial marketing authorisation is full dossier (food producing animals)	€ 26.048,-	4.14.5	62/64/66.3
1017	VRA-E in case initial marketing authorisation is full dossier (non-food producing animals)	€ 17.049,-	4.14.5	62/64/66.3
1018	VRA-E in case initial marketing authorisation is generic or hybrid dossier	€ 6.767,-	4.14.5	62/64/66.3

\* If the application covers several marketing authorisations for which additional assessment is not considered necessary, no assessment costs will be charged for each additional application, but only € 398,- each for administrative processing.

\*\* No distinction is made in the number of ticked variations with the same timetable (classified as single or grouped variations). For combination of variations with different timetables, the product type/rate of the longest timetable applies.

## National - National worksharing procedure (in which only national procedures are involved) NL is not the Reference Authority<sup>1,2</sup>

Product type	Type of application**	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1019	National WS VRA-Reduced*	€ 2.320,-	4.14.4.a	62/64/65
1020	National WS VRA-Standard*	€ 7.673,-	4.14.3.a	62/64/65
1021	National WS VRA-E in case initial marketing authorisation is full dossier (food producing animals)	€ 26.048,-	4.14.6	62/64/65/66.3
1022	National WS VRA-E in case initial marketing authorisation is full dossier (non-food producing animals)	€ 17.049,-	4.14.6	62/64/65/66.3
1023	National WS VRA-E in case initial marketing authorisation is generic or hybrid dossier	€ 6.767,-	4.14.6	62/64/65/66.3

<sup>1</sup> The rates depend on the role of the Netherlands: if NL = Reference Authority: see RMS procedures

<sup>2</sup> For VRA with Extended timetable(VRA-E), the rate also depends on the legal basis of the first authorisation application.

\* If the application covers several marketing authorisations for which additional assessment is not considered necessary, no assessment costs will be charged for each additional application, but only € 398,- each for administrative processing.

\*\* No distinction is made in the number of ticked of variations with the same timetable (classified as single or grouped variations). For combination of variations with different timetables, the product type/rate of the longest timetable applies.

## National - Transfer of marketing authorisation to another Marketing Authorisation Holder (MAH)

Product type	Type of application	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1024	Transfer of marketing authorisation to another MAH*	€ 398,-	4.16.1	
1025	Transfer of marketing authorisation to another MAH - mass change **	€ 3.546,-	4.16.2	

\* If the same transfer MAH covers several marketing authorisations, € 398,- will be charged for each marketing authorisation for the administrative processing, see also \*\*;

\*\* If the same transfer MAH is requested for 9 or more marketing authorisations, the total cost will not exceed € 3.546,-.

## National - Application and variations for homeopathic veterinary medicinal products

Product type	Type of application	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1006	Homeopathic marketing authorisation - full dossier* (food producing animals)	€ 6.767,-	4.5.1	85.2 (art. 5) 8/20/22/23
1007	Homeopathic marketing authorisation - full dossier* (non-food producing animals)	€ 2.913,-	4.11.1	85.2 (art.5) 8/20/22/23
1008	Homeopathic marketing authorisation - generic or hybrid dossier (food producing animals)	€ 6.767,-	4.5.1	85.2 (art.5) 18/19
1009	Homeopathic marketing authorisation - generic or hybrid dossier (non-food producing animals)	€ 2.913,-	4.11.1	85.2 (art.5) 18/19
1010	Request registration homeopathic - simplified dossier (without indication)	€ 1.423,-	4.6.1 / 4.12.1	85.1 (86 and 87)
1099	VRNA homeopathic marketing authorisation	€ 398,-	4.14.1	60.1 and 61
1100	VRA homeopathic marketing authorisation	€ 1.063,-	4.14.3.c	62
1101	Administrative variation homeopathic registration	€ 123,-	4.18a.2	N/A
1102	Variation homeopathic registration	€ 398,-	4.18a.1	N/A

\* This also includes bibliographical, fixed combination, duplicate and limited market applications.

## National - Application and variations for parallel trade licence

Product type	Type of application	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1004	Application for parallel trade licence	€ 1.063,-	4.17.1	102
1078	Application for parallel trade licence (administrative)	€ 398,-	4.17.2	102
1087	Variation for parallel trade licence	€ 123,-	4.17.3	102

**National - Application and variations for veterinary medicinal products intended for animals exclusively kept as pets**

Product type	Type of application	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1086	Application for VMP registration intended for animals exclusively kept as pets	€ 712,-	4.12a.1	5.6
1103	Variation VMP registration intended for animals exclusively kept as pets	€ 398,-	4.18a.1	5.6
1104	Administrative variation VMP registration intended for animals exclusively kept as pets	€ 123,-	4.18a.2	5.6

**National - Other procedures**

Product type	Type of application	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1105	QR code notification	-	-	-
248	Withdrawal of marketing authorisation	-	-	-
249	Hearing (consultation) with assessors	€ 4.091,-	4.18.2	-
1026	Meeting about a intended submission	€ 398,-	4.18.1	-
255	Permission for trials with feed additives	€ 35,75 (per 15 min.)	*	n.v.t.
256	Application for authorisation clinical trial for pharmaceuticals (incl. assessment)	€ 1.705,-	4.21.b + 4.21.a	9
257	Application for authorisation clinical trial for immunologicals (incl. assessment)	€ 1.705,-	4.21.b + 4.21.a	9
258	Clinical trial amendment/renewal	€ 342,-	4.21.c	9
245	Copy of original GMP certificate	€ 66,-	4.24	98
246	Certificate of batch release — national (administrative)	€ 265,-	4.19.1	128
589	Certificate of batch release — national (administrative) on the basis of mutual recognition OBPR/OCABR issued by other Member States	€ 66,-	4.19.2	128
590	Batch release certificate OBPR (administrative)	€ 265,-	4.19.1	128
557	Export certificate	€ 66,-	4.24	98
1027	Declaration at the request of the marketing authorisation holder (manufacturer/importer/distributor/MAH)	€ 66,-	4.24	
1088	Inspection veterinary pharmacovigilance	-	-	126

\* In accordance with Article 59, paragraph 1, of the Dutch Animal Feed Decree 2012.

## Netherlands = Reference Member State (RMS)

### RMS - Decentralised procedure - Application for marketing authorisation (DCP-RMS)

Product type	Type of application	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1028	Application for DCP - RMS marketing authorisation full dossier* - food-producing animals	€ 41.471,-	4.3.2.a	8/20/22/23
1029	Application for DCP - RMS marketing authorisation full dossier* - non-food producing animals	€ 28.617,-	4.9.2.a	8/20/22/23
1030	Application DCP - RMS marketing authorisation generic or hybrid dossier	€ 22.281,-	4.4.3.a/ 4.10.3.a	18/19
1031	Application DCP - RMS marketing authorisation informed consent	€ 1.594,-	4.3.5/4.9.5	21

\* This also includes bibliographical, fixed combination, duplicate and limited market applications.

### RMS - Mutual recognition procedure - Application for marketing authorisation (MRP-RMS)

Product type	Type of application	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1032	Application MRP - RMS marketing authorisation full dossier* - food-producing animals	€ 41.471,-	4.3.3.a	47 en 52 8/20/22/23
1033	Application MRP - RMS marketing authorisation full dossier* - non-food producing animals	€ 28.618,-	4.9.3.a	47 en 52 8/20/22/23
1034	Application MRP- RMS marketing authorisation generic or hybrid dossier	€ 16.161,-	4.4.4.a/ 4.10.4.a	47 en 52 18/19
1035	Application MRP - RMS marketing authorisation informed consent <i>or</i> Subsequent Recognition Procedure (SRP) informed consent	€ 1.594,-	4.3.5/ 4.9.5	21 <i>of</i> 21 en 53
1036	Application MRP/DCP RMS Subsequent Recognition Procedure (SRP), informed consent excluded	€ 5.313,-	4.3.4/ 4.9.4	53

\* This also includes bibliographical, fixed combination, duplicate and limited market applications.

### RMS - Application for a variation not requiring assessment (VNRA submission via UPD)

Product type	Type of application	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1037	RMS - VNRA*	€ 1.859,-	4.14.2.a	60.1 en 61
1038	RMS - VNRA mass change**	€ 3.546,-	4.15	60.1 en 61
1106	VNRA Supergrouping	€ 3.546,-	4.15	60.1 en 61

\* If the same application covers several marketing authorisations, € 531,- will be charged for each marketing authorisation for the administrative processing, see also \*\*;

\*\* If the applicant submits simultaneously identical variations for 5 or more marketing authorisations in the UPD, the total cost will not exceed € 3.546,-

## RMS or Reference Authority in a Worksharing (RA) - Application for a variation requiring assessment (VRA)

Product type	Type of application <sup>1</sup>	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1039	RMS VRA-Reduced*	€ 2.320,-	4.14.4.a	62/64/65
1040	RMS VRA-Standard*	€ 7.673,-	4.14.3.a	62/64/65
1083	RMS VRA-Standard-G.I.18 update QRD template 9.0*	€ 2.320,-	4.14.4.a	62/64/65
1041	RMS VRA-E in case initial marketing authorisation is full dossier (food producing animals)	€ 41.471,-	4.14.5/ 4.14.6/ 4.14.7/ 4.14.9	62/64/65/ 66.3
1042	RMS VRA-E in case initial marketing authorisation is complete dossier (non-food producing animals)	€ 28.618,-	4.14.5/ 4.14.6/ 4.14.7/ 4.14.9	62/64/65/ 66.3
1043	RMS VRA-E in case initial marketing authorisation is generic or hybrid dossier	€ 16.161,-	4.14.5/ 4.14.6/ 4.14.7/ 4.14.9	62/64/65/ 66.3

<sup>1</sup> No distinction is made between single/grouped/worksharing variations. For combination of variations with different timetables, the product type/rate of the longest timetable applies.

\* If the application concerns several marketing authorisations, for which additional assessment is not considered necessary, no assessment costs shall be charged for each additional application, but only € 531,- for administrative processing.

## Netherlands = Concerned Member State (CMS)

### CMS - Decentralised procedure - Application for marketing authorisation (DCP-CMS)

Product type	Type of application	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1044	Application for DCP - CMS marketing authorisation full dossier* - food-producing animals	€ 16.161,-	4.3.2.b	8/20/22/23
1045	Application for DCP - CMS marketing authorisation full dossier* - non-food producing animals	€ 10.229,-	4.9.2.b	8/20/22/23
1046	Application DCP - CMS marketing authorisation generic or hybrid dossier	€ 4.297,-	4.4.3.b/ 4.10.3.b	18/19
1047	Application DCP - CMS marketing authorisation informed consent	€ 1.594,-	4.3.5 4.9.5	21

\* This also includes bibliographical, fixed combination, duplicate and limited market applications.

### CMS - Mutual Recognition Procedure - Application for Marketing Authorisation (MRP-CMS)

Product type	Type of application	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1048	Application for MRP - CMS marketing authorisation full dossier* - food-producing animals	€ 10.229,-	4.3.3.b	8/20/22/23

1049	Application for MRP - CMS marketing authorisation full dossier* - non-food producing animals	€ 10.229,-	4.9.3.b	8/20/22/23
1050	Application for MRP - CMS marketing authorisation generic or hybrid dossier	€ 4.297,-	4.4.4.b 4.10.4.b	18/19
1051	Application for MRP - CMS marketing authorisation informed consent	€ 1.594,-	4.3.5 4.9.5	21
1052	Application for MRP - CMS Subsequent Recognition Procedure (SRP) – in case NL was already CMS in previous procedure	-	-	53

\* This also includes bibliographical, fixed combination, duplicate and limited market applications.

### CMS - Application for a variation not requiring assessment (VNRA submission via UPD)

Product type	Type of application	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1053	CMS - VNRA*	€ 531,-	4.14.2.b	60.1 en 61
1054	CMS - VNRA mass change**	€ 3.546,-	4.15	60.1 en 61
1106	VNRA Supergrouping	€ 3.546,-	4.15	60.1 en 61

\* If the same application covers several marketing authorisations, € 531,- will be charged for each marketing authorisation for the administrative processing, see also \*\*;

\*\* If the applicant submits simultaneously identical variations for 7 or more marketing authorisations in the UPD, the total cost will not exceed € 3.546,-.

### CMS - Application for a variation requiring assessment (VRA)

Product type	Type of application <sup>1</sup>	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1055	CMS VRA-Reduced, only CMS VMP*	€ 531,-	4.14.4.d	62/64/65
1079	CMS VRA-Reduced Worksharing, including RMS/national products are involved*	€ 2.320,-	4.14.4.a	62/64/65
1056	CMS VRA-Standard ( <i>quality</i> ) <sup>oo</sup> *	€ 531,-	4.14.4.d	62/64/65
1057	CMS VRA-Standard*	€ 5.115,-	4.14.3.a	62/64/65
1084	CMS VRA-Standard G.I.18 update QRD template 9.0*	€ 976,-	4.14.4.b	62/64/65
1077	CMS VRA-Standard* administrative ( <b>only for internal use, after intake BD-CM</b> )	€ 531,-	4.14.4.d	62/64/65
1058	CMS VRA-E <sup>2</sup> in case initial marketing authorisation complete dossier (food producing animals)	€ 10.229,-	4.14.8	62/64/65/ 66.3
1059	CMS VRA-E <sup>2</sup> in case initial marketing authorisation complete dossier (non-food producing animals)	€ 10.229,-	4.14.8	62/64/65/ 66.3
1060	CMS VRA-E <sup>2</sup> in case initial marketing authorisation generic or hybrid dossier Legal basic initial marketing authorisation generic or hybrid dossier	€ 4.297,-	4.14.8	62/64/65/ 66.3

<sup>1</sup> No distinction is made between single/grouped/worksharing variations. For combination of variations with different timetables, the product type/rate of the longest timetable applies.

\* In the case of an application for multiple marketing authorisations, for each marketing authorisations € 531,- is charged for administrative processing.

<sup>oo</sup> Only applicable for pharmaceuticals concerning variations related to part II and applied for CMS marketing authorisations only. In the case of a worksharing procedure with national and/or RMS marketing authorisations, product type 1057 applies.

<sup>2</sup> In the case of worksharing procedures involving RMS and/or national marketing authorisations and where NL is not the reference authority, the fees shall be charged in accordance with initial CMS submission fees.



## SPC harmonisation

Product type	Type of application	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1061	RMS/RA - SPC harmonisation	-		70
1062	CMS - SPC harmonisation	-		70

## Annual fees veterinary medicinal product

Product type	Annual fee for marketing authorisation	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
-	Annual fee for marketing authorisation veterinary medicinal product*	€ 619,-	4.1.1	-
-	Annual fee homeopathic veterinary medicinal product*	€ 310,-	4.1.2	-
-	Annual fee for authorisation parallel trade	€ 62,-	4.1.8	-
-	Annual fee for authorisation VMP intended for animals exclusively kept as pets*	€ 310,-	4.1.9	-

\* Once the authorisation has been granted, the fee shall be calculated in proportion to the number of months in which it is authorised to place the veterinary medicinal product on the market.

N.B. This applies only when a marketing authorisation is granted, not in case it is withdrawn.

## **Licenses for production and distribution**

### **Rates for licenses for manufacturing, import, wholesale and/or retail in veterinary medicinal products**

Product type	Type of application	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
1094	Application for a manufacturing license (administrative)	€ 619,-	4.20.1	88.1
1097	Change to the manufacturing license (administrative)	€ 247,-	4.20a.1	88.1
271	GMP-inspection manufacturer/importer – per half day session	€ 1.238,-	4.20.1 4.20a.1 4.23	90.1 94
1080	Application for a wholesale license (incl. company visit)	€ 761,-	4.20.2.a	99.1
1093	Application for a wholesale license (administrative)	€ 465,-	4.20.2.b	99.1
1081	Change to the wholesale license (incl. company visit)	€ 650,-	4.20a.2.a	99.1
1096	Change to the wholesale license (administrative)	€ 185,-	4.20a.2.b	99.1
267	Application for a retail license (including company visit)	€ 619,-	4.20.3.a	103.1
1092	Application for a retail license (administrative)	€ 310,-	4.20.3.b	103.1
276	Change to the retail license (including company visit)*	€ 433,-	4.20a.3.a	103.1
1095	Change to the retail license (administrative)	€ 123,-	4.20a.3.b	103.1

272	Withdrawal of manufacture, wholesale and/or retail license	-	-	-
1075	Notification of activities manufacturer, importer or distributor of active substances (API)	€ 310,-	4.25.1	95.1
1076	Change of notification activities manufacturer, importer or distributor of active substances (API)	€ 123,-	4.25.2	95.1
1085	Withdrawal of activities manufacturer, importer or distributor of active substances (API)	-	-	-
1089	Registration register for internet trade in veterinary medicinal products	€ 213,-	4.25a.1	104.5
1090	Variation register for internet trade in veterinary medicinal products	€ 119,-	4.25a.2	104.5
1091	Withdrawal from register for internet trade in veterinary medicinal products	-	-	-

\* Applicable in case of change of the location for storage/delivery of veterinary medicinal products specified in the license.

### **Annual fee per license or activity**

Product type	Annual fee	Rate (€)	VMPD Article	Regulation. (EU) 2019/6 Article
-	Annual fee per manufacturing, wholesale and retail licenses for veterinary medicinal products	€ 62,-	4.1.4, 4.1.5, 4.1.6	88.1, 99.1, 103.1
-	Annual fee per notification activities manufacturer, importer or distributor of active substances	€ 35,-	4.1.7	95.1
-	Annual fee for inclusion in the register for internet trade in veterinary medicinal products	€ 35,-	4.1.10	104.5