

**FEES for Marketing Authorisation (MA) and Parallel Import  
(application of decree n°2015-1172 published on 22/09/2015)  
Revision May 2016**

## 1 National procedure

### 1.1 Marketing authorisation application

Type	Article of the decree: D.5141-55	Fee for one veterinary medicinal product (VMP)	Fee for n VMP of the same range
Full application for a new active substance	I 1°	20 000 €	20 000 + (n-1) x 5 000 €
Full application for a known active substance/New association /Well established use/Hybrid/Biosimilar/Exceptional circumstances	I 2°a) – f)	14 000 €	14 000 + (n-1) x 5 000 €
Generic	I 3°	10 000 €	10 000 + (n-1) x 5 000 €
Informed Consent	I 4°	5 000 €	n x 5 000 €

### 1.2 Single variations and extension

Type	Article of the decree: D.5141-55	Fee for one veterinary medicinal product (VMP)	Fee for n VMP
Extension	II 1° and 2°	14 000 €	14 000 x (n-1) x 5 000 €
Single Type II variation	III 1° a) and c)	4 000 €	4 000 + (n-1) x 500 €
Type II variation for SPC	III 1° b) and c)	1 000 €	1 000 + (n-1) x 500 €
Single Type IB variation	III 2°a) and b)	1 000 €	1 000 + (n-1) x 250 €
Single Type IA variation	III 3°a) and b)	500 €	500 + (n-1) x 250 €

### 1.3 Grouped variations

**When only one veterinary medicinal product is concerned by several variations**

Type	Article of the decree: D.5141-58-4	Fee
Grouped IA variations	b)	1 000 €
Grouped variations (at least one Type IB variation)	c)	2 000 €
Grouped variations (at least one Type II variation)	d)	4 000 €

**When several veterinary medicinal products are concerned by one variation**

Type	Article of the decree: D.5141-58-4	Fee
Type IA variation concerning change of : Name of the MAH or address of the MA Holder or address of the manufacturer	a)	500 €

## 1.4 Application for Herbal products under well established use (10° D. 5141-20)

### 1.4.1 Marketing authorisation

Type	Article of the decree: D.5141-58-1-1	Fee for one veterinary medicinal product (VMP)	Fee for n VMP of the same range
Well established use	I 1°	5 000 €	5 000 + (n-1) x 1 000 €
Informed Consent	I 2°	1 000 €	n x 1 000 €

### 1.4.2 Single variations and extension

Type	Article of the decree: D.5141-58-1-1	Fee for one veterinary medicinal product (VMP)	Fee for n VMP
Extension	II 1° and 2°	3 000 €	3000 x (n-1) x 1 000 €
Single Type II variation	III 1°	800 €	800 + (n-1) x 100 €
Single Type IB variation	III 2°	200 €	200 + (n-1) x 100 €
Single Type IA variation	III 3°	100 €	n x 100 €

### 1.4.3 Grouped variations

#### When only one veterinary medicinal product is concerned by several variations

Type	Article of the decree: D.5141-58-4	Fee
Grouped IA variations	b)	200 €
Grouped variations (at least one Type IB variation)	c)	400 €
Grouped variations (at least one Type II variation)	d)	800 €

#### When several veterinary medicinal products are concerned by one variation

Type	Article of the decree: D.5141-58-4	Fee
Type IA variation concerning change of : Name of the MAH or address of the MA Holder or address of the manufacturer	a)	500 €

## 1.5 Application for Homeopathic VMP

### 1.5.1 Marketing authorisation application and variations

Type	Article of the decree: D 5141-58-2	Fee for one veterinary medicinal product (VMP)	Fee for n VMP
Full application	I 1°	5 000 €	5 000 + (n-1)x 1 000 €
Application with informed consent	I 2°	1 000 €	n x 1 000 €
Extension	II 1° and 2°	3 000 €	3 000 + (n-1) x 1 000 €
Single type II variation	III 1°	800 €	800 + (n-1) x 100 €
Single Type IB variation	III 2°	200 €	200 + (n-1) x 100 €
Single Type IA variation	III 3°	100 €	n x 100 €

### 1.5.2 Grouped variations

**When only one veterinary medicinal product is concerned by several variations**

Type	Article of decree: D.5141-58-4	Fee
Grouped Type IA variations	b)	200 €
Grouped variations (at least one Type IB variation)	c)	400 €
Grouped variations (at least one Type II variation)	d)	800 €

**When several veterinary medicinal products are concerned by one variation**

Type	Article of the decree: D.5141-58-4	Fee
Type IA variation concerning change of : Name of the MAH or address of the MA Holder or address of the manufacturer	a)	500 €

### 1.5.3 Registration

Type	Article of the decree: D 5141-58-3	Fee for one veterinary medicinal product (VMP)
Registration	1°	200 €
Variation of a registration	2°	100 €
Transformation of a Marketing Authorisation for Homeopathic VMP to registration	3°	10 000 €

## 2 Mutual Recognition Procedure – France as Reference Member State (RMS)

### 2.1 First Recognition of the French MA or repeat use of the mutual recognition

Type	Article of the decree: D.5141-56	Fee for one veterinary medicinal product	Fee for n VMP of the same range
<b>Full application for a new active substance</b> - Within one year after the French MA : - More than one year after the French MA	I 1°  II	12 000 €  24 000 €	12 000 + (n-1) x 3 000 €  24000 + (n-1) x 3000 €
<b>Full application for a known active substance/New association /Well established use/Hybrid/Biosimilar/ Exceptional circumstances</b> - Within one year after the French MA : - More than one year after the French MA	I 2°a) – f)  II	8 400 €  16 800 €	8 400 + (n-1)x 3 000 €  16 800 + (n-1)x 3 000 €
<b>Generic</b> - Within one year after the French MA : - More than one year after the French MA	I 3°  II	6 000 €  12 000 €	6 000 + (n-1)x 3 000 €  12 000 + (n-1)x 3 000 €
<b>Informed Consent</b> - Within one year after the French MA or More than one year after the French MA :	I 4°	3 000 €	n x 3 000 €

### 2.2 Repeat-use

Article of the decree : D. 5141-56 III

See 2.1- Applications submitted more than one year after the french marketing authorisation I1° to I 4°

## 2.3 Single variations or extensions

Type	Article of the decree: D.5141-56	Fee for one veterinary medicinal product (VMP)	Fee for n VMP
Extension			
- Within one year after the French MA :	IV 1° and 2°	8 400€	8 400 + (n-1) x 3 000 €
- More than one year after the French MA	V	16 800 €	16 800 + (n-1) x 3 000 €
Single Type II variation	VII 1° a) and c)	6 000 €	6 000 + (n-1) x 500 €
Type II variation/SPC	VII 1° b) and c)	1 500 €	1 500 + (n-1) x 500 €
Single Type IB variation	VII 2°	1 500 €	1 500 + (n-1) x 250 €
Single Type IA variation	VII 3° a) and b)	750 €	750 + (n-1) x 250 €

## 2.4 Grouped variations

### When only one veterinary medicinal product is concerned by several variations

Type	Article of the decree: D.5141-58-4	Fee
Grouped Type IA variations	b)	1 500 €
Grouped Type IB variations (at least one type IB variation)	c)	3 000 €
Grouped Type IB variations (at least one type II variation)	d)	6 000 €

### When several veterinary medicinal products are concerned by one variation

Type	Article of the decree: D.5141-58-4	Fee
Type IA variation concerning change of : Name of the MAH or address of the MA Holder or address of the manufacturer	a)	500 €

### 3 Mutual recognition procedure – France as Concerned member state (CMS)

#### 3.1 Recognition of a marketing authorisation from another Member State by France

Type	Article of the decree: D.5141-57	Fee for one veterinary medicinal product	Fee for n VMP of the same range
Full application for a new active substance	I 1°	11 000 €	11 000 + (n-1) x 2 750 €
Full application for a known active substance/New association /Well established use/Hybrid/Biosimilar/ Exceptional circumstances	I 2°a) – f)	7 700 €	7 700 + (n-1) x 2750 €
Generic	I 3°	5 500 €	5 500 + (n-1) x 2750 €
Informed Consent	I 4°	2 750 €	n x 2 750 €

#### 3.2 Single variations or extensions

Type	Article of the decree: D.5141-57	Fee for one veterinary medicinal product (VMP)	Fee for n VMP
Extension	II a) and b)	7 700 €	7 700 + (n-1) x 2750 €
Single Type II variation	III 1°a) and c)	3 000 €	3 000 + (n-1) x 500 €
Type II variation/SPC	III 1°b) and c)	1 000 €	1 000 + (n-1) x 500 €
Single Type IB variation	III 2°a) and b)	1 000 €	1 000 + (n-1) x 250 €
Single Type IA variation	III 3° a) and b)	500 €	500 + (n-1) x 250 €

#### 3.3 Grouped variations or extension

##### When only one veterinary medicinal product is concerned by several variations

Type	Article of the decree: D.5141-58-4	Fee
Grouped Type IA variations	b)	1 000 €
Grouped Type IB variations (at least one type IB variation)	c)	2 000 €
Grouped Type IB variations (at least one type II variation)	d)	3 000 €

##### When several veterinary medicinal products are concerned by one variation

Type	Article of the decree: D.5141-58-4	Fee
Type IA variation concerning change of : Name of the MAH or address of the MA Holder or address of the manufacturer	a)	500 €

## 4 Decentralised procedure- France as Reference member state (RMS)

### 4.1 Marketing authorisation application

Type	Article of the decree: D 5141-56-1	Fee for one veterinary medicinal product	Fee for n VMP of the same range
Full application for a new active substance	1°	25 000 €	25 000 + (n-1) x 10 000 €
Full application for a known active substance/New association /Well established use/Hybrid/Biosimilar/ Exceptional circumstances	2° a) – f)	20 000 €	20 000 + (n-1) x 10 000 €
Generic	3°	12 500 €	12 500 + (n-1) x 10 000 €
Informed Consent	4°	10 000 €	n x 10 000 €

### 4.2 Single variations or extensions

Type	Article of the decree: D.5141-56-1	Fee for one veterinary medicinal product (VMP)	Fee for n VMP
Extension	II 1° and 2°	20 000 €	20 000 + (n-1) x 10 000 €
Single Type II variation	III- D. 5141-56 VII 1 <sup>er</sup> a) et b)	6 000 €	6 000 + (n-1) x 500 €
Type II variation/SPC	III- D. 5141-56 VII 1 <sup>er</sup> c)	1 500 €	1 500 + (n-1) x 500 €
Single Type IB variation	III- D. 5141-56 VII 2°	1 500 €	1 500 + (n-1) x 250 €
Single Type IA variation	III- D. 5141-56 VII 3° a) et b)	750 €	750 + (n-1) x 250 €

### 4.3 Grouped variations or extension

#### When only one veterinary medicinal product is concerned by several variations

Type	Article of the decree: D.5141-58-4	Fee
Grouped Type IA variations	b)	1 500 €
Grouped Type IB variations (at least one type IB variation)	c)	3 000 €
Grouped Type IB variations (at least one type II variation)	d)	6 000 €

#### When several veterinary medicinal products are concerned by one variation

Type	Article of the decree: D.5141-58-4	Fee
Type IA variation concerning change of : Name of the MAH or address of the MA Holder or address of the manufacturer	a)	500 €

## 5 Decentralised procedure- France as Concerned member state (CMS)

### 5.1 Marketing authorisation application

Type	Article of the decree: D 5141-57	Fee for one veterinary medicinal product	Fee for n VMP of the same range
Full application for a new active substance	I 1°	11 000 €	11000 + (n-1) x 2 750 €
Full application for a known active substance/New association /Well established use/Hybrid/Biosimilar/ Exceptional circumstances	I 2° a) – f)	7 700 €	7 700 + (n-1) x 2750 €
Generic	I 3°	5 500 €	5 500 + (n-1) x 2750 €
Informed Consent	I 4°	2 750 €	n x 2 750 €

### 5.2 Extension application

Type	Article of the decree: D 5141-57	Fee for one veterinary medicinal product	Fee for n VMP of the same range
Extension	II a) and b)	7 700 €	7 700 + (n-1) x 2 750 €



## 6 Application for “MUMS” (minor use/minor specie) products

### 6.1 Marketing authorisation

Type	Article of the decree: D.5141-58	Fee for one veterinary medicinal product (VMP)	Fee for n VMP of the same range
Full application for a new active substance	I 1°	5 000 €	5 000 + (n-1) x 1 000 €
Full application for a known active substance/New association /Well established use/Hybrid/Biosimilar/ Exceptional circumstances immunological	I 2° a) – f)	3 000 €	3 000 + (n-1) x 1 000 €
Generic	I 3°	2 000 €	2 000 + (n-1) x 1 000 €
Informed Consent	I 4°	1 000 €	n x 1 000 €

### 6.2 Extension or single variations

Type	Article of the decree: D 5141-58	Fee for one veterinary medicinal product (VMP)	Fee for n VMP
Extensions	II 1° et 2°	3 000 €	3 000 + (n-1) x 500 €
Single Type II variation	III 1° a) et c)	800 €	800 + (n-1) x 100 €
Type II variation for SPC	III 1° b) et c)	200 €	200 + (n-1) x 100 €
Single Type IB variation	III 2° a) et b)	200 €	200 + (n-1) x 100 €
Single Type IA variation	III 3°)	100 €	n x 100 €

### 6.3 Grouped variations

#### When only one veterinary medicinal product is concerned by several variations

Type	Article of the decree: D.5141-58-4	Fee
Grouped Type IA variations	b)	200 €
Grouped variations (at least one Type IB variation)	c)	400 €
Grouped variations (at least one Type II variation)	d)	800 €

#### When several veterinary medicinal products are concerned by one variation

Type	Article of the decree: D.5141-58-4	Fee
Type IA variation concerning change of : Name of the MAH or address of the MA Holder or address of the manufacturer	a)	500 €

## 7 Application under article 4.2 of directive CE/2001/82 (VMP intended solely for aquarium fish, cage birds.....)

### 7.1 Marketing Autorisation

Type	Article of the decree: D 5141-58-1	Fee for one veterinary medicinal product (VMP)	Fee for n VMP
Full application	I 1°	2 500 €	2 500 + (n-1) x 500 €
Application with informed consent	I 2°	500 €	n x 500 €

### 7.2 Extension or single variations

Type	Article of the decree: D 5141-58-1	Fee for one veterinary medicinal product (VMP)	Fee for n VMP
Extension	II 1° and 2°	1 500 €	1 500 + (n-1) x 500 €
Single Type II variation	III 1° and 2°	400 €	400 + (n-1) x 100 €
Type II variation/SPC	III 2°	100 €	n x 100 €
Single Type IB variation	III 3°	100 €	n x 100 €
Single Type IA variation	III 4°	100 €	n x 100 €

### 7.3 Grouped variations

#### When only one veterinary medicinal product is concerned by several variations

Type	Article of the decree: D.5141-58-4	Fee
Grouped Type IA variations	b)	200 €
Grouped variations (at least one Type IB variation)	c)	200 €
Grouped variations (at least one Type II variation)	d)	400 €

#### When several veterinary medicinal products are concerned by one variation

Type	Article of the decree: D.5141-58-4	Fee
Type IA variation concerning change of : Name of the MAH or address of the MA Holder or address of the manufacturer	a)	500 €

## 8 Worksharing

Type	Article of decree: D.5141-58-5	Fee
FR = Reference member state	a)	8 000 €
FR = Concerned member state	b)	3 000 €

## 9 MA transfert

Type	Article of the decree: D. 5141-59	Fee for one veterinary medicinal product (VMP)	Fee for n VMP
MA transfer	1°	1 500 €	n x 1 500 €
MA transfer for MUMS /under Exceptional Circumstances or homeopathic	2°	400 €	n x 400 €
Registration transfer (homeopathic)	3°	100 €	n x 100 €

## 10 Parallel Import

Type	Article of the decree: D.5141-123-21	Fee for one veterinary medicinal product (VMP)
First application	a)	2 500 €
Application for a VMP already Imported	c)	1 500 €
Renewal	b)	1 500 €