

**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

❶ A separate remittance form (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.

❷ 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.**

❸ 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).

❹ 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)

❺ The document must be dated and signed and include the name and title of the signatory.

❻ 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)

❼ 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 products		
Request Code <i>(To be copied on the remittance for payments)</i>	Description of Request	Rates <i>(To be copied on the remittance for payments)</i>
	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	<ul style="list-style-type: none"> • Unitary homeopathic medication or series of homeopathic medications obtained from the same homeopathic strain 	1,768 euros
TD0002	<ul style="list-style-type: none"> • Complex homeopathic medication or series of homeopathic medications obtained from two to five homeopathic strains 	2,478 euros
TD0003	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Unitary homeopathic medication or series of homeopathic medications obtained from the same homeopathic strain 	760 euros
TD0005	<ul style="list-style-type: none"> • Complex homeopathic medications or series of homeopathic medications obtained from two to five homeopathic strains 	1,256 euros
TD0006	<ul style="list-style-type: none"> • 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
Request to register, amend or renew traditional herbal medicinal products		
	Request for Registration:	
TD0009	<ul style="list-style-type: none"> • Decentralised Procedure – France as Country of Reference 	21,000 euros
TD0010	<ul style="list-style-type: none"> • Decentralised Procedure – Other Country of Reference 	14,000 euros
TD0011	<ul style="list-style-type: none"> • Mutual Recognition Procedure – Other Country of Reference 	14,000 euros

TD0012	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Decentralised Procedure – France as Country of Reference 	55,000 euros
TD0016	<ul style="list-style-type: none"> Decentralised Procedure – Other Country of Reference 	35,700 euros
TD0017	<ul style="list-style-type: none"> Mutual Recognition Procedure – Other Country of Reference 	35,700 euros
TD0018	<ul style="list-style-type: none"> 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)	17,600 euros
TD0019	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Decentralised Procedure – France as Country of Reference 	27,500 euros
TD0021	<ul style="list-style-type: none"> Decentralised Procedure – Other Country of Reference 	17,850 euros
TD0022	<ul style="list-style-type: none"> Mutual Recognition Procedure – Other Country of Reference 	17,850 euros
TD0023	<ul style="list-style-type: none"> 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)	8,800 euros
TD0024	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Decentralised Procedure – France as Country of Reference 	38,500 euros
TD0026	<ul style="list-style-type: none"> Decentralised Procedure – Other Country of Reference 	24,150 euros

TD0027	<ul style="list-style-type: none"> • Mutual Recognition Procedure – Other Country of Reference 	24,150 euros
TD0028	<ul style="list-style-type: none"> • Mutual Recognition Procedure – France as Country of Reference <p>(Request for recognition by at least one other member country for an MAA already issued by the Agency)</p>	13,200 euros
TD0029	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Decentralised Procedure – France as Country of Reference 	19,250 euros
TD0031	<ul style="list-style-type: none"> • Decentralised Procedure – Other Country of Reference 	12,075 euros
TD0032	<ul style="list-style-type: none"> • Mutual Recognition Procedure – Other Country of Reference 	12,075 euros
TD0033	<ul style="list-style-type: none"> • Mutual Recognition Procedure – France as Country of Reference <p>(Request for recognition by at least one other member country for an MAA already issued by the Agency)</p>	6,600 euros
TD0034	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Decentralised Procedure – France as Country of Reference 	38,500 euros
TD0036	<ul style="list-style-type: none"> • Decentralised Procedure – Other Country of Reference 	24,150 euros
TD0037	<ul style="list-style-type: none"> • Mutual Recognition Procedure – Other Country of Reference 	24,150 euros
TD0038	<ul style="list-style-type: none"> • Mutual Recognition Procedure – France as Country of Reference <p>(Request for recognition by at least one other member country for an MAA already issued by the Agency)</p>	12,000 euros
TD0039	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> Decentralised Procedure – France as Country of Reference 	19,250 euros
TD0041	<ul style="list-style-type: none"> Decentralised Procedure – Other Country of Reference 	12,075 euros
TD0042	<ul style="list-style-type: none"> Mutual Recognition Procedure – Other Country of Reference 	12,075 euros
TD0043	<ul style="list-style-type: none"> 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
TD0044	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Decentralised Procedure – France as Country of Reference 	38,500 euros
TD0046	<ul style="list-style-type: none"> Decentralised Procedure – Other Country of Reference 	24,150 euros
TD0047	<ul style="list-style-type: none"> Mutual Recognition Procedure – Other Country of Reference 	24,150 euros
TD0048	<ul style="list-style-type: none"> 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
TD0049	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Decentralised Procedure – France as Country of Reference 	19,250 euros
TD0051	<ul style="list-style-type: none"> Decentralised Procedure – Other Country of Reference 	12,075 euros
TD0052	<ul style="list-style-type: none"> Mutual Recognition Procedure – Other Country of Reference 	12,075 euros

TD0053	<ul style="list-style-type: none"> • Mutual Recognition Procedure – France as Country of Reference <p>(Request for recognition by at least one other member country for an MAA already issued by the Agency)</p>	6,600 euros
TD0054	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Decentralised Procedure – France as Country of Reference 	38,500 euros
TD0056	<ul style="list-style-type: none"> • Decentralised Procedure – Other Country of Reference 	24,150 euros
TD0057	<ul style="list-style-type: none"> • Mutual Recognition Procedure – Other Country of Reference 	24,150 euros
TD0058	<ul style="list-style-type: none"> • Mutual Recognition Procedure – France as Country of Reference <p>(Request for recognition by at least one other member country for an MAA already issued by the Agency)</p>	13,200 euros
TD0059	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Decentralised Procedure – France as Country of Reference 	19,250 euros
TD0061	<ul style="list-style-type: none"> • Decentralised Procedure – Other Country of Reference 	12,075 euros
TD0062	<ul style="list-style-type: none"> • Mutual Recognition Procedure – Other Country of Reference 	12,075 euros
TD0063	<ul style="list-style-type: none"> • Mutual Recognition Procedure – France as Country of Reference <p>(Request for recognition by at least one other member country for an MAA already issued by the Agency)</p>	6,600 euros
TD0064	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Mutual Recognition Procedure – Other Country of Reference 	14,700 euros
TD0078	<ul style="list-style-type: none"> • Mutual Recognition Procedure – France as Country of Reference <p>(Request for recognition by at least one other member country for an MAA already issued by the Agency)</p>	7,700 euros
TD0079	<ul style="list-style-type: none"> • 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 <i>the bioequivalence in relation to the reference proprietary product was not able to be shown</i> by means of bioavailability studies and the proprietary product does not meet the conditions stipulated in Article R. 5121-29-1:	
TD0080	<ul style="list-style-type: none"> • Decentralised Procedure – France as Country of Reference 	23,100 euros
TD0081	<ul style="list-style-type: none"> • Decentralised Procedure – Other Country of Reference 	14,700 euros
TD0082	<ul style="list-style-type: none"> • Mutual Recognition Procedure – Other Country of Reference 	14,700 euros
TD0083	<ul style="list-style-type: none"> • Mutual Recognition Procedure – France as Country of Reference <p>(Request for recognition by at least one other member country for an MAA already issued by the Agency)</p>	7,700 euros
TD0084	<ul style="list-style-type: none"> • 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 <i>change in bioavailability or the pharmacokinetics</i> :	
TD0085	<ul style="list-style-type: none"> • Decentralised Procedure – France as Country of Reference 	23,100 euros
TD0086	<ul style="list-style-type: none"> • Decentralised Procedure – Other Country of Reference 	14,700 euros
TD0087	<ul style="list-style-type: none"> • Mutual Recognition Procedure – Other Country of Reference 	14,700 euros
TD0088	<ul style="list-style-type: none"> • Mutual Recognition Procedure – France as Country of Reference <p>(Request for recognition by at least one other member country for an MAA already issued by the Agency)</p>	7,700 euros
TD0089	<ul style="list-style-type: none"> • 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 (Request for recognition by at least one other member country for an MAA already issued by the Agency)	7,700 euros
TD0094	• 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 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. Regardless of the procedure used.	22,000 euros
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). Regardless of the procedure used.	3,500 euros
TD01042	Request to amend a marketing authorisation for variations of type IA given in the enumerative list of exceptions published in article 326 quater of annex II of the CGI or for variations of type IB referred to in Article 2(5) of Commission Regulation (EC) no. 1234/2008 of 24 November 2008. Regardless of the procedure used.	2,500 euros
TD01043	Request to amend a marketing authorisation requested in compliance with Articles R. 5121-41 and R. 5121-46 of the Public Health Code. Regardless of the procedure used.	2,500 euros
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. Regardless of the procedure used.	7,000 euros

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 Article R. 5121-125 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