

TAXES ON VETERINARY MEDICINAL PRODUCT MARKETING AUTHORISATIONS

SUBJECT

January 28th, 2022

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

Summary

Application for marketing authorisation	2
Request for a variation requiring an assessment.....	3
Isolated variation of MA.....	3
Group variations to MAs.....	3
Worksharing.....	4
Application for the transfer of marketing authorisation.....	4
Application for registration of homeopathic medicinal product.....	4

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 eligible tax for a medicinal product NATIONAL ¹ or FR RMS ²	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 eligible tax for a medicinal product FR CMS ³	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 25,000	1° 6th subparagraph	EUR 25,000 + (N-1) x EUR 5,000	II(1)(a) II (1) (b) II (1) (c)	EUR 12,000	II (1) 20th subparagraph	EUR 12,000 + (N-1) x EUR 3,000
Generic Hybrid	I(2)(a) I(2)(b)	EUR 20,000	I 2° 10th subparagraph	EUR 20,000 + (N-1) x EUR 5,000	II(2)(a) II(2)(b)	EUR 7,500	II 2° 24th subparagraph	EUR 7,500 + (N-1) x EUR 3,000
Consent	I 3(a)	EUR 5,000	I 3° (a)	EUR 5,000 + (N-1) x EUR 5,000	II 3° (a)	EUR 5,000	II 3° (a)	EUR 5,000 + (N-1) x 3,000
Limited Market Exceptional Circumstances	I 3° (b) I 3° (c)	EUR 5,000	I 3° (b) I 3° (c)	EUR 5,000 + (N-1) x EUR 5,000	II 3° (b) II 3° (c)	EUR 5,000	II 3° 29th subparagraph	EUR 5,000 + (N-1) x 3,000

¹ National: application for authorisation under national procedure

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

³ 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 eligible tax 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 eligible tax 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 5,000	EUR 5,000 + (N-1) x EUR 1,000	EUR 3,000	EUR 3,000 + (N-1) x EUR 1,000	EUR 50,000

Grouping of variations

Title	Amount of eligible tax 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 eligible tax 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 6,000	EUR 6,000 + (N-1) x EUR 1,000	EUR 4,000	EUR 4,000 + (N-1) x EUR 1 000	EUR 50,000

Worksharing

Title	Amount of eligible tax 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 eligible tax 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 5,000	EUR 5,000 + (n-1) x EUR 500	EUR 3,000	EUR 3,000 + (n-1) x EUR 500	EUR 50,000

APPLICATION FOR THE TRANSFER OF MARKETING AUTHORISATION

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

Title	Amount of eligible tax 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 1,500	N x EUR 1,500	EUR 50,000

APPLICATION FOR REGISTRATION OF HOMEOPATHIC MEDICINAL PRODUCT

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

Title	Amount of eligible tax for a 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 1,500	N x EUR 1,500	EUR 50,000