



N°51592#05

INSTRUCTIONS FOR FILLING IN THE REMITTANCE FORM FOR PAYMENTS TO THE DGFiP for duties payable pursuant to Article 1635 bis AE of the French General Tax Code

INSTRUCTIONS

Please keep this document.

It contains instructions for completing the remittance form.

It explains how to make payments for registration duties payable pursuant to Article 1635 *bis* AE of the French General Tax Code (e.g. Articles L.5121-15, L.5121-16 and L.5122-5 of the Public Health Code), including:

- Registration of homeopathic products and any amendments or renewals
- Registration of traditional herbal medicinal products and any amendments or renewals
- Marketing authorisations and any amendments or renewals
- Recognition of a marketing authorisation issued by the Agency
- Parallel import authorisations
- Advertising filings
- A separate remittance from (template available for download from impots.gouv.fr) must be submitted for each payment (only bank transfers are accepted). The amount on the form must match the transfer amount.
- **②** The form **must** be sent by email to the address indicated in the "Our Contact Details" box no later than the date of the transfer to ensure it is properly recorded. **Do not include the debit notice.**
- Please make sure to correctly enter the details on the form (particularly the email address you wish to have your payment receipt sent to) and the contact name.

Businesses have a right to access and correct any information that may be used by the Public Finances Directorate General (DGFiP).

4 Each line on the form may correspond to one or more applications.

In the first column, enter one of the following:

- > the appropriate code from the enclosed table
- the letter "C" if it is for a supplementary payment (for an amount that does not appear in the table)
- The document must be dated and signed and include the name and title of the signatory.
- **6** The bank transfer must include the following details:
- the laboratory reference numbers on the remittance form, which must appear as follows: first three letters of the applicant's name + a five-digit number (e.g. EAM00012)
- the applicant's intracommunity VAT number (or the applicant's name if they do not have a VAT number)
- A receipt will be issued for each application that meets all of the above conditions. A copy will be sent by email once receipt of payment is confirmed.

Scale of Rates for Fees

	Request to register, amend or renew homeopathic product	 S
Request Code (To be copied on the remittance for payments)	Description of Request	Rates (To be copied on the remittance for payments)
	Request to register a homeopathic medication or series of homeopathic medications obtained from the same homeopathic strain(s) related to authorised homeopathic medications placed on the market after 18 th January 1994:	
TD0001	Unitary homeopathic medication or series of homeopathic medications obtained from the same homeopathic strain	1,768 euros
TD0002	Complex homeopathic medication or series of homeopathic medications obtained from two to five homeopathic strains	2,478 euros
TD0003	Complex homeopathic medication or series of homeopathic medications obtained from six or more homeopathic strains	7,600 euros
	Request to register a homeopathic medication or series of homeopathic medications obtained from the same homeopathic strain(s) related to authorised homeopathic medications placed on the market before 18 th January 1994:	
TD0004	Unitary homeopathic medication or series of homeopathic medications obtained from the same homeopathic strain	760 euros
TD0005	Complex homeopathic medications or series of homeopathic medications obtained from two to five homeopathic strains	1,256 euros
TD0006	Complex homeopathic medications or series of homeopathic medications obtained from six or more homeopathic strains	3,800 euros
TD0007	Request to amend the registration	496 euros
TD0008	Request to renew the registration	1,500 euros
Reque	st to register, amend or renew traditional herbal medicinal p	products
	Request for Registration:	
TD0009	Decentralised Procedure – France as Country of Reference	21,000 euros
TD0010	Decentralised Procedure – Other Country of Reference	14,000 euros
TD0011	Mutual Recognition Procedure – Other Country of Reference	14,000 euros

TD0012	National Procedure	14,000 euros
TD0013	Request to amend the registration	1,400 euros
TD0014	Request to renew the registration	5,000 euros
	Marketing authorisation request	
	Request for marketing authorisation for a proprietary pharmaceutical product or other medication mentioned in Article L. 5121-8 of the Public Health Code, presented in compliance with Articles R. 5121-21 and R. 5121.25:	
TD0015	Decentralised Procedure – France as Country of Reference	55,000 euros
TD0016	Decentralised Procedure – Other Country of Reference	35,700 euros
TD0017	Mutual Recognition Procedure – Other Country of Reference	35,700 euros
TD0018	Mutual Recognition Procedure – France as Country of Reference	17,600 euros
	(Request for recognition by at least one other member country for an MAA already issued by the Agency)	
TD0019	National Procedure	35,700 euros
	For each additional dose or pharmaceutical form of the same proprietary product or for another medication mentioned in Article L. 5121-8 of the Public Health Code presented simultaneously with the initial request for authorisation related to the request defined below:	
TD0020	Decentralised Procedure – France as Country of Reference	27,500 euros
TD0021	Decentralised Procedure – Other Country of Reference	17,850 euros
TD0022	Mutual Recognition Procedure – Other Country of Reference	17,850 euros
TD0023	Mutual Recognition Procedure – France as Country of Reference (Request for recognition by at least one other member)	8,800 euros
	country for an MAA already issued by the Agency)	
TD0024	National Procedure	17,850 euros
	Request for marketing authorisation or extension for a proprietary pharmaceutical product or other medication mentioned in Article L. 5121-8 of the Public Health Code, presented in compliance with paragraph 2° of Article R. 5121-26, containing a new combination :	
TD0025	Decentralised Procedure – France as Country of Reference	38,500 euros
TD0026	Decentralised Procedure – Other Country of Reference 2/11	24,150 euros

TD0027	Mutual Recognition Procedure – Other Country of Reference	24,150 euros
TD0028	Mutual Recognition Procedure – France as Country of Reference	13,200 euros
	(Request for recognition by at least one other member country for an MAA already issued by the Agency)	
TD0029	National Procedure	24,150 euros
	For each additional dose or pharmaceutical form of the same proprietary product or for another medication mentioned in Article L. 5121-8 of the Public Health Code presented simultaneously with the initial request for authorisation related to the request defined below:	
TD0030	Decentralised Procedure – France as Country of Reference	19,250 euros
TD0031	Decentralised Procedure – Other Country of Reference	12,075 euros
TD0032	Mutual Recognition Procedure – Other Country of Reference	12,075 euros
TD0033	Mutual Recognition Procedure – France as Country of Reference	6,600 euros
	(Request for recognition by at least one other member country for an MAA already issued by the Agency)	
TD0034	National Procedure	12,075 euros
	Request for marketing authorisation or extension for a proprietary pharmaceutical product or other medication mentioned in Article L. 5121-8 of the Public Health Code, presented in compliance with paragraph 3° of Article R. 5121-26 or paragraph 2° of Article R. 5121-28 and related to an administrative process different from that of the original request:	
TD0035	Decentralised Procedure – France as Country of Reference	38,500 euros
TD0036	Decentralised Procedure – Other Country of Reference	24,150 euros
TD0037	Mutual Recognition Procedure – Other Country of Reference	24,150 euros
TD0038	Mutual Recognition Procedure – France as Country of Reference	12,000 euros
	(Request for recognition by at least one other member country for an MAA already issued by the Agency)	
TD0039	National Procedure	24,150 euros

	For each additional dose or pharmaceutical form of the same proprietary product or for another medication mentioned in Article L. 5121-8 of the Public Health Code presented simultaneously with the initial request for authorisation related to the request defined below:	
TD0040	Decentralised Procedure – France as Country of Reference	19,250 euros
TD0041	Decentralised Procedure – Other Country of Reference	12,075 euros
TD0042	Mutual Recognition Procedure – Other Country of Reference	12,075 euros
TD0043	Mutual Recognition Procedure – France as Country of Reference	6,600 euros
	(Request for recognition by at least one other member country for an MAA already issued by the Agency)	
TD0044	National Procedure	12,075 euros
	Request for marketing authorisation or extension for a proprietary pharmaceutical product or other medication mentioned in Article L. 5121-8 of the Public Health Code, presented in compliance with paragraph 1° of Article R. 5121-26 concerning a proprietary product with well-established medical use demonstrated by reference to bibliographic documents :	
TD0045	Decentralised Procedure – France as Country of Reference	38,500 euros
TD0046	Decentralised Procedure – Other Country of Reference	24,150 euros
TD0047	Mutual Recognition Procedure – Other Country of Reference	24,150 euros
TD0048	Mutual Recognition Procedure – France as Country of Reference (Request for recognition by at least one other member)	13,200 euros
	country for an MAA already issued by the Agency)	
TD0049	National Procedure	24,150 euros
	For each additional dose or pharmaceutical form of the same proprietary product or for another medication mentioned in Article L. 5121-8 of the Public Health Code presented simultaneously with the initial request for authorisation related to the request defined below:	
TD0050	Decentralised Procedure – France as Country of Reference	19,250 euros
TD0051	Decentralised Procedure – Other Country of Reference	12,075 euros
TD0052	Mutual Recognition Procedure – Other Country of Reference	12,075 euros

TD0053	Mutual Recognition Procedure – France as Country of Reference	6,600 euros
	(Request for recognition by at least one other member country for an MAA already issued by the Agency)	
TD0054	National Procedure	12,075 euros
	Request for marketing authorisation or extension for a proprietary pharmaceutical product or other medication mentioned in Article L. 5121-8 of the Public Health Code, presented in compliance with paragraph 2° of Article R. 5121-28, and related to one or more different therapeutic indications:	
TD0055	Decentralised Procedure – France as Country of Reference	38,500 euros
TD0056	Decentralised Procedure – Other Country of Reference	24,150 euros
TD0057	Mutual Recognition Procedure – Other Country of Reference	24,150 euros
TD0058	Mutual Recognition Procedure – France as Country of Reference (Request for recognition by at least one other member country for an MAA already issued by the Agency)	13,200 euros
TD0059	National Procedure	24,150 euros
	For each additional dose or pharmaceutical form of the same proprietary product or for another medication mentioned in Article L. 5121-8 of the Public Health Code presented simultaneously with the initial request for authorisation related to the request defined below:	
TD0060	Decentralised Procedure – France as Country of Reference	19,250 euros
TD0061	Decentralised Procedure – Other Country of Reference	12,075 euros
TD0062	Mutual Recognition Procedure – Other Country of Reference	12,075 euros
TD0063	Mutual Recognition Procedure – France as Country of Reference (Request for recognition by at least one other member country for an MAA already issued by the Agency)	6,600 euros
TD0064	National Procedure	12,075 euros

	Request for marketing authorisation or extension for a proprietary pharmaceutical product or other medication mentioned in Article L. 5121-8 of the Public Health Code, presented in compliance with paragraph 3° of Article R. 5121-26 or paragraph 2° of Article R. 5121-28 and related to a dose different from that of the original request without changing either the administrative process or the therapeutic indication:	
TD0065	Decentralised Procedure – France as Country of Reference	23,100 euros
TD0066	Decentralised Procedure – Other Country of Reference	14,700 euros
TD0067	Mutual Recognition Procedure – Other Country of Reference	14,700 euros
TD0068	 Mutual Recognition Procedure – France as Country of Reference (Request for recognition by at least one other member country for an MAA already issued by the Agency) 	7,700 euros
TD0069	National Procedure	14,700 euros
	Request for marketing authorisation or extension for a proprietary pharmaceutical product or other medication mentioned in Article L. 5121-8 of the Public Health Code, presented in compliance with paragraphs 1°, 3° or 4° of Article R. 5121-28 or with Article R. 5121-29-1, related to generic products , similar biological medications and to medications with the same qualitative and quantitative composition in terms of active ingredients and of the same pharmaceutical form as an authorised medication:	
TD0070	Decentralised Procedure – France as Country of Reference	23,100 euros
TD0071	Decentralised Procedure – Other Country of Reference	14,700 euros
TD0072	Mutual Recognition Procedure – Other Country of Reference	14,700 euros
TD0073	Mutual Recognition Procedure – France as Country of Reference (Request for recognition by at least one other member country for an MAA already issued by the Agency)	7,700 euros
TD0074	National Procedure	14,700 euros
	Request for marketing authorisation or extension for a proprietary pharmaceutical product or other medication mentioned in Article L. 5121-8 of the Public Health Code, related to a new pharmaceutical form without changing either the administrative process or the therapeutic indication:	
TD0075	Decentralised Procedure – France as Country of Reference	23,100 euros
TD0076	Decentralised Procedure – Other Country of Reference	14,700 euros

TD0077	Mutual Recognition Procedure – Other Country of Reference	14,700 euros
TD0078	Mutual Recognition Procedure – France as Country of Reference (Request for recognition by at least one other member)	7,700 euros
	country for an MAA already issued by the Agency)	
TD0079	National Procedure	14,700 euros
	Request for marketing authorisation or extension for a proprietary pharmaceutical product or other medication mentioned in Article L. 5121-8 of the Public Health Code, presented in compliance with paragraph 2° of Article R. 5121-28 and concerning differences related to the active ingredient or when the bioequivalence in relation to the reference proprietary product was not able to be shown by means of bioavailability studies and the proprietary product does not meet the conditions stipulated in Article R. 5121-29-1:	
TD0080	Decentralised Procedure – France as Country of Reference	23,100 euros
TD0081	Decentralised Procedure – Other Country of Reference	14,700 euros
TD0082	Mutual Recognition Procedure – Other Country of Reference	14,700 euros
TD0083	Mutual Recognition Procedure – France as Country of Reference (Paguage for recognition by at least one other recognition.)	7,700 euros
	(Request for recognition by at least one other member country for an MAA already issued by the Agency)	
TD0084	National Procedure	14,700 euros
	Request for marketing authorisation or extension for a proprietary pharmaceutical product or other medication mentioned in Article L. 5121-8 of the Public Health Code, presented in compliance with paragraph 3° of Article R. 5121-26 and concerning differences related to the active ingredient or the change in bioavailability or the pharmacokinetics:	
TD0085	Decentralised Procedure – France as Country of Reference	23,100 euros
TD0086	Decentralised Procedure – Other Country of Reference	14,700 euros
TD0087	Mutual Recognition Procedure – Other Country of Reference	14,700 euros
TD0088	Mutual Recognition Procedure – France as Country of Reference (Request for recognition by at least one other member)	7,700 euros
	country for an MAA already issued by the Agency)	
TD0089	National Procedure	14,700 euros

	Request for marketing authorisation or extension for a proprietary pharmaceutical product or other medication mentioned in Article L. 5121-8 of the Public Health Code, consisting of an allergen , by family of products:	
TD0090	Decentralised Procedure – France as Country of Reference	23,100 euros
TD0091	Decentralised Procedure – Other Country of Reference	14,700 euros
TD0092	Mutual Recognition Procedure – Other Country of Reference	14,700 euros
TD0093	Mutual Recognition Procedure – France as Country of Reference	7,700 euros
	(Request for recognition by at least one other member country for an MAA already issued by the Agency)	
TD0094	National Procedure	14,700 euros
	Request for marketing authorisation or extension for a proprietary pharmaceutical product or other medication mentioned in <u>Article L. 5121-8</u> of the Public Health Code consisting of a homeopathic medication that was authorised and placed on the market after 18 th January 1994:	
TD0095	Decentralised Procedure – France as Country of Reference	23,100 euros
TD0096	Decentralised Procedure – Other Country of Reference	14,700 euros
TD0097	Mutual Recognition Procedure – Other Country of Reference	14,700 euros
TD0098	National Procedure	14,700 euros
	Request for marketing authorisation or extension for a proprietary pharmaceutical product or other medication mentioned in Article L. 5121-8 of the Public Health Code consisting of a homeopathic medication that was authorised and placed on the market before 18 th January 1994:	
TD0099	Decentralised Procedure – France as Country of Reference	2,310 euros
TD0100	Decentralised Procedure – Other Country of Reference	1,470 euros
TD0101	Mutual Recognition Procedure – Other Country of Reference	1,470 euros
TD0102	National Procedure	1,470 euros

Request to amend or renew marketing authorisation		
TD0103	Request to amend a marketing authorisation for a proprietary pharmaceutical product or other medication mentioned in Article L. 5121-8 of the Public Health Code, and related to adding a therapeutic indication or amending an existing one.	22,000 euros
	Regardless of the procedure used.	
TD01041	Request to amend a marketing authorisation for a proprietary pharmaceutical product or other medication mentioned in Article L. 5121-8 of the Public Health Code, for variations of type II as defined in Commission Regulation (EC) no. 1234/2008 of 24 November 2008, except for those listed in paragraph III(4°) of Article 344 <i>undecies</i> A of the General Tax Code (TD0103).	3,500 euros
	Regardless of the procedure used.	
TD01042	Request to amend a marketing authorisation for variations of type IA given in the enumerative list published in Decree no. 2019-388 of 30 April 2019 or for variations of type IB referred to in Article 2(5) of Commission Regulation (EC) no. 1234/2008 of 24 November 2008.	2,500 euros
	Regardless of the procedure used.	
TD01043	Request to amend a marketing authorisation requested in compliance with Articles R. 5121-41 and R. 5121-46 of the Public Health Code.	2,500 euros
	Regardless of the procedure used.	
TD0105	Request for renewal concerning a marketing authorisation for a proprietary product or other medication mentioned in Article L. 5121-8 of the Public Health Code.	7,000 euros
	Regardless of the procedure used.	

Request for parallel import authorisation			
TD0106	Request for parallel import authorisation mentioned in Article R. 5121-120 of the Public Health Code	5,000 euros	
TD0107	Application to amend a parallel import authorisation	500 euros	
TD0108	Request for 5-year renewal of a parallel import authorisation mentioned in <u>Article R. 5121-125</u> of the Public Health Code	674 euros	
	Request for advertising		
TD0109	Request for approval or renewal of approval for advertising mentioned in Articles L. 5122-8, L. 5122-9 and L. 5122-14 of the Public Health Code	510 euros	
TD0110	Request for authorisation or renewal of authorisation for advertising in Articles L. 5213-4 and L. 5223-3 of the Public Health Code	510 euros	
Supplementary request			
TD0111	Supplementary request	Variable	