Ministère de l'emploi
et de la solidarité

Direction générale de la santé

Direction de la sécurité sociale

PRACTICAL GUIDE

for the reimbursement
of healthcare products other than medicines and/or associated services
referred to in article L. 165-1 of the Code of French Social Security

The aim of this document intended for applicants (manufacturers or distributors) is to explain the practical process of registration, registration renewal, changes in registration terms, determination or revision of rates and/or prices of a health product other than a medicine and/or above mentioned associated services

Scope of the procedure:

- medical devices for individual use (MDIU)
- tissues and cells from the human body and their derivatives
- healthcare products other than medicines
- associated services and adaptations

The applicant:

Who can apply for registration, registration renewal or changes in registration terms on the reimbursement list of a health product and/or associated service?

- A French or foreign manufacturer (located or not in France)
- A distributor (importer, dealer or services contractor)

On the other hand, the application can be formalized by any person acting on the behalf of the applicant (professional organization or consulting organization).

Terms of application submission

The application shall be submitted in French.

I Content of the application

The application is made up of three parts:

- Part I: description of the application (see annex II a)
- Part II: medico-technical file (see annex II b)
- Part III: economic file (see annex II c)

II Terms of application submission

II-1) Initial registration, registration renewal, changes in registration terms (scenarios 2, 3, 4, 5, 6, 7 and 8)

- 10 copies of the submission (parts I, II and III) are submitted to the Medical Devices Department of the Economic Committee for Health Products ("Comité économique des produits de santé - CEPS") :
  - either by direct submission to CEPS
  - or by registered letter with request for acknowledgement of receipt to CEPS (département des dispositifs médicaux - Ministère de l'emploi et de la solidarité, 8 avenue de Ségur, F-75350 Paris Cedex 07 SP)

CEPS (Medical Devices department) checks the acceptability of the application (especially content of the file) and sends an acknowledgement of receipt to the applicant.

- **At the same time** the following materials (listed below) shall be submitted to the "Secrétariat de la Commission d'évaluation" located within "Agence Française de Sécurité Sanitaire des Produits de Santé (AFFSAPS - DEMEIS, Unité des dispositifs médicaux, 143-147 boulevard Anatole France, F-93285 Saint Denis Cedex):
  - 45 copies of parts I and II of the application (hard copy)
  - 3 duplicates (electronic format, Word format, Windows Excel 97 format, floppy disk or CD Rom)
  - for a Medical Device for Individual Use (MDIU), cheque payable to the "Agent comptable de l'AFSSAPS" [accounting agent of AFSSAPS] according to terms defined in clause III with the related delivery slip

These materials shall be either directly delivered to the AFFSAPS (ground floor) on Tuesday morning (between 9 am and 12 am) and Wednesday afternoon (between 2pm and 4.30pm) or sent by registered mail.

II-2) Changes in rates or prices (scenario 9)

- The request (parts I and III only) shall be submitted to the secretariat of the Economic Committee for Healthcare Products [secrétariat du Comité économique des produits de santé – CEPS] - (medical devices department [département des dispositifs médicaux]):
  - either by direct submission
  - or by registered letter with request for acknowledgement of receipt to the secretariat of the CEPS (medical devices department - Ministère de l'emploi et de la solidarité, 8 avenue de Ségur, 75350 Paris Cedex 07 SP)

The CEPS (medical devices department) checks the acceptability of the application (especially content of the file) and sends an acknowledgement of receipt to the applicant.

III AFSSAPS fees

Fees are charged for MDIU (medical device for individual use [dispositif médical à usage individuel]).

Thus, only MDIU are subject to fees up to now.

Scenario	Fee amount	Observations
Registration	2 300 €	
Registration renewal	460 €	
Changes in registration terms	460 €	

PRACTICALITIES

I - **Product or service not yet included in the pricing list**

II - **Product or service already included in the pricing list**

Attachments

I Product or service not yet included in the pricing list

The applicant markets a product or provides service and is applying for a tailor made pricing procedure.
The following scenarios are possible:

Scenario 1: the applicant considers that the characteristics of his product or his service correspond to one of the generic lines of the existing list (technical specifications, and where applicable therapeutic or diagnostics indications, particular intended conditions of prescription and use).he applicant does not claim either an improvement in service rendered compared to this generic line or a price or rate higher than those fixed:

There is no application to submit.

The applicant labels his product which can, thus, be registered on the list.
For a service, the applicant invoices it according to the related generic line of the list.
Labelling (of a product) or invoicing (for a service) constitutes a commitment by the applicant that his product or service strictly fulfils the requirements of the heading on the list with respect to technical specifications, indications and particular described conditions for prescription or use.

Nevertheless, a voluntary notification (cf. Template at annex I) may be submitted by the applicants at the same time both to the AFFSAPS and to CEPS in order for the AFFSAPS (in the case of healthcare safety and service rendered) and the CEPS (in the case of agreements with industry) to have a better overview of the market.
No acknowledgement of receipt is sent by the administration to the applicant for this notification..

Scenario 2: the applicant considers that the characteristics of his product or his service correspond to one of the generic lines of the existing list but he claims an improvement in service rendered, which he wishes to use to ensure a higher tariff or price than tose fixed for the existing line:

- The applicant submits his request with the three parts (see annex II) in 10 copies to the secretariat of the CEPS (medical devices department) département des dispositifs médicaux), Ministère de l'Emploi et de la solidarité, 8 avenue de Ségur, F-75350 Paris Cedex 07 SP who will acknowledge receipt.

The receipt of the submission triggers a 180 days period covering the whole of the evaluation process (from submission of request to the issue of the registration order [arrêté]). In case further information is requested by the CEPS, this time period is suspended.
If there is no decision within this period, this means that the application is rejected (**by** application of Article 21 of the Law of 12 April 2000 and of article R. 165-8 of the code of social security).

- * The applicant submits to the Secretariat of the evaluation commission [Secrétariat de la commission d'évaluation]" located at the AFSSAPS, 45 copies of parts I and II of the request and 3 copies in electronic format as well as, in the case of a medical device for individual use (MDIU), the

cheque made payable to the "Agent comptable de l'AFSSAPS" [accounting agent of AFSSAPS] for the amount of the in accordance with article L 5211-5-1 of the Code of Social Security [Code de la Sécurité Sociale] with the related delivery slip.

Scenario 3: the applicant considers that the characteristics of his product correspond to one of the generic lines of the existing list but he wishes to make modifications to the registration terms of the existing generic line of the list (i.e. extension of indication(s),...).

Refer to scenario 2.

Scenario 4: the applicant does not find any generic line in the list to which his product or service corresponds.

Refer to scenario 2.

Nota Bene: products for which the applicant claims innovative aspects are covered either by scenario 2 or scenario 4.

II The product is already included in the pricing list

Reminder: any change(s) in product characteristics and/or the data on which registration on the list is based shall be supported by a written notification to the Social Security Minister whether or not the manufacturer or the distributor requests a modification for the registration on the pricing list.
(In practice, the manufacturer or the distributor shall send a letter to the Secretariat of the CEPS [secrétariat du CEPS] with a copy to the AFSSAPS notifying any change(s) in the characteristics, indications or use of the product).

Scenario 5: the applicant requests the registration renewal of his product, registered under a trade name or a commercial name for a limited duration.
Nota Bene: the request shall be submitted at the latest 180 days before the expiry date for registration.
The terms of submission and time periods are identical to those described in scenario 2.
However, the absence of decision beyond the 180 days time period means a tacit agreement for registration renewal according to the same terms as registration.

Scenario 6: the applicant requests registration under the heading of a generic line to which it corresponds but he claims an improvement in service rendered with a tariff and/or price for his product above those defined for the products in this generic line.
Refer to scenario 2.

Scenario 7: the applicant requests changes in the registration terms of his product (i.e. changes in indications, of the reimbursement rate, prescription conditions,...).
Refer to scenario 2.

Scenario 8: The applicant requests cancellation of the registration of his product registered under a trade name or commercial name before the expiry date for registration.: he requests the removal of his product from the pricing list.
He submits an application made of part I and a note explaining reasons for cancellation from the list, more particularly:
- requested effective date for cancellation
- reason(s) for request (withdrawal from the market...)
- impact of cancellation on Public Health (existence or not of therapeutic alternatives which are already reimbursed)

The terms of submission are identical to those described in scenario 2.

Scenario 9: The applicant requests revision of rate and/or sale price of his product.
He submits an application made of parts I and III in 10 copies secretariat of the CEPS [Secrétariat du CEPS], medical devices department [(département dse dispositifs médicaux], Ministère de l'emploi et de la solidarité, 8 avenue de Ségur, F-75350 Paris Cedex 07 SP" who will acknowledge receipt.
The receipt of the submission triggers a 180 days period covering evaluation process (from submission of request to the issue of the registration"arrêté"). In case of further information requested by the CEPS, this time period is suspended.

The absence of decision beyond the 180 days time period means a tacit agreement for registration renewal according to the same terms as registration.

Nota Bene: in case of products subject to a limited sale price, any request for change in this price shall be submitted to the secretariat of the CEPS [Secrétariat du CEPS], medical devices department [(département dse dispositifs médicaux], and not to the DGCCRF.

ANNEX I

Template for voluntary notification of a product covered by a generic line of the list and not subject to the submission of a file

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This document will be sent simultaneously to the CEPS and to the AFSSAPS

Nota Bene: This notification will be provided when the product, covered by a generic line, is placed on the market. At the time the first notification is performed, applicants whose turnover is less than 5 Millions FF will provide on the notification all products already registered under a generic line.

Company X
Address

Comité Economique des produits de santé
Section des Dispositifs Médicaux
Minsitère de l'emploi et de la solidarité
8 avenue de Ségur
F-75350 Paris Cedex 07 SP

AFSSAPS - DEMEIS
Unité des dispositifs médicaux
143/147 boulevard Anatole France
F-93285 Saint Denis Cedex

Dear Sirs,
This is to inform you that the company X markets several products covered by a generic line on the healthcare products list and services other than medicines according to article L 165-1 of the Code of Social Security [Code de la Sécurité Sociale].

Please find below the list of references involved and the related information.

Precice name of the product: reference or trade name	Identification of the product or service: -code or company's internal reference - European nomenclature according to NF EN ISO 15225 - ACL code if applicable - EAN 13 code if applicable	Corresponding code on the nomenclature or the list	Generic designation or title of the nomenclature line	Identification of the manufacturer: - name, - address, fax n°, e-mail, SIREN n°, - title and responsibilities of the contact person	Annual sales volume on the basis of article L 165-1 of the Code of Social Security.	Any observ-ations

ANNEX II a

Content of part I
Description of the application

It includes:
- ✶ a request letter to the Social Security Minister
- ✶ the following information form
- ✶ the summary form

FORM FOR INFORMATION RELATIVE TO THE REQUEST

I The applicant

- ✶ Is the applicant:
  - manufacturer of the product
  - distributor of the product or service

- ✶ Name and contact details of the applicant
- ✶ If the applicant is not the manufacturer of the product, contact details of the manufacturer

	Applicant	Manufacturer
Name/company name		
Address, phone n°, fax, e-mail		
SIREN n°		
Name and responsibilities of the contact person		

II-Type of request

Is the request related to:

- ✶ a product Yes No
- ✶ a service Yes No (circle the right answer)

Is it:

- ✶ a registration request
- ✶ a registration renewal request
  - date of the Official Journal ("JO") for the first registration
  - date of the Official Journal ("JO") for the last renewal
- ✶ a request for changes in registration terms
  - date of the Official Journal ("JO") for the first registration
  - date of the Official Journal ("JO") for the last renewal
- ✶ a request for revision of rate and / or sale price
  - date the Official Journal of the last revision
- ✶ a request for cancellation of a product on the reimbursement list
  - date of the Official Journal of registration Official Journal ("JO")

III Information on the scope of the request

III A / If the request concerns a product:

- Name or and commercial reference of the product:
  - in France
  - in the EU
  - other countries

- Identification of the product or service
  - Code or company's internal reference for the product
  - European nomenclature NF EN ISO 15225
  - ACL code (if applicable)
  - EAN code (if applicable)

- - Name and address of the product CE marking holder:
    - Date of CE mark
    - Name and address of the Notified Body who has delivered the CE mark (if applicable)

- Date of first placing of product on the market and marketing name:
  - worldwide (specify the countries?)
  - in the EU (specify the countries?)
  - in France

- Packaging:
  - Content description: does it contain fixing/installation accessories, ancillary devices ...
  - Type of packaging (number of units / pack)
    - in foreign countries
    - in France:
      - available in hospitals subject to global annual budgets ("dotation globale de fonctionnement")(if applicable)
      - available in private for profit hospitals (if applicable)
      - available from the final distributor (if applicable)

III B / If the request concerns a service:

- Description of the different components (general, administrative and others: penalties, any delivery...)

Documents to provided as attachments

- Materials supporting the history of the reimbursement request, if applicable.

SUMMARY FORM

1. CHARACTERISTICS OF THE PRODUCT OR SERVICE

Name	
Field of application	
Identification of the applicant (manufacturer, distributor or contractor)	Name Address Tel/fax/e-mail SIREN n°
Name, title and responsibilities of the contact person	
Identification of the manufacturer (if different from the applicant)	Name Address Tel/fax/e-mail SIREN n°

2. ADMINISTRATIVE INFORMATION

- **CE marking classification**

Class	Notified Body	Date of notification
☐ **I** ☐ **IIa** ☐ **IIb** ☐ **III**		

- **History of reimbursement request**

Registration	☐
Registration change - Date of Official Journal when of the first registration was published Scope of change:	☐ / /
Renewal - Official Journal issue date of the first registration Scope of renewal:	☐ / /

- **Name of the TIPS nomenclature (if applicable)**

ANNEX IIb

CONTENT OF PART II
MEDICO-TECHNICAL FILE

Due to the great variety of products and services, the file may not be suitable for all requests. The relevance of each item should be considered by the applicant who may adapt it to his product or service.

Particular recommendations

- Reference to any clinical studies shall include details on:
  - methodology: type of trial, comparative product, ramdomization...
  - number of patients (specifying the number of patients included in each group)
  - inclusion criteria
  - evaluation criteria: main criteria, secondary criteria (effectiveness, performance, tolerance, safety of use, quality of life, cost,...)
  - statistical techniques used
  - results: results provided shall be related to the main criterion, regardless of its nature. The type of analysis (intention to treat or otherwise) shall be argued.

For study presentation, comply as far as possible to the format suggested on pages 20 and 21. The available studies to be used to justify the service rendered or the improvement in service rendered will not conform systematically to this format. In such case, an overview shall be made in French, including the context, the objective, the data retrieval and analysis method, the results and discussion elements. Related publications (when applicable) shall be attached. It is not compulsory for studies to have been carried out in France.

Thus, the type of study selected to provide relevant data for the evaluation shall de discussed in the file especially where it was impossible to perform a controlled randomized trial. The process chosen shall be discussed and argued as well as methodology and results.

- In paragraph 2.3 of the medico-technical dossier, the notion of therapeutic alternative can be discussed and argued in the wide sense (quality of life, alternatives to hospitalisation…).
- Epidemiological data and provisional sales forecasts shall be addressed: identify sources and attach related documents (especially for data involved in identifying target population).
- When presenting an improvement of service rendered (clause II), selection of comparative products or services against which improvement of service rendered is claimed shall be argued.
- Files related to renewal of registration shall include additional studies (if applicable) requested at the time of registration, as well as an update of the file with most recent available data.

- Files related to changes in registration terms shall detail requested changes and the arguments supporting the request.

1 PRODUCT OR SERVICE CHARACTERISTICS

- Performances
- Technical description
- Compliance to standards, specifications, norms; testing and checks performed (attach manufacturing specifications "Cahier des charges" if applicable)
- Plans, drawings or other representations of the product
- Indications and instructions for use
- Shelf life, duration of use
- Design history (state of art in the same field, design milestones, continuous improvement and design changes, involvement of users,...)
- Other information relative to the product or the service

2 EVALUATION OF SERVICE RENDERED

For a registration renewal, provide

additional studies requested by the Commission for the last registration
updated data regarding the pathology involved and its reimbursement policy

For changes in registration terms, the evaluation of improvement of service rendered shall be applied to the new indications and / or new use conditions or procedures.

2-1 Seriousness aspects

- pathology (vital prognosis, acute/chronic,...)
- disability (severity, duration, permanent or temporary,...)
- deterioration in quality of life and medico-social consequences
- other data which may assist in defining the character of seriousness

2-2 Ratio of performance to Adverse effects

- performance criteria chosen (technical efficiency, direct or indirect benefit to patients)
- type and incidence of adverse effects
- risks inherent to use (summary of risk analysis, vigilance data,...)
- any other data which may assist in defining the ration of performance to adverse effects.

2-3 Presentation of alternatives

Position in the strategy; contribution to health care quality, to patients follow-up and to disability offsets with regards to other therapies or available techniques.

2-4 Contribution to public health

Pathology / disability features: frequency, type of population nvolved (age, sex, socio-demographic characteristics), impact in terms of mortality / morbidity, impact on individual and global health expenditure…

3 IMPROVEMENT OF SERVICE RENDERED COMPARED TO OTHER PRODUCTS / SERVICES REGISTERED

Evaluation of new clinical data for registration renewal.

3-1 Selection of comparators already registered (to be argued) and where applicable with therapeutic alternatives
3-2 Evaluation of comparative studies and / or data
3-3 Level of improvement of service rendered (ASR) and criteria for which improvement is claimed (clinical aspects, quality of life, ergonomic aspects,...)

4 Description of usage techniques

Updating of data for registration renewal request or changes in registration terms.

4-1 Particular usage and prescription conditions
4-2 Description of the medical procedure or service
4-2 Minimal technical specifications
4-4 Recommendations regarding prescription and usage procedures

5 Target population and sales volumeforecasts

5-1 Target population

Defined as the potential population which is likely to benefit from the product or service

For a registration renewal request: patients currently involved with the product or service since registration.
For changes in registration terms: target population related to aspects supporting the request (i.e., new indication).

Population issue shall take into account:
→ indications used
→ ratio of diagnosed and treated patients
→ recommended strategy for medical reimbursement of the indication(s)
→ contribution of the product / service to the strategy

In order to estimate the target population, it is necessary to define:
- indications used
- the characteristics of the pathology(ies) and / or of the targeted disabilities
- incidence of each targeted pathology or disability (by sub groups if possible) (age, sex, seriousness,...)
- definition of each population related to each indication for which registration is requested
- current prescription of comparable products or services

5-2 Sales volume forecasts

For a registration renewal request: annual sales volumes following first registration.
For changes in registration terms: provisional volumes taking into account new registration terms.

Using epidemiological data, provide with sales volume forecasts for coming years.

Attachments to be provided:

- CE marking certificate
- Instructions for Use
- Overview of published recommendations: international recommendations, RMO ("Recommandations minimales opposables"), consensus onferences

MEDICO-TECHNICAL SUMMARY FORM

- **Contract specifications ("Cahier des charges")**
  Yes ❑ No ❑

- **Scope of application with respect to CE marking (if applicable)**

- **Proposed indications in the reimbursement request or indications covered by the first registration**

Indications	Use instructions	Treatment duration and/or device shelf life

Other therapeutic strategies
List other available therapies or alternatives (medicines, procedures, other devices...)

If applicable, level of claimed improvement in service rendered (ASR)

Criteria	**Ranking of improvement in service rendered**
❑ Clinical	I. Major contribution
❑ Quality of life	II. Important improvement
❑ Usage/ergonomics	III. Moderate improvement
❑ Others (to be defined)	IV. Minor improvement
	V. No improvement

Overview of trials performed for each indication

Study name	Main objective	Number of subjects	Comparators	Main result

Overview of epidemiological data and sales forecasts for each indication

Prevalence of	Estimation of	Amount of sales	Annual sales

pathology(ies)	target population	according to the proposed therapeutic for the last three years strategy	volume forecast for the next three years
		TOTAL	

CLINICAL TRIAL SUMMARY FORM

MANUFACTURER, DISTRIBUTOR OR CONTRACTOR
PRODUCT OR SERVICE

TITLE OF THE TRIAL	
PRINCIPAL INVESTIGATOR	
CENTER(S)	
PUBLICATION (reference)	
START OF THE TRIAL END OF THE TRIAL	DEVELOPMENT PHASE
OBJECTIVES OF THE TRIAL	
METHODOLOGY	
NUMBER OF PATIENTS (specify for each group) Foreseen Randimozed Analyzed	
DIAGNOSTIC AND MAIN INCLUSION CRITERIA	
EVALUATED DEVICE: INDICATIONS AND CONDITIONS OF USE	
USAGE DURATION	
COMPARATOR (OR OTHER COMPARATIVE THERAPEUTIC STRATEGY): INDICATIONS AND CONDITIONS OF USE	

MANUFACTURER, DISTRIBUTOR OR CONTRACTOR
PRODUCT OR SERVICE

EVALUATION CRITERIA - End-point primary - End-point secondary (if applicable)
STATISTICAL METHODS
• RESULTS • CONCLUSION

ANNEX IIc

CONTENT OF PART III
ECONOMIC FILE

This section includes:
- economic form for the product or service (form A or Abis completed)
- form regarding the company or applicant (form B completed)

A - Product form

I DATA RELATED TO THE REQUEST

- public sale price foreseen for each presentation
- "tarif de responsabilité" requested for each presentation
  - ✶ date of the Official Journal of last pricing change (if applicable)
- market shares **estimated in France** for each presentation

Specify the forecast time period in order to attain a stabilised volume of sales:

	FORECAST OF ANNUAL SALES VOUME as from the date of the stabilisation of the market			
Type of presentation/ Packaging	Package 1	Package 2	Package 3	Package 4
In healthcare establishments which are subject to the global function budget				
In healthcare establishments not subject to the global function budget				
With the final distributor				

II JUSTIFICATIONS FOR SALES FORECASTS

II-1 The market

The potential market:

- ✶ Data on the potential market for the product, in current volume and as it evolves.
- ✶ Data on the market share, in current volume and as it evolves, that the product can have in the total market concerned.

The market achieved

✶ *If the product is already on the market in France*

- Volumes sold by presentation/packaging in the last full year and turnover achieved (in euros)

✶ *If the product is already on the market outside France*

For each country of the European Union concerned, and for the USA, specify:

- the volumes sold by presentation/pakcaign in the last full year and turnover achieved (in euros)
- the status of the product with regard to reimbursement in the country concerned.

III JUSTIFICATIONS OF THE REQUESTED PRICE AND TARIFF

III-1 Economic data available on the indication in question: savings or excess achieved by the product compared to other therapeutic strategies.

III-2 Data on the break-down of the public sale price:

III-2.1 Data relating to the manufacturer price

- Indicate the manufacturer price

CASE A: *The company is the manufacturer of the product*:

- Analytical accounting breakdown of the price of the product by presentation,

If not:

- Global cost of manufacture by presentation;
- Cost of research and development;
- Cost of marketing and promotion;
- Margins

CASE B: *The company is not the manufacturer of the product*

- Real cost of acquiring the product;
- Cost of marketing and promotion;
- Margins

III-2.2 Data relating to the costs linked to the distribution chain of the product:

These data concern the wholesaler (if there is one) on the one hand and the final distributor on the other (pharmacy, service provider).
Provide for each of the stages of distribution:

- the sales price of the product and discounts;
- charges
- margins

III.3 Data on the market prices:

✶ *In France:*

- Catalogue price per presentation,
- Agreed discounts as a function of quantity and of the distribution chain.

✶ Prices charged in different countries of the European Union.

A bis – FORM concerning services

Describe all the economic elements which go into the different components of the service:

As an illustration: specify **for each component**:

- the personnel employed:
  - their qualifications (secretary, technician, nurse, pharmacist …)
  - their number per qualification or average time spent for each category of personnel
  - the average hourly salary of the category of personnel concerned,
- the materials used:
  - the purchase price,
  - its amortisement period (e.g. Type of vehicle in the case of delivery ….).
- all the specific elements which incur costs for the service provider (e.g. average kilometrage covered in case of deliveries)
- the share of fixed costs, the costs of structure

B – FORM for the applicant company

I IDENTIFICATION OF THE COMPANY:

Name of the company
Contact details

Name of the owner/manager
Name of the person responsible for contact with the CEPS

Is the company:
- a privately owned/autonomous company ?
- a subsidiary of a group: which one?

If the company was already marketing, under another name, reimbursable products, specify under which name:

In this case, if the products which were already marketed have changed names, specify these names (by quoting the correspondence between the old and new names).

II GENERAL INFORMATION ON THE COMPANY:

- Company's sector of activity:
  - ✶ in the healthcare sector:
    specify
    - the sector (cardiology, imaging, anaesthesia …):
    - the type of products concerned:
      - Medical devices (specify the types: disposables; implants, imaging …)
      - Medicines:
  - ✶ Sectors other than healthcare (specify):

- Locations of the production sites:
  - ✶ In France:
  - ✶ In the European Union;
  - ✶ In the world:

- Number of employees of the company:
  - ✶ In France:
  - ✶ In the European Union;
  - ✶ In the world:

- Turnover (in euros):
  - ✶ Turnover achieved in France:
  - ✶ In the European Union:
  - Turn over achieved in the world:

Specify the turnover in each sector and the turnover of the whole company.

- Last annual report and accounts for the last fiscal year of the company to be supplied as well as the report to the shareholders.

III LIST OF PRODUCTS OF THE COMPANY WHICH ARE REIMBURSABLE, specifying for each the corresponding turnover and if the company is the manufacturer or the distributor of the product

Type of products	✶ **Manufacturer** ✶ **Distributor:** - Exclusively on the national territory Or - in France and in other countries: specify)	**Turnover in the world (in euros)**	**Turnover in the EU (in euros)**	**Turnover in France (in euros)**