

## TAXES ON VETERINARY MEDICINAL PRODUCT MARKETING AUTHORISATIONS

### SUBJECT

January 1<sup>st</sup>, 2023

Application of Decree No 2021-1859 of 28 December 2021  
on the adaptation and simplification of taxes on veterinary  
medicinal products

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## APPLICATION FOR MARKETING AUTHORISATION

Reference: Article D. 5141-55 of the Public Health Code

Title Legal bases	Regulatory reference Art. D. 5141-55	Amount of tax payable for a medicinal product NATIONAL <sup>1</sup> or FR RMS <sup>2</sup>	Regulatory reference Art. D. 5141-55	Amount of tax payable for several medicinal products NATIONAL or FR RMS	Regulatory reference Art. D. 5141-55	Amount of tax payable for a medicinal product FR CMS <sup>3</sup>	Regulatory reference Art. D. 5141-55	Amount of tax payable for several medicinal products FR CMS
Complete file New Association Well-established use	I(1)(a) I (1) (b) I(1)(c)	EUR 26,075	1° 6th subparagraph	EUR 26,075 + (N-1) x EUR 5,215	II(1)(a) II (1) (b) II (1) (c)	EUR 12,516	II (1) 20th subparagraph	EUR 12,516 + (N-1) x EUR 3,129
Generic Hybrid	I(2)(a) I(2)(b)	EUR 20,860	I 2° 10th subparagraph	EUR 20,860 + (N-1) x EUR 5,215	II(2)(a) II(2)(b)	EUR 7,823	II 2° 24th subparagraph	EUR 7,823 + (N-1) x EUR 3,129
Consent	I 3(a)	EUR 5,215	I 3° (a)	EUR 5,215 + (N-1) x EUR 5,215	II 3° (a)	EUR 5,215	II 3° (a)	EUR 5,215 + (N-1) x 3,129
Limited Market Exceptional Circumstances	I 3° (b) I 3° (c)	EUR 5,215	I 3° (b) I 3° (c)	EUR 5,215 + (N-1) x EUR 5,215	II 3° (b) II 3° (c)	EUR 5,215	II 3° 29th subparagraph	EUR 5,215 + (N-1) x 3,129

<sup>1</sup> National: application for authorisation under national procedure

<sup>2</sup> FR RMS: application for authorisation under decentralised procedure, mutual recognition or subsequent recognition for which France acts as a reference Member State

<sup>3</sup> FR CMS: application for authorisation under decentralised procedure, mutual recognition or subsequent recognition for which France acts as the Member State concerned

## REQUEST FOR VARIATION REQUIRING AN ASSESSMENT

Reference: Article D. 5141-56 of the Public Health Code

### Single variation

Title	Amount of tax payable for a medicinal product NATIONAL Or FR RMS Art. D. 5141-56 I	Amount of tax payable for several NATIONAL medicinal products Or FR RMS Art. D. 5141-56 I	Amount of tax payable for a medicinal product FR CMS Art. D. 5141-56 II	Amount of tax payable for several medicinal products FR CMS Art. D. 5141-56 II	Maximum amount Article D. 5141-56 VI
Single variation requiring an assessment	EUR 5,215	EUR 5,215 + (N-1) x EUR 1,043	EUR 3,129	EUR 3,129 + (N-1) x EUR 1,043	EUR 52,150

### Grouping of variations

Title	Amount of tax payable for a NATIONAL medicinal product Or FR RMS Art. D. 5141-56 III	Amount of tax payable for several NATIONAL medicinal products Or FR RMS Art. D. 5141-56 III	Amount of tax payable for a medicinal product FR CMS Art. D. 5141-56 IV	Amount of tax payable for several medicinal products FR CMS Art. D. 5141-56 IV	Maximum amount Article D. 5141-56 VI
Grouping of variations requiring an assessment	EUR 6,258	EUR 6,258 + (N-1) x EUR 1,043	EUR 4,172	EUR 4,172 + (N-1) x EUR 1,043	EUR 52,150

## Worksharing

Title	Amount of tax payable for a medicinal product FR RMS Art. D. 5141-56 V	Amount of tax payable for several medicinal products FR RMS Art. D. 5141-56 V	Amount of tax payable for a medicinal product FR CMS Art. D. 5141-56 V	Amount of tax payable for several medicinal products FR CMS Art. D. 5141-56 V	Maximum amount Article D. 5141-56 VI
Worksharing	EUR 5,215	EUR 5,215 + (n-1) x EUR 522	EUR 3,129	EUR 3,129 + (n-1) x EUR 522	EUR 52,150

## APPLICATION FOR THE TRANSFER OF MARKETING AUTHORISATION

Reference: Article D. 5141-55 of the Public Health Code

Title	Amount of tax payable for a medicinal product Art. D. 5141-55 III	Amount of tax payable for several medicinal products Art. D. 5141-55 III	Maximum amount Art. D. 5141-55 IV
New application	EUR 1,565	N x EUR 1,565	EUR 52,150

## APPLICATION FOR REGISTRATION OF HOMEOPATHIC MEDICINAL PRODUCT

Reference: Article D. 5141-55-1 of the Public Health Code

Title	Amount of tax payable for <u>one</u> medicinal product Art. D. 5141-55-1 I	Amount of tax payable for several medicinal products Art. D. 5141-55-1 II	Maximum amount Art. D. 5141-55-1 III
New application	EUR 1,565	N x EUR 1,565	EUR 52,150